# Comunicazioni orali

## PERCUTANEOUS CORONARY INTERVENTIONS – 1

### C1

**INTRAVASCULAR LITHOTRIPSY FOR THE TREATMENT OF SEVERELY CALCIFIED CORONARY ARTERY STENOSIS: INSIGHTS FROM THE PROSPECTIVE, MULTICENTER, REAL WORLD ROLLINGSTONE REGISTRY**

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**Introduction**

Intravascular Lithotripsy (IVL) technology has been recently introduced as an adjunctive technique for the treatment of complex patients with highly calcified coronary lesions. However, there are few data about its performance in the real-world, all-comers setting.

**Methods**

The ROLLINGSTONE prospective multicenter study enrolled patients treated with IVL and/or mechanical debulking (rotational atherectomy [RA] or orbital atherectomy[OA]) from 23 centers in Italy from January 2023 to December 2024. The primary safety endpoint was freedom from major adverse cardiovascular events [MACE] (cardiac death, myocardial infarction [MI] or target vessel revascularization [TVR]) at 30 days. The primary effectiveness endpoint was procedural success (stent delivery with a residual stenosis <30% and without in-hospital MACE). An independent core laboratory made the angiographic analysis and event-rate adjudication.

**Results**

From 1020 patients enrolled in the ROLLINGSTONE study, 618 patients (660 lesions) underwent IVL treatment (55% with Acute Coronary Syndrome as clinical presentation). Concomitant RA and OA were performed respectively in 8.6% and 1.4% of cases, and intracoronary imaging-guided procedure in 38.3% of patients. Coronary lithotripsy for under-expandend stent was performed in 18% of patients (9.3% as a bailout strategy after stent implantation and 8.7% for in-stent restenosis). The primary effectiveness endpoint was achieved in 85% of patients. At 30-days follow-up, MACE rate was 9.9% and CV death rate was 1.1%.

**Conclusions**

Our prospective analysis demonstrated the safe, effective and easy to use profile of Intravascular Lithotripsy technology to improve stent implantation in patients with heavily calcified coronary stenosis also in a real-world, multicenter and all-comers setting.

| PROCEDURAL OUTCOMES | N = 618 |
|---|---|
| Procedural success | 526 (85.1) |
| Periprocedural MI | 22 (3.5) |
| Dissection | 37 (6.0) |
| Perforation | 14 (2.1) |
| Persistent slow-flow/no-reflow | 6 (1.0) |
| Need for a covered stent | 11 (1.8) |
| Abrupt vessel closure | 3 (0.5) |
| Stent thrombosis | 1 (0.2) |
| Arrhytmias | 5 (0.8) |
| Pericardial effusion | 7 (1.1) |
| Access site complications | 6 (1.0) |

| 30-days MACE | N = 618 |
|---|---|
| Clinical event | 61 (9.9) |
| Cardiovascular death | 7 (1.1) |
| Non-CV death | 14 (2.3) |
| Spontaneous MI | 8 (1.3) |
| Ischemia driven TLR | 17 (2.8) |
| Non target vessel revascularization | 22 (3.6) |
| Stent thrombosis | 3 (0.5) |

| In-hospital MACE | N = 618 |
|---|---|
| Death | 68 (11.0) |
| Cardiovascular Death | 15 (2.4) |
| CIAKI | 12 (1.9) |
| Stroke | 2 (0.3) |
| Pericardial effusion | 5 (0.8) |
| Target vessel MI | 1 (0.2) |
| Non target vessel revascularization | 2 (0.4) |
| Stent thrombosis | 0 |

### C2

**ORBITAL ATHERECTOMY FOR THE TREATMENT OF SEVERELY CALCIFIED CORONARY ARTERY STENOSIS: INSIGHTS FROM THE PROSPECTIVE, MULTICENTER, REAL-WORLD ROLLINGSTONE REGISTRY**

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**Introduction**

The aim of this study was to evaluate the safety and feasibility of coronary orbital atherectomy (OA) for the treatment of heavily calcified coronary artery stenosis in a real-world, all-comers setting.

**Methods**

The ROLLINGSTONE prospective multicenter study enrolled patients treated with mechanical debulking (rotational atherectomy [RA] or orbital atherectomy [OA]) and/or intravascular lithotripsy (IVL) from 23 centers in Italy from January 2023 to December 2024. The primary safety endpoint was freedom from major adverse cardiovascular events [MACE] (cardiac death, myocardial infarction [MI] or target vessel revascularization [TVR]) at 30 days. The primary effectiveness endpoint was procedural success (stent delivery with a residual stenosis <30% and without in-hospital MACE). An independent core laboratory made the angiographic analysis and event-rate adjudication.

**Results**

From 1020 patients enrolled in the ROLLINGSTONE study, 82 (8%) patients underwent orbital atherectomy (48.8% presented with Acute Coronary Syndrome). Concomitant RA and IVL were performed respectively

in 7.3% and 9.8% of cases, and intracoronary imaging-guided procedure in 39% of patients. The OA debulking involved more commonly the Left Anterior Descendent artery (53.6%), while the Left Main in 8% of cases. The primary effectiveness endpoint was achieved in 89% of patients. At 30-days follow-up, MACE rate was 4.8% and CV death rate was 1.2%.

**Conclusions**

In Our multicenter real-world cohort analysis Orbital atherectomy appears to be a safe and effective treatment option for patients with heavily calcified coronary stenosis.

| PROCEDURAL OUTCOMES | N = 82 |
|---|---|
| Procedural success | 73 (89.0) |
| Periprocedural MI | 7 (8.5) |
| Dissection | 4 (4.9) |
| Perforation | 3 (3.7) |
| Persistent slow-flow/no-reflow | 2 (2.4) |
| Need for a covered stent | 3 (3.7) |
| Abrupt vessel closure | 2 (2.4) |
| Stent thrombosis | 0 |
| Arrhytmias | 1 (1.2) |
| Pericardial effusion | 3 (3.7) |
| Access site complications | 2 (2.4) |

| 30-days MACE | N = 82 |
|---|---|
| Clinical event | 4 (4.8) |
| Cardiovascular death | 1 (1.2) |
| Non-CV death | 0 |
| Spontaneous MI | 0 |
| Ischemia driven TLR | 1 (1.2) |
| Non target vessel revascularization | 1 (1.2) |
| Stent thrombosis | 0 |

| In-hospital MACE | N = 82 |
|---|---|
| Death | 14 (17.1) |
| Cardiovascular Death | 2 (2.4) |
| CIAKI | 7 (8.5) |
| Stroke | 0 |
| Pericardial effusion | 2 (2.4) |
| Target vessel MI | 0 |
| Non target vessel revascularization | 2 (2.4) |
| Stent thrombosis | 1 (1.2) |

## C3

### MAGICTOUCH DCB: MECHANISM, CLINICAL EFFICACY AND FUTURE PERSPECTIVE

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The MagicTouch Drug-Coated Balloon (DCB) represents a significant advancement in the treatment of coronary artery disease (CAD), utilizing a unique mechanism to deliver antiproliferative agents directly to the arterial wall. This innovation addresses the issue of restenosis by combining balloon angioplasty with targeted drug delivery. Clinical trials have demonstrated the efficacy of the MagicTouch DCB in reducing late lumen loss, showcasing a favorable safety profile and improved long-term outcomes. The future perspective for MagicTouch DCB includes expanded indications, enhanced drug delivery mechanisms, combination therapies, and personalized medicine approaches. Continued research and development are expected to further optimize its clinical utility and broaden its applications in interventional cardiology.

**Introduction**

Coronary artery disease (CAD) remains a leading cause of morbidity and mortality worldwide. Traditional treatment modalities, including balloon angioplasty and stent implantation, have significantly improved patient outcomes but are often complicated by restenosis, a condition characterized by the re-narrowing of the treated artery. Drug-coated balloons (DCBs) have emerged as a novel therapeutic option designed to mitigate this issue. The MagicTouch DCB is a cutting-edge device that combines the mechanical benefits of balloon angioplasty with the pharmacological effects of a sirolimus coating, providing a dual approach to combat restenosis. This paper aims to explore the mechanism, clinical efficacy, and future perspectives of the MagicTouch DCB in the context of CAD treatment.

**Aim**

The primary aim of this paper is to provide a comprehensive overview of the MagicTouch Drug-Coated Balloon, including its underlying mechanism of action, clinical efficacy based on recent studies, and potential future directions in interventional cardiology. Specific objectives include:

- Explaining the mechanism by which the MagicTouch DCB delivers therapeutic agents to the arterial wall.
- Reviewing clinical trials and real-world studies that assess the efficacy and safety of the MagicTouch DCB.
- Discussing future perspectives and potential advancements in the technology and application of DCBs in CAD treatment.

**Mechanism of Action**

The MagicTouch DCB operates through a sophisticated mechanism that combines mechanical dilation of the artery with localized drug delivery. Upon inflation, the balloon expands within the artery, compressing plaque and dilating the vessel. Concurrently, the sirolimus coating on the balloon surface is transferred to the arterial wall, where it is absorbed by the surrounding tissue. Sirolimus, an antiproliferative agent, inhibits the proliferation of smooth muscle cells, thereby reducing the risk of restenosis. This localized drug delivery ensures that the therapeutic effects are concentrated at the site of the lesion, minimizing systemic exposure and associated side effects.

**Clinical Efficacy**

Several clinical trials and observational studies have demonstrated the efficacy of the MagicTouch DCB in reducing late lumen loss and improving long-term patient outcomes. Key findings include:

- Reduction in Late Lumen Loss: Studies have consistently shown that the MagicTouch DCB significantly reduces late lumen loss compared to plain balloon angioplasty and other DCBs.
- Favorable Safety Profile: The device has exhibited low rates of major adverse cardiac events (MACE), including myocardial infarction, target lesion revascularization, and cardiac death.
- Long-Term Benefits: Patients treated with the MagicTouch DCB have shown sustained benefits, including lower rates of restenosis and repeat revascularization procedures, over extended follow-up periods.

**Future Perspectives**

The future of the MagicTouch DCB and similar technologies is promising, with several potential developments on the horizon:

- Expanded Indications: Ongoing research is exploring the use of DCBs for a variety of vascular diseases beyond CAD, including peripheral artery disease and in-stent restenosis.
- Enhanced Drug Delivery Systems: Advances in drug delivery technology aim to improve the efficiency and consistency of drug transfer from the balloon to the arterial wall.
- Combination Therapies: There is potential for combining DCBs with other therapeutic modalities, such as bioresorbable scaffolds or newer pharmacological agents, to further enhance treatment outcomes.
- Personalized Medicine: Future research may focus on tailoring DCB therapy to individual patient profiles, considering genetic, biological, and clinical factors to optimize efficacy and minimize adverse effects.

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## C4

### NAVIGATING CALCIFIED CORONARY ARTERIES IN SMALL CENTER SETTINGS

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**Introduction**

The treatment of complex calcified lesions presents a formidable challenge in interventional cardiology. In this setting, rotational atherectomy (RA) has been a valuable tool in the context of complex PCI. This abstract introduces the outcomes of a single-center registry with low volume PCI (less than 350/year) dedicated to the use of RA in the treatment of complex coronary lesions.

**Methods**

This study is a retrospective analysis of clinical data regarding a population referred to the catheterization laboratory of the San Paolo Hospital in Milan for acute or chronic coronary syndromes (ACS or CCS). RA stenting procedures were carried out on 134 consecutive patients from May 2014 to Ju-

ly 2023. The primary outcome of this registry was the occurrence of MACE considering both in hospital and follow-up period. The secondary outcomes were procedural success and each component of the primary outcome.
**Results**
44% of patients underwent RA during an acute coronary syndrome. Multi-vessel disease was present in 79% of patients and mean Syntax Score value was 29 ± 6 SD. 93% of cases were treated without any complication with an upfront RA strategy. MACE manifested in 20 individuals (14%), primarily driven by target lesion revascularization (11 cases). Upon conducting a multivariable analysis only age emerged as an independent predictor of MACE (95% CI: 0,98-1.11, p<0.05). MACE between ACS patients and CCS patients were superimposable as well (p= 0,133). Among patients presented with a reduced baseline ejection fraction (FE< 50%) we did find a statistically significant improvement with the follow-up ejection fraction ( p = 0,036).
**Conclusions**
RA is safe and effective in low-volume PCI centers with a high success rate and low rates of procedural complications with comparable results between ACS and CCS patients. Our registry demonstrated that age is the only predictor of MACE at 1 year follow-up. Procedural success is essential to achieve an improvement of LVEF among patients with reduced LVEF.

## C5

**MANAGEMENT OF SEVERE AORTIC STENOSIS AND COMPLEX, HIGH RISK PERCUTANEOUS CORONARY INTERVENTION (ASCOP): INSIGHTS FROM AN INTERNATIONAL REGISTRY**

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**Introduction**
Transcatheter Aortic Valve Replacement (TAVR) is recommended by international guidelines to treat severe aortic stenosis and a relevant proportion of TAVI patients also presents with coronary artery disease (CAD). Therefore, how to manage prognostically relevant CAD with complex and/or high-risk, percutaneous coronary intervention (PCI) features in the context of ongoing severe, symptomatic aortic stenosis is of clinical interest.
**Methods**
A retrospective data collection of patients with severe AS and complex PCI (ASCoP) was performed in 14 large centers in Europe and Middle East. Criteria for inclusion are in Figure 1A. The study endpoint was a composite of all-cause deaths, strokes (any), myocardial infarction, bleedings and vascular complications.
**Results**
In total, 555 patients undergoing TAVR and complex PCI were included. Mean age was 79 years (±
12.3) and 62.8% were male. Most common criteria for complex PCI were bifurcation PCI (38.9%) left-main PCI (28.8%), need of calcium debulking (22.7%) and of long stenting (mean stent length 48±30 mm) while 15% had severe left ventricular impairment.
The majority of our cohort underwent staged procedures (68.4%) and in 92.4% of cases complex / high risk PCI was performed before TAVR. In patients undergoing staged procedures, median time between procedures was 48 days. Follow-up was censored after 1,000 days. at median 463 days, 43 (7.7%) patients died and 119 (21.4%) experienced the study endpoint, including 54 bleedings, 54 vascular complications and 16 acute myocardial infarctions. Survival analysis showed that there was no difference between a staged or same-procedure strategy in terms of all-cause death (8.0% vs. 7.4%; p=0.82; Figure 1B), although the former was associated with a statistically significant lower occurrence of composite endpoint (20.0% vs. 25.0%; p=0.039; Figure 1C).
**Conclusions**
In this large, retrospective analysis, ASCoP patients were not rare in high volume centers and they were most commonly treated with staged TAVI after complex/high risk PCI. Although no difference in raw mortality was observed, significantly lower composite of clinical events were observed at follow-up.

## C6

**INTRAVASCULAR LITHOTRIPSY IN STEMI: A PROOF OF CONCEPT**

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**Introduction**
While safety and efficacy data supporting intravascular lithotripsy (IVL) are growing, confirming the technique as safe and effective treating stable coronary lesions, no data are available in STEMI culprit calcific lesions treatment.
**Methods**
We conducted a retrospective all comers registry in five high volume European centres for STEMI culprit calcific lesions treated with IVL from October 2020 to November 2023.
**Results**
22 patients were identified. 7 (32%) previously underwent PCI. Mean left ventricle ejection fraction was 45%, 4 patients (19%) presented in cardiogenic shock. Access was radial in 20 (91%). In 11 (50%) culprit lesion was in anterior descending, in 7 (33%) in right coronary, in 3 patients in circumflex (14%) and in one in left main. A large part (15, 68%) presented a three-vessel disease.
Culprit lesion involved bifurcation in 8 (36%), intravascular imaging was used in 8(36%). Most used IVL balloon was 3.00 mm (15 cases, 68%). Predilatation mean pressure was 19 ATM, with a minimum of 14 and a maximum of 26. Mean stent diameter was 3.2 mm, from 2.5 up to 4.5. 1.55 stent per lesion were implanted.
Only in 2 (9%) multivessel revascularization was done. In 2 (9%) left ventricular assistance was implanted.
One intraprocedural death was recorded for cardiogenic shock, despite ECMO and Impella positioning.
Procedural success was reached in all other patients, with TIMI III flow.
Two (9%) died shortly after the procedure, due to refractory cardiogenic shock, one (4.5%) come back shortly after for re-PCI.
Follow up was available for 16 patients, with no cardiac event at the mean time of 13.3 months.
**Conclusions**
It is well known that optimal stent expansion and apposition reduce events. IVL is an established technique for revascularization in stable calcific lesions, with improvement of PCI immediate results, better stent expansion, higher minimum stent area.
In our hypothesis generating registry, some elements stand out and can prompt reflections about the combination of STEMI and calcific culprit lesion.
The high incidence of three vessel disease: calcific lesions often signify advanced atherosclerosis with widespread plaque burden. When these plaques rupture or erode can trigger acute thrombotic events leading to STEMI. The extensive nature of atherosclerosis in these cases makes it more likely for multiple coronary vessels to be affected, contributing to the higher prevalence of three-vessel disease.
Secondly, calcific plaques are known for their complex and heterogeneous morphology. Lesions may extend into multiple coronary branches, further complicating the treatment strategy, making them challenging to treat. The calcified nature of the lesions prolongs revascularization procedure, increasing the rate of staged revascularization for non-culprit lesion.
Another finding is the high rate of intravascular imaging use 36%): it plays a crucial role in assessing the characteristics of calcific lesions, providing information about plaque composition, thickness, and distribution, aiding in selecting appropriate strategies for lesion preparation and stent placement. For calcific lesions, intravascular imaging becomes indispensable to guide interventions improving procedural outcomes. Fare clic o toccare qui per immettere il testo.
2 patients (9%) needed left ventricular assistance. STEMI resulting from calcific lesions can lead to extensive myocardial damage and impaired cardiac function. The severity of three-vessel disease, compounded by the challenges in revascularization, may result in a higher prevalence of

post-MI heart failure. In such cases, the need for mechanical circulatory support becomes more pronounced.
Besides, in 100% of cases, after lithotripsy and stenting, the final flow is TIMI III despite no usage of GP IIb/IIIa inhibitors, and the risk of embolization seems to be reduced. The supposed mechanism may involve fracturing the calcific plaques into smaller, less obstructive particles, minimizing the likelihood of downstream embolic events. This finding needs to be confirmed and further studied.
Achieving complete revascularization in the context of calcific lesions can be challenging. The presence of diffuse and intricate calcifications may limit the success of traditional PCI techniques. Moreover, attempting complete revascularization in the setting of STEMI requires careful consideration of the patient's clinical condition, lesion complexity, and procedural risks. These factors contribute to a small percentage of cases achieving complete revascularization, as clinicians often prioritize timely restoration of blood flow to the infarct-related artery.
IVL has emerged as adjunctive technology in the management of calcific lesions. [5] With calcific lesions causing STEMI, IVL enhance lesion preparation and stent delivery, and increase the likelihood of successful revascularization. IVL may address some of the challenges posed by calcific lesions, potentially improving procedural outcomes and minimizing the need for mechanical circulatory support.
In conclusion, calcific lesions as culprits of STEMI present a complex scenario characterized by a higher prevalence of three-vessel disease and use of intravascular imaging, an increased need for left ventricular assistance device, and challenges in achieving complete revascularization. The integration of advanced technologies holds promise in overcoming some of the hurdles associated with these challenging cases, offering new avenues for improving patient outcomes and optimizing the management of calcific lesions in the setting of STEMI.
To validate these findings trials are needed. If confirmed, this innovative approach may improve procedural results, reducing procedural time and minimizing events.

## TRANSCATHETER AORTIC VALVE IMPLANTATION - 1

### C7

**THE INTEGRATED TAVI NETWORK WITHIN THE HEART VALVE CENTRE AND HEART VALVE CLINICS: SEVEN YEARS OF EXPERIENCE IN TUSCANY**

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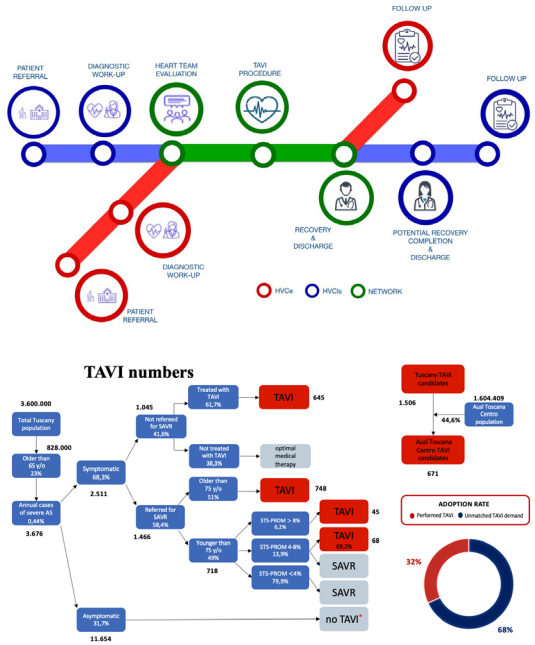
**Introduction**
Transcatheter aortic valve implantation (TAVI) has emerged in recent years as the dominant treatment for patients with severe symptomatic aortic stenosis (AS). Demand for TAVI is steadily increasing, necessitating the implementation of effective organisational strategies to ensure equitable access to treatment and adequate volumes.
**Methods**
In the Area Vasta Toscana Centro, Tuscany, Italy, an integrated network model was developed based on deep integration between a Heart Valve Centre (HVCE) at the Careggi Hospital and the referring Heart Valve Clinics (HVCL). The aim was to combine the advantages of both centralised and decentralised models. An innovative referral modality was implemented, whereby screening, diagnostic workup and follow-up are managed by the initial access hospital, while the heart team and intervention at the HVCE are managed by the referring cardiologist. The study is a retrospective observational analysis of 1,003 patients within this integrated network. The study analyses data from a seven-year period between 2017 and 2023, comparing patients who underwent TAVI via the "classic" HVCE pathway with those who underwent TAVI via the HVCL pathway.
**Results**
The results of the study indicate that the integrated model is safe and effective, with no significant differences in patient selection, procedural data, or outcomes between the two groups. The facilitated access led to a steady increase in patient volume, and a trend towards increased waiting times for the procedure was observed in both groups. This was mainly due to the increased waiting time from Heart Team approval to TAVI. Notably, despite longer waiting times, overall 30-day mortality (1.0%) and 1-year cardiovascular mortality (0.9%) remained low, with minimal differences between the two groups.
**Conclusions**
The necessity for standardisation of patient selection and TAVI integration pathways is highlighted to ensure uniform adoption of this technology and the establishment of a patient-centred organisation. The demonstrated model could potentially serve as a basis for a comprehensive approach to TAVI and its expanding indications.

**The Network organization**




### C8

**LONG-TERM DURABILITY OF BALLOON-EXPANDABLE VS SELF-EXPANDING TRANSCATHETER AORTIC VALVE PROSTHESES**

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**Aims**
To compare long-term durability of balloon-expandable (BEV) and self-expanding (SEV) transcatheter aortic valve prostheses in patients undergoing transcatheter aortic valve implantation (TAVI).
**Methods**
In this systematic review and meta-analysis, all observational studies and randomized controlled trials comparing long-term durability of SEV and BEV in patients with severe aortic stenosis (AS) treated with TAVI were evaluated for inclusion. Electronic databases were searched up to March 2024. Pooled odds ratios (OR) with 95% confidence interval (CI) were used as summary statistics and were calculated using a random-effects model. Primary endpoint was the occurrence of all-cause bioprosthetic valve failure (BVF) at the longest available follow-up. As secondary endpoints, we considered the rate of moderate and severe structural valve deterioration (SVD) and the occurrence of all-cause death at the longest available follow-up. BVF and SVD were defined according to the criteria used in each included study.
**Results**
A total of eighteen studies and 7,132 patients were included in the meta-analysis; 49.2% of patients (n=3,508) were treated with a BEV, while a SEV was used in 50.8% of cases (n=3,624). In more than 90% of cases, an old generation bioprosthetic valve was used. In all included studies, prostheses durability was evaluated during a follow-up period of at least 5 years (for 12 studies outcomes occurring after 5 years from TAVI were reported). Overall, the pooled estimate of all-cause BVF was 4% (95% CI: 3-5%), and no difference was observed between patients treated with BEV and SEV (OR: 1.38; 95% CI: 0.89-2.15; p-value: 0.147). The pooled estimate of moderate and severe SVD in the entire population was 4% (95% CI: 4-5%), and it mainly occurred due to prosthetic valve stenosis (50% of cases). When compared to those undergoing TAVI with a SEV, patients treated with a BEV experienced a significantly higher rate of any SVD (OR: 1.85; 95% CI: 1.52-2.24; p-value <0.001). Finally, the risk of all-cause death did not differ between patients who received a BEV and those who received a SEV (OR: 1.07; 95% CI: 0.74-1.54; p-value: 0.729; overall pooled estimated 55%, 95% CI: 41-68%).
**Conclusions**
In patients with severe AS undergoing TAVI, the design of the platform used could have an impact on long-term durability of transcatheter aortic valve prostheses. After more than 5 years from TAVI procedure, patients treated with a BEV experienced a higher risk of any SVD compared to those for whom a SEV was implanted. Nevertheless, no difference in the occurrence of all-cause BVF and all-cause death was observed.

## C9

### DOES SHEATH TECHNOLOGY AFFECT HEMOSTASIS WITH SINGLE SUTURE-MEDIATED CLOSURE SYSTEM AFTER TRANSFEMORAL TRANSCATHETER AORTIC VALVE IMPLANTATION?

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**Introduction**

The use of suture-mediated percutaneous closure devices (PCDs) is the most frequently adopted strategy to achieve hemostasis after transfemoral transcatheter aortic valve implantation (TF-TAVI). Safety and efficacy data about the "off-label" use of a single Perclose ProGlide™ (Abbott Vascular Devices) have been recently published. Notwithstanding, there is only one study investigating the PCD performance according to a specific sheath technology, not highlighting sufficient results. In fact, the expandable sheath (e-sheath) does not completely retract to its native dimensions after valve passage; moreover, its final external diameter also changes according to the chosen prosthesis size. Therefore, the aim of our retrospective study was to evaluate if TF-TAVI performed after sheathless insertion of a 14 F-equivalent fix delivery system (f-sheath) or through a 14 F e-sheath could affect PCD failure rate.

**Methods**

All consecutive patients undergoing TF-TAVI at the "Montevergine" Clinic of Mercogliano, Italy, between June 2014 and December 2021, have been enrolled (N = 912) in the observational prospective "Magna Graecia" TAVI registry. After excluding 235 patients, the final study population consisted of 677 patients: 501 in the 14 F f-sheath group and 176 in the 14 F e-sheath group. E-sheath patients were implanted with the balloon-expandable Sapien 3™ (Edwards Lifesciences) (N = 123) and Myval™ (Meril Lifesciences) (N = 35) transcatheter heart valves (THVs), while f-sheath ones with the self-expanding Evolut R™ (Medtronic) (N = 496), Evolut PRO+™ (Medtronic) (N = 1), and Portico™ (Abbott Vascular Devices) (N = 4) THVs. A postprocedural evaluation of size, tortuosity, atherosclerotic and calcification burdens of the main ilio-femoral access route was made by one operator, blinded to procedural outcomes, in an independent corelab. All measurements were derived by multiplanar reconstruction from the preprocedural contrast-enhanced multidetector computed tomography, using the software Horos™ (Horos Project, an open-source community sponsored by Nimble Co LLC d/b/a Purview). All the common femoral artery (CFA) punctures were performed under fluoroscopy guidance with roadmapping technology, and a single Perclose ProGlide was placed with preclose technique in all cases. At procedural end, a selective angiographic control of the whole main ilio-femoral access route has always been performed; postprocedural protamine administration was up to the operator. The hemostasis has been considered effective if achieved without requiring additional surgical or endovascular treatment (other than adjunctive endovascular balloon inflation), including the deployment of at least one further PCD. Control vascular ultrasound was only performed when clinically indicated. Vascular complications (VCs), PCD failure, bleedings, and composite endpoints – i.e. technical success, device success, and early safety - were adjudicated by an internal clinical event committee according to the Valve Academic Research Consortium (VARC)-3 consensus document. Statistical analysis was performed using SigmaStat 3.5, SPSS 25.0, and STATA 13.0. After data analysis, a propensity score matching (PSM) was built including as covariates those factors that could imbalance vascular access characteristics. For all tests, a p-value <0.05 was considered statistically significant.

**Results**

The total study population had a mean age of 81.32±5.25 years. 461 patients (68.09%) were females and diabetes had an incidence of 29.29%. Mean Society of Thoracic Surgeons Predictive Risk of Mortality score was intermediate (4.51%). PCD failure occurred in only 30 (4.43%) patients. At group analysis, e-sheath and f-sheath groups significantly differed for some baseline clinical characteristic such as age (p=0.050) and female sex rate (p=0.002), that were both higher in the f-sheath group, whereas diabetes (p=0.038), body surface area (BSA) (p=0.001), porcelain aorta (p=0.007), and prior cerebrovascular event (p<0.001) resulted significantly higher in the e-sheath group. We found also significant differences according to main vascular access characteristics, with sheath-to-femoral-artery ratio, CFA calcifications and tortuosity that were all significantly (p<0.05) worse in the e-sheath than in the f-sheath group. PCD failure incidence resulted to be significantly higher in the e-sheath group than in the f-sheath group (7.95% vs 3.19%, p=0.020). This association remained significant after PSM (z-statistic: 2.33; p=0.020) that balanced both the vascular access characteristics and other factors that could affect PCD failure (age, female sex, and BSA). Group analysis showed no significant difference about main access VCs, mortality, VARC-3 technical and device success rates. E-sheath group reported a higher incidence of type 3 VARC-3 bleeding (p=0.022) and longer hospital stay (p=0.020).

**Conclusions**

Our study demonstrates that expandable 14 F sheath technology significantly increase PCD failure rate when a single Perclose ProGlide™ is used to obtain the hemostasis after TF-TAVI. This link keeps its statistical significance after balancing both vascular access characteristics and VCs/PCD failure risk factors. This is probably due to the higher vascular stretching induced by such expandable technology during and after THV crossing, making the single suture-mediated hemostasis technique less safe and effective in this setting. More data, involving also different PCDs, are needed to confirm this preliminary evidence.

**Baseline characteristics of the study population, procedural features and outcomes according to sheath type before and after propensity score matching.**

| Variable | All | Unmatched | | | Matched | | |
|---|---|---|---|---|---|---|---|
| | | f-sheath (n=501) | e-sheath (n=176) | p value | f-sheath (n=483) | e-sheath (n=158) | p value |
| ***Demographic and clinical characteristics*** | | | | | | | |
| Age (years) | 81.32±5.25 | 81.61±4.93 | 80.48±6.01 | 0.050 | 79.54±4.93 | 80.25±6.01 | 0.252 |
| Female | 461/677 (68.09%) | 358 (71.46%) | 103 (58.52%) | 0.002 | 65.19% | 56.96% | 0.134 |
| Body Mass Index (kg/m²) | 27.59±4.36 | 27.43±4.17 | 28.07±4.85 | 0.231 | | | |
| Body Surface Area (m²) | 1.74±0.16 | 1.72±0.16 | 1.77±0.17 | 0.001 | 1.80±0.17 | 1.77±0.17 | 0.052 |
| Hypertension | 659/677 (97.34%) | 488 (97.40%) | 171 (97.16%) | 0.922 | | | |
| Diabetes mellitus | 199 (29.39%) | 136 (27.15%) | 63 (35.79%) | 0.038 | 41.38% | 38.61% | 0.605 |
| Insulin-requiring | 46 (6.79%) | 31 (6.19%) | 15 (8.52%) | 0.376 | | | |
| Dyslipidemia | 443 (65.43%) | 338 (67.46%) | 105 (59.66%) | 0.075 | | | |
| Current smoker | 48 (7.09%) | 37 (7.38%) | 11 (6.25%) | 0.738 | | | |
| Anemia | 381 (56.28%) | 280 (55.89%) | 101 (57.39%) | 0.798 | | | |
| CKD | 263 (38.85%) | 200 (39.92%) | 63 (35.79%) | 0.381 | | | |
| Hemodialysis | 1 (0.15%) | 0 (0.00%) | 1 (0.57%) | 0.584 | | | |
| COPD | 114 (16.84%) | 67 (13.37%) | 47 (26.70%) | <0.001 | | | |
| Neurological dysfunction | 66 (9.75%) | 50 (9.98%) | 16 (9.09%) | 0.846 | | | |
| Severe liver disease | 9 (1.33%) | 7 (1.40%) | 2 (1.14%) | 0.902 | | | |
| Porcelain aorta | 6 (0.91%) | 1 (0.21%) | 5 (2.84%) | 0.007 | | | |
| PAD | 178 (26.29%) | 128 (25.55%) | 50 (28.41%) | 0.521 | | | |
| Prior cerebrovascular event | 44 (6.50%) | 21 (4.19%) | 23 (13.07%) | <0.001 | | | |
| Carotid stenosis ≥50% | 134 (19.79%) | 104 (20.76%) | 30 (17.04%) | 0.340 | | | |
| Critical preoperative state | 17 (2.51%) | 9 (1.80%) | 8 (4.54%) | 0.084 | | | |
| CAD history | 126 (18.74%) | 91 (18.20%) | 35 (19.89%) | 0.703 | | | |
| Prior myocardial infarction | 57 (8.42%) | 38 (7.58%) | 19 (10.79%) | 0.245 | | | |
| Prior cardiac surgery | 54 (7.98%) | 39 (7.78%) | 15 (8.52%) | 0.881 | | | |
| Far from TAVI prior myocardial revascularization | | | | | | | |
| None | 559 (82.57%) | 417 (83.23%) | 142 (80.68%) | 0.514 | | | |
| PCI | 83 (12.26%) | 60 (11.98%) | 23 (13.07%) | 0.805 | | | |
| CABG | 24 (3.54%) | 16 (3.19%) | 8 (4.54%) | 0.550 | | | |
| PCI + CABG | 11 (1.62%) | 8 (1.60%) | 3 (1.70%) | 0.803 | | | |
| Close to TAVI PCI | 126 (18.61%) | 89 (17.76%) | 37 (21.02%) | 0.399 | | | |
| Residual significant CAD in TAVI | 93 (13.76%) | 64 (12.80%) | 29 (16.48%) | 0.275 | | | |

| Variable | All | Unmatched | | | Matched | | |
|---|---|---|---|---|---|---|---|
| | | f-sheath (n=501) | e-sheath (n=176) | p value | f-sheath (n=483) | e-sheath (n=158) | p value |
| Prior PM/ICD/CRT implantation | 82 (12.11%) | 60 (11.98%) | 22 (12.50%) | 0.961 | | | |
| NYHA functional class III-IV | 619 (91.43%) | 464 (92.61%) | 155 (88.07%) | 0.090 | | | |
| Sinus rhythm ± PM-induced rhythm | 570 (81.19%) | 429 (85.63%) | 141 (80.11%) | 0.108 | | | |
| History of paroxysmal atrial fibrillation/flutter | 87/570 (15.26%) | 54 (12.59%) | 33 (23.40%) | 0.003 | | | |
| Atrial fibrillation/flutter ± PM-induced rhythm | 107 (15.80%) | 72 (14.37%) | 35 (19.89%) | 0.108 | | | |
| LVEF (%) | 54.74±9.43 | 55,03±9,19 | 53,90±10,06 | 0.162 | | | |
| Peak aortic gradient (mmHg) | 77.57±21.98 | 77.36±21.76 | 78.09±22.60 | 0.955 | | | |
| Mean aortic gradient (mmHg) | 47.76±15.32 | 47.62±15.01 | 48.17±16.24 | 0.967 | | | |
| Moderate-to-severe mitral regurgitation | 221 (31.69%) | 164 (32.80%) | 57 (32.39%) | 0.994 | | | |
| Pulmonary artery systolic pressure (mmHg) | 40.51±13.82 | 40.462±14.21 | 40.65±12.65 | 0.473 | | | |
| ***Main access anatomical characteristics*** | | | | | | | |
| CFA min diameter (mm) | 6.67±1.67 | 6.20±1.24 | 8.12±1.95 | <0.001 | | | |
| SFAR | 0.95±0.24 | 1.01±0.22 | 0.77±0.22 | <0.001 | 0.81±0.22 | 0.77±0.22 | 0.024 |
| SFAR >1.05 | 176 (27.46%) | 157 (32.50%) | 19 (12.02%) | <0.001 | | | |
| SFAR ≥1.05 | 205 (31.98%) | 183 (37.89%) | 22 (13.92%) | <0.001 | | | |
| Indexed CFA min diameter (mm/m²) | 3.73±1.18 | 3.52±0.95 | 4.32±1.54 | <0.001 | | | |
| CFA calcification (any) | | | | | | | |
| no | 241 (37.60%) | 177 (36.65%) | 64 (40.51%) | 0.438 | 39.87% | 41.51% | 0.909 |
| mild | 257 (40.09%) | 189 (39.13%) | 68 (43.04%) | 0.437 | | | |
| moderate | 101 (15.76%) | 83 (17.18%) | 18 (11.39%) | 0.108 | | | |
| severe | 42 (6.55%) | 34 (7.04%) | 8 (5.06%) | 0.493 | | | |
| Moderate-to-severe CFA calcification | 143 (22.31%) | 117 (24.22%) | 26 (16.46%) | 0.054 | | | |
| CFA tortuosity (any) | | | | | | | |
| no | 564 (87.99%) | 472 (97.72%) | 92 (58.23%) | <0.001 | 55.70% | 59.33% | 0.651 |
| mild | 72 (11.23%) | 10 (2.07%) | 62 (39.24%) | <0.001 | | | |
| moderate | 5 (0.78%) | 1 (0.21%) | 4 (2.53%) | 0.018 | | | |
| severe | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | - | | | |
| Moderate-to-severe CFA tortuosity | 5 (0.78%) | 1 (0.21%) | 4 (2.53%) | 0.018 | | | |
| EIA min diameter (mm) | 7.15±1.95 | 6.53±1.17 | 9.04±2.55 | 0.001 | | | |
| SEIAR | 0.89±0.22 | 0.95±0.17 | 0.71±0.23 | <0.001 | | | |

| Variable | All | Unmatched | | | Matched | | |
|---|---|---|---|---|---|---|---|
| | | f-sheath (n=501) | e-sheath (n=176) | p value | f-sheath (n=483) | e-sheath (n=158) | p value |
| Indexed EIA min diameter (mm/m²) | 4.14±1.12 | 3.81±0.74 | 5.12±1.46 | <0.001 | | | |
| EIA calcification (any) | | | | | | | |
| no | 349 (55.92%) | 315 (65.22%) | 44 (27.67%) | <0.001 | | | |
| mild | 206 (32.09%) | 133 (27.54%) | 73 (45.91%) | <0.001 | | | |
| moderate | 65 (10.12%) | 30 (6.21%) | 35 (22.01%) | <0.001 | | | |
| severe | 12 (1.87%) | 5 (1.03%) | 7 (4.40%) | 0.017 | | | |
| Moderate-to-severe EIA calcification | 77 (11.99%) | 35 (7.25%) | 42 (26.41%) | <0.001 | | | |
| EIA tortuosity (any) | | | | | | | |
| no | 21/642 (3.27%) | 7 (1.45%) | 14 (8.80%) | <0.001 | | | |
| mild | 277 (43.15%) | 206 (42.65%) | 71 (44.65%) | 0.726 | | | |
| moderate | 244 (38.01%) | 193 (39.96%) | 51 (32.07%) | 0.093 | | | |
| severe | 100 (15.58%) | 77 (15.94%) | 23 (14.46%) | 0.730 | | | |
| Moderate-to-severe EIA tortuosity | 344 (53.58%) | 270 (44.10%) | 74 (46.54%) | 0.050 | | | |
| CIA min diameter (mm) | 2.65±0.10 | 8.27±1.86 | 11.09±3.46 | <0.001 | | | |
| Indexed CIA min diameter (mm/m²) | 1.53±0.06 | 4.83±1.14 | 6.29±1.98 | <0.001 | | | |
| Antiplatelet (any) | | | | | | | |
| no | 190 (28.06%) | 127 (25.35%) | 63 (35.79%) | 0.011 | | | |
| single | 172 (25.41%) | 106 (21.16%) | 66 (37.50%) | <0.001 | | | |
| dual | 315 (46.53%) | 268 (53.49%) | 47 (26.70%) | <0.001 | | | |
| Oral anticoagulant (any) | | | | | | | |
| no | 492 (72.67%) | 377 (75.25%) | 115 (65.34%) | 0.015 | | | |
| only anticoagulant | 55 (8.12%) | 33 (6.59%) | 22 (12.50%) | 0.025 | | | |
| anticoagulant + SAPT | 114 (16.84%) | 82 (16.37%) | 32 (18.18%) | 0.663 | | | |
| anticoagulant + DAPT | 16 (2.36%) | 9 (1.80%) | 7 (3.98%) | 0.177 | | | |
| Logistic EuroSCORE | 14.96±10.37 | 14.43±9.70 | 16.48±11.99 | 0.039 | | | |
| EuroSCORE II | 5.73±10.30 | 5.59±11.39 | 6.12±6.23 | 0.255 | | | |
| STS-PROM | 4.51±3.00 | 4.33±2.92 | 5.01±3.16 | 0.003 | | | |
| Orotracheal intubation | 4 (0.59%) | 3 (0.60%) | 1 (0.57%) | 0.599 | | | |
| Left side access | 63 (9.30%) | 39 (7.78%) | 24 (13.64%) | 0.032 | | | |
| Protection 0.018" guidewire in the main access | 6 (0.89%) | 4 (0.80%) | 2 (1.14%) | 0.955 | | | |

| Variable | All | Unmatched | | | Matched | | |
|---|---|---|---|---|---|---|---|
| | | f-sheath (n=501) | e-sheath (n=176) | p value | f-sheath (n=483) | e-sheath (n=158) | p value |
| Valve substitute | | | | | | | |
| self-expanding | 10 (1.47%) | | | | | | |
| balloon-expandable | 1 (0.15%) | | | | | | |
| Valve size (mm) | | | | | | | |
| <26 mm | 151 (22.30%) | 45 (8.98%) | 106 (60.23%) | <0.001 | | | |
| 26 mm | 293 (43.28%) | 225 (44.91%) | 68 (38.64%) | 0.175 | | | |
| >26 mm | 233 (34.42%) | 231 (46.11%) | 3 (1.14%) | <0.001 | | | |
| Postdilation | 201 (29.69%) | 191 (38.12%) | 10 (5.68%) | <0.001 | | | |
| CM volume (mL) | 112.83±45.44 | 105.67±40.35 | 133.23±52.53 | <0.001 | | | |
| Fluoroscopy time (min) | 17.05±7.87 | 17.39±8.53 | 16.05±5.43 | 0.364 | | | |
| Radiation dose (mGy) | 1145.41±737.16 | 1142.03±748.16 | 1158.37±696.09 | 0.672 | | | |
| Main arterial access vascular complication (VARC-3) | | | | | | | |
| no | 93 (13.73%) | 65 (12.97%) | 28 (15.91%) | 0.398 | | | |
| minor | 54 (7.98%) | 40 (7.98%) | 14 (7.95%) | 0.881 | | | |
| major | 39 (5.76%) | 25 (4.99%) | 14 (7.95%) | 0.206 | | | |
| PCD (single ProGlide) failure | 30 (4.43%) | 16 (3.19%) | 14 (7.95%) | 0.015 | 3.16% | 8.86% | 0.020 |
| no | 670 (99.07%) | 498 (99.40%) | 172 (97.73%) | 0.146 | | | |
| minor | 3 (0.44%) | 0 (0.00%) | 3 (1.70%) | 0.023 | | | |
| major | 4 (0.59%) | 3 (0.60%) | 1 (0.57%) | 0.599 | | | |
| no | 665 (99.33%) | 495 (98.80%) | 170 (96.59%) | 0.114 | | | |
| minor | 4 (0.59%) | 1 (0.20%) | 3 (1.70%) | 0.093 | | | |
| major | 8 (1.18%) | 5 (1.00%) | 3 (1.70%) | 0.733 | | | |
| Bleeding (VARC-3) | | | | | | | |
| no | 482 (71.20%) | 356 (71.06%) | 126 (71.59%) | 0.970 | | | |
| type 1 | 50 (7.38%) | 34 (6.79%) | 16 (9.09%) | 0.402 | | | |
| type 2 | 176 (18.61%) | 102 (20.36%) | 24 (13.64%) | 0.061 | | | |
| type 3 | 17 (2.51%) | 8 (1.60%) | 9 (5.11%) | 0.022 | | | |
| type 4 probable | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | - | | | |
| type 4 definite | 2 (0.29%) | 1 (0.20%) | 1 (0.57%) | 0.974 | | | |
| Need of transfusion | | | | | | | |
| none | 577 (85.23%) | 424 (84.63%) | 153 (86.93%) | 0.537 | | | |
| 1 unit | 40 (5.91%) | 31 (6.19%) | 9 (5.11%) | 0.738 | | | |
| 2 units | 40 (5.91%) | 34 (6.79%) | 6 (3.41%) | 0.147 | | | |
| >2 units | 20 (2.95%) | 12 (2.39%) | 8 (4.54%) | 0.234 | | | |

| Variable | All | Unmatched | | | Matched | | |
|---|---|---|---|---|---|---|---|
| | | f-sheath (n=501) | e-sheath (n=176) | p value | f-sheath (n=483) | e-sheath (n=158) | p value |
| Any AKI | 147 (21.84%) | 117 (23.45%) | 30 (17.24%) | 0.110 | | | |
| Moderate-to-severe residual aortic regurgitation | 57 (8.64%) | 50 (10.18%) | 7 (4.14%) | 0.024 | | | |
| Permanent PM implantation | 75 (12.60%) | 58 (13.15%) | 17 (11.04%) | 0.590 | | | |
| ECM/cardiac arrest | 9 (1.33%) | 4 (0.80%) | 5 (2.84%) | 0.098 | | | |
| New-onset atrial fibrillation/flutter | 65 (11.40%) | 39 (9.09%) | 26 (18.44%) | 0.004 | | | |
| no | 657 (97.04%) | 487 (97.21%) | 170 (96.59%) | 0.876 | | | |
| minor | 6 (0.89%) | 5 (1.00%) | 1 (0.57%) | 0.955 | | | |
| major | 14 (2.07%) | 9 (1.80%) | 5 (2.84%) | 0.596 | | | |
| Acute myocardial infarction | 3 (0.44%) | 2 (0.40%) | 1 (0.57%) | 0.712 | | | |
| Stroke/TIA | 16 (2.36%) | 15 (2.99%) | 1 (0.57%) | 0.125 | | | |
| Technical success (VARC-3) | 632 (93.35%) | 30 (5.99%) | 15 (8.52%) | 0.324 | | | |
| Hospital length of stay (days) after TAVI | 4.79±3.59 | 4.73±3.73 | 4.99±3.15 | 0.020 | | | |
| Mortality | | | | | | | |
| No (in-hospital+follow-up) | 648 (95.72%) | 493 (98.40%) | 155 (88.07%) | <0.001 | | | |
| intraprocedural | 4 (0.59%) | 3 (0.60%) | 1 (0.57%) | 0.599 | | | |
| periprocedural | 3 (0.44%) | 2 (0.40%) | 1 (0.57%) | 0.712 | | | |
| Device success (VARC-3) | 574 (84.78%) | 422 (84.23%) | 152 (86.36%) | 0.579 | | | |
| Early safety (VARC-3) | 429 (63.37%) | 310 (61.88%) | 119 (67.61%) | 0.205 | | | |

## C10

### IMPACT OF UNFAVORABLE AORTIC ANATOMY ON TRANSCATHETER AORTIC VALVE REPLACEMENT OUTCOMES: INSIGHTS FROM THE OPERA-TAVI REGISTRY

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**Introduction**

Despite device improvements for transcatheter aortic valve replacement (TAVR) and increased operator expertise, unfavorable aortic root anatomy might subtend worse procedural and clinical outcomes.

The aim of this study was to assess procedural and clinical outcomes of transfemoral TAVR in patients with and without unfavorable aortic root anatomy and receiving Evolut PRO/PRO+ (PRO) and SAPIEN 3 Ultra (ULTRA) devices in contemporary clinical practice.

**Methods**

Patients enrolled in the multicenter OPERA-TAVI registry were considered. Patients were compared using one-to-one propensity score matching (PSM) according to the presence or absence of unfavorable anatomical characteristics of the aortic root [bicuspid aortic valve, moderate to severe calcification of left ventricular outflow tract (LVOT), horizontal aorta]. Primary endpoints were Valve Academic Research Consortium (VARC)-3 device success and early safety. The co-primary endpoint was a composite of 1-year all-cause death, disabling stroke and rehospitalization for heart failure (HF).

**Results**

Among a total of 1,815 patients, 629 patients (34.7%) had at least one unfavorable characteristic. After PSM, 624 pairs of patients with or without unfavorable anatomical characteristics were compared.

VARC-3 device success (85.3% vs. 92.0%, p<0.001) and early safety (72.9% vs. 79.6%, p=0.006) were lower in patients with one or more unfavorable characteristics. The co-primary composite endpoint was higher in patients with unfavorable anatomical characteristics (Kaplan-Meier estimates 15.3 vs. 12.0%; $p_{logrank}$=0.019).

**Conclusions**

Patients undergoing transfemoral TAVR with PRO and ULTRA devices had lower rates of device success and early safety in the presence of unfavorable anatomical characteristics, along with worse one-year clinical outcomes.

## C11

**BALLOON-EXPANDABLE SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE IN INTERMEDIATE SIZING ZONES: INSIGHTS FROM THE OPERA-TAVI REGISTRY**

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**Introduction**

Accurate balloon-expandable valves (BEV) sizing for transcatheter aortic valve replacement (TAVR) is particularly important considering the high-radial force and hence adverse consequences of inaccurate sizing. Current practice suggests that the ideal annular area oversizing with BEV is between 0-10%.In this analysis of the multicenter OPERA-TAVI registry, we aimed to compare outcomes of patients receiving the BEV SAPIEN 3 ULTRA within or outside this recommended oversizing zone.

**Methods**

All patients enrolled in the international, multicenter OPERA-TAVI registry who underwent TAVR for severe, tricuspid aortic valve stenosis and receiving the SAPIEN 3 ULTRA device were considered. Patients who received the SAPIEN 3 ULTRA transcatheter heart valve (THV) in optimal (within 0% and 10% of area oversizing) or intermediate (outside 0-10% area oversizing range) sizing zones were compared. A propensity score matching (PSM) adjustment was used to take into account for baseline confounders. The primary outcomes were device success and early safety as defined by Valve Academic Research Consortium (VARC) 3 consensus. Co-primary outcomes were rates of patient-prosthesis mismatch (PPM) and paravalvular regurgitation (PVR).

**Results**

Among a total of 723 TAVR patients who received the SAPIEN 3 ULTRA THV, 275 patients (38.0%) were within the optimal sizing zone, whereas 448 patients (62.0%) were in the intermediate sizing zones. After PSM, 223 pairs of patients with similar clinical and anatomical characteristics were compared. Both VARC-3 device success (90.9% vs. 90.0%, p=0.84) and VARC-3 early safety (87.6% vs. 83.4%, p=0.24) did not differ between matched patients in optimal or intermediate sizing zones. At 30-days, rates of PPM (42.2% vs. 27.5%, p=0.10) and PVR (moderate/severe 2.1% vs. 0.0%, p=0.10; mild 20.1% vs. 13.5%, p=0.06) were numerically lower for patients in intermediate sizing zones.

**Conclusions**

Early TAVR outcomes using the balloon-expandable SAPIEN 3 ULTRA platform in real-world practice are favorable in terms of safety and effectiveness, regardless of whether patients are in optimal or intermediate sizing zones.

## C12

**A NOVEL SCORE FOR IDENTIFYING MODERATE AORTIC STENOSIS PATIENTS AT HIGH RISK OF ADVERSE CARDIOVASCULAR OUTCOME**

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**Introduction**

Observational studies have shown that patients with moderate aortic stenosis (AS) present a higher rate of cardiovascular (CV) events when compared to the general population. The present study aimed to identify the predictors of adverse CV outcomes in patients with moderate AS and to combine them in a new scoring system suitable for clinical practice.

**Methods**

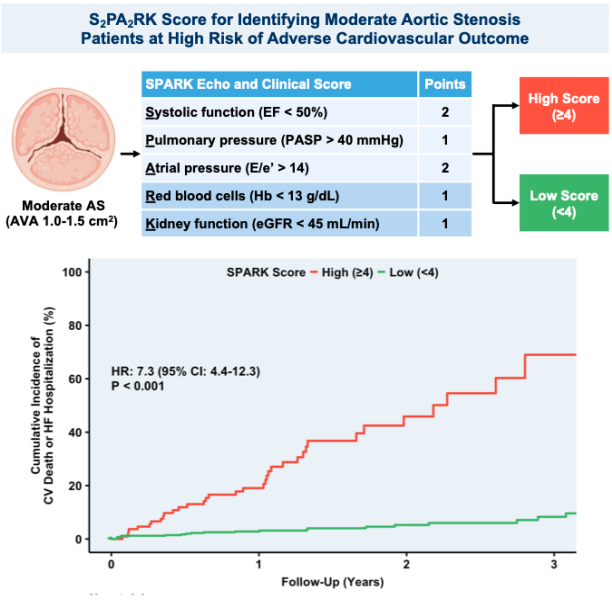
We retrospectively enrolled consecutive moderate AS patients from 2019 to 2023 from three Italian centers. Baseline and follow-up data were retrieved from electronic health records and telephone interviews. We defined the primary endpoint as a composite of CV death or heart failure (HF) hospitalization. We censored patients who developed severe AS during follow-up.

**Results**

Our study included 520 patients (mean age 77.8 ± 9.5 years; 46% female) with a mean follow-up of 2.0 ± 1.2 years. During follow-up, 59 patients (12%) experienced the primary endpoint. The independent predictors of the primary endpoint at follow-up were (1) Hb < 13 mg/dL (HR 1.94, 95% CI 1.01-3.79, p = 0.049), (2) eGFR < 45 mL/min (HR 1.87, 95% CI 1.07-3.27, p = 0.028), (3) LVEF < 50% (HR 3.39, 95% CI 1.98-5.81, p < 0.001), (4) Lateral E/e' > 14 (HR 4.35, 95% CI 2.63-7.7; p < 0.001), and (5) PASP > 40 mmHg (HR 1.99, 95% CI 1.17 - 3.39, p = 0.011). A new scoring system, the SPARK score, was developed and internally validated based on these variables (High- vs. Low-risk SPARK score: HR: 7.3; 95% CI 4.4-12.3; p < 0.001).

**Conclusions**

This study identified the predictors of adverse CV outcomes in patients with moderate AS and combined them in a new scoring system. The present score could be useful for clinical practice (i.e., more frequent active clinical surveillance) and serve as a benchmark for future clinical studies and trials.




# PERCUTANEOUS CORONARY INTERVENTIONS - 2

## C13

**INIZIALE ESPERIENZA "REAL WORLD" DEL DISPOSITIVO NEVA ENVAST NEL CONTESTO DELLE SINDROMI CORONARICHE ACUTE ED ECTASIA CORONARICA: A CASE SERIES**

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**Introduzione**

La dilatazione aneurismatica coronarica (CAE) si riscontra in un 5% dei pazienti che vengono sottoposti a coronarografia e si associa ad una prognosi peggiore nel lungo periodo specialmente se associata in un contesto di sindrome coronarica acuta (SCA). La CAE in corso di SCA si associa ad un alto burden trombotico, determinando una sfida per il Cardiologo Interventista al ripristino di un flusso intracoronarico valido (TIMI 3). Inoltre, le recenti linee guida ESC si sono pronunciate in maniera negativa (Classe III, livello evidenza A) sull'utilizzo routinario della tromboaspirazione manuale in setting acuto, data la mancata riduzione della mortalità e l'aumentato rischio di complicanze neurologiche. Tuttavia in presenza di elevato burden trombotico e coesistente dilatazione aneurismatica coronarica, la tromboaspirazione potrebbe avere un suo razionale soprattutto alla luce dei nuovi dispositivi in grado di garantire una maggior asportazione del materiale e garantire la sicurezza della procedura. Tra questi nuovi dispositivi vi è il sistema NeVA Envast basato sul meccanismo della trombectomia meccanica con stent auto espandibili in nitinolo in grado di catturare il materiale trombotico, di frammentarlo ed asportarlo.

**Metodi**

In questa case series riportiamo la nostra preliminare esperienza sull'utilizzo del dispositivo NeVA Envast nel contesto di due SCA STEMI con coronarie aneurismatiche ed importante burden trombotico. La tromboaspirazione meccanica mediante dispositivo Envast è stata utilizzata come metodica di bailout dopo insuccesso della tromboaspirazione manuale o delle tecniche convenzionali di riapertura del vaso coronarico. Sono stati utilizzati un catetere 7Fr, due guide coronariche workhorse, un estensione di catetere GuideLinear, un microcatetere Rebar 18 ed il dispositivo NeVA Envast. Si è definito successo procedurale il ripristino

di flusso coronarico adeguato (>TIMI 2) e risoluzione > 50% del sopraslivellamento del tratto ST.

**Risultati**

Due pazienti sono stati arruolati nello studio. Nel primo caso il dispositivo Envast è stato utilizzato in corso di angioplastica primaria della coronaria destra (CD), in seguito ad instabilizzazione elettrica ed emodinamica per incapacità a ripristinare un adeguato flusso anterogrado dopo tromboaspirazione manuale, somministrazione di tirofiban e dilatazione con pallone semicompliante. È stata effettuata pertanto trombectomia meccanica con dispositivo NeVa 4,5 x 46 mm, efficace per ripristino di flusso coronarico (TIMI 2/3). Data la persistenza dell'apposizione trombotica, seppur notevolmente ridotta, si è optato per una strategia di stenting differito, mantenendo il tirofiban in infusione per 16-18 h unitamente a terapia anticoagulante con eparina. Il controllo angiografico è stato eseguito dopo 18h: all'imaging intravascolare con IVUS si evidenziava voluminosa apposizione trombotica con aspetti di organizzazione, nel contesto di aneurisma fusiforme e diametro medio di 8 mm. Non potendo procedere ad impianto di stent, il paziente veniva dimesso in triplice terapia anticoagulante con warfarin ed antiaggregante.

Anche nel secondo caso il dispositivo è stato utilizzato in seguito ad una strategia di stenting differito durante STEMI inferiore per occlusione trombotica della coronaria destra aneurismatica al tratto paraostiale e persistenza di abbondante burden trombotico nonostante infusione di tirofiban e tromboaspirazione manuale. Al controllo angiografico a 18 h, l'utilizzo del dispositivo EnVast 4,5 x 46 mm ha permesso la rimozione della pressoché totalità dell'apposizione trombotica, il ripristino di flusso coronarico TIMI3 e quindi l'impianto di 5 DES con buon esito procedurale.

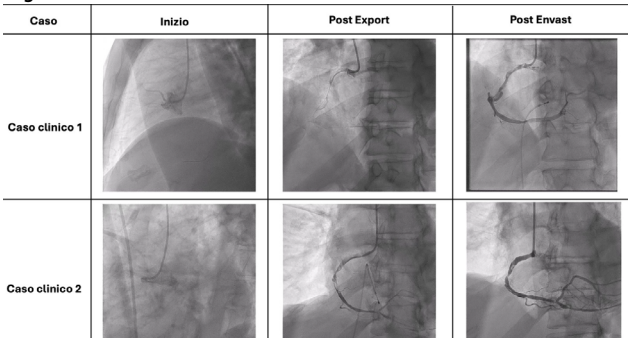
**Conclusioni**

La nostra case series mostra come nel contesto "real life" di SCA in vasi aneurismatici l'utilizzo del diposisitivo NeVa Envast si sia rivelato efficace e sicuro. Pertanto, nella CAE, alla luce dell'elevato burden trombotico, la tromboaspirazione potrebbe avere un suo razionale fisiopatologico e clinico facilitando una corretta ricanalizzazione del vaso, riducendo l'embolizzazione distale e garantendo una corretta riperfusione del miocardio. Alla luce di ciò aspettiamo i risultati degli studi randomizzati in corso per valutarne l'effettiva efficacia e sicurezza nel setting delle SCA e l'eventuale cambiamento di paradigma nell'indicazione alla tromboaspirazione.

**Table 1.** Baseline characteristics of the case series

| Paziente | Informazioni Cliniche | Coronaria culprit | Device utilizzati | Dimensioni EnVast | Risultati | Complicanze | Terapia dimissione |
|---|---|---|---|---|---|---|---|
| Caso clinico 1 | Uomo, 50 aa.<br>SCA STEMI infero-postero laterale<br>Primaria | CD Ostiale | Export<br>Ryurei 2.5 x 26 mm | 4,5 x 46 mm | Flusso TIMI 2-3<br>No impianto DES | Nessuna | Triplice terapia 12 mesi (ASA, VK, Plavix) |
| Caso Clinico 2 | Uomo 62 aa<br>SCA STEMI infero postero laterale<br>Procedura staged | CD Ostiale | Export<br>POBA con palloni SC | 4,5 x 46 mm | Flusso TIMI 3<br>Impianto di 5 DES | Nessuna | DAPT (ASA + Prasugrel) |

**Legend to table: CD** coronaria destra




## C14

**PERCUTANEOUS RETRIEVAL OF RIGHT INTRACARDIAC THROMBUS**

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**Introduction**

The presence of right intracardiac thrombi in patients with central venous catheters is far from rare, represents a serious potentially dangerous complication and a treatment challenge. The Inari Flow-Triever System thromboaspiration system can be a useful tool to remove right intracardiac thrombus mass and reduce the risk of pulmonary embolization.

**Methods**

Herein we present a clinical case of a 30-year-old male patient on dialysis, who had previously undergone bilateral nephrectomy due to polycystic nephropathy and percutaneous closure of an ostium secundum-type atrial septal defect, was urgently admitted to our unit due to the echocardiographic finding of a floating thrombotic formation in the right atrium occupying the tricuspid orifice probably originating at the distal end of a central venous catheter. Upon admission the patient appeared febrile and with an empyema mass in the right pleural space.

**Results**

A chest CT scan documented extensive fluid collection in the right pleural space with marked atelectatic effects on the lung parenchyma and chronic thrombotic mass involving the left brachiocephalic vein extending to superior vena cava. Thoracentesis and blood cultures were performed. Methicillin resistant Staphylococcus Aureus has been isolated in blood cultures, on the tip of the removed central venous catheter and in the pleural fluid. Transesophageal echocardiography showed a large multilobulated mass, with maximum diameter of 3.5 cm, originating from the superior vena cava and protruding into the right atrium up to the tricuspid plane (Figure 1).

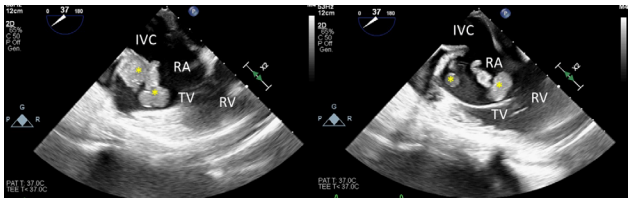


**Figure 1:** Transesophageal echocardiogram: the asterisk indicates the multilobulated intracardiac mass; IVC: inferior vena cava; RA: right atrium; RV: right ventricle; TV: tricuspid valve.

Considering the elevated embolic risk, we decided to remove the thrombotic mass by using off-label the Inari FlowTriever System 24 French (Inari Medical, Irvine, CA, USA), an over the wire retrieval/aspiration system. The system consists of a support cable to which three nitilol alloy discs of different diameters are attached distally which are opened downstream of the thrombotic formation to block and withdraw it into the guiding catheter. In order to increase the suction force, a syringe in which a vacuum is made is attached to the guiding catheter. The system was inserted through a 33 cm long Gore DrySeal 24 French introducer positioned through the right femoral vein. The guiding catheter was initially placed across the tricuspid valve to obtain complete adherence to the thrombotic mass and to facilitate the aspiration of the floating thrombus through the valve. Several extraction attempts were carried out using discs of different sizes (from 15-18 mm to 19-25 mm). Each attempt was associated with blood aspiration using the syringe connected to the guiding catheter. Only a few tissue fragments were extracted from this attempt. Assuming that the mass was adherent to the lateral atrial wall in continuity with the inflow tract, the guiding catheter was then repositioned in the superior vena cava, and the thromboaspiration maneuver was performed again (Figure 2). After repeated attempts, the floating mass was eventually extracted. Macroscopically it had a cauliflower appearance, featuring a portion of fresh red thrombus and other parts covered with fibrin (Figure 3). The specimen was sent to the laboratory for histological and microbiological analysis.

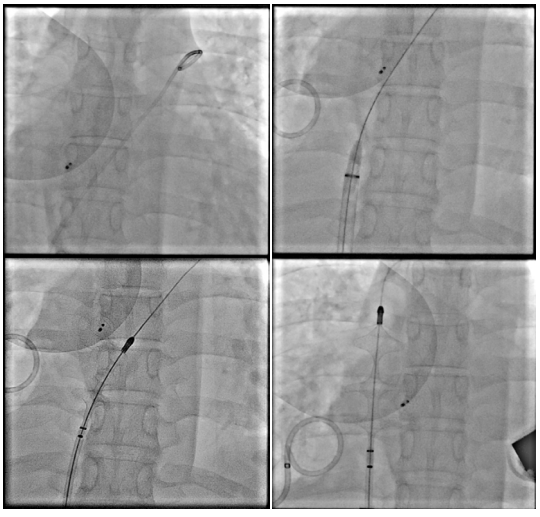

**Figure 2.** Intracardiarc thrombus retrival procedure. A: Placement of a pigtail catheter in the pulmonary artery; B: Exchange with a stiff gui-

de and insertion of the suction system at the level of the tricuspid valve; C: Opening of the three mesh disks adjacent to the tricuspid valve; D: Opening of the three mesh disks on the guidewire positioned in the superior vena cava. The asterisk indicates the drainage catheter placed in the pleural space.

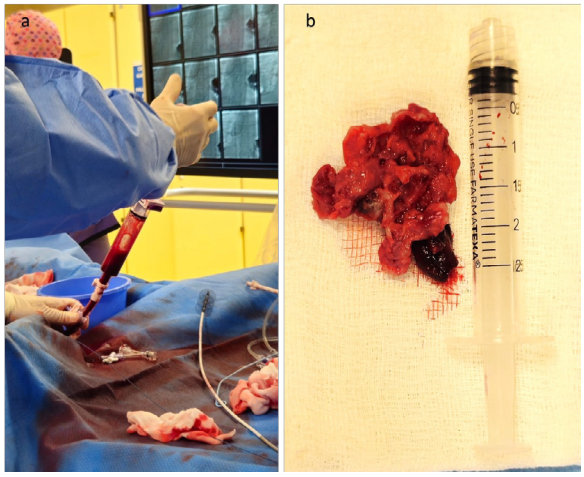


**Figure 3:** Retrieved mass. A: The mass was mechanically retrieved into the syringe using negative suction pressure. B: Histological findings showing fresh red thrombus and fibrin.

The post-procedural course was free of complications. A post-procedure echocardiogram showed a persistent spur of thrombotic material on the posterior wall of the right atrium measuring up to 15x5 mm (Figure 4) and intravenous heparin infusion was promptly started. The microbiological culture resulted positive for Meticillin-resistant Staphilococcus Aureus and the antibiotic therapy was enhanced by replacing vancomycin with daptomicin and fosfomicin.

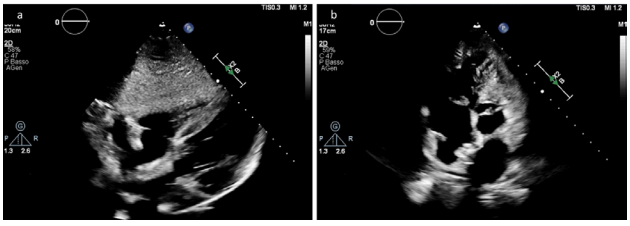


**Figure 4:** Post-procedure echocardiography. The subcostal (a) and the four-chamber projection (b) showed a persistent small spur of thrombotic material on the posterior wall of the right atrium measuring up to 15x5 mm.

**Conclusions**

The generation of intracardiac thrombi in patients with central venous catheters is far from rare and their management is often complex and challenging. In our patient the thrombotic mass was large, mobile, obstructing the tricuspid valve and with a great risk of embolization. Probably at the basis of the genesis of the thrombosis, there were mechanical and infectious elements as demonstrated by the histological examination. The percutaneous removal of intracardiac thrombotic formations is an emergency procedure not recommended by current guidelines and, at present, there are no devices authorized for this purpose. However, considering the emergency condition, we decided anyway to percutaneously remove the thrombotic mass using a mechanical and hydraulic suction system. Using the necessary precautions and prudence, we were able to remove the majority of the thrombotic mass, significantly abolishing the possibility of peripheral embolization and obstruction of the tricuspid valve. Furthermore, the previous closure of the atrial septal defect made us more confident in implementing this strategy as the possibility of a systemic embolism was unlikely and the only potential complication could only be the embolization of the thrombus or part of it in the vessels of the lungs where in any case we could have used the same thromboaspiration system. In conclusion, this clinical case demonstrates that it is possible in emergency conditions to remove large intracardiac thrombotic formations using the Inari FlowTriever System which should therefore be part of the armamentarium of emergency devices in every cath laboratory.

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## C15

### CORONARY CALCIUM PATTERNS DETECTED WITH COMPUTED TOMOGRAPHY AND THEIR IMPACT ON PROCEDURAL OUTCOMES IN CTO-PCI: INSIGHTS FROM TWO HIGH-VOLUME CENTERS

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**Introduction**

This study aimed to propose a novel classification for chronic total occlusion (CTO) calcifications through computed tomography (CT) imaging and to assess its implications on clinical and procedural outcomes in CTO percutaneous coronary intervention (PCI).

**Methods**

A total of 217 patients undergoing elective CTO-PCI in two European centers underwent upstream preprocedural coronary computed tomography angiography (CCTA). A specialized CT analysis software was used for image evaluation. A novel classification system for CTO calcifications was devised based on CT findings. The primary endpoint was procedural failure. Secondary endpoints were coronary perforations, fluoroscopic time, procedural time (defined as the amount of time from the administration of local anesthesia to the insertion of the hemostasis device), number of guidewires and balloons, stent length, number and diameter and contrast volume. Student's t-test or the Mann-Whitney U test were uses, as appropriate, to compare continuous data. Categorical variables were expressed by percentages and frequencies. Frequency differences were assessed using the Fisher exact test or Pearson's chi square test, and the results were reported as incidence rate ratios (IRR). Cohen's weighted Kappa was used to measure the reproducibility and inter-observer agreement of calcium quantification in a randomly chosen sample of 20 individuals. Logistic regression analysis was performed to identify the effect size of calcium burden on the primary outcome of procedural success. The effect size was quantified using Odds Ratios (OR) with 95% CI. Linear regression was performed to assess the impact of calcium burden on quantitative procedural secondary endpoints, and the results were expressed as a B coefficient with 95% CI.

**Results**

Among the 148 patients with available pre-procedural CT, a novel classification identified seven distinct calcification patterns. According to this classification, patients were categorized based on low and high calcium burden across the cross-sectional area (CSA). Procedural success was achieved in 83.8% of cases. High calcium burden correlated with older age, diabetes, and prior coronary artery bypass grafting. Patients with high calcium burden had significantly higher rates of procedural failure (25.9% vs 10.6%; IRR 2.43; 95% CI 1.0-6.1; p=0.03), longer procedural and fluoroscopic times (p=0.02 and 0.04 respectively), increased use of balloons (p=0.03), and a higher incidence of coronary perforation (13.0 vs 3.2%; IRR 4.0; 95% CI 0.9-24.3; p=0.03). Logistic regression analysis showed that calcification burden, according to our classification, predicted the primary outcome (OR 1.24; 95% CI 1.04-1.49; p=0.01). Linear regression analysis showed a significant interaction between calcification burden and procedural time (B coefficient 5.4; 95% CI 1.48-9.33; p =0.007), fluoroscopic time (B coefficient 2.8; 95% CI 0.89-4.79; p =0.005) and number of balloons (0.30; 95% 0.11-0.49; p=0.002)

**Conclusions**

The study emphasizes the role of CT in characterizing CTO-plaque morphology and calcification burden. Identification of high calcium burden lesions via CT predicted procedural failure and increased procedural complexity markers. Pre-CTO-PCI CT imaging facilitates the prediction of procedural complexity, enhancing procedural safety and success. It offers valuable insights for precision planning in CTO-PCI procedures.

## C16

### LONG-TERM OUTCOMES FOLLOWING PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH CANCER: RESULTS FROM THE BALANCE-PCI REGISTRY

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**Introduction**
Given the progress in successfully treating many cancer types, attention to the complexity and challenges of managing cardiovascular events in cancer survivors is of critical importance. Percutaneous coronary intervention (PCI) in patients with cancer is particularly challenging as they present a higher risk of bleeding and thrombotic complications. Many studies have tried to evaluate the prognosis of cancer patients undergoing PCI. However, analyses of long-term outcomes, especially in the setting of chronic coronary syndromes, are still lacking.
**Methods**
The BALANCE-PCI (Balancing risks And Long-term Adverse eveNts in Cancer patiEnts undergoing Percutaneous Coronary Interventions) is a prospected ongoing monocentric registry of cancer patients with acute or chronic coronary syndrome undergoing PCI. We enrolled 295 consecutive patients with neoplastic diseases who underwent PCI between 2009 and 2023, stratified into patients with active cancer, prior cancer, and patients with metastasis. We also included a randomly assigned cohort of 612 patients without cancer (control group) undergoing PCI over the same period. The primary endpoint was the occurrence of major adverse cardio-cerebrovascular events (MACCE) defined as a composite of cardiac mortality, stroke, myocardial infarction (MI), any revascularization. Secondary endpoints were all-cause mortality, target lesion (TLR), target vessel (TVR) revascularization and major bleeding events.
**Results**
The 10-year rates of MACCE were significantly higher in the cancer group than in the control group (24.7% vs 17.0%, p = 0.006). No significant differences were found in terms of MI and stroke between both cohorts. However, cancer patients showed increased 1-, 5- and 10-year cardiac mortality compared to the control group (26.1 vs 10.8%, p<0.001). The adjusted risk of early and long-term all-cause mortality was increased among patients with cancer [hazard ratio (HR) 2.25, 95% confidence interval (95% CI) 1.62-3.13, p < 0.001). Moreover, cancer patients had higher trends of repeat percutaneous or surgical revascularization. After stratifying cancer patients into subgroups, primary endpoint rates were greater among patients with active cancer compared to the control group (25.9% vs 17.0%, p = 0.017). According to the overall neoplastic population, patients with active cancer showed a higher incidence of TLR and TVR (7.6% vs 3.4%, p = 0.027, and 11.4 vs 5.3%, p = 0.01, respectively), as well as instent restenosis (p<0.001). However, despite the high bleeding risk cohort of cancer patients, there were no significant differences in terms of major bleeding events compared to controls (5.4% vs 4.4 %, p = 0.480).
**Conclusions**
Patients with cancer, especially in the active state, are associated with higher long-term MACCE incidence, mainly due to the progression of atherosclerosis that necessitates new revascularization. Management of patients with cancer and coronary artery disease requiring PCI should be tailored and based on a multidisciplinary approach, carefully evaluating the single patient's thrombotic risk, bleeding risk and life expectancy to decide the optimal procedural and medical strategy.

## C17

### PERCUTANEOUS CORONARY INTERVENTIONS FOR ANEURYSMATIC RIGHT CORONARY ARTERY IN ACUTE CORONARY SYNDROME: RIGHTMARE REGISTRY OUTCOMES

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**Introduction**
The optimal strategy during percutaneous coronary intervention (PCI) of aneurysmatic right coronary artery (ARCA) remains uncertain and has never been tested in the acute setting.
**Methods**
Among 102.376 PCIs performed in 18 European centers, a total of 85 patients presenting with an acute coronary syndrome undergoing ARCA PCI were finally included in the analysis. PCI strategy (stenting performed during the immediate vs a staged procedure) and pharmacological approach adopted were collected. The primary outcome was procedural success (technical success without in-hospital MACE).
**Results**
The primary outcome occurred in 48.2% of cases with no significant differences observed between the immediate and staged PCI groups (50.9% vs 43.3%, p=0.504). Patients in the staged-PCI group had a significantly higher rate of intravenous anticoagulants use (83.3% vs 48.1%, p=0.002), BARC type 3 and 5 bleedings (12.9% vs 1.9%, p=0.037), and longer in-hospital stay (7.40 ± 5.11 vs 9.5 ± 5.25 days, p=0.049). No independent predictors for procedural success were found in either group after multivariate analysis. Target lesion failure occurred in 24.1% of cases without differences between groups at a median follow-up of three years.
**Conclusions**
Among patients undergoing ARCA PCI in the setting of ACS, immediate or staged-PCI were associated with similar in-hospital and long-term outcomes. However, staged-PCI was associated with higher risk of major bleeding events and longer length of stay compared to immediate PCI strategy.

# TRANSCATHETER AORTIC VALVE IMPLANTATION - 2

## C18

### LONG TERM FOLLOW-UP OF NATURAL HISTORY OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH AORTIC STENOSIS UNDERGOING TAVI: THE ROLE OF QUANTITATIVE FLOW RATIO

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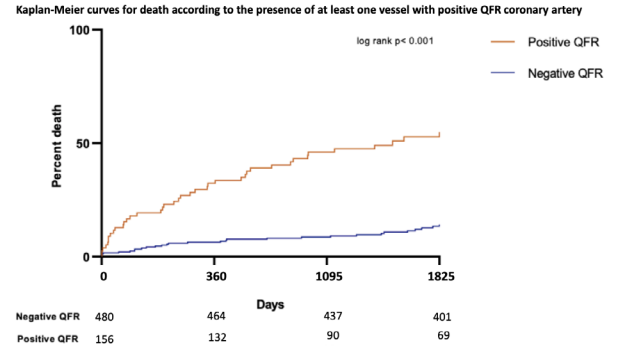
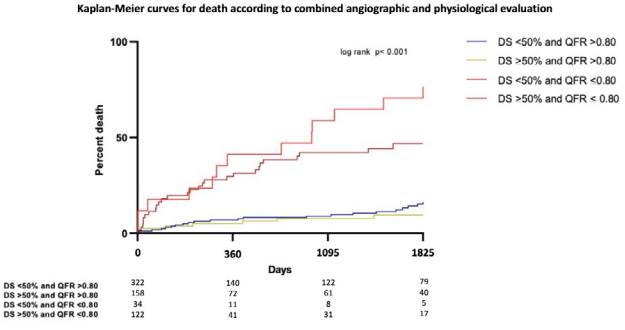
**Introduction**
The prognostic impact of functionally significant coronary artery disease (CAD), as assessed with quantitative flow ratio (QFR), in patients with severe aortic stenosis (AS) treated with transcatheter aortic valve replacement (TAVR) is unknown.
**Methods**
This is a retrospective study with blind analysis of angiographic data, enrolling consecutive patients with severe AS treated with TAVR at 4 Italian centers. None of the patients enrolled received pre-TAVR or concomitant coronary revascularization, either for the absence of significant coronary stenoses or by clinical decision. Visual estimation of diameter stenosis (DS) and quantitative flow ratio (QFR) analysis were carried out in all coronary arteries. The endpoint was all-cause mortality at 5-year follow-up
**Results**
A total of 636 patients were enrolled. At visual estimation, 280 patients (44%) presented a diameter stenosis ≥50% in at least 1 coronary artery, whereas 156 patients (24.5%) had at least 1 vessel with QFR <0.80 and, therefore, were included in the positive QFR group. Overall, 138 (21.7%) patients died during the follow-up.
In the Kaplan-Meier analysis, patients with positive QFR experienced significantly higher rates of death during follow-up compared with those without (51.1% versus 12.1%; P<0.001), whereas no significant difference was evident in terms of death between patients with or without significant coronary artery disease according to angiographic evaluation (24.3% versus 19.7%; P=0.244).
In a multivariate regression model, positive QFR was an independent predictor of all-cause death during follow-up (hazard ratio, 5.31 [95% CI, 3.21–8.76]).
**Conclusions**
Coronary QFR can predict mortality in patients with severe AS treated with TAVR without revascularization.

Fig. 1




Positive QFR: QFR values ≤0.80

Fig 2.



## C19

### CHARACTERISTICS AND OUTCOMES OF PATIENTS WITH SEVERE ISOLATED TRICUSPID REGURGITATION ACROSS DIFFERENT TREATMENT STRATEGIES: SINGLE HEART VALVE CENTRE EXPERIENCE

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**Introduction**

Tricuspid regurgitation (TR) has a significant impact on mortality, yet optimal management strategy remains debated. This study aims to compare characteristics and outcomes of patients with isolated severe TR across conservative management and surgical or transcatheter interventions.

**Methods**

We retrospectively analyzed consecutive patients diagnosed with isolated severe TR from a high-volume tertiary center between 2018 and 2023. Exclusion criteria were defined as: previous tricuspid valve (TV) intervention, concomitant severe valvular disease, and severe left ventricular systolic dysfunction. Baseline and follow-up data were retrieved from electronic health records and telephone interviews.

**Results**

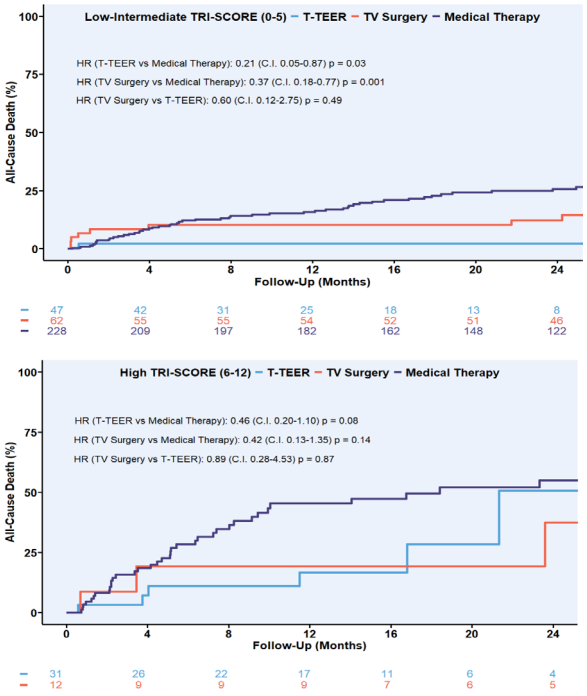
A total of 481 consecutive patients were enrolled, of which 79 (17%) were treated with transcatheter tricuspid edge-to-edge repair (T-TEER), 74 (15%) underwent TV surgery and 328 (68%) were managed with medical therapy alone. The mean age of the cohort was 74±12 years, with 186 patients (39%) being female.

Patients treated with T-TEER, when compared to medical therapy and TV surgery, had the highest TRI-SCORE (4.8 vs. 4.1 and 3.1 respectively, p<0.001), and were the most symptomatic (NYHA III-IV 52% vs. 33% and 38% respectively, p<0.001). Echocardiographically, their parameters were intermediate between the conservative and surgical groups concerning functional etiology of TR (86%), RV dysfunction (24%) and pulmonary hypertension (mean sPAP 42 ± 9 mmHg).

Intervention was successful in reducing TR grade to ≤ moderate in 64 (86%) of patients treated with T-TEER and 74 (100%) of patients treated with TV surgery. In-hospital mortality rate was significantly higher for TV surgery than for T-TEER (9.5% vs. 1.3%, p=0.03). At 2-year follow-up, conservative strategy was associated with a higher incidence of all-cause death compared to TV surgery (HR 0.33, 95% CI 0.18-0.63, p<0.001) and T-TEER (HR 0.40, 95% CI 0.20-0.83, p=0.014). This result was mainly dragged by low-risk patients (TRI-SCORE 0-5) because the benefit of intervention was lost in high-risk patients (TRI-SCORE 6-12).

**Conclusions**

Severe isolated tricuspid regurgitation exhibits diverse clinical and echocardiographic characteristics, which influence treatment efficacy. Surgical and transcatheter interventions demonstrate improved outcomes compared to medical therapy in low-risk patients (TRISCORE 0-5). However, in advanced stages of the disease (TRISCORE 6-12), the benefits of these interventions decline.




## C20

### ANNULAR VERSUS SUPRA-ANNULAR SIZING IN BICUSPID TAPERED AORTIC VALVES UNDERGOING TAVI: THE AD HOC REGISTRY

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**Introduction**

Raphe-type bicuspid aortic valve (BAV) is a potential hostile scenario in trans-catheter aortic valve replacement (TAVR) due to its pronounced calcium burden, possibly associated with a tapered valve configuration. Trans-catheter heart valve (THV) choice and sizing strategy (annular vs. supra-annular) are controversial in this valve subtype. The aim of the study was to describe the phenotypical characteristics of severe, raphe-type, bicuspid aortic stenosis undergoing TAVR and to explore the safety and the efficacy of modern-generation THVs, analysing the impact of different sizing strategies (annular vs supra-annular) on short- and mid-terms outcomes.

**Methods**

This is an observational, retrospective, international, multicentre registry in which consecutive stenotic Sievers type 1 BAV undergoing TAVR were enrolled. Based on retrospective analysis of MSCT, consisting in calculation of all the four available methods to address a supra-annular sizing (LIRA, BAVARD, CASPER, CIRCLE), the study population was divided into tapered (in case of at least one positive sizing method) and non-tapered configuration. A matched comparison between annular and supra-annular sizing groups was performed in patients presenting with tapered configuration.

**Results**

From January 2016 to June 2023, 897 patients were enrolled across 20 centres. Of them, 696 patients displayed a tapered configuration. Of those, 510 received a THV according to annular sizing. Applying a propensity score matching, 186 matched pairs were selected. Technical success (96.2% vs 94.1%, OR 1.61 [0.61-4.24], p=0.34), 30-day device success (83.6% in both groups, OR 1.42 [0.78-2.57], p=0.25) and 30-day early safety (71.8% vs 70.5%, OR 1.07 [0.68-1.68], p=0.78) were similar between the annular and supra-annular sizing groups; a higher post-TAVR gradient was observed in supra-annular group, although it was only 2 mmHg mean. In the entire population, at mid-term follow-up, the rate of clinical efficacy was 84.7%.

**Conclusions**

TAVR with modern-generation devices is safe and effective for patients with tapered raphe-type BAV, showing comparable results for annular and supra-annular sizing strategies.

## C21

### COMPARISON BETWEEN R-L AND R-NC BAV TREATED WITH TAVR: INSIGHT FROM THE INTERNATIONAL AD HOC REGISTRY

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**Rational**

Sievers type 1 bicuspid aortic valve (BAV) stenosis poses peculiar challenges for trans-catheter aortic valve replacement (TAVR), especially in the presence of calcified raphe. Whether raphe localization may impact on TAVR outcomes is still unknown.

**Technical resolution**

From January 2016 to October 2023, 969 consecutive patients with severe Sievers type 1 BAV stenosis who underwent trans-femoral (TF)-TAVR were retrospectively enrolled in 21 tertiary centers. All the available trans-catheter heart valves (THVs) on the market during the study period were considered. In all the enrolled patients pre-procedural computed tomography was retrospectively analyzed. To account for the non-randomized nature of the study, a 1:1 propensity score matching (PSM) between the most frequent patterns (R-L and R-NC) was applied. Clinical and echocardiographic outcomes were assessed in-hospital, at 30 days and at the last available follow-up. Primary endpoints were VARC-3 technical success, 30-day device success, 30-day early safety and mid-term major adverse events (all-cause death + stroke + hospitalization for heart failure).

**Clinical Implications**

Of the enrolled patients, 825 (85.1%) displayed a right-left (R-L) raphe localization, whereas 131 (13.5%) a right-non-coronary (R-NC) raphe position. After PSM, 126 pairs were identified. The median age was 76 years, with a predominance of male sex. The majority of the patients were at low-risk (STS-PROM 2.7). There was no baseline clinical, ECG, echocardiographic or CT differences between the two groups. In the same way, procedural features (type of implanted THV, rate of pre- and post-dilatation and use of cerebral embolic protection device) did not differ between R-L and R-NC groups. Raphe localization did not impact on technical success (>95% in both groups). Similar short-term and mid-term outcomes have been observed between R-L and R-NC. However, R-L pattern is associated with a nearly 3-fold higher incidence of new permanent pacemaker implantation (PPI) compared to R-NC (16.1% vs 6.7%, OR 0.37, C.I. 0.16 to 0.89).

| | R-L (n=126) | R-NC (n=126) | OR | 95%CI | P-value |
|---|---|---|---|---|---|
| VARC-3 technical success, n (%) | 120 (95.2) | 121 (96.0) | 1.21 | 0.36 to 4.07 | 0.758 |
| **IN-HOSPITAL OUTCOMES** | | | | | |
| All-cause mortality, n (%) | 1 (0.8) | 2 (1.6) | 2.02 | 0.18 to 22.52 | 0.569 |
| Cerebral ischemic event, n (%): | 4 (3.2) | 2 (1.6) | 0.49 | 0.09 to 2.74 | 0.418 |
| VARC-3 major vascular complication, n (%): | 4 (3.2) | 3 (2.4) | 0.74 | 0.16 to 3.39 | 0.702 |
| **New permanent PM implantation, n (%)** | **19 (16.1)** | **8 (6.7)** | **0.37** | **0.16 to 0.89** | **0.026** |
| More than mild PVR, n (%) | 5 (4.0) | 6 (4.8) | 1.22 | 0.36 to 4.11 | 0.748 |
| Severe PPM, n (%) | 4 (3.3) | 5 (4.1) | 1.26 | 0.33 to 4.81 | 0.735 |
| **30-DAY OUTCOMES** | | | | | |
| VARC-3 30-day device success, n (%) | 105 (88.2) | 99 (81.8) | 0.60 | 0.29 to 1.24 | 0.167 |
| VARC-3 30-day early safety, n (%) | 89 (74.8) | 89 (73.6) | 0.94 | 0.53 to 1.67 | 0.827 |
| **MID-TERM OUTCOMES (median FU 1.3yy)** | | | | | |
| VARC-3 clinical efficacy, n (%) | 92 (81.4) | 95 (87.2) | 1.08 | 0.81 to 1.44 | 0.590 |

**Perspectives**

Raphe localization in Sievers type 1 BAV does not impact on major TAVR outcomes, except for PPI risk, which resulted 3-fold higher in R-L compared to R-NC group. TAVR in BAV is per se associated with a higher risk of permanent pacemaker implantation, as observed in our study.

The presence of R-L raphe (the most frequent pattern) may increase the risk of PPI, pushing the THV toward the conduction fiber pathway along the central fibrous body (located at the opposite of RL raphe). This aspect should be taken into consideration in a "tailored TAVR" view.

## C22

### INCIDENCE, PREDICTORS AND OUTCOMES OF PARAVALVULAR REGURGITATION AFTER TAVR IN SIEVERS TYPE-1 BICUSPID AORTIC VALVES

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**Introduction**

Transcatheter aortic valve replacement (TAVR) in patients with bicuspid aortic valve (BAV) stenosis is technically challenging and is burdened by an increased risk of paravalvular regurgitation (PVR).

**Methods**

Consecutive patients with severe Sievers type 1 BAV stenosis undergoing TAVR with current generation transcatheter heart valves (THVs) in 24 international centres were enrolled. PVR was graded as none/trace, mild, moderate, and severe according to echocardiographic criteria. The endpoint of major adverse events (MAE), defined as a composite of all-cause death, stroke, or hospitalization for heart failure, was assessed at the last available follow-up. The primary objective of this study was to identify the incidence, predictors, and clinical outcomes of PVR following TAVR in Sievers type 1 BAV stenosis.

**Results**

A total of 946 patients were enrolled. PVR occurred in 423 patients (44.7%): mild, moderate, and severe in 387 (40.9%), 32 (3.4%), and 4 (0.4%) patients, respectively. Independent predictors of moderate or severe PVR were larger virtual raphe ring (VRR) perimeter (ORadj 1.07, 95% CI 1.02-1.13), severe annular or left ventricular outflow tract (LVOT) calcification (ORadj 5.21, 95% CI 1.45-18.77), self-expanding valve (ORadj 9.01, 95% CI 2.09-38.86), and intentional supra-annular THV positioning (ORadj 3.31, 95% CI 1.04-10.54). At a median follow-up of 1.3 [IQR 0.5-2.4] years, moderate or severe PVR was associated with an increased risk of MAE (HRadj 2.52, 95% CI 1.24-5.09).

**Conclusions**

After TAVR with current-generation THVs in Sievers type 1 BAV stenosis, moderate or severe PVR occurred in about 4% of cases and was associated with an increased risk of MAE during follow-up.

# MISCELLANEOUS - 1

## C23

### BALLOON PULMONARY ANGIOPLASTY IN CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION: A SINGLE CENTRE 9-YEARS EXPERIENCE

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**Introduction**

Balloon pulmonary angioplasty (BPA) has been developed as an alternative and less-invasive treatment strategy for chronic thromboembolic pulmonary hypertension (CTEPH), but safety and long-term therapeutic efficacy must be confirmed. The aim of this study is to examine the clinical and hemoynamic effects of BPA in patients with inoperable disease

or with residual pulmonary hypertension (PH) after pulmonary endarterectomy (PEA).

**Methods**

From June 2015 to May 2024, symptomatic (WHO functional class ≥II) inoperable CTEPH patients and patients with residual PH after PEA were enrolled. At baseline and after three to six months after last BPA session all patients underwent clinical evaluation, six-minute walking distance (6MWD) and right heart catheterization (RHC). Data are presented as median and interquartile range. The comparison of the same parameter between before and after BPA was conducted with a two-tailed T-test for paired data and the significance was assessed with the Wilcoxon Signed-Rank Test for the asymmetric (non-normal) distribution of the data.
Kaplan-Meier curve was used to evaluate long-term survival.

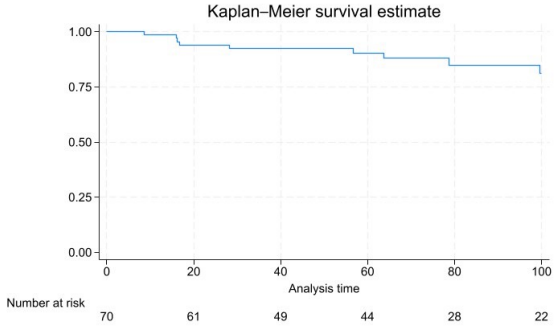
**Results**

Seventy patients [male 42%, median age 69 (55-76) years, 59 inoperable and 11 with residual PH after PEA] were treated for a total of 197 sessions [median number of sessions for each patient: 2 (1-4); median number of vessels treated for each patient: 5 (3-9)]. Sixty-seven patients (96%) were assuming pulmonary arterial hypertension specific drugs before BPA (22 pts, 33% were in combination therapy). All patients received life-long anticoagulation therapy (vitamin K-antagonist: 36 pts, direct oral anticoagulation: 33 pts, fondaparinux: 1 pt).
Six pulmonary artery dissection and 8 hemoptysis with clinical impairment were documented during the procedures; 5 patients had access site complications.

Clinical and haemodynamic results are shown in the Table. Survival starting from baseline RHC is showed in Kaplan–Meier Curve.

| | RAP (mmHg) n=64 | mPAP (mmHg) n=64 | CI (l/min/m2) n=64 | PVR (WU) n=64 | PAC (ml/mmHg) n=64 | 6MWD (m) n=56 | NYHA FC n=70 |
|---|---|---|---|---|---|---|---|
| **Pre-BPA** | 6 (4-7) | 40 (32-48) | 2.7 (2.3-3.0) | 6.1 (4.3-9.4) | 1.34 (0.85-2.00) | 434 (358-506) | 3 (2-3) |
| **Post-BPA** | 6 (4-7) | 33 (26-39) | 2.9 (2.5-3.4) | 4.0 (2.7-6.2) | 2.03 (1.23-3.03) | 479 (370-584) | 2 (2-2) |
| **p-value** | ns | <0.00001 | 0.00019 | <0.00001 | <0.00001 | <0.0005 | <0.00001 |

Legend: RAP, Right Atrial Pressure; mPAP, mean Pulmonary Arterial Pressure; CI, Cardiac Index; PVR, Pulmonary Vascular Resistance; PAC, Pulmonary arterial compliance; 6MWD, 6 Minute Walking Distance




**Conclusions**

BPA is safe and effective at improving symptoms and hemodynamic profile in inoperable CTEPH patients and in patients with residual PH after PEA.

## C24

### CLINICAL FEATURES, MANAGEMENT, AND OUTCOMES OF LEFT MAIN SPONTANEOUS CORONARY ARTERY DISSECTION: A PATIENT-LEVEL META-ANALYSIS

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**Introduction**

Spontaneous coronary artery dissection (SCAD) is an uncommon cause of acute myocardial infarction (MI) and is associated with substantial adverse events. SCAD involving the left main coronary artery (LM) is a rare but potentially life-threatening condition. Currently, minimal data on LM-SCAD have been reported. This study aimed to investigate clinical features, contemporary management, and outcomes of LM-SCAD patients.

**Methods**

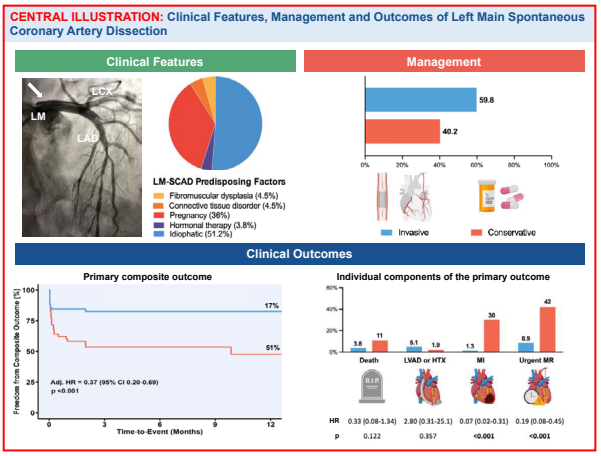
We conducted a systematic review and patient-level meta-analysis of literature using "left main" and "dissection" as search keywords. We sought to determine if reported outcomes were associated with initial management strategy.

**Results**

We screened 492 manuscripts in MEDLINE and EMBASE published between 1990 and 2023. The final analysis included 135 patients (40±11 years, 80% women) diagnosed with LM-SCAD. Remarkably, 36% of cases were associated with pregnancy. Almost all patients (95%) presented with acute coronary syndrome, two-thirds of which were diagnosed with ST-elevation MI. Cardiogenic shock was documented in 22% of patients at presentation, while serious ventricular arrhythmias occurred in 10%. Among published cases, early revascularization strategy with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) was superior to conservative management for the composite endpoint of all-cause death, left ventricular assist device implantation, heart transplant, recurrent MI, and urgent myocardial revascularization (adjusted HR 0.37, 95% CI 0.20-0.69, p<0.001).

**Conclusions**

LM-SCAD is associated with significant acute morbidity and mortality. Revascularization (PCI or CABG) was associated with a lower incidence of early adverse outcomes compared to a conservative strategy, largely driven by the occurrence of recurrent myocardial infarction and urgent revascularization.




## C25

### SIROLIMUS-COATED BALLOONS IN DE NOVO CORONARY LESIONS: LONG-TERM CLINICAL OUTCOMES FROM A MULTI-CENTER INTERNATIONAL REGISTRY

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**Introduction**

Drug-coated balloons (DCB) offer an excellent alternative to drug-eluting stents (DES) in specific lesions and patient subsets. The vast majority of available data in de novo lesions come mainly from paclitaxel-coated balloons (PCB). There is limited data on sirolimus-coated balloons (SCB) performances and especially on long-term outcomes. We provide long-term outcomes in a large cohort of patients treated with SCB in 4 high-volume centres in Europe.

**Methods**

We evaluated all patients undergoing SCB-based coronary angioplasty between 2016 and 2023 at 4 European centres (Heartlands Hospital, United Kingdom; Humanitas Hospital, Italy; San Donato Hospital, Italy; San Giuseppe Moscati Hospital, Aversa, Italy). Patient-level pooled data were collected for analysis. The general indications for DCB were: ISR, small-vessels, de novo lesions, ostial stenosis of a significant side-branch or coronary angioplasty in patients unable to take DAPT beyond one month.

**Results**

During the study period, 1360 patients were treated with SCBs with a mean age of 68.1 ±10.6 years. Of these, 81% (n=1101) were male and 771 (56.7%) had SCB in de novo lesions. Small vessels (<3.0 mm) accounted for 78% (n=601) of cases and 76% (n=584) were long-lesions (20 mm). The median follow-up was 640-days (IQR: 303-736 days) and each patient had a minimum follow-up period of 6-months. Death occurred in 39 (5%) patients and Cardiac Death in 10 patients (1.3%). Target Vessel Myocardial Infarction (TVMI) occurred in 20 patients (2.6%), Target Lesion Revascularization (TLR) and Target Vessel Revascularization (TVR) were 5.6% and 5.8% respectively. The overall Major Adverse Cardiovascular Events (MACE) rate was 8%. We had no documented cases of acute vessel closure.

**Conclusion**

This long-term retrospective analysis of SCB use in a broad all-comers population of patients from high-volume centres demonstrated a good safety profile of the device used with low rates of adverse hard clinical outcomes and acceptable rates of repeat revascularisations given the complexity of the population of patients and lesion sub-sets. Our data might encourage operators who are considering to use this novel technology or are in the early stage of their experience.

## C26

### IMMEDIATE VERSUS STAGED COMPLETE REVASCULARIZATION IN A REAL-WORLD COHORT OF PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION AND MULTIVESSEL DISEASE: INSIGHTS FROM SPUM-ACS REGISTRY

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**Introduction**

Complete revascularization (CR) with percutaneous coronary intervention (PCI) as compared with infarcted-related artery (IRA)-only in patients with ST-elevation myocardial infarction (STEMI) and multivessel disease (MVD) has been consistently associated with lower risk of major adverse cardiac events (MACE). Whether CR should be performed in single or multi-stage procedures is still debated.

**Methods**

We sought to assess among a real-word ACS population enrolled in the prospective multi-center Special-Program-University-Medicine (SPUM, NCT01000701) the impact of staged CR (sCR) on 1-year MACE (myocardial infarction, stroke and all-cause mortality). MVD was defined s significant stenosis (>70%) in two or more major epicardial coronary arteries. A multivariate analysis including independent predictors of MACE, selected by simplifying the overall logistic regression of long-term outcomes using the stepwise backward selection was performed.

**Results**

Out of 2,168 ACS-patients, 333 (15.4%) had STEMI with MVD; of these 217 (65.2%) underwent sCR. sCR patients were overall younger (age ≥75 years 17.5% vs 25.9%; p=0.05), with higher LDL-cholesterol levels (3.7±1.2 vs 3.2±1.0 mmol/l; p<0.001) and mildly reduced left ventricular ejection fraction (LVEF 49.0±10.0 vs 45.6±12.6%, p=0.022) compared to those treated with iCR, who presented with a more complex CV disease burden (previous CABG 10.3% vs 1.4%, p<0.001). Patients who underwent sCR had lower rates of MACE at 1 year, compared to those subjected to iCR (2.3% vs 8.6%, p=0.01), which persisted after adjusting for baseline differences (adjusted HR 0.32, 95% CI: 0.11-0.93, p=0.04). No statistically significant differences were found as regards acute renal failure (AKI 2.3% vs 2.6%, p=0.57) or unplanned revascularization (UR 5.5% vs 7.8%, p=0.28). At multivariate analysis age≥75 years and hypercholesterolemia remained predictor of MACE, after stepwise backward analysis.

**Conclusions**

In real-word ACS patients with STEMI and MVD, sCR is associated with a lower rate of MACE compared to iCR, without differences in term of AKI or TLR. These data have to be confirmed in larger and dedicated trials.

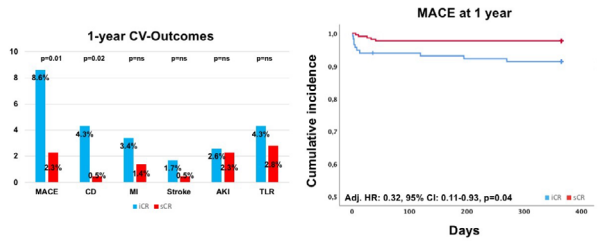


Figure 1. 1-year cardiovascular outcomes and cumulative incidence by KM-curves of 1-year MACE in STEMI patients with MVD underwent immediate vs staged complete revascularization; MACE=major adverse cardiac events; CD=cardiac death; MI=myocardial infarction; AKI=acute kidney failure; TLR=target lesion revascularization.

## C27

### IMPACT OF ACUTE CORONARY SYNDROME PRESENTATION ON CLINICAL OUTCOMES AT ONE-YEAR FOLLOW-UP: EVIDENCE FROM THE 23,700 PRAISE INTERNATIONAL REGISTRY

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**Introduction**

Acute coronary syndromes (ACS) remain the leading cause of mortality within cardiovascular diseases, accounting for one-third of all fatalities. Despite sharing common risk factors, ST-elevation myocardial infarction (STEMI) and non-ST-elevation myocardial infarction (NSTEMI) present distinct prognoses post-discharge, with STEMI being associated with worse outcomes. Aim of the present study is to evaluate long-term prognostic differences between STEMI and NSTEMI patients.

**Methods**

Of the 23,270 ACS patients enrolled in the international PRAISE registry between 2003 and 2019, 1,911 were excluded due to missing data and 21,789 were included in this analysis. Our analysis focused primarily on patient features, medications prescribed at discharge, and outcomes at 1-year follow-up. Outcomes of interest were all-cause mortality, re-infarction, and major bleeding events within one year after hospital discharge. Additionally, composite outcomes were assessed.

**Results**

The study included 12,365 patients (57%) diagnosed with STEMI and 9,424 patients (43%) diagnosed with NSTEMI. Numerous baseline differences were observed; for instance, patients with NSTEMI had a higher rate of cardiovascular risk factors, except for diabetes, prior revascularization, and a higher prevalence of multivessel disease, despite having a slightly higher mean left ventricular ejection fraction (all $p < 0.05$). Upon discharge, patients with STEMI were more frequently prescribed Prasugrel and more often received guideline-directed medical therapy ($p<0.001$), whereas NSTEMI patients were more frequently given Ticagrelor. At the 1-year mark, both groups exhibited comparable clinical outcomes, except for non-fatal reinfarction, which was more prevalent among NSTEMI patients (2.8% vs 3.4%; $p = 0.022$). Bivariate analysis aimed at assessing the independent impact of STEMI on clinical outcomes at 1 year follow-up after discharge showed an inverse association with non-fatal reinfarction (OR 0.81; CI 0.69 – 0.97; p= 0.022), which, however, was not significant after an extensive multivariate adjustment (OR 0.79; CI 0.59 – 1.05; p= 0.108), including cardiovascular risk factors, comorbidities, and medical therapy at discharge.

**Conclusions**

Outcomes between STEMI and NSTEMI groups appear similar at one-year follow-up, with the exception of non-fatal reinfarction being more frequent among NSTEMI patients. This difference may be attributed to less intensive medical treatment and a greater burden of CV risk factors and comorbidities, as suggested by the multivariate analysis. Thus, care should be taken not to underestimate NSTEMI patients, despite the prevailing perception that they may have a better prognosis than STEMI patients.

## C28

### VESSEL-ORIENTED ANALYSIS ON THE RELATIONSHIP BETWEEN QUANTITATIVE-FLOW RATIO AND MORTALITY IN PATIENTS WITH SEVERE AORTIC STENOSIS AND INTERMEDIATE CORONARY LESIONS

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**Introduction**

The prognostic impact of functionally significant coronary artery disease (CAD), as assessed with quantitative flow ratio (QFR), in patients with severe aortic stenosis (AS) treated with transcatheter aortic valve replacement (TAVR) is unknown.

**Methods**

This is a retrospective study with blind analysis of angiographic data, enrolling consecutive patients with severe AS treated with TAVR at 4 Italian centers. None of the patients enrolled received pre-TAVR or concomitant coronary revascularization, either for the absence of significant coronary stenoses or by clinical decision. 3D-QCA estimation of coronary stenosis and quantitative flow ratio (QFR) analysis were carried out in all coronary arteries. The endpoint was all-cause mortality at 5-year follow-up

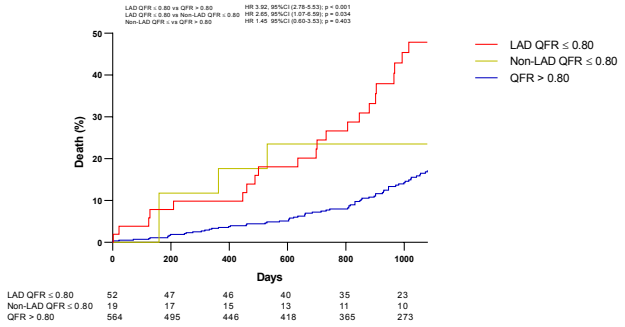
**Results**

280 patients with 635 intermediate coronary lesions were included in this study. QFR-positive lesions were associated with significantly lower minimal lumen diameter (MLD) (1.50 mm vs. 1.70 mm, p<0.001), greater lesion length (LL) (24.50 mm vs. 15.00 mm, p<0.001), and higher diameter stenosis (DS%) (45.50% vs. 37.00%, p<0.001) compared to QFR-negative lesions. At five years, the mortality rate was 50.7% for QFR-positive lesions versus 19.3% for QFR-negative lesions. QFR ≤ 0.80 was an independent predictor of mortality (HR 2.91, 95% CI 1.94-4.36, p<0.001). Further, LAD QFR-positive lesions demonstrated a stronger association with mortality (HR 3.92, 95% CI 2.78-5.53, p<0.001) compared to non-LAD QFR-positive lesions (HR 2.65, 95% CI 1.07-6.59, p=0.034).

**Conclusions**

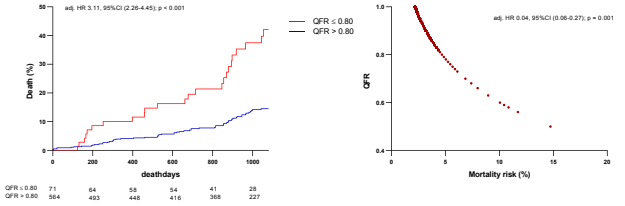
QFR is a significant predictor of mortality in patients with severe AS and intermediate coronary lesions undergoing TAVR. Vessel-level analysis highlights the critical role of QFR, particularly in LAD lesions, in guiding clinical decisions and improving patient outcomes.

**Fig. 1 mortality rates according QFR-positive lesions' location**




Positive QFR: QFR values ≤0.80

**Figure 2: discrete and continuous relationship between QFR and mortality**




## MISCELLANEOUS - 2

### C29

**THE USE OF COILS DURING PERCUTANEOUS CORONARY INTERVENTIONS: INSIGHT FROM COILSEAL REGISTRY**

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**Introduction**

The use of coils is a consolidated practice in interventional cardiology in both elective and emergency setting, often proving lifesaving in this latter setting. Despite these premises, use of coils in interventional cardiology has received limited studies and the application of this technology in coronary field is actually "off-label" and not included in the Instruction for Use (IFU).

**Methods and Results**

From 2001 to 2023, 143 patients (77% male; median age 71.5) from 17 Italian and Spanish centres underwent the placement of 308 coronary coils and included in the COILSEAL Registry. 113 patients (79%) underwent coils implantation to resolve a coronary perforation and 30 patients (21%) were treated with coils' sealing of coronary fistulas or aneurisms. About patients treated for coronary perforation, 47% were admitted for acute coronary syndrome and 53% for chronic coronary syndrome; furthermore about 47% of the procedure complicated by perforations were chronic total occlusion PCI.

Coronary arteries more frequently involved in perforations were the left anterior descending artery (21%), septals (18%), postero-lateral branch (12%) and diagonals (11%). Guidewires that caused perforations were in most cases workhorse wires (57%) and less frequently polymeric wires (33%), stiffer wires (8%) and extrasupport wires (2%) [Figure 1].

The most frequent types of perforations treated, according to PCR classification, were type 5 (67%) and 3 (20%) [Figure 2]. Only 2 patients required cardiac surgery and 22 patients (19%) were treated with emergent pericardiocentesis. The technical success has been achieved in 96% of procedures and in-hospital MACE were 12 (8.4%) with 10 deaths, 4 targe vessel myocardial infarction (TVMI) and 1 stroke. The median follow-up was 889 days with 22 death (6 for cardiac cause) and 11 TVMI.

**Conclusions**

Use of coils in coronary interventions was successful in sealing coronary artery perforations, fistulas and aneurism in the majority of cases. Coronary artery perforations, one of the most feared and treacherous complication, can be solved with coils implantation, a device characterized by high efficacy and safety.

**Figure 1. Guidewire involved in coronary perforation**

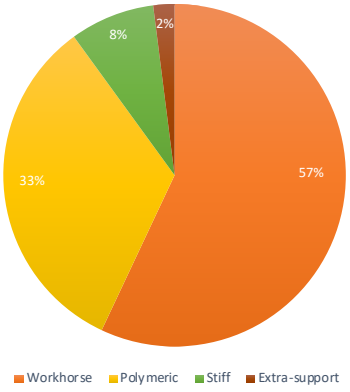
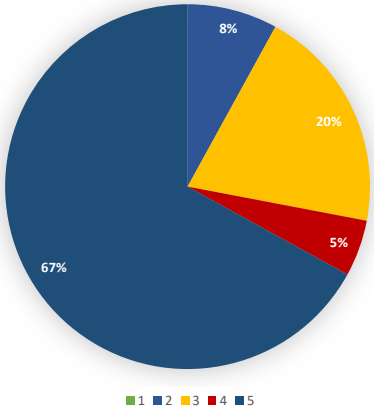



**Figure 2. Type of perforation (PCR classification)**




### C30

**RISK FACTORS AND CLINICAL PRESENTATION OF CORONARY HEART DISEASE IN YOUNGER PATIENTS**

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**Introduction**

Coronary artery disease (CAD) is a significant health concern that can affect also younger individuals. However, limited data exist regarding CAD in younger populations. This study aims to characterize the clinical features, manifestations, and outcomes of individuals aged 40 years or younger with an indication for coronary angiography.

**Methods**

We retrospectively included consecutive patients aged 40 years or younger who underwent coronary angiography at our institution from 2010 to March 2024. We collected data regarding baseline clinical characteristics, traditional cardiovascular risk factors (hypertension, smoking, hypercholesterolemia, obesity, family history, and diabetes), and non-traditional ones (such as peripheral artery disease and active neoplasia). Differences between patients requiring percutaneous coronary interventions (PCI) and those with no significant coronary disease were assessed too.

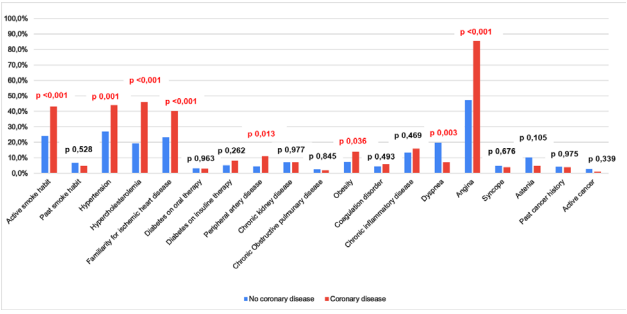
**Results**

A total of 456 interventional cases (424 patients, 32 of whom had repeated accesses <40 years) were included in the study: 100 (22%) underwent PCI, whilst 356 (78%) underwent coronary angiography only. The mean age was 34 ± 6 years (37 ± 4 vs 33 ± 7 in the PCI and angiography group, respectively). The most prevalent cardiovascular risk factors were arterial hypertension (30.7%), active smoking (28.1%), hypercholesterolemia (25.2%), and family history of ischemic heart disease

(27%). The prevalence of diabetes was lower (5.7% on insulin therapy and 3.1% treated with oral therapy). All traditional cardiovascular risk factors were more prevalent in the PCI than in the angiography only group (hypertension 44% vs. 27%, p < 0.001; active smoking 43% vs. 24%, p < 0.001; hypercholesterolemia 46% vs. 19.4%, p < 0.001; family history of ischemic heart disease 40% vs. 23.3%, p < 0.001; obesity 14% vs. 7.3%, p = 0.036), except for the prevalence of diabetes, which was similar in the two groups (3% vs 3.1%, p = 0,963 in oral therapy and 8 % vs 5.1%, p = 0.262 in insulin therapy). Angina was the predominant symptom in 88% of the PCI cases (vs. 47.2%, p < 0.001), while dyspnea was less common in the PCI group (7% vs. 19.8%, p = 0.003). Among non-traditional cardiovascular risk factors, peripheral artery disease was more common in the PCI vs angiography only group (11.1% vs. 4.4%, p = 0.013), while chronic kidney disease (7.1 % vs 7.1 %, p = 0.977), chronic obstructive pulmonary disease (2 % vs 2.4 %, p = 0.845), active cancer (1 % vs 2.6 %, p = 0.339) and past cancer history (4 % vs 4.1 %, p = 0.975) were not significantly different between the two groups **(Figure)**.

**Conclusions**

Traditional cardiovascular risk factors have a high prevalence also in younger patients, with rates in line with international registries of older population. Only diabetes mellitus was less represented in our study, reflecting its higher prevalence with aging. Peripheral artery disease emerged as a further possible red flag for CAD in younger populations. These results underly the need for increased efforts to prevent and eventually treat these modifiable risk factors through primary and secondary prevention strategies.




## C31

**UNMASKING MYOCARDIAL BRIDGE-RELATED ISCHEMIA BY QUANTITATIVE FLOW RATIO FUNCTIONAL EVALUATION**

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**Introduction**

A myocardial bridge (MB) refers to an epicardial coronary artery segment coursing within the myocardial muscle, often associated with the left anterior descending (LAD) artery. Traditionally deemed benign, MBs can lead to silent ischemia, stable angina, acute coronary syndromes, Takotsubo cardiomyopathy and fatal arrhythmias. Accurate assessment of MBs' hemodynamic significance is crucial for treatment guidance. Intracoronary functional evaluations using fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) have been proved useful in this setting, especially when tested during inotropic stimulus. However, their invasive nature limits their use in clinical practice. Quantitative Flow Ratio (QFR) offers a minimally invasive alternative for MB functional evaluation even though limited data are present. Aim of this study was to compare the use of the three different tests for the evaluation of MBs, both at rest and during stress stimulus.

**Methods**

This study retrospectively analyzed data from patients with typical angina or abnormal non-invasive tests indicating myocardial ischemia, with confirmed MB on the LAD (2013-2024). All the included subjects underwent coronary angiography with invasive functional evaluation, both at rest and during inotropic stimulus with dobutamine. QFR was calculated retrospectively for all cases during both at rest and during stress stimulus. Statistical analysis involved the evaluation of the presence of correlation between the three tests and comparison among their sensitivities.

**Results**

A total of 16 patients was included in the study. Mean age was 56.0 ± 14.3 years, and 31% of patients were female. Hypertension was present in 50% of patients, while 31% had dyslipidemia, and 19% had a history of diabetes mellitus. During invasive stress testing, 75% of the patients reached the target dobutamine dose, with 25% experiencing severe angina that required test interruption. The inotropic challenge significantly increased the median double product from 8515 to 17295 (p < 0.001). 3D computed diastolic minimal lumen diameter at the level of MB significantly reduced from 2.1 mm to 0.95 mm (p < 0.001) during stress stimulus. Median FFR values showed no significant change from rest (0.87) to stress (0.85), with only one patient demonstrating a positive stress-FFR. In contrast, median iFR values significantly decreased from 0.91 at rest to 0.80 during stress (p < 0.001), with stress-iFR ≤ 0.89 in all but three patients. QFR at rest did not indicate significant ischemia (median 0.91), but during inotropic infusion, QFR identified ischemia (≤ 0.84) in 12 out of 16 patients (median 0.79, p < 0.001). There was a significant positive correlation between stress-QFR and stress-iFR (Spearman's rank correlation coefficient 0.602, p = 0.047), but not between QFR and FFR. QFR and iFR values were concordant during stress in 13 patients. The sensitivity of QFR during inotropic infusion was comparable to stress-iFR and higher than stress-FFR, demonstrating QFR's potential as a reliable, minimally invasive tool for assessing MB-related ischemia.

**Conclusions**

QFR, computed during inotropic infusion, shows high sensitivity for detecting MB-related ischemia, comparable to stress-iFR and superior to stress-FFR. The correlation between stress-induced iFR and QFR suggests QFR as a reliable, minimally invasive alternative for functional lesion-specific evaluation in MB patients. Larger studies are necessary to confirm these preliminary findings and standardize QFR use in dynamic coronary stenosis assessments.

## C32

**SUTURE-MEDIATED PFO CLOSURE: LONG-TERM OUTCOMES AND PREDICTORS OF SUCCESS**

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**Introduction**

Percutaneous suture-mediated PFO closure offers a safe and effective alternative to device-based methods, albeit with slightly lower success rates in unselected patients. This study aims to assess the long-term safety and efficacy of suture-mediated PFO closure in the largest and longest-followed patient cohort to date, and to identify predictors of procedural success.

**Methods**

Between 2016 and 2023, 703 consecutive patients (mean age 47±12 years, 62% women) with PFO-associated stroke or transient ischemic attack (TIA) underwent suture-mediated PFO closure (Heartstitch, Fountain Valley, CA) at our institution. At the 1-year follow-up, all patients were assessed using transthoracic echocardiography (TTE) with a bubble study to detect significant residual shunt (≥ grade 2 on a scale of 0-3).

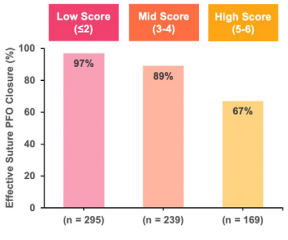
**Results**

The procedure was successfully completed in all patients without any procedural complications. A total of 42 patients (6.0%) required more than one suture. At the 1-year follow-up, the TTE bubble study identified significant residual shunt in 91 patients (12.9%). Independent predictors of significant residual shunt, identified via pre-procedural transoesophageal echocardiography (TEE), included PFO maximum width (HR 1.49; 95% CI 1.30 - 1.71; p < 0.001), PFO minimum length (i.e., extent) (HR 0.89; 95% CI 0.82 - 0.96; p = 0.004), and severe (grade 3) shunt (HR 3.38; 95% CI 1.71 - 7.10; p < 0.001). A new scoring system, the WiSE score, was developed and internally validated based on these variables (AUC 0.78; 95% CI 0.73 - 0.83). At a mean clinical follow-up of 4.0 ± 2.2 years, no recurrent embolic events (stroke or TIA) were reported, and only one episode of atrial fibrillation occurred.

**Conclusions**

Suture-mediated PFO closure demonstrates long-term safety and efficacy. The WiSE score can be a valuable tool for optimally selecting patients for this procedure.

| PFO Features | | Points |
|---|---|---|
| A. Maximum Width | ≤2 mm | 0 |
| | >2 <4 mm | 1 |
| | ≥4 mm | 3 |
| B. Shunt severity grade 3 | | 2 |
| C. Minimum Extent ≤ 6 mm | | 1 |



## C33

### PROGNOSTIC VALUE MEAN PULMONARY ARTERIAL PRESSURE AND PULMONARY VASCULAR RESISTANCE IN PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION AT FOLLOW-UP

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**Introduction**

Hemodynamic variables related to right ventricular (RV) function have consistently been associated with survival in pulmonary arterial hypertension (PAH). New PAH treatments, however, seems to improve RV coupling reducing RV afterload [e.g. mean pulmonary arterial pressure (mPAP) and pulmonary vascular resistance (PVR)], but without increasing cardiac output. The prognostic role of a mPAP <35 mmHg at follow–up and PVR values <5 WU in prevalent patients have been described.
The aim of this work was to define the prognostic role of a mPAP <35 mmHg and PVR <5 WU in patients with idiopathic, hereditary, drug–induced PAH (I/H/D–PAH) and PAH associated with connective tissue disease (CTD–PAH) or congenital heart disease (CHD–PAH) at follow–up after first–line treatment strategy.

**Methods**

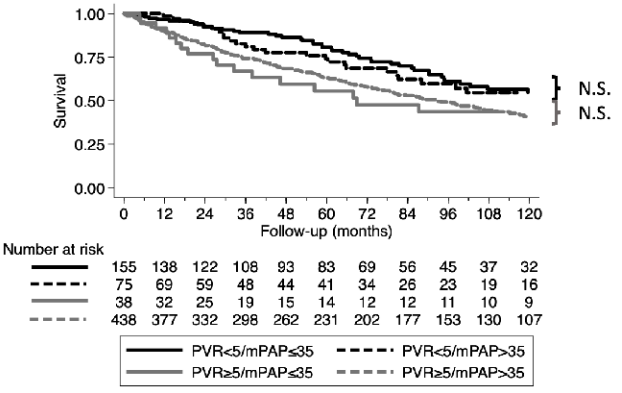
Treatment naïve PAH patients were assessed at 1st follow–up (3–6 months after starting PAH–specific therapy; 1st F–UP) with right heart catheterization. The primary outcome was all–cause death. Analyses were performed using Kaplan Meier curves and comparisons were done with Log–rank test. Cox regression analysis was used to find the predictive value of mPAP and PVR at bivariate analysis. Data are expressed as median (IQR).

**Results**

794 patients with PAH were enrolled (54% I/H/D, 28% CTD, 18% CHD) and 706 have a complete re–evaluation 4 (3–6) months after starting first–line treatment. Death occurred in 54% of patients over a median follow–up duration of 5.8 (2.4–11) years. Survival curves according to a cut–off value of 35 mmHg for mPAP and 5 WU for PVR are shown in the Figure. Patients with PVR <5 WU and mPAP ≤35 mmHg have a better prognosis than patients with PVR ≥5 WU (independently from mPAP; p–values <0.02) but have the same prognosis of patients with PVR <5 WU and mPAP >35 mmHg (p–value= 0.666). Patients with PVR <5 WU and mPAP >35 mmHg have a better prognosis than patients with PVR ≥5 WU and mPAP >35 mmHg (p–value= 0.031) and a trend toward a better prognosis than patients with PVR ≥5 WU and mPAP ≤35 mmHg (p–value= 0.06). Patients with PVR ≥5 WU have the same prognosis independently from mPAP (p–value= 0.683). In a bivariate Cox regression analysis only PVR <5 WU predict prognosis [HR (95%CI)= 0.61 (0.44–0.84); p–value= 0.002] while a mPAP <35 mmHg is not prognostic [HR (95%CI)= 1.00 (0.72–1.40); p–value= 0.991].

**Conclusioni / Conclusions**

mPAP <35 mmHg does not further discriminate the survival over a cut–off value of 5 WU of PVR.




## C34

### EFFICACIA E SICUREZZA DELL'EMBOLECTOMIA POLMONARE MECCANICA IN UN CENTRO DI TERZO LIVELLO: IL REGISTRO LANCISI

Lorenzo Torselletti[1], Elisa Nicolini[1], Alessandro Maolo[1], Luca Mariani[1], Massimiliano Serenelli[1], Andi Muçaj[1], Cristian Mattei[1], Paolo Tofoni[1], Flavia Ciuffreda[1], Lucia Zannini[1], Gianni Profeta[1], Andrea Chitarroni[1], Donatella Squadroni[1], Silvia Stella[1], Leonardo Palmieri[1], Sabrina Cartelletti[1], Matteo Fabrizio[1], Sabrina Fradeani[1], Maria Pandolfi[1], Tommaso Piva[1]
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**Introduzione**

L'embolia polmonare (PE) rappresenta la terza più frequente sindrome acuta cardiovascolare ed è gravata da una mortalità inaccettabilmente elevata nelle forme ad alto rischio (25%-50%) ed intermedio (6%-15%). In accordo con le linee guida ESC 2019 sull'embolia polmonare acuta, la terapia fibrinolitica è raccomandata come trattamento di prima linea nelle forme ad alto rischio o intermedio-alto con instabilità emodinamica. Oltre ad essere gravata da un alto tasso di sanguinamento (9.2%-1.5%), in più della metà dei casi la terapia fibrinolitica non viene somministrata per un percepito rischio emorragico elevato. É in questo setting che strategie invasive quali l'embolectomia chirurgica o strategie transcatetere (TAM) dovrebbero essere prese in considerazione. Tuttavia è stato dimostrato in studi in vitro ed in vivo che la trombo-frammentazione e la trombectomia reolitica risultano essere inferiori rispetto alla tromboaspirazione per il minor rischio di embolizzazione distale. Tra i vari device disponibili in commercio per la TAM: 8F Penumbra indigo catetere da aspirazione (EXTRACT-PE trial) ed il 24-20-16F Inari FlowTriver system ( FLARE e FLASH STUDY). Lo scopo di questo studio è quello di riportare l'iniziale esperienza del nostro centro nell'embolectomia meccanica percutanea nel setting ad alto rischio ed intermedio alto negli ultimi due anni.

**Metodi**

Nel nostro studio retrospettivo osservazionale, monocentrico, abbiamo reclutati pazienti con PE ad alto rischio o intermedio-alto con instabilità emodinamica, controindicazione assoluta alla fibrinolisi o mancato successo di quest'ultima. L'instabilità emodinamica veniva valutata seguendo le definizioni delle linee guida del ESC 2019 sul tromboembolismo. I pazienti sono stati seguiti fino alla dimissione o al decesso intraospedaliero. Tutti i pazienti prima della procedura di trombectomia venivano trattati con terapia anticoagulante e veniva posto un supporto farmacologico al circolo e ventilatorio qualora vi risultasse la necessità clinica. Inoltre, tutti i pazienti eseguivano un'angio-TC per il planning pre-procedurale. Tre diverse tipologie di dispositivo a nostra disposizione sono state utilizzate: "Inari Flow Triver system", "Penumbra Indigo" e " AngioJet". La scelta del dispositivo veniva fatta dal cardiologo interventista sulla base del quadro clinico, della TC e della disponibilità del device al momento dell'evento. Il successo procedurale era definito come riduzione del quadro di instabilità emodinamica in termini di riduzione della pressione arteriosa polmonare media, dei segni, dati laboratoristici e strumentali di ipoperfusione e shock, riduzione della necessità di supporto inotropo. L'endpoint primario è stato definito come un composito intra-ospedaliero di mortalità per tutte le cause, necessità di terapie in bailout entro 48h, sanguinamenti maggiori secondo la classificazione BARC e deterioramento clinico. L'endpoint secondario di sicurezza intraospedaliero comprendeva: i componenti dell'endpoint primario, stroke ischemico o emorragico, complicanze correlate al device (danno alla valvola tricuspide, tamponamento cardiaco, lesione delle arterie polmonari), complicanza maggiore dell'accesso vascolare secondo criteri VARC3.

**Risultati**

Sono stati arruolati un totale di 11 pazienti dal 25/02/2022 al 30/05/2024. 9 pazienti sono stati sottoposti a trombectomia meccanica (8 Flow Triver ed 1 Penumbra), 1 paziente è stato sottoposto a terapia reolitica con sistema AngioJet. La casistica del campione era caratterizzata in prevalenza da donne 8 (72%), con età mediana di 66 anni (IQR 28-77), 9 (81.8%) pazienti erano stati sottoposti a recente intervento chirurgico, 5 pazienti con trombosi venosa concomitante e sPESI score di 2. La maggior parte dei pazienti aveva un rischio alto (6, 60%), mentre il restante aveva un rischio intermedio-altro (40%). Tutti i pazienti presentavano disfunzione ventricolare destra (RV/LV ratio 1,5 ± 0,4). 8 pazienti (72.7%) avevano una presentazione alla TC di embolia bilaterale, 3 pazienti (27,3%) avevano anche la presenza di un trombo in transito. 10 pazienti (90%) sono stati sottoposti alla procedura in anestesia locale e sedazione superficiale. Si è avuta una riduzione della PAPm 8,67 ± 5,61 risultata stasticamente significativa (p = 0.002). Il tempo mediano della procedura è stato di 165 minuti (IQR 155-245). Il tempo mediano di degenza in UTIC 4 (IQR 3-5), la degenza mediana ospedaliera di 8 giorni (IQR 4-13). Non si è verificata nessuna morta intraprocedurale né intraospedaliera, non è stato necessario il ricorso a terapie in bailout a 48 h, non si è registrato alcun sanguinamento maggiore né deterioramento clinico, così come ogni componente dell'endpoint secondario. Tuttavia tale endpoint non valutava la presenza di anemia lieve post procedurale che interessato 6 pazienti (54,5%) ed in 3 casi (30%) ha richiesto la trasfusione di emazie (max 2 sacche). Va segnalato che una paziente è stata sottoposta a seconda procedura di TEM a distanza di 15 giorni per recidiva di EP massiva nonostante terapia anticoagulante con eparina non frazionata. Un solo paziente ha residuato una severa ipertensione polmonare (PHTN).

**Conclusioni**

La trombectomia meccanica percutanea ha dimostrato essere un'alternativa efficace e sicura nei pazienti con embolia polmonare a rischio alto ed intermedio-alto nella nostra casistica, seppur in una fase iniziale di curva di apprendimento.
Il beneficio immediato in termine di stabilizzazione emodinamica, miglioramento dei sintomi e dei parametri vitali associato ad un buon profilo di sicurezza suggerisce che la trombectomia meccanica percutanea potrebbe modificare il rapporto rischio-beneficio verso un algoritmo di trattamento più aggressivo in questa categoria di pazienti.

**Tabella 1.** Caratteristiche demografiche basali

| Caratteristiche | Popolazione Totale (n= 11) |
|---|---|
| ***Clinical characteristics*** | |
| Età (anni) | 66 (28;77) |
| Donna | 8 (72.7%) |
| BMI, kg/m2 | 25.6 ± 5.4 |
| Abitudine tabagica | 2 (7.4%) |
| Ipertensione arteriosa | 32 (23.0) |
| Dislipidemia | 5 (45.5%) |
| DM | 0 (0%) |
| Infarto miocardico | 0 (0%) |
| AOP | 0 (0%) |
| BPCO | 0 (0%) |
| Scompenso cardiaco cronico | 2 (18.2 %) |
| Stroke precedente | 1 (9.1%) |
| IRC (eGFR< 45 ml/m2/1.73) | 2 (18.2%) |
| Device intracardiaco | 3 (27.3) |
| Cancro Attivo | 1 (9.1%) |
| Precedente TVP | 1 (9.1%) |
| Precedente EP | 1 (9.1%) |
| Mutazione genetica* | 2 (18.2%) |
| Recente chirurgia | 9 (81.8%) |
| Gravidanza | 1 (9.1%) |
| Terapia estroprogestinica | 1 (9.1%) |
| Sindrome da allettamento n (%) | 2 (18.2%) |

I dati sono riportati come n (%) e mediana (IQR).
**Legenda della tabella: PE** embolia polmonare**, DM** diabete mellito**, CKD** insufficienza renale cronica **(>Stage IIIb); Prior stroke** (TIA-Ictus)**; *Mutazioni Genetiche** (FV leiden, Fattore II mutato, MTHFR, Protombin)**; Intervento chirurgico recente** (< 30 days).

**Table 2.** Caratteristiche cliniche dell'embolia polmonare.

| Caratteristiche | Popolazione Generale (n= 11) |
|---|---|
| ***Clinical characteristics*** | |
| PESI mediana | 103 (59;133) |
| sPESI | |
| 1 | 4 (36.4%) |
| 2 | 5 (45.5%) |
| 3 | 1 (9.1%) |
| Classe ESC | |
| Intermedio alto | 5 (45.5%) |
| Alto rischio | 5 (45.5%) |
| Instabilità emodinamica* | 5 (45.5%) |
| GCS<8 | 1 (9.1%) |
| PAS (mmHg) | 130 (92.5-152) |
| ***Caratteristiche elettrocardiografiche*** | |
| HR (bpm) | 106 ±20.3 |
| RBBB | 4 (36.4%) |
| S1Q3T3 | 2 (18.2%) |
| ***Caratteristiche ecocardiografiche*** | |
| FE | 55 (52.5-60) |
| Disfunzione ventricolare destra | 10 (100%) |
| RV/LV>1 | 7 (70%) |
| IT moderata/severa | 5 (45.4%) |
| ***Caratteristiche laboratoristiche*** | |
| HB (g/dl) | 10,95 ± 2.2 |
| PLT (x 10^3) | 225 ± 87 |
| Creatinina | 0,94 ± 0,43 |
| eGFR (ml/min/m2) | 74 (47;154) |
| Troponina Hs (ng/ml) | 179 (39;1698) |
| Lattati (mmol/L) | 1,5 (0,6;2,3) |
| D-dimer (mg/dl) | 6164 (2615;21721) |
| ***Caratteristiche radiologiche*** | |
| Unilaterale destro | 1 (9.1%) |
| Unilaterale sinistro | 0 (0%) |
| Bilaterale | 8 (72.7%) |
| Ventricolare | 3 (27.3%) |

I dati sono riportati come n (%) o mediana (IQR) o media (SD)
**Legenda alla tabella: *Instabilità emodinamica** Una delle seguenti caratteristiche: presentazione clinica di arresto cardiaco, shock ostruttivo definite come una PA < 90 mmHg o una PA>90 mmHg con support inotropo ed una combinazione di danno d'organo da ipoperfusione o una persistente ipotensione non causata da aritmie, ipovolemia o sepsi. **Disfunzione ventricolare destra** (TAPSE < 18, FAC < 40; d-shape, 60/60 sign; RV/LV>1); **GCS** Glasgow coma scale.

**Tabella 3.** Caratteristiche della procedura

| Caratteristiche | Popolazione generale (n= 11) |
|---|---|
| ***Device utilizzato*** | |
| Flow Triver | 9 (81.8%) |
| Penumbra | 1 (9.1%) |
| AngioJet | 1 (9.1%) |
| ***Statistiche intraprocedurali*** | |
| Tempo procedural in minuti; | 165 (155;245) |
| Dose di contrasto (ml) | 80 (70-110) |
| Tempo di fluoro (min) | 40,2 ±14,2 |
| ***Accessi*** | |
| Accesso vena femorale comune | 11 (100%) |
| Puntura ecoguidata | 11 (100%) |
| Chiusura dell'accesso | |
| Compressione manuale | 1 (9.1%) |
| Stitching | 3 ( 27,3%) |
| Device di chiusura | 7 (63,6%) |
| ***Supporto alla procedura*** | |
| Supporto ventilatorio | |
| Nessuno | 1 (9.1%) |
| Nasocanula | 2 (18,2%) |
| VM | 5 (45.5%) |
| C-PAP | 3 (9.1%) |
| IOT | 1 (9.1%) |
| MCS | 0 (0%) |
| Supporto inotropo | 5 (45.5%) |
| Anticoagulazione pre | 10 (90.9%) |
| ***Trombolisi*** | |
| Pre-trombolisi | 1 (9.1%) |
| Successo pre-trombolisi | 0 (0%) |
| Controindicazioni alla trombolisi | 9 (81%) |
| Stroke emorragico | 0 (0%) |
| Stroke ischemico < 6 month | 0 (0%) |
| Intervento chirurgico o trauma maggiore < 6 month | 5 (45.5%) |
| Sanguinamento attivo | 4 (36.4%) |

I dati sono riportati come n (%) o mediana (IQR) o media (SD)
**Legenda della tabella: VM**, venti-mask; **IOT,** intubazione oro tracheale, **MCS** supporto meccanico al circolo,

**Table 4.** Outcomes post intervento

| Caratteristiche | Popolazione Generale (n= 11) |
|---|---|
| ***Endpoint primario*** | **0 (0%)** |
| Mortalità intraospedaliera | 0 (0%) |
| Strategie Bailout | 0 (0 %) |
| Sanguinamenti maggiori | 0 (0%) |
| Deterioramento emodinamica | 0 (0%) |
| ***Endpoint Secondario*** | **0 (0%)** |
| Stroke ischemico | 0 (0%) |
| Danno valvola tricuspide | 0 (0%) |
| Tamponamento cardiaco | 0 (0%) |
| Rottura polmonare | 0 (0%) |
| Complicanza maggiore accesso vascolare | 0 (0%) |
| | 11 (100%) |
| Successo Procedurale | 4 (36.4%) |
| Aspirazione completa | 0 (0%) |
| CPR rianimazione | 4 (36.4%) |
| Supporto inotropo post procedurale | 6 (54.5%) |
| Anemia post procedurale | 3 (30%) |
| Trasfusioni post procedruali | |
| N. sacche transfuse | |
| 1 | 1 (11%) |
| 2 | 2 (22%) |
| Infarto miocardio | 0 (0%) |
| AKI n, (%) | 2 (20%) |
| 1 | 1 (9.1%) |
| 2 | 1 (9.1%) |
| Residua severe PHTN | 1 (9.1%) |
| ***Dimissioni*** | |
| Giorni in UTIC | 4 (3-5) |
| Giorni di ospedalizzazione | 8 (4-13) |

I dati sono riportati come n (%) o mediana (IQR) o media (SD)
**Legenda alla tabella: CPR** rianimazione cardio-polmonare, **AKI** insufficienza renale acuta **PHTN** ipertensione polmonare.