Late Breaking Clinical Science

LBCS1

LONG TERM PROGNOSTIC VALUE OF RIGHT INVASIVE HEMODYNAMIC PARAMETERS IN PATIENT UNDERGOING M-TEER

Federico Arturi[1], Giulia Masiero[1], Francesco Cardaioli[1], Luca Nai Fovino[1], Tommaso Fabris[1], Massimo Napodano[1], Andrea Panza[1], Elisa Boscolo Soramio[1], Andrea Bertolini[1], Giulia Lorenzoni[1], Chiara Fraccaro[1], Giuseppe Tarantini[1]

[1]1Azienda Ospedale Università Padova, Padova, Italia

Introduction

Right heart catheterization is a common step in mitral valve transcatheter edge to edge repair (M-TEER) work-up. Right ventricle hemodynamic parameters have been identified as predictors of adverse outcomes in patient treated with M-TEER. New cut-offs for pulmonary hypertension have been proposed by the last European Society of Cardiology (ESC) guidelines. We thus investigate the impact of right ventricle invasive hemodynamic indexes and the prognostic value of the proposed ESC 2022 pulmonary hypertension definition on adverse outcomes after M-TEER.

Methods

Out of 152 patients treated with M-TEER due to symptomatic severe mitral regurgitation (MR) between December 2014 and February 2024 at our facility, 71 underwent elective invasive right heart catheterization before the procedure. Comprehensive baseline echocardiographic was also performed. Follow-up was conducted through outpatient visit or telephone call. The main outcomes of interest were all cause mortality, and a composite of hospitalization for heart failure (HFH) and death at longest follow up available.

Results

The majority of the overall patient population was male (64%), with a median age of 79 years. The median STS-PROM score was 3.6%, and the median EuroSCORE II was 4.7%. A considerable proportion of the patients (72%) were highly symptomatic for dyspnea, classified as NYHA class III or higher. Degenerative, functional ventricular and atrial etiologies comprised respectively 47%, 41% and 12% of patients. Technical, device and procedural success were achieved in 97%, 88% and 84% of procedures, respectively, with a median of 2 devices deployed for each patient. Both MitraClip (Abbott, Santa Clara, CA) and Pascal (Edwards Lifesciences, Irvine, CA.) devices were used. Residual MR ≤ 2+ rates were 94% at discharge and 87% at six months follow-up, respectively. During a median follow-up of 681 days (IQ range (217-1.500), the primary composite outcome occurred in 94 (61%) patients and the all-cause mortality rate was 50%. At the univariate analysis, nor echocardiographic systolic pulmonary artery pressure (sPAP) or TAPSE/sPAP ratio showed any significant association with death at longest follow up. Conversely, invasive sPAP (p=0.003) and TAPSE/sPAP ratio (p=0.002) exhibited a significant association with death at longest follow up. Pulmonary capillary wedge pressure (PCWP, p=0.038), mean pulmonary artery pressure (PAPm, p=0.003), right atrial pressure (RAP, p=0.006), and right ventricular stroke work index (RWSWi, p=0.042) were other predictors of midterm mortality. Moreover, sPAP (p=0.001), mPAP (p=0.009), PA compliance (p=0.046) and RWSi (p=0.049) were predictors also for the composite outcomes. After adjusting for confounding variables, pulmonary vascular resistance (PVR) (p=0.04) and mPAP (p=0.04) remained independently associated with an increased risk of mortality at longest follow up, along with baseline estimated glomerular filtration rate (eGFR), periferal artery disease (PAD), left ventricle ejection fraction (LVEF), TR grade ≥2 +, and MVARC procedural success (Tab 1). Only eGFR and MVARC device success remained independently associated to the composite outcomes. Receiver operating characteristic (ROC) curve analysis identified the following cut-off values with the highest sensitivity for predicting one-year mortality: 20.5 mmHg for mPAP, 14.5 mmHg for PCWP and 1.31 Wood units (WU) for PVR (Fig 1). Utilizing these cut-off values, Kaplan-Meier analysis demonstrated a significant association with long-term mortality for mPAP greater than 20 mmHg (p=0.003) and PCWP greater than 15 mmHg (p=0.04), as well as a trend towards significance for PVR greater than 2 WU (p=0.06) (Fig 2).

Conclusions

In patient with severe MR treated with edge-to-edge repair, several RV invasive hemodynamic parameters are associated with adverse outcomes at long-term follow up, differently from their echocardiographic counterparts. Among those, mPAP and PVR are independent predictors of poor prognosis. Even with the limitation of the small population involved, we demonstrated that the updated pulmonary hypertension ESC cut-offs is a reliable instrument for prognosis evaluation.

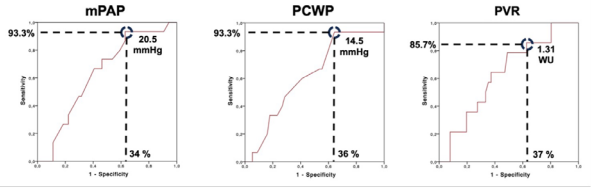


Fig 1: ROC analysis for mPAP, PCWP and PVR. *mPAP: mean pulmonary artery pressure; PCWP: pulmonary capillary wedge pressure; PVR: pulmonary vascular resistance*.

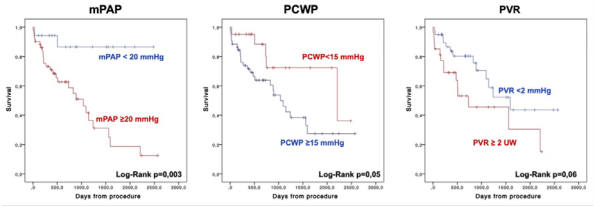


Fig 2: Kaplan Meier curve for mPAP, PCWP and PVR. *mPAP: mean pulmonary artery pressure; PCWP: pulmonary capillary wedge pressure; PVR: pulmonary vascular resistance.*

LBCS2

INTEGRATED ASSESSMENT OF CORONARY PHYSIOLOGY AND PLAQUE VULNERABILITY BASED ON CORONARY ANGIOGRAPHY IN HEART TRANSPLANTED PATIENTS

Simone Fezzi[1], Ludovica Guerrieri[1], Allegra Urbani[1], Jiayue Huang[2], Roberto Scarsini[1], Domenico Tavella[1], Gabriele Pesarini[1], William Wijns[3], Shengxian Tu[2], Flavio Ribichini[1]

[1]Università di verona, Verona, Italia; [2]Jiao Tong University, Shanghai , China; [3]university of galway, Galway, Ireland

Introduction

Cardiac allograft vasculopathy (CAV) refers to an accelerated form of coronary artery disease that represents the primary cause of mortality and morbidity in heart transplant (HTx) patients. The diffuse nature of the pathology makes it difficult to detect in its early stages using conventional methods such as angiography, while the use of intracoronary imaging is flawed by technical and economic issues. The recent development of computational techniques derived from angiography to interpret plaque physiology and vulnerability could allow for the early identification of lesions at higher risk of adverse events in early phases of this disease.

Methods

The primary objective of our study is to evaluate whether the combined use of Radial Wall Strain (RWS), an index capable of defining plaque vulnerability, and Murray's law-based Quantitative Flow Ratio (μFR), an index capable of interpreting the epicardial coronary flow reserve, both derived from angiography, can improve risk stratification in vessels without angiographically significant disease in heart transplant patients.

Our study cohort included 86 HTx patients (200 epicardial vessels) without significant CAD at baseline (degree of stenosis <50%), for whom μFR and RWS computation was feasible on 286 coronary segments. Plaque vulnerability was defined as a RWS value ≥13%, while coronary ischaemia as a μFR≤0.80, as previously validated. Clinical events were assessed at a median clinical follow-up of 43 [23-66] months. The primary endpoint of the study was to assess the interaction between plaque vulnerability (RWS≥13%) and the occurrence of target vessel failure (TVF), defined as the incidence of cardiac death, target-vessel myocardial infarction, silent vessel progression (degree of stenosis≥50%) at the elective angiographic follow-up and target vessel revascularization.

Results

At baseline, the mean μFR value was 0.94±0.08, with 15 segments (5.2%) considered flow-limiting (μFR ≤0.80), while the RWS value was 13.4 ± 4.9%, with 71 segments (24.8%) considered at high risk (RWS ≥13%). At follow-up, TVF occurred in 47 cases (16.4%). TVF-related segments were associated with lower mean μFR values (0.89 ± 0.14 vs. 0.95 ± 0.05; p<0.007) and higher RWS values (16.4 ± 8.7 vs. 11.8 ± 0.8; p<0.001) compared TVF-free segments. At a per-vessel analysis a RWS value≥13% showed a significant interaction with TVF occurrence at 43 months

(40.8% vs. 8.3%; HR 5.577; 95% CI 2.726-11.407; p<0.001). At the receiver operating characteristic curve (ROC) a RWS value ≥13% demonstrated an area under the curve (AUC) of 0.658 (95% CI 0.600-0.713; p=0.003) in predicting TVF occurence, with a sensitivity of 55.3% (95% CI 40.1-69.8), a specificity of 86.5% (95% CI 81.5-90.6), a positive predictive value of 78.4% (95% CI 68.7-86.2), and a negative predictive value of 68.6% (95% CI 61.5-75.1).

Conclusions

In our original study, we demonstrated that the combined use of RWS and μFR could improve the risk stratification of angiographically non-significant lesions in HTx patients.

LBCS3

DEVELOPMENT AND VALIDATION OF THE D-PACE SCORING SYSTEM TO PREDICT DELAYED HIGH-GRADE CONDUCTION DISTURBANCES AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION

Francesco Bendandi[1], Nevio Taglieri[1], Leonardo Ciurlanti[1], Alessandro Mazzapicchi[1], Marco Foroni[1], Francesco Chietera[1], Laura Lombardi[1], Gabriele Ghetti[1], Antonio Giulio Bruno[1], Mateusz Orzalkiewicz[1], Giuliano Costa[2], Valentina Frittitta[2], Alessandro Comis[2], Sofia Sammartino[2], Mariachiara Calì[2], Elena Dipietro[2], Luigi La Rosa[2], Corrado Tamburino[2], Tullio Palmerini[1], Marco Barbanti[3], Francesco Saia[1]

[1]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico S. Orsola-Malpighi, Bologna, Italia; [2]AOU Policlinico G. Rodolico-San Marco, Catania, Italia; [3]Università degli Studi di Enna "Kore, Enna, Italia

Introduction

Atrioventricular block (AVB) remains common after transcatheter aortic valve implantation (TAVI), frequently occurring more than 24 hours after the procedure, limiting next-day discharge.

This study was designed to identify predictors of high-grade AVB occurring between 24 hours and 30 days after TAVI and to develop a risk score to identify patients suitable for next-day discharge.

Methods

We analyzed clinical, procedural, and electrocardiographic parameters (with their dynamic postprocedural changes) of 1290 consecutive patients undergoing TAVI at a single center. Independent predictors of late-onset high-grade AVB were used to develop the Late atrioventricular block Prediction for eArly disChargE (Late-PACE) score. We externally validated the score in a mixed prospective and retrospective cohort.

Results

Incidence of late-onset high-grade AVB was 5.7%. Implantation of self-expandable valves, greater implantation depth, longer PR interval in preprocedural electrocardiogram (ECG) and a greater increase of its duration in next-day ECG, preprocedural right bundle branch block (RBBB) and new-onset left bundle branch block or RBBB that persisted in next-day ECG were independent predictors.

The Late-PACE score was derived by assigning each of the predictors a value proportional to their regression coefficient. Patients with atrial fibrillation, in whom the PR interval could not be assessed, were excluded from the derivation cohort. Patients who underwent valve-in-valve TAVI were also excluded, since none of them developed late-onset AVB, suggesting a strong protective effect. The final derivation cohort of the score consisted of 915 patients. The overall score can range from 0 to 14 points, with an OR of 1.95 (95% confidence interval [CI] 1.69-2.26) for each one-point increment. The area under the curve (AUC) of the score was 0.88 (95% CI 0.84-0.92) in the derivation cohort. Three risk categories were defined, according to predicted AVB risk:

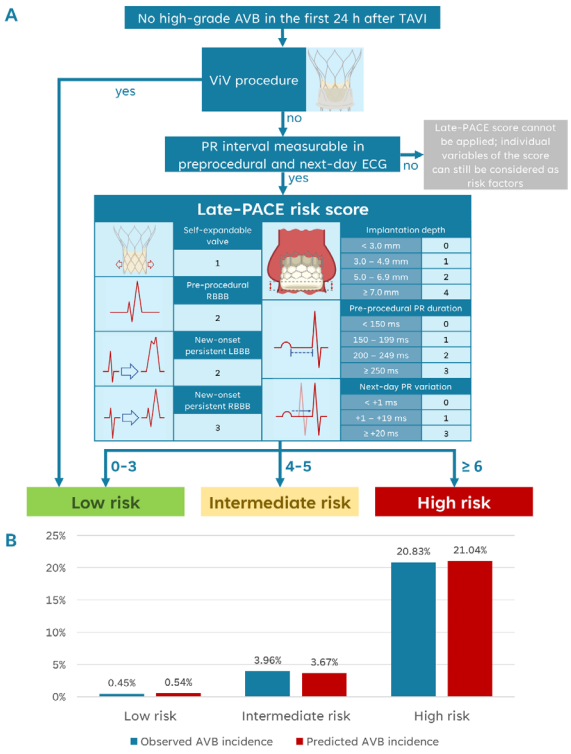
- Low-risk: patients with a Late-PACE score from 0 to 3, corresponding to a predicted AVB risk < 2%.
- Intermediate-risk: patients with a Late-PACE score from 4 to 5, corresponding to a predicted AVB risk between 2% and 5%.
- High-risk: patients with a Late-PACE score ≥ 6, corresponding to a predicted AVB risk ≥ 5%.

Among patients of the derivation cohort, 48.6% were classified as low-risk, 30.4% as intermediate-risk and 21.0% as high-risk.

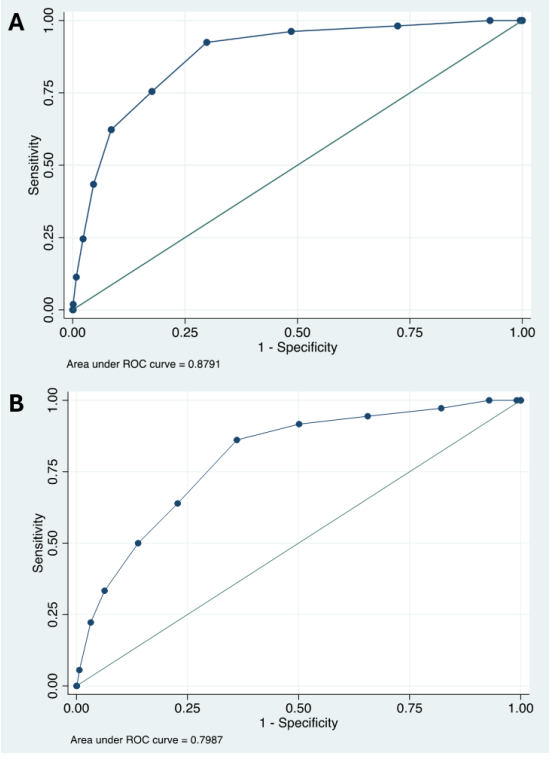
The external validation cohort consisted of 936 patients, with 3.8% late-onset AVB incidence. The Late-PACE score performed well in the validation cohort in terms of both discrimination (AUC of 0.80 [95% CI 0.73-0.87]) and goodness of fit (Hosmer and Lemeshow test p = 0.53).

Conclusions

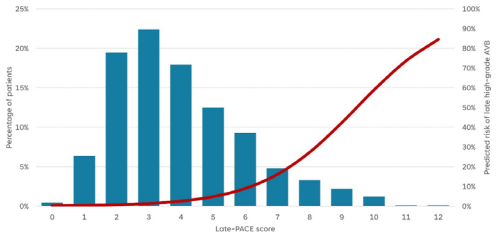
The Late-PACE score is a simple 7-item algorithm to predict the occurrence of high-grade AVB between 24 hours and 30 days after TAVI. By dividing patients into three risk categories, it is possible to use the score to identify those eligible for next-day discharge.



Algorithm for late-onset high-grade AVB risk stratification. (A) The algorithm should be applied 24 hours after TAVI, if there were no episodes of high-grade AVB in this time interval. Bundle branch blocks are considered persistent if they are present in both post-procedural and next-day (12-24 hours after TAVI) ECGs. Next-day PR variation is the difference in PR interval duration between preprocedural and next-day ECGs. (B) Observed and predicted rates of late-onset high-grade AVB according to risk category in the derivation cohort: blue bars show the event rate in the study population, according to risk category; red bars show the predicted event rate. AVB = atrioventricular block; LBBB = left bundle branch block; RBBB = right bundle branch block; TAVI = transcatheter aortic valve implantation; ViV = valve-in-valve.



Receiver-operating characteristic curves for the Late-PACE score. (A) Curve from the derivation cohort. (B) Curve from the validation cohort.



Late-PACE score distribution in the derivation cohort and predicted AVB incidence. Blue bars show the percentage of the derivation cohort for each score value; the red line displays the mean predicted probability of late-onset high-grade AVB for each score value. AVB = atrioventricular block.

Logistic Regression Model				
Variables	Univariate		Multivariate	
	OR	p	OR	p
Age	1.014 (0.977-1.058)	0.501		
Male sex	1.287 (0.804-2.064)	0.293		
BMI	1.027 (0.978-1.074)	0.269		
Hypertension	1.138 (0.523-2.991)	0.767		
Dyslipidemia	0.684 (0.424-1.118)	0.123		
Diabetes	0.984 (0.561-1.654)	0.953		
Smoking	0.807 (0.485-1.312)	0.396		
NYHA class III-IV	0.692 (0.429-1.107)	0.126		
Prior syncope	1.047 (0.477-2.044)	0.900		
Prior myocardial infarction	1.238 (0.688-2.122)	0.454		
Coronary artery disease	0.770 (0.479-1.232)	0.277		
Prior balloon aortica valvluoplasty	0.799 (0.491-1.282)	0.356		
Atrial fibrillation/flutter	**1.537 (0.950-2.466)**	**0.076**		
Prior stroke	0.690 (0.207-1.713)	0.480		
Peripheral artery disease	0.904 (0.510-1.530)	0.717		
Prior TAVI or SAVR with sutureless valve	**7.778 (1.066-40.540)**	**0.019**		
Prior non-SAVR cardiac surgery	1.797 (0.812-3.556)	0.116		
Bicuspid aortic valve	0.403 (0.023-1.894)	0.372		
STS score	1.017 (0.961-1.062)	0.502		
Euroscore II	0.991 (0.940-1.031)	0.708		
Estimated glomerular filtration rate	**0.988 (0.976-0.999)**	**0.046**		
Left ventricular end-diastolic volume	0.998 (0.992-1.004)	0.560		
Left ventricular ejection fraction < 50%	0.645 (0.327-1.276)	0.208		
Interventricular septum thickness	1.111 (0.973-1.260)	0.110		
Aortic valve area (indexed to BSA)	1.329 (0.179-7.535)	0.765		
Self-expandable valve	**1.984 (1.216-3.198)**	**0.005**	**2.166 (1.075-4.366)**	**0.031**
Non-transfemoral access	0.844 (0.202-2.356)	0.778		
Implantation depth	**1.472 (1.325-1.638)**	**<0.001**	**1.463 (1.266-1.691)**	**<0.001**
Transient procedural AVB	**3.488 (1.275-8.124)**	**0.007**		
Preprocedural HR (each 1 bpm)	1.004 (0.987-1.020)	0.608		
Preprocedural PR (each 1 ms)	**1.014 (1.008-1.020)**	**<0.001**	**1.016 (1.009-1.023)**	**<0.001**
Preprocedural LBBB	0.547 (0. Diffusione del minimalist approach in Europa come strategia migliorativa per il trattamento percutaneo della stenosi valvolare aortica. Studio osservazionale multicentrico-1.351)	0.249		
Preprocedural RBBB	**3.619 (2.072-6.125)**	**<0.001**	**5.569 (2.359-13.145)**	**<0.001**
Preprocedural LAFB	**1.745 (0.950-3.037)**	**0.058**		
Postoprocedural HR variation * (each 1 bpm)	0.986 (0.968-1.004)	0.120		
Postprocedural PR variation * (each 1 ms)	**1.014 (1.002-1.025)**	**0.017**		
Next-day HR variation ^ (each 1 bpm)	0.986 (0.970-1.003)	0.104		
Next-day PR variation ^ (each 1 ms)	**1.029 (1.020-1.038)**	**<0.001**	**1.029 (1.019-1.040)**	**<0.001**
New-onset LBBB				
Persistent †	**3.944 (2.253-6.693)**	**<0.001**	**4.488 (2.011-10.014)**	**<0.001**
Transient ‡	0.301 (0.169-1.399)	0.237		
New-onset RBBB				
Persistent †	**7.298 (1.548-26.860)**	**0.005**	**9.283 (1.119-77.037)**	**0.039**
Transient ‡	4.151 (0.211-28.450)	0.206		
New-onset LAFB				
Persistent †	1.097 (0.060-5.526)	0.929		
Transient ‡	2.366 (0.126-13.544)	0.423		

*Difference between values in postprocedural and in preprocedural ECGs. ^Difference between values in next-day and in preprocedural ECGs. †Conduction disturbances are considered persistent if they are present in both post-procedural and next-day ECGs. ‡Conduction disturbances are considered transient if they are present in post-procedural but not in next-day ECG. AVB = atrioventricular block; BMI = body mass index; BSA = body surface area; HR = heart rate; LAFB = left anterior fascicular block; LBBB = left bundle branch block; NYHA = New York Heart Association; OR = odds ratio; RBBB = right bundle branch block; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVI = transcatheter aortic valve implantation.

LBCS4

TREATMENT OF LONG CORONARY LESIONS IN MULTIVESSEL PATIENTS WITH THE RESORBABLE MAGNESIUM SCAFFOLD (MAGMARIS): ACUTE AND 12-MONTH RESULTS FROM THE ITALIAN MULTICENTER IT-MASTERS REGISTRY

Stefano Galli[1], Domenico Tavella[2], Marco Sesana[3], Ferdinando Varbella[4], Dario Buccheri[5], Chiara Bernelli[6], Massimo Leoncini[7], Salvatore Saccà[8], Francesco Pisano[9], Gabriele Tumminello[10], Angelo Leone[11], Claudio Larosa[12], Alfredo Marchese[13], Giuseppe Tarantini[14]

[1]Centro Cardiologico Monzino, Milano, Italia; [2]Università di Verona, Verona, Italia; [3]Azienda Ospedaliera Desenzano Del Garda, Desenzano Del Garda, Italia; [4]Ospedale degli infermi di Rivoli-Torino, Rivoli, Italia; [5]Ospedale S. Antonio Abate, Trapani, Italia; [6]Ospedale Santa Corona ASL2 Liguria, Pietra Ligure, Italia; [7]Ospedale di Sanremo, Sanremo, Italia; [8]Ospedale di Mirano, Mirano, Italia; [9]Ospedale Umberto Parini, Aosta, Italia; [10]Dipartimento Cardio-Toraco-Vascolare Fondazione IRCCS Ca' Granda Ospedale Policlinico, Milano, Italia; [11]Ospedale Annunziata AO Cosenza, Cosenza, Italia; [12]Ospedale Lorenzo Bonomo, Andria, Italia; [13]S.Maria Hospital GVM Care&Research, Bari, Italia; [14]Azienda Ospedale Università di Padova, Padova, Italia

Introduction

The Resorbable Magnesium Scaffold Magmaris™ (RMS) showed in previous clinical studies good long-term safety and efficacy in focal lesions. The aim of the IT-MASTERS registry is to widen the device assessment in a setting of more complex lesions including multivessel and long lesions.

Methods

The IT-MASTERS study is a multicenter, prospective, observational registry conducted in 21 Italian sites and including patients with multivessel disease (up to three lesions), or single long lesion (<25 mm, to cover with one study device). The primary endpoint is cumulative incidence of target lesion failure (TLF) at 1 year. Scaffold thrombosis (ST) is assessed as secondary endpoint. Adherence to the 4P strategy for correct device implantation (i.e. patient/lesion selection, 1:1 pre-dilatation, apPropriate scaffold sizing, post-dilatation) is fundamental condition for the inclusion in the registry. Dual antiplatelet therapy (DAPT) is recommended for 12 months. Follow-up evaluations are performed at 30 days, 6, 12 and 24 months.

Results

We analyzed data of 359 enrolled patients with 409 lesions. The average age of patients was 60±10 years, 82% were male, 18% had diabetes, and 55% had >3 major cardiovascular risk factors. Patients underwent PCI for the following indications: 48% SCA (34% NSTEMI and 14% unstable angina), 29% stable angina, and 23% silent ischemia. Target vessel encompassed LAD 57.5%, RCA 24% and LCx 18.5%. Lesion complexity was characterized by 49% of type B2/C lesions with 17% of >2.5 mm bifurcation lesions and multivessel implantation in 20% of cases. The mean lesion length was 19.4±5.2 mm, with a mean reference vessel diameter of 3.5±0.3 mm and stenosis of 81±12%. Mean number of scaffolds per patient was 1.06. The 4P strategy was fully respected in 98% of cases, specifically 93% pre-dilatation and 97% post-dilatation with non-compliant balloons. Use of intravascular imaging was 56% (32% OCT and 24% IVUS). Procedural and device success were 100% and 99%, respectively. No major adverse events occurred until 30 days. DAPT was taken by 86% of patients up to 12 months. A total of 320 patients who reached the 12-month follow-up showed a TLF of 4.1% [95% confidence interval, CI: 1.9%, 6.3%]: 1.3% target-vessel myocardial Infarction; 3.8% clinically driven target lesion revascularization (TLR); 0.3% CABG. There were no cardiac deaths. Only 2 late ST (0.6%) were observed, both successfully treated with PCI at 2 and 4 months.

Conclusion

The IT-MASTERS registry including a wide series of patients but with a setting of more complex lesions than BIOSOLVE studies, showed comparable safety and efficacy in terms of TLF. Furthermore, results on use of the Magmaris RMS in this setting of patients/lesions were similar to those available in literature for contemporary DES.

LBCS5

BALLOON-EXPANDABLE VERSUS SELF-EXPANDING VALVES FOR TRANSCATHETER TREATMENT OF SIEVERS TYPE 1 BICUSPID AORTIC STENOSIS

Andrea Buono[1], Andrea Zito[2], Kim Won-Keun[3], Tommaso Fabris[4], Chiara De Biase[5], Michele Bellamoli[1], Nicholas Montarello[6], Giuliano Costa[7], Mesfer Alfadhel[8], Ofi Koren[9], Simone Fezzi[10], Barbara Bellini[11], Mauro Massussi[12], Andrea Scotti[13], Lin Bai[14], Giulia Costa[15], Alessandro Mazzapicchi[16], Enrico Giacomin[17], Riccardo Gorla[18], Carlo Briguori[19], Luca Bettari[1], Antonio Messina[1], Mauro Boiago[5], Matthias Renker[3], Mario Garcia Gomez[20], Chiara Fraccaro[4], Giulia Laterra[21], Alessia Latini[22], Dario Pellegrini[23], Alfonso Ielasi[24], Ady Orbach[25], Uri Landes[26], Tobias Rheude[27], Luca Testa[18], Ignacio Amat Santos[20], Antonio Mangieri[22], Francesco Saia[16], Luca Favero[17], Mao Chen[14], Marianna Adamo[12], Azeem Latib[13], Anna Sonia Petronio[15], Matteo Montorfano[28], Francesco Burzotta[2], Marco Barbanti[21], Ole De Backer[6], Didier Tchètchè[5], Diego Maffeo[1], Maria Luisa De Rosa[29], Giuseppe Tarantini[4]

[1]Valve Center Fondazione Poliambulanza Istituto Ospedaliero, Brescia, Italia; [2]Department of Cardiovascular and Pulmonary Sciences, Catholic University of the Sacred Heart, Roma, Italia; [3]Kerckhoff Heart Center, Bad Nauheim, Germany; Med. Clinic I, Department of Cardiology & Angiology, Justus-Liebig University of Giessen/Marburg, Giessen, Germany; [4]Department of Cardiac, Thoracic and Vascular Sciences and Public Health, University of Padua Medical School, Padova, Italia; [5]Groupe Cardiovasculaire Interventionnel (GCVI), Clinique Pasteur, Tolosa, France; [6]The Heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark; [7]U.O.C. Cardiologia, Centro Alte Specialità e Trapianti, P.O. G. Rodolico, A.O.U. Policlinico–V. Emanuele, Università di Catania, Catania, Italia; [8]Department of Cardiology, Leeds Teaching Hospitals NHS Trust , Leeds, United Kingdom; [9]Department of Cardiology, Smidt Heart Institute, Cedars-Sinai Medical Center, Los Angeles, United States; [10]Department of Cardiology, University Hospitals , Galway, Ireland; [11]Interventional Cardiology Unit, IRCCS San Raffaele Scientific Institute, Milano, Italia; [12]Civil Hospital and University of Brescia, Brescia, Italia; [13]Montefiore Medical Center, New york, United States; [14]Department of Cardiology, West China Hospital, Sichuan University, Chengdu, China; [15]Cardiac Catheterization Laboratory, University of Pisa and Azienda Ospedaliero-Universitaria Pisana, Pisa, Italia; [16]Cardiology Unit, Cardiac Thoracic and Vascular Department, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italia; [17]Cardiology Unit, Cardio-Neuro-Vascular Department, Foncello Hospital Azienda N 2 Marca Trevigiana, Treviso, Italia; [18]Department of Cardiology, IRCCS Policlinico San Donato, San Donato Milanese, Milano, Italia; [19]Interventional Cardiology Unit, Mediterranea Cardiocentro, Napoli, Italia; [20]CIBERCV, Division of Cardiology, Hospital Clínico

Universitario de Valladolid, Valladolid, Spain; [21]Università degli Studi di Enna "Kore", Enna, Italia; [22]Cardio Center, IRCCS Humanitas Research Hospital, Rozzano-Milano, Italia; [23]Division of Cardiology, IRCCS Hospital Galeazzi-Sant'Ambrogio, Milano, Italia; [24]Division of Cardiology, IRCCS Hospital Galeazzi-Sant' Ambrogio, Milano, Italia; [25]Edith Wolfson Medical Center, Cardiology Department, Holon, Israel and Tel-Aviv University, Tel-Aviv, Israel; [26]Edith Wolfson Medical Center, Cardiology Department, Holon, Israel and Tel-Aviv University, Tel-Aviv, Israel; [27]Department of Cardiovascular Diseases, German Heart Center Munich, Technical University Munich, Monaco, Germany; [28]School of Medicine, Vita-Salute San Raffaele University, Milan, Italy. Interventional Cardiology Unit, IRCCS San Raffaele Scientific Institute, Milano, Italia; [29]Università degli studi di Napoli Federico II , Napoli, Italia

Introduction

Balloon-expandable valve (BEV) and self-expanding valve (SEV) have different technical features that may impact the outcomes of patients with raphe-type 1 bicuspid aortic valve (BAV) stenosis undergoing transcatheter aortic valve replacement (TAVR). The aim of this study is to compare procedural and clinical outcomes of BEV and SEV in patients with raphe-type 1 BAV stenosis.

Methods

The AD-HOC is an observational registry, enrolling patients with raphe-type 1 BAV stenosis undergoing TAVR with current-generation BEV and SEV at 24 international centres. A 1:1 propensity score matching (PSM) analysis was performed to adjust for clinical, electrocardiographic, echocardiographic, and computed tomography features. The primary endpoint was major adverse events (MAE), defined as a composite of all-cause death, stroke, or hospitalization for heart failure.

Results

Among 954 eligible patients, PSM resulted in 301 pairs. Post-procedural technical success was similar between BEV and SEV (odds ratio [OR] 1.41, 95% confidence interval (CI) 0.69-2.93, p=0.358). At 30-day, BEV were associated with a lower risk of new permanent pacemaker implantation (PPI) (OR 0.45, 95% CI 0.27-0.74, p=0.002) and moderate or greater paravalvular regurgitation (PVR) (OR 0.18, 95% CI 0.07-0.47, p<0.001), but a higher risk of severe patient-prosthesis mismatch (PPM) (OR 3.10, 95% CI 1.11-8.64, p=0.031) compared with SEV. At a median follow-up of 1.3 years, BEV and SEV had a similar risk of MAE (hazard ratio 0.78, 95% CI 0.53-1.14, p=0.199).

Conclusions

Current-generation BEV and SEV proved similar technical success and mid-term clinical efficacy in raphe-type 1 BAV stenosis. Compared to SEV, BEV were associated with a lower risk of new PPI and moderate or greater PVR, but with a higher risk of severe PPM.