TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)
A REFERENCE MODEL IN PERCUTANEOUS CARDIOVASCULAR INTERVENTIONS
(VOLUME I)

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TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI). A REFERENCE MODEL IN PERCUTANEOUS CARDIOVASCULAR INTERVENTIONS

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September 2022

To my family

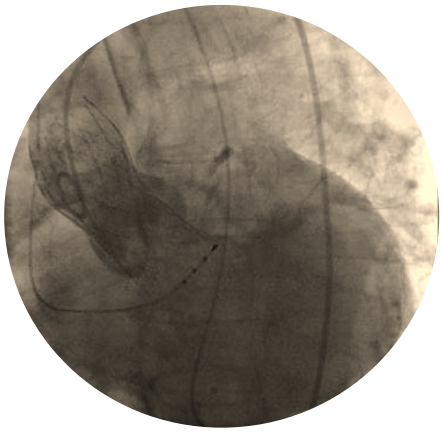
To my colleagues

To my patients

To my friends

"In a gentle way, you can shake the world."

Mahatma Gandhi



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VOLUME I

VOLUME II

1. Abbreviation and Acronyms

ACC American College of Cardiology
ACROSS Angiography and Coronary revascularization Registry of Santa Cruz Hospital
ACS acute coronary syndrome
AF atrial fibrillation
AHA American Heart Association
AMI acute myocardial infarction
AOR aortic percutaneous area
ARC Academic Research Consortium
AoS aortic stenosis
ASD atrial septal defect
BARC Bleeding Academic Research Consortium
BAV balloon aortic valvuloplasty
BMC balloon mitral commissurotomy
BMS bare metal stent
BPA balloon pulmonary angioplasty
BVF bioprosthetic valve failure
CABG coronary artery bypass graft
CAD coronary artery disease
CARDS Cardiology Audits and Registration Data Standards
CAS carotid artery stenting
CCU coronary care unit
CDI catheter-directed interventions
CEC clinical events committee
CHD congenital heart disease
CIN contrast-induced nephropathy
CKD chronic kidney disease
COPD chronic obstructive pulmonary disease
COT cusp overlap technique
CTO chronic total occlusion
CMRI cardiac magnetic resonance imaging
DAPT dual antiplatelet therapy
DCM dilated cardiomyopathy
DEB drug-eluting balloon
DSA digital subtraction angiography

EAPCI European Association of Percutaneous Cardiovascular Interventions
EAS European Atherosclerosis Society
EBSC European Board for the Specialty of Cardiology
ESC European Society of Cardiology
ECG electrocardiogram
EMB endomyocardial biopsy
EORP EURObservational Research Programme
ESH European Society of Hypertension
ETC Education and Training Committee
EVAR endovascular aneurysm repair (or endovascular aortic repair)
Fr French (size)
FFR fractional flow reserve
GUCH grown-up congenital heart
HCM hypertrophic cardiomyopathy
HF heart failure
IC interventional cardiologist
ICD implantable cardioverter-defibrillator
ICH intracerebral haemorrhage
iFR instantaneous wave-free ratio
IFU instruction for use
IMR index of microcirculatory resistance
IAP intra-aortic pressure
IVUS intravascular ultrasound
LAAO left atrial appendage occlusion
LVEF left ventricle ejection fraction
MR mitral regurgitation
MS mitral stenosis
MSCT multislice computed tomography
MTC mitral and tricuspid area
NSTE-ACS non-ST-segment elevation acute coronary syndrome
NSTEMI non-ST-segment elevation myocardial infarction
PCI percutaneous coronary intervention
PE pulmonary embolism
PFO patent foramen ovale
POBA plain old balloon angioplasty

PMR primary mitral regurgitation
PPCI primary PCI
PPM patient prosthesis mismatch
PPMI permanent pacemaker implantation
PPVI percutaneous pulmonary valve implantation
PTA percutaneous transluminal angiography
PVD peripheral vascular disease
PVL paravalvular regurgitation
RBBB right bundle branch block
RFR relative flow reserve
RVOT right ventricular outflow tract
SAVR surgical aortic valve replacement
STEMI ST-segment elevation myocardial infarction
SHD Structural heart disease
SVD Structural valve degeneration
SVG saphenous vein graft
SYNTAX synergy between percutaneous coronary intervention with TAXUS and cardiac surgery
SMR Secondary mitral valve regurgitation
TASH transcoronary ablation of septal hypertrophy
TAVI transcatheter aortic valve implantation
TEE transoesophageal echocardiography
TTE transthoracic echocardiography
THV transcatheter heart valve
TMTCI transcatheter or mixed interventions
TMVI transcatheter mitral valve implant
TMVR transcatheter mitral valve repair
TV tricuspid valve
VARC Valve Academic Research Consortium
VCROSS Valve Catheter Restorative Operation on Santa Cruz hospital
VIV valve-in-valve
VHD valvular heart disease
VSD ventricular septal defect

2. Acknowledgments

Many contributed decisively to this thesis since 2013.

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To my patients.
For their trust. I hope I never disappoint you.

To my dear family.
Joana, always and above. Miguel, João e Rodrigo, our stars and joy. Mother, father and brother, a permanent example. Relatives. To all, my love and deep recognition.

BACKGROUND

3. Background

Cardiovascular diseases (CVDs) are the leading causes of death and hospitalization and represent an enormous clinical and public health burden, which disproportionately affects older adults. According to the Instituto Nacional de Estatística (INE), life-expectancy at born and at 65 years has increased, respectively, 9,6% (73,93 to 81,06 years) and 5,1% (80,60 to 84,69 years), between 1990 and 2020. This evolution is observed worldwide and the World Health Organization (WHO) expects octogenarians to quadruple to 396 million by 2050. The 2060 INE estimates for life expectancy at born in Portugal are 84,21 years for men and 89,88 years for women[1,2]. This has increased the relative importance of heart valve diseases whose prevalence reached more than one in every ten octogenarians.

This document summarizes a coherent professional path dedicated to the cardiovascular area, marked by the search for professional excellence, based on solid evidence-based clinical experience, phased research and the constant challenge of technical-scientific evolution.
In the following pages, you will find the testimony of the drastic change caused by the structural cardiac intervention model in the aortic valve, with consequences in the organization and training of cath labs, as well as in the entire Cardiology department in terms of care and investigations.

Before becoming a cardiologist, I intended already to be an interventional cardiologist and it was with the formulation of this question that I first addressed Prof. Dr. Ricardo Seabra-Gomes, in 1996. His provocative answer has since then placed the responsibility over my shoulders by the success, or not, of this ambition. The endeavor was, and still is, extremely demanding - no more than for everyone - and guided by the critical spirit of the tutored clinical activity in the light of emerging evidence-based medicine.
Hospital de Santa Cruz is a pioneer unit in several techniques and percutaneous coronary intervention assumed dominance in 1990, when it surpassed, in number, surgical myocardial revascularization.
In 2008 the Cardiology Director, Dr. Aniceto Silva, accepted my proposal for the organization, structuring and development of a program based on the individualized approach of each patient, using all types of percutaneous and other techniques - and all sorts of devices. Thus, it was born the Percutaneous Valves (VaP) program, transversal between Cardiology and Cardiac Surgery, encompassing referral, assessment, patient study, multidisciplinary meetings, discharge and follow-up during the consultation. Parallel and progressively, there was a strong

pedagogical and training project to endow the team with a critical mass that allowed the senior operators to achieve autonomy and transversal competence, like that of coronary intervention, unique in the national reality. Finally, several international research consortia were conquered and integrated, in parallel with the international path followed that culminates in the prestigious Board of the European Association of Interventional Cardiology (EAPCI).

Safety and efficacy have always been the first requirements for any cardiovascular technique, because mortality and complications are extremely important from a clinical point of view, resulting in prolonged admission and increased hospital costs. Coordinating the structural program is an enormous challenge that intersects all professional groups and colleagues, from resident to the cardiology head, highlighting the importance of building and caring for the referral network. It essentially went through four phases, each requiring an adaptation of the clinical, organizational, research, communication and management strategic plan:

I. From 2008 to 2013, the technical and device launch phase, with a concentration of the volume on the three most experienced operators, intensive use of imaging and general anesthesia as default;

II. From 2014 to 2016, the strategic innovation and sustained growth phase, with the expansion of the team to other senior operators, with the use of new techniques and devices - including mitral valves - with the cautious introduction of more simplified protocols for TAVI anesthesia and replication of image expertise to non-aortic space. The institution became a national leader and the period includes an official institutional survey that creates waiting lists in 2015 and provides a growth opportunity. The Presidency of Associação Portuguesa de Cardiologia de Intervenção (APIC) poses challenges and provides national and international collaborative opportunities that were distant, until then;

III. From 2016 to 2017, the accelerated growth phase to respond to waiting lists and achieve maturation in the entire structural field. The visit of similar institutions is carried out with the adoption of an innovative model of sedation-analgesia with the support of anesthesiology, the teaching of the technique to all senior operators as well as the simplification of intra-hospital processes. The space of transseptal techniques enlarges and with it, all the imaging knowledge. Integration into EAPCI's European Valve For Live project projects APIC into EAPCI. The invitation to join its Board is challenging and allows you to competitively integrate prestigious European and North American research consortia.

IV. From 2018 onwards, the consolidation phase, that is based on the daily routine of structural intervention techniques, with underlying administrative coordination and the implementation of a long-distance program that concentrates clinical examinations and

evaluations in a single day. There is a growing and unique transversal experience that makes the center the Iberian leader in TAVI and that makes it a hands-on training center for other centers such as Centro Hospitalar do Funchal and Centro Hospitalar da Universidade de Coimbra, in addition to very important care partnerships with the Hospital Garcia de Orta, Hospital Fernando da Fonseca and Centro Hospitalar de Leiria.

The biggest current challenge is to provide our network with a simple, expeditious and efficient articulation, expanding the center's narrative to the area of quality from the perspective of the patient and the referrer, based on scientific research within the scope of consortia. Other challenges, such as percutaneous mitral and tricuspid valve intervention, closure of the left atrial appendage and percutaneous closure of valve leaks, arise from this maturity and become a natural evolution in the field of percutaneous structural interventions.

LIST OF PUBLICATIONS

4. List of publications

		2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	total	
International	**First Author**						**1**			**1**			**2**	10
	Total	2	2	1	2	2	3	2	4	9	7	2	**36**	57
National	**First Author**		**2**			**1**	**2**			**3**			**8**	
	Total		2	2	2	1	3	2	1	6	2		**21**	

The Ethics Research Committee of NMS|FCM-UNL (CEFCM) has unanimously approved the project entitled "Transcatheter aortic valve implantation (TAVI). A reference model in percutaneous cardiovascular interventions" (No. 32/2022/CEFCM), submitted by the PhD student Rui Campante Teles, in the scope of the Doctoral Programme in Medicine at the NOVA Medical School.

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ROADMAP

5. Author's roadmap

N.	Type	Topic	1st Author	Co-Author				IF 2021	NMS PHD
				Design	Data acquistion	Statistisc	Writing		
1	Case report	Scope and Innovation, Safety & Vascular Access, Procedural subsets, Interventional Devices, Outcomes		X	X	X	X	4,753	4,753
2	Original	Scope and Innovation, Procedural subsets, Outcomes		X	X		X	4,753	4,753
3	Original	Scope and Innovation, Outcomes			X		X	4,164	4,164
4	Original	Scope and Innovation, Procedural subsets, Outcomes			X		X	24,094	12,047
5	Original	Scope and Innovation, Procedural subsets, Outcomes			X		X	56,272	28,136
6	Original	Safety & Vascular Access, Outcomes			X		X	2,692	2,692
7	Original	Safety & Vascular Access			X		X	2,000	2,000
8	Original	Outcomes			X		X	1,439	1,439
9	Original	Bench, Interventional Devices,Training and Certification					X	6,534	3,267
10	Case report	Scope and Innovation, Heart Valves Spectrum, Interventional Devices, Outcomes		X	X	X	X	1,730	1,730
11	Review	Multidisciplinary risk assessment, Heart Valves Spectrum		X			X	4,164	4,164
12	Original	Scope and Innovation, Outcomes	X					6,534	13,068
13	Original	Safety and vascular access					X	29,983	14,992
14	Case report	Scope and Innovation, Pharmacological therapies		X	X	X	X	4,753	4,753
15	Original	Outcomes			X		X	24,094	12,047
16	Review	Frailty & Sarcopenia, Multidisciplinary risk assessment			X		X	4,164	4,164
17	Original	Multidisciplinary risk assessment, Procedural subsets, Outcomes		X	X		X	2,000	2,000
18	Original	Scope and Innovation, Multidisciplinary risk assessment			X		X	4,379	4,379
19	Original	Procedural subsets, Interventional Devices			X		X	11,195	5,598
20	Letter	Safety & Vascular Access			X		X	11,195	11,195
21	Original	Procedural subsets			X		X	2,692	2,692
22	Original	Scope and Innovation, Bench, Frailty & Sarcopenia, Multidisciplinary risk assessment, Safety & Vascular Access, Procedural subsets, Training and Certification, Pharmacological therapies, Outcomes	X					6,534	13,068
23	Original	Scope and Innovation, Procedural subsets, Outcomes			X		X	6,534	3,267
24	Original	Procedural subsets			X		X	1,170	1,170
25	Original	Scope and Innovation, Training and Certification		X			X	6,534	3,267
26	Original	Scope and Innovation, Heart Valves Spectrum, Interventional Devices, Outcomes			X		X	29,690	14,845
27	Letter	Scope and Innovation, Outcomes			X		X	24,094	12,047
28	Original	Scope and Innovation, Interventional Devices			X		X	24,094	12,047
29	Original	Heart Valves Spectrum, Interventional Devices			X		X	2,692	2,692
30	Original	Procedural subsets, Outcomes		X	X		X	2,357	2,357
31	Original	Multidisciplinary risk assessment, Outcomes			X		X	2,692	2,692
32	Original	Procedural subsets, Outcomes			X		X	2,022	2,022
33	Original	Procedural subsets,, Interventional Devices			X		X	24,094	24,094
34	Original	Scope and Innovation, Procedural subsets, Outcomes			X		X	2,692	1,346
35	Original	Procedural subsets, Safety & Vascular Access			X		X	5,197	2,599
36	Original	Heart Valves Spectrum			X		X	4,753	4,753

N.	Type	Topic	1st Author	Co-Author				IF 2021	NMS PHD
				Design	Data acquistion	Statistisc	Writing		
37	Editorial	Scope and Innovation, Training and Certification	X					1,374	2,748
38	Review	Scope and Innovation, Training and Certification	X					1,374	2,748
39	Original	Multidisciplinary risk assessment, Safety & Vascular Access		X	X	X	X	1,374	1,374
40	Original	Scope and Innovation, Outcomes			X		X	1,374	1,374
41	Original	Scope and Innovation, Multidisciplinary risk assessment, Outcomes		X	X		X	1,374	1,374
42	Original	Outcomes			X	X	X	1,374	1,374
43	Editorial	Scope and Innovation, Multidisciplinary risk assessment	X					1,374	2,748
44	Case report	Scope and Innovation, Interventional Devices, Training and Certification, Outcomes	X					1,374	2,748
45	Editorial	Scope and Innovation, Procedural subsets, Interventional Devices	X					1,374	2,748
46	Original	Multidisciplinary risk assessment, Outcomes		X	X	X	X	1,374	1,374
47	Original	Bench, Outcomes			X		X	1,374	1,374
48	Original	Frailty & Sarcopenia, Multidisciplinary risk assessment			X		X	1,374	1,374
49	Original	Outcomes			X		X	1,374	1,374
50	Case report	Scope and Innovation, Safety & Vascular Access, Procedural subsets, Heart Valves Spectrum, Interventional Devices	X					1,374	2,748
51	Letter	Scope and Innovation, Multidisciplinary risk assessment			X		X	1,374	1,374
52	Editorial	Scope and Innovation, Outcomes	X					1,374	2,748
53	Original	Scope and Innovation, Interventional Devices,Outcomes			X		X	1,374	0,687
54	Original	Scope and Innovation, Multidisciplinary risk assessment, Safety & Vascular Access, Interventional Devices, Outcomes		X	X		X	1,374	1,374
55	Editorial	Pharmacological therapies	X					1,374	2,748
56	Original	Multidisciplinary risk assessment			X		X	1,374	1,374
57	Review	Scope and Innovation, Interventional Devices					X	1,374	1,374
Total IF								**387,587**	**285,457**
IF of the original contributions								**25,434**	**50,868**

COHERENCE OF RESEARCH

6. Coherence of Research

1. Scope and Innovation

- Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis. REC 2012 (Manuscript #1)
- Implante Percutaneo de Válvula Aórtica: Seguridad y Eficácia del Tratamiento del Homoenxierto Aortico Disfuncionante. REC 2012 (Manuscript #2)
- The Ibero-American transcatheter aortic valve implantation registry with the CoreValve prosthesis. Early and long-term results. IJC 2013 (Manuscript #3)
- Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. JACC 2013 (Manuscript #4)
- Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA 2014 (Manuscript #5)
- Transcatheter tricuspid valve-in-valve replacement: one-year results: Alternative to surgery in high-risk patients. HV 2017 (Manuscript #10)
- Portugal: coronary and structural heart interventions from 2010 to 2015. EIJ. 2017 (Manuscript #12)
- Successful Clinical and Therapeutic Approach for Valve-in-valve Leaflet Thrombosis. REC 2018. (Manuscript #14)
- Diagnostic accuracy of computed tomography angiography for the exclusion of coronary artery disease in candidates for transcatheter aortic valve implantation.SR 2019 (Manuscript #18)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Long-term outcomes after transcatheter aortic valve implantation in failed bioprosthetic valves.
- ESC Core Curriculum for the Cardiologist. EHJ 2020 (Manuscript #25)
- Transcatheter Mitral Valve Replacement After Surgical Repair or Replacement: Comprehensive Midterm Evaluation of Valve-in-Valve and Valve-in-Ring Implantation From the VIVID Registry. Circ 2021 (Manuscript #26)
- Impact of COVID-19 Pandemic on Mechanical Reperfusion for Patients With STEMI. JACC 2020 (Manuscript #27)
- Transcatheter Aortic Valve Replacement With the LOTUS Edge System: Early European Experience. JACC 2021 (Manuscript #28)
- Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves: The TRANSIT International Project. CCI 2021 (Manuscript #34)
- Trailing behind: limitations on transcatheter aortic valve implantation in Portugal. RPC 2013 (Manuscript #37)
- Position statement on transcatheter aortic valve implantation in Portugal. RPC 2013 (Manuscript #38)
- Late results (>10 years) of intracoronary beta brachytherapy for diffuse in- stent restenosis. RPC 2014. (Manuscript #40)
- Aortic valve replacement for severe aortic stenosis in octogenarians: patient outcomes and comparison of operative risk scores. RPC 2015 (Manuscript #41)
- Avaliação do risco e uso apropriado da intervenção coronária percutânea. Portagem manual ou via verde eletrónica automática? RPC 2016 (Manuscript #43)
- Sequential transcatheter aortic valve implantation due to valve dislodgement - a Portico valve implanted over a CoreValve bioprosthesis. RPC 2017 (Manuscript #44)
- Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era: A challenge to organization of the heart team. RPC 2017 (Manuscript #45)
- Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure. RPC 2020 (Manuscript #50)
- Caring for cardiac patients amidst the SARS-CoV-2 pandemic: The scrambled pieces of the puzzle. RPC 2020 (Manuscript #51)

- "A momentary lapse of opinion": The reader should be aware of the iatrogenic potential of this publication. RPC 2020 (Manuscript #52)
- Ten-year survival of patients undergoing coronary angioplasty with first-generation sirolimus-eluting stents and bare-metal stents. RPC 2020. (Manuscript #53)
- Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI. RPC 2020 (Manuscript #54)
- Non-pharmacological treatment of refractory angina: The coronary sinus reducer, the new kid on the block. RPC 2021 (Manuscript #57)

The two decades of intervention with percutaneous aortic valves constitute a reference model in the history of contemporary cardiology and of patients with cardiovascular disease.

The revolution of aortic valve disease percutaneous treatment, in 2002, by Alain Cribier, modified the existing solutions, providing a progressive and impressive range of therapeutic alternatives proposed to patients with this pathology, whose prevalence has grown, in parallel with the population's longevity , since the most prevalent etiology of aortic stenosis is degenerative [3–5].

In 2008, the diagnosis, assessment, stratification and multidisciplinary decision within the scope of multidisciplinary teams revolutionized the methodology and organization of cardiologists and cardiac surgeons who were obliged to actively collaborate in the treatment of patients whose risk of surgical intervention was considered prohibitive or high. The anatomical and technical requirements to safely perform this type of procedure were strict, due to the high caliber of the devices, which were neither repositionable nor recapturable. In this way, dedicated tutoring protocols were established, providing progressive autonomy to operators and surgeons, in order to mitigate the usual learning curves that innovative techniques and successive devices iterations present [6,7].

After a few years of limited growth in the technique, it was evident and widely accepted that we would benefit from a harmonization of our clinical practices and their comparison with international references, to increase patient access to percutaneous valve treatment in Portugal. Scientific societies and research programs promoted quality by monitoring and public presentation of results in through a national registry with expression in the European Society of Interventional Cardiology (EAPCI) [8,9].

At the same time, the integration in European and North American research networks, laid the foundations for research within the scope of the most relevant themes in this area, which provided a critical view of daily clinical activity, namely:

- The patient selection: frailty assessment, risk stratification, usefulness of the intervention, the imponderables [10–15];
- The patient subgroups: the use in those with a history of cardiac valve surgery – aortic, mitral and tricuspid - as well as in octogenarians [16–19];
- The economic impact of incremental cost on health economics [20,21];

- The device selection, hybrid techniques, access routes and resolution of complications [12,15,22,23];
- Concomitant medical therapy and longevity assessment of all associated interventions through long-term national and international prospective registries [24–28];
- The expansion to other areas of structural intervention [18,29,30].

Along this path, the quest to prepare an interventional cardiologists for this particular area became patent. That was reflected not only in proctoring but also in a *core curriculum* that constitutes the formal and practical basis of an education and training program. This aims to ensure patient safety and excellence in percutaneous interventions programs by certifying physicians and allied professionals [6].

The SHD interventional cardiologist (IC) is a subspecialist team worker that can consider and apply percutaneous interventional techniques. A background of cardiac intensive care experience, with a special emphasis on vascular, acute heart failure and rhythm management, is needed. As this field encompasses specific and, often, complex techniques, the IC needs experience and a differentiation that complements the general IC skills. It is mandatory that an operator masters the interpretation of advanced cardiology imaging techniques required for periprocedural assessment, particularly echocardiography, MSCT, CRMI and angiographic studies. A key role of the SHD IC is to collaborate with the Heart Team to select the most suitable and balanced treatment, for patient information and shared decision making[6].

The pandemic impact could not be ignored and thus, percutaneous intervention programs were monitored and conclusions drawn [32].

Currently, the biggest challenge is the expansion of the percutaneous interventions to patients with a lower risk profile and to younger patients, with distinct challenges in their stratification, comorbidities, clinical presentation, anatomy and potential longevity. For Portugal, a need for 2516 cases per year for treatment is expected only in aortic stenosis with TAVIs (95% CI 1535-3776), which may reach 50% more volume with the 2021 ESC recommendations for valvular disease [5,36,37].

This evolution has an holistic impact on the cardiology and cardiac surgery organization, imposing a deep restructure as the path taken in the aortic pathology is being transposed, relatively, to other structural clinical areas, namely the mitral, the tricuspid and the acute stroke prevention [18,34–37].

In summary, the endeavor carried out illustrates the systematic research that supports the TAVI program progression and that has unequivocally contributed to improve this area in Portugal.

2. Bench

- In vitro evaluation of implantation depth in valve-in-valve using different transcatheter heart valves. EIJ 2016 (Manuscript #9)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020(Manuscript #22)
- Post-procedural N-terminal pro-brain natriuretic peptide predicts one-year mortality after transcatheter aortic valve implantation. RPC 2018 (Manuscript #47)

Interventional cardiology is a discipline that links technological progression to basic applied research in in-vitro, animal and human models. The intervention cardiologist's *core curriculum* considers that research, from the laboratory bench to intervention and follow-up, is an integral part of training and therefore all structural intervention programs must encompass these aspects [6].

Globally, one can divide this translation into 3 fundamental areas: biomarkers, bio and microtechnology.

The former have been used to interpret the pathophysiology of valvular disease, risk stratification, prognostic assessment and guidance of patients undergoing treatment. In particular, proBNP constitutes a routine biomarker in diagnostic stratification as well as in the interpretation of symptomatic recurrence, as evaluated early by our group in an emerging population of patients treated with VAP [38].

Biotechnology and laboratory bench research have underpinned technological progress based on an innovative set of endovascular prosthetic materials, such as the metallic nitinol alloy, progressively more compatible with the vascular environment, allowing, along with the artificial leaflet treatments, for the reduction of thromboembolic phenomena and the adoption of pharmacological regimens factors that lower the hemorrhagic profile.

From the perspective of microtechnology, we have seen a miniaturization of the various delivery systems for prosthetic devices, accompanied by greater precision and stability, providing high gradients and effective valve areas after the procedure, in parallel with less invasiveness and complications. This challenge is particularly relevant in patients with a history of aortic valve surgery with bioprostheses, where we assessed the importance of the relationship between implantation depth and hemodynamics, making recommendations on the technique in this context [39].

3. Frailty and Sarcopenia

- Usefulness of skeletal muscle area detected by computed tomography to predict mortality in patients undergoing transcatheter aortic valve replacement: a meta-analysis study. IJCI 2019 (Manuscript #16)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020(Manuscript #22)
- Comparison of multiparametric risk scores for predicting early mortality after transcatheter aortic valve implantation. RPC 2018 (Manuscript #48)

In a large US cohort, there was a 33% decline in cardiac deaths at 5 years after hospital discharge following percutaneous coronary intervention (PCI), but a 57% increase in non-cardiac deaths [40]. Thus, clinical care must be developed to address a coordinated and comprehensive management of multiple co-occurring conditions rather than focus on single diseases. An holistic approach is seldom considered into clinical decision-making, especially as it relates to interventions like the percutaneous ones.

Frailty it is widely spoken among the medical community. Prevalence estimates are affected by how it is defined but nevertheless it seems to affect around 3 to 6% of individuals aged over 65 and 16% of octogenarians. It is crucial to identify frailty because is associated with immobility, disability, hospitalization, institutionalization and death. In 2013, a frailty consensus statement recommended screening for all persons 70 years or older and those with significant (2,3 kg) annual unintentional weight loss [40,41]. The diagnostic criteria vary widely but there are two main methods, the (1) phenotype, and (2) accumulation of deficits. The Frailty Fried' s phenotype enjoys broad consensus in the scientific community as a biologic syndrome that includes five major criteria: weight loss, fatigue and exhaustion, weakness, low physical activity and slowness, and mobility impairment. The second, the accumulation deficit model, is based upon exhaustive and large scales; it considers symptoms, diseases, conditions, and disability and is hard to implement in consecutive all comers' registries.

A number of tools are available to facilitate individualized perioperative risk assessment that will influence treatment selection. Physician resources include a variety of validated prognostic indices and mortality calculators based on published prognostic indices (eg, http: //www.eprognosis.org/). However, there are no geriatric-specific tools and no single instrument incorporates every important geriatric variable [34].

We collaborated with a consortium to perform a meta-analysis of all the available literature to analyze the benefit of sarcopenia CT-derived skeletal muscle area in providing a prognostic value and predicting post-TAVR. We were able to illustrate that a higher skeletal muscle area (SMA) was associated with a 49% reduction in long-term mortality. A simple method may

improve risk stratification for TAVI procedure and guide clinical decisions. Moreover, it may help identifying and targeting high-risk patients with nutritional and exercise interventions to improve muscle mass prior to and following the procedure [42].

4. Multidisciplinary risk assessment

- Transcatheter mitral valve interventions for mitral regurgitation, with special focus on MitraClip: The position of Spanish, Portuguese and Italian interventional societies. IJC 2017 (Manuscript #11)
- Usefulness of skeletal muscle area detected by computed tomography to predict mortality in patients undergoing transcatheter aortic valve replacement: a meta-analysis study. IJCI 2019 (Manuscript #16)
- Impact of Transcatheter Aortic Valve Implantation on Kidney Function. ABC 2019 (Manuscript #17)
- Diagnostic accuracy of computed tomography angiography for the exclusion of coronary artery disease in candidates for transcatheter aortic valve implantation.SR 2019 (Manuscript #18)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Surgical versus transcatheter aortic valve replacement in low-risk patients: a long-term propensity score-matched analysis. CCI 2021 (Manuscript #31)
- Válvula Aórtica Percutânea TransapicaL: 5 anos de experiência [Transapical aortic valve replacement: a 5-years experience]. RPC 2014 (Manuscript #39)
- Aortic valve replacement for severe aortic stenosis in octogenarians: patient outcomes and comparison of operative risk scores. RPC 2015 (Manuscript #41)
- Avaliação do risco e uso apropriado da intervenção coronária percutânea. Portagem manual ou via verde eletrónica automática? RPC 2016 (Manuscript #43)
- Advantages of a prospective multidisciplinary approach in transcatheter aortic valve implantation: Eight years of experience. RPC 2017 (Manuscript #46)
- Comparison of multiparametric risk scores for predicting early mortality after transcatheter aortic valve implantation. RPC 2018 (Manuscript #48)
- Caring for cardiac patients amidst the SARS-CoV-2 pandemic: The scrambled pieces of the puzzle. RPC 2020 (Manuscript #51)
- Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI. RPC 2020 (Manuscript #54)
- Adoption and patterns of use of invasive physiological assessment of coronary artery disease in a large cohort of 40 821 real-world procedures over a 12-year period. RPC2021 (Manuscript #56)

Innovative percutaneous techniques aim to add well-being and provide alternative options. When the target population presents a risk profile that, until then, was considered unfavorable to other interventions, we are often faced with situations of extreme gravity, for which it is important to know the associated risks and benefits as correctly as possible [6].

Since the beginning of the course in valve intervention, it was anticipated that risk stratification was a pillar of multidisciplinary action. The central question is the implementation and usefulness of assessment. A well-defined, carefully staged, protocol to optimize patient selection program was set in place to study the risk profile and the technical suitability of TAVI, in addition to the rationalization of resources, considering the complexity and costs of TAVI[43]. The different aspects are complementary and, generally, sequential, from the non-invasive evaluation to the invasive hemodynamic exams. The clinical evaluation, the interpretation of diagnostic tests and

the use of risk scores constitute the basis of the orientation towards therapeutic usefulness or, on the other hand, towards futility.

Surgical scores are widely used and recommended to identify patients at high surgical risk who may benefit from transcatheter aortic valve implantation (TAVI)[34]. Their application is frequently overrated due the complexity of AS and CAD presentations. We assumed early that the individual assessment is multiparametric and cannot rely solely on risk scores, not only because of our institutional experience but also as there are conflicting data regarding the role of simple surgical scores for early mortality prediction in TAVI and CAD patients.

Thus, we searched for the best tools and used our Valve Catheter Restorative Operation on Santa cruz hoSpital (VCROSS) single-center, prospective, observational registry.

- We studied 240 consecutive patients who underwent TAVI between January 2008 and December 2015 and compared the 30-day mortality prediction performance of the FRANCE-2, European System for Cardiac Operative Risk Evaluation score (EuroSCORE II) and Society of Thoracic Surgeons (STS) scores. All scores showed low discriminative power for prediction of early mortality, though with adequate calibration[14]. Probably the endeavour for accurate and sensitive TAVI scores will require more complex, dynamic and comprehensive scores that can be instantaneously available at the patient's bedside, in order to facilitate decisions regarding catheterization and treatment strategy[11].
- We also examined the operative mortality and morbidity to compare the predictive accuracy of the logistic EuroSCORE I, EuroSCORE II and STS score in octogenarians submitted to isolated surgical aortic valve replacement (SAVR). Here, all scores showed good discriminative power, although the logistic EuroSCORE I overestimated mortality by almost three times the observed value[10].
- A total of 158 patients low-risk patients -79 SAVR and 79 TAVI, at a median follow-up of 4.5 years (IQR 3.0–6.9) presented similar mortality and rehospitalization, while Euroscore II remained the only independent predictor of long-term all-cause mortality (adjusted HR 1.40, 95% CI 1.04–1.90, p = 0.029) [44].

This prompt us to examine other factors that can influence prognosis and help the decision-making process. Given the prevalence of several comorbidities and disabilities in the AV disease patients, research was conducted to understand how to best manage the most relevant ones in our practice:

- Sarcopenia, defined as an age-related disease described by a significant loss of skeletal muscle mass, is easily measured from preoperative computed tomography (CT) images and was investigated as quantitative surrogate of frailty. We concluded that it is an independent predictor of outcomes in patients undergoing TAVI [42].
- The TAVI access route impact on the results was one of the first team concerns. Our group conducted a longitudinal prospective single center study including our initial cohort of 54 consecutive patients who underwent the transpical route. Mortality at 30 days was 5.6% and unplanned extracorporeal circulation was used in 5 cases [23]. An expanded study

accessed in 2362 consecutive patients included in the prospective national TAVI registry, designed and created by the author in 2012. The selected route did not raise short-term safety concerns but the non-transfemoral approach appeared as an adverse long-term mortality factor with an hazard ration 1.8 [37].

- The prevalence of coronary artery diseases (CAD) in TAVI patients ranges from 15 to 81% and correlates inversely age presentation [45]. A systematic evaluation of the coronary anatomy is warranted and, usually, invasive coronary angiography (ICA) is undertaken. We demonstrated that, in 27% of cases, multislice computed tomography angiography (MSCT) can provide enough information about the coronary tree and dismiss the risks and costs of ICA [46].
- In CKD, particularly important in our TAVI cohort, we were able to evidence that, when moderate-to-severe CKD is present, the kidney function improves one year after the procedure. This outcome is probably due to better kidney perfusion post-procedure. We believe that when evaluating patients that might need TAVI, this 'reversibility of CKD effect' should be considered [47].

Any innovative therapy to improve patient care and clinical outcomes requires strategies to promote its adoption. When CAD is present in AS, the use of invasive physiological assessment may be an helpful tool but is frequently underused and we have demonstrated that, even with the availability of resting indices - that do not require pharmacological infusions- no increase was seen at our cath lab [48]. We analyzed the caring for cardiac patients amidst the SARS-CoV-2 pandemic and described the unique challenges for the care of non- COVID-19 patients, including those with established cardiovascular disease – as TAVI candidates- and those at risk due to acute coronary syndromes and heart failure decompensation, stressing the paramount importance that patients remained alert to cardiovascular symptoms that needed urgent assessment in non-COVID-19 hospital circuits that were strategically adapted to provide the necessary care [32].

In a broader perspective, the aortic valve experience was extremely valuable in an IC center because it was the first SHD therapy and did influence all others. Mitral regurgitation (MR) is the second most common symptomatic valvular disease worldwide. The presence of MR after MI or with dilated cardiomyopathy is associated with an increased risk of cardiac insufficiency and death. Several transcatheter devices to correct mitral regurgitation in patients at high-risk for surgery have emerged with promising results. While evidence is being built it is important to cooperate and issue recommendations based on SHD experience and broad expert consensus to optimise patient selection, to asses risk and to discuss the optimal timing for transcatheter mitral valve interventions (TMVI) [49].

5. Safety and vascular access

- Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis. REC 2012 (Manuscript #1)
- Neurologic complications after transradial or transfemoral approach for diagnostic and interventional cardiac catheterization: A propensity score analysis of 16,710 cases from a single centre prospective registry. CCI 2015 (Manuscript #6)
- Predictors of Conversion from Radial Into Femoral Access in Cardiac Catheterization. ABC 2015 (Manuscript #7)
- 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular. EHJ 2018 (Manuscript #13)
- The Spotlight Is on Secondary Access for TAVR: Radial Versus Femoral Revisited. JACC Int 2020 (Manuscript #20)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Percutaneous vs surgical axillary access for transcatheter aortic valve implantation: the TAXI registry. Panminerva Med (Manuscript #35)
- Válvula Aórtica Percutânea TransapicaL: 5 anos de experiência [Transapical aortic valve replacement: a 5-years experience]. RPC 2014 (Manuscript #39)
- Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure. RPC 2020 (Manuscript #50)
- Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI. RPC 2020 (Manuscript #54)

As previously discussed, the access route has a major impact on the clinical outcomes and becomes the real division between the percutaneous and hybrid techniques that require other routes, namely the subclavian, axillary, transaortic and transapical.

This concern with peripheral arterial disease (PAD) is expressed in the 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS), on peripheral and local arterial diseases of vascular access for cardiac interventions, as a reviewer [50]. And in the EAPCI Core Curriculum of Interventional Cardiology, as the main author [6]. It is justified not only by the risk that usually increases in percutaneous procedures, but particularly by the autonomy that the operator must acquire in potential complications with the diagnosis, evaluation and treatment, mainly endovascular.

From the first procedures to current clinical practice, there have been very important changes in vascular approach sites and techniques, in the caliber of existing or available devices, as well as a progressively growing portfolio of dedicated solutions for closing arterial puncture sites greater than 5 mm.

Initially, due to the caliber of the devices used, which often exceeded 8 mm, alternative accesses were used which, being more complex and presenting a greater potential risk, allowed the only therapeutic option for patients at very high risk. The experience in the transapical route, carried

out in the cath lab room through a hybrid procedure, was reported and superlative in the results leading to a prize obtained as testimony to research for patient-centered solutions. VARC-2 composite targets for device success reached 90.7%, early safety 75.9% and clinical efficacy at 30 days 83.7%, validating this treatment approach. As a result, the various access routes were kept open, adopting the transfemoral route whenever possible and extending the scope of the investigation to other centers [37]. Consequently, 2346 consecutive patients treated by different accesses were evaluated at the Registo Nacional de Cardiologia de Intervenção (RNCI). It was observed that the transfemoral route was safe at 30 days, although the survival was lower after one year, reflecting a higher risk profile in the context of femoral access not accessible to available devices [37]. The maintenance of proficiency is virtuous and allows to treat in an original way in a hybrid procedure some very particular cases, as reported, using transapical-transfemoral arteriovenous loops in patients with multivalvular pathology [22].

In addition to the primary access selection, through which the definitive device is delivered, we dedicated particular attention to the secondary access, whose approach is sometimes neglected. The experience in radial access is today a different reality compared to that of a decade ago, as this route has evolved from 1% use to more than 70% in the coronary approach. The experience with this option was researched in 7632 patients in the prospective registry of UNICARV, ACROSS (Angioplasty and Coronary Revascularization at Santa Cruz Hospital), where, among others, the use of short sheaths was found to be independent predictors of conversion from radial to femoral access (OR 3.047, CI: 2.380-3.902; p<0.001), females (OR 1.569, CI: 1.234-1.996; p<0.001), multivessel disease (OR 1.457, CI: 1.167-1.819; p=0.001) , body surface area (BSA) ≤ 1.938 (OR 1.448, CI: 1.120-1.871; p = 0.005) and age > 66 years (OR 1.354, CI: 1.088-1.684; p = 0.007) [51]. In the context of prolonged interventions such as VAP, the option of using the radial route as the secondary route was very attractive. The pilot experience in renal denervation was the starting point for an investigation including 16710 consecutive patients undergoing catheterization at the institution, demonstrating that, after correction for differences, this path is not an independent predictor of definitive (CVA) or transient cerebrovascular accident (TIA) (OR 1.21; 95% CI 0.49-2.98 and 1.3; 95% CI 0.55-3.54, respectively) namely in the pre-specified subgroup aged ≥ 65 years [52,53]. The adoption of this arterial route advocated a visionary alternative that lead to a reality that is, currently, discussed and accepted [54].

Finally, the resolution of complications, namely pericardial tamponade of various etiologies, acute prosthesis failure and major vascular ruptures, may require timely access to

complementary cardiac and vascular surgery techniques, which may become crucial in case of patient instability [15].

In conclusion, the experience in the percutaneous field perceived very early the vascular access as key factor for success. Experiences with alternative routes and closure devices were researched, building a background for increased safety in the SHD field.

6. Procedural subsets

- Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis. REC 2012 (Manuscript #1)
- Implante Percutaneo de Válvula Aórtica: Seguridad y Eficácia del Tratamiento del Homoenxierto Aortico Disfuncionante. REC 2012 (Manuscript #2)
- Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. JACC 2013 (Manuscript #4)
- Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA 2014 (Manuscript #5)
- Impact of Transcatheter Aortic Valve Implantation on Kidney Function. ABC 2019 (Manuscript #17)
- TAVI-SMALL Investigators. Transcatheter Self-Expandable Valve Implantation for Aortic Stenosis in Small Aortic Annuli: The TAVI-SMALL Registry. JACC Int 2020 (Manuscript #19)
- Transcatheter aortic valve implantation (TAVI) in cardiogenic shock: TAVI-shock registry results. CCI 2020 (Manuscript #21)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Long-term outcomes after transcatheter aortic valve implantation in failed bioprosthetic valves.
- Low rate of invasive coronary angiography following transcatheter aortic valve implantation: Real-world prospective cohort findings. CRM 2020 (Manuscript #24)
- Predictors of pacemaker implantation after TAVI in a registry including self, balloon and mechanical expandable valve. IJCVS 2021 (Manuscript #30)
- Gender Differences and Mortality Trends After Transcatheter Aortic Valve Implantation: A 10-Year Analysis From a Single Tertiary Center. JIC 2021 (Manuscript #32)
- Predictors and Clinical Impact of Prosthesis-Patient Mismatch After Self-Expandable TAVR in Small Annuli. JACC Int 2021. (Manuscript #33)
- Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves: The TRANSIT International Project. CCI 2021 (Manuscript #34)
- Percutaneous vs surgical axillary access for transcatheter aortic valve implantation: the TAXI registry. Panminerva Med (Manuscript #35)
- Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era: A challenge to organization of the heart team. RPC 2017 (Manuscript #45)
- Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure. RPC 2020 (Manuscript #50)

The progress of percutaneous valve intervention presents specific challenges related to certain clinical presentations or subgroups of patients whose complexity requires a particular scientific foundation [4].

Due to its frequency, particularly in many centers with a long history of cardiac surgery, reintervention in patients who develop homograft or bioprosthesis degeneration is of great importance. The first publication of five clinical cases with an Iberian consortium demonstrated the potential of valve-in-valve (VIV) procedures in patients at high surgical risk, who were treated safely, with reasonable efficacy, considering the experience at that time with off-label devices, as well as the absence of dedicated valves - which continues to this day- to this subgroup [16]. The evolution in this field was sustained and based on scientific evidence collected in the real world

through an international multicenter registry of 459 patients. An investigator cooperation joining those with considerable experience in this risky context due to the inherent risk of a re-intervention, the risk of occlusion or sequestration of the coronary sinuses, as well as device embolization. The main mechanisms of bioprosthesis failure were described, with a slight preponderance of stenosis (39.4%) over regurgitation (30.3%) and combined presentation (30.3%). Originally, it was noted that smaller surgical bioprostheses (annulus <= 21 mm) had an independent risk of mortality at one year 2.04 times higher (95% CI, 1.14-3.67; p = 0.02) [55,56]. The same main consortium extended the follow-up to 5 years, studying 1006 procedures, showing that the severe patient-prosthesis mismatch (PPM) was an independent predictor for reintervention [HR 4.34 (95% CI 1.31 -14.39)], in parallel with the poor positioning of the device [HR 3.75 (95% CI 1.36–10.35)], the balloon expandable valves [HR 3.34 (95% CI 1.26) –8.85)] and age [HR 0.59 (95% CI 0.44–0.78)]. The approach is technically complex, due to the altered anatomy of the coronary sinuses and, sometimes, combined disease, requiring an ingenious approach, as described by the group. [22]. More recently, in an extreme dimension, the impact of reintervention with TAVI was evaluated in the context of a VIV with a previous TAVI, which is a rarity because only 172 patients underwent it in more than 40,000 cases. At 1-month, the overall mortality rate was acceptable 2.9%. Of note, while rates of new hospitalization and NYHA class III/IV were 3.6% and 7%, three cases of valve thrombosis were recorded. Despite the feasibility, this deserves special consideration, as well has the coronary access maintenance [19].

This issue of annulus size, that emerged in the context of the VIV, became extremely pertinent nowadays. In fact, the relationship of the smallest dimensions of the native ring with the prosthesis-patient disproportion (PPM, patient prosthesis mismatch) is known, which, in turn, can reduce the functional improvement, may increase the possibility of distant prosthetic degeneration and aggravate mortality. In patients with small annulus, we must adapt the pre- and post-dilation, the implantation technique and the choice of size and device type - supra annular vs intra annular and self-expandable vs balloon expandable - as an international multicenter collaborative research retrospective, including 859 individuals, suggested [57,58].

The contemporary management of CAD in TAVI candidates remains open. While there is no evidence of increased survival or symptoms relief with a full revascularization strategy, the greater cumulative risk of CAD progression in younger, lower-risk patients raises concerns. It possible that up 10-20% of patients present an increased risk of coronary obstruction. Thus, despite accurate imaging and TAVI procedural planning, coronary access and PCI are expected to increase and should be considered. A prospective observational single center registry, including 563 consecutive patients detected a total of 18 patients (3.2%) that needed invasive

coronariography after TAVI. A total of 11 PCIs were performed in 9 patients, with a complete success rate of 63.6%. The challenge of engaging the coronary ostia varies according to the aortic root anatomy, coronary take-off, transcatheter heart valves (THV) design and commissural alignment [59].

Another topic is chronic kidney disease (CKD). Aortic stenosis reduces cardiac output and CKD is frequently present. Several studies have described a poor short- and long-term outcomes in patients with CKD submitted to TAVI and therefore there are concerns related with the aortic valve replacement utility in this setting and the reversibility of CKD after TAVI. We performed a retrospective analysis of 233 consecutive patients evidencing that moderate-to-severe CKD improves one year after the TAVI procedure, probably due to better kidney perfusion post-procedure [47].

Rarely patients with severe aortic valve stenosis present cardiogenic shock (CS). Palliation with balloon aortic valvuloplasty (BAV) is associated with a poor prognosis[13]. This is an exclusion criteria in randomized controlled trials and data on TAVI in CS setting is scarce. A multicentric international study of 51 patients was performed and evidenced a reasonable safety and one-year outcomes: at 30-day mortality reached 11.8%, stroke 2.0%, vascular complications 5.9%, and acute kidney injury 34%. At 1-year of follow-up, the mortality rate was 25.7% and the readmission for congestive heart failure was 8.6% [60].

Ultimately, on the other side of the spectrum, we have the low-risk patients that received the highest recommendations in the 2021 ESC/EACTS Guidelines for the management of valvular heart disease[34]. Evidence about the safety and efficacy of TAVI is emerging in this setting to cover the new challenges of a long-life expectancy that demands improvements in the THV development. Thus, an alternative balloon expandable device, the Myval, was assessed in low-surgical risk patients by a multicentric retrospective registry performed at 9 different sites across 4 countries. A low rate of procedural-related complications was evidenced, with no cases of annular rupture, coronary obstruction or mortality at 30 days. Importantly, 8% required a new pacemaker implant, documenting an important progress in a sensitive field for patients with longer life-expectancy [61].

The occurrence of high degree atrioventricular conduction disturbances and the subsequent need of permanent pacemaker implantation (PPMI) is a major contemporary concern in young patients. A single-center prospective cohort study of 227 consecutive individuals who underwent TAVI since March 2017 was published demonstrating that both RBBB pattern and

short membranous septum (<8 mm) were strongly and independently associated with PPMI, regardless of the device type. As a consequence, we added the MS length to guide device selection and implantation technique aiming to facilitate early discharge [62].

The question of gender differences is particularly important nowadays, since prognostic differences have been reported in the SHD area and can impact patient shared decision making. A prospective longitudinal analysis demonstrated that females, over a median follow-up of 23 months (IQ, 21 months), demonstrated better overall survival rates (70.3% vs 60.5% in men; P=.01; log-rank p<0.01) suggesting a benefit in this population, despite the trend towards an increased number of periprocedural complications (p=0.08) [63].

Several other sub-groups still deserve special consideration, particularly the bicuspid anatomy, the ambulatory oxygen dependent patients and peripheral artery disease individuals. Their management is challenging and benefits from the multidisciplinary heart team workflow [6].

7. The Heart Valves spectrum

- Transcatheter tricuspid valve-in-valve replacement: one-year results: Alternative to surgery in high-risk patients. HV 2017 (Manuscript #10)
- Transcatheter mitral valve interventions for mitral regurgitation, with special focus on MitraClip: The position of Spanish, Portuguese and Italian interventional societies. IJC 2017 (Manuscript #11)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Transcatheter Mitral Valve Replacement After Surgical Repair or Replacement: Comprehensive Midterm Evaluation of Valve-in-Valve and Valve-in-Ring Implantation From the VIVID Registry. Circ 2021 (Manuscript #26)
- Next-generation balloon-expandable Myval transcatheter heart valve in low-risk aortic stenosis patients. CCI 2021 (Manuscript #29)
- Iberian experience with PASCAL transcatheter edge-to-edge repair for mitral valve regurgitation.. REC 2012 (Manuscript #36)
- Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure. RPC 2020 (Manuscript #50)

The field of interventional cardiology in structural heart disease (SHD), includes heart valves disease and vessels, as well as congenital or acquired wall and muscular defects. As the field of aortic intervention has expanded and matured, new challenges related to mitral and tricuspid valve intervention, tricuspid valve treatment, pulmonary valve intervention, left atrial appendage occlusion (LAAO), atrial septal defect (ASD) closure, patent foramen ovale (PFO) closure, pulmonary embolism thrombectomy, percutaneous paravalvular leaks (PVL) closure, septal ablation for hypertrophic obstructive cardiomyopathy, ventricular septal defect (VSD) closure and transcatheter interventions in grown-up congenital heart (GUCH) disease. Therefore, a solid background on coronary interventions, peripheral artery disease and management of any procedural complications is needed [6].

Although rheumatic heart disease is becoming uncommon in industrialized countries, its global burden is still significant. There are complex patients who can benefit from a combined valvular intervention (aortic, mitral or tricuspid). Despite these are anatomical structures with overlapping functions and treatment principles, there are differences regarding diagnostic and therapeutic methods, namely percutaneous. Referral, diagnosis, stratification, training and intervention programs have a common root, and are then different depending on the valve to be treated. As such, the experience gained at TAVI provides an favorable ground for approaching other valves[6].

The mitral valve focus is currently a first-line concern because regurgitation is the second most common symptomatic valvular disease worldwide and its prevalence is expected to increase with population ageing. It's presence after myocardial infarction or in the setting of dilated cardiomyopathy is associated with an increased risk of heart failure and death. In the recent years we have witnessed the evolution of several transcatheter devices to correct mitral regurgitation in patients at high-risk for surgery, namely annuloplasty devices, edge to edge repair systems and TMVR. There are regional disparities in southern European countries and, strategically, a position paper from three European interventional was published analyzing the evidence-based approach of patient selection, expected results and timing for TMVI taking into account that patients usually present in an advanced stage of the disease in these countries[21]. The mitral valve-in-valve (ViV) and valve-in-ring (ViR) are special cases because they are relevant alternatives to surgical reoperation in patients with recurrent mitral valve failure after previous surgical valve repair or replacement. A consortium performed a large-scale analysis examining the mid-term outcomes after mitral ViV and ViR. The rates of device success were relatively low for both procedures (39.4% total; 32.0% ViR versus 41.3% ViV; P=0.01). Correlates for residual mitral stenosis were smaller true internal diameter, younger age, larger body mass index and the only correlate for residual mitral regurgitation was ViR. Both were associated with a need for repeat valve replacement, depicting the need to improve postprocedural hemodynamics in mitral ViV and ViR and supporting a contemporary conservative approach for the time being [29]. Since the uptake of this technology is slower in Portugal and Spain, we have addressed the first 68 patients that were treated for MR with the Pascal device to search for geographical gaps. At 30 days the results were encouraging, since the all-cause mortality rate was 1.6% and 98% of patients improved to NYHA functional class II [64].

Some valvular patients present a concomitant valvular disease that impacts both the aortic and mitral space. The possibility of offering the patient uncommon therapeutic alternatives depends on the ability to find solutions that are variations on the standard techniques, using access routes that only multidisciplinary teams can plan and provide, such as the percutaneous axillary access for TAVI in cases with adverse prohibitive transfemoral anatomies and no surgical options. In the TAXI registry a total of 432 patients were included, 189 (43.8%) receiving surgical access, and 243 (56.2%) undergoing percutaneous access. Despite primary hemostasis failure was more common in the percutaneous group the percutaneous access was associated with shorter hospital stay (-2.6 days [95% confidence interval: -5.0; -0.1], p=0.038) and a lower risk of major adverse events (a composite of death, myocardial infarction, stroke, type 3 bleeding, and major access-site related complication; odds ratio=0.44 [0.21; 0.95], p=0.036) [65]. Another option

that was explored and expanded was the transapical access to approach the mitral complex. An innovative valve-in-valve case was published describing a patient deemed inoperable due to frailty and prohibitive surgical risk. He presented a stenotic aortic 19-mm Mitroflow and a mitral 31-mm Carpentier-Edwards bioprostheses. The Heart Team decided on a compassionate double valve-in-valve procedure, with transfemoral implantation of a 23-mm aortic CoreValve Evolut R and transapical implantation of a 29-mm mitral Edwards Sapiens 3. During the procedure, after extreme difficulty in retrograde crossing of the aortic valve, a transapical-transfemoral loop was successfully performed. The procedure had no complications and the patient was discharged in NYHA class II with normally functioning valves [22].

Finally, although aortic and mitral valves are usually the focus of diagnostic and therapeutic concerns, tricuspid valve disease is not uncommon amongst these patients. It is very accessible via the transvenous route, with a lower risk of vascular access and a good potential for a percutaneous approach. An original case of a 70-year-old male with a history of rheumatic heart disease, permanent atrial fibrillation (AF) and hepatitis C (secondary to a blood transfusion in 1980) was reported. He initially underwent a double mitral and aortic bioprosthesis implantation in 1980, due to refractory HF. Due to severe regurgitation, both bioprosthesis were replaced in 1991, with a 27 mm- St. Jude mitral and 23 mm-aortic mechanical prosthesis, respectively, and a concomitant 28 mm ring - tricuspid valve annuloplasty was also performed because of tricuspid regurgitation. Furthermore, in 2007, both mitral and tricuspid dysfunctional prosthesis were replaced with a 27 mm- St. Jude and a 31 mm- tricuspid bioprosthesis, correspondingly. The Heart Team deemed the patient inoperable. A compassionate off-label transcatheter tricuspid valve-in-valve replacement was decided upon and later executed through the right femoral vein, with the insertion of an 29 mm- Edwards Sapiens XT through the inferior vena cava, towards the RV, followed by direct implantation in the tricuspid bioprosthesis (ViV), without complications, achieving a NYHA functional class II that persisted through the 1-year follow-up [18].

In conclusion, the Heart Team organization and technical skills learned in the TAVI field may prove useful to treat other valvular diseases, despite the extremely important and distinct specifics of each domain.

8. Interventional devices

- Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis. REC 2012 (Manuscript #1)
- In vitro evaluation of implantation depth in valve-in-valve using different transcatheter heart valves. EIJ 2016 (Manuscript #9)
- Transcatheter tricuspid valve-in-valve replacement: one-year results: Alternative to surgery in high-risk patients. HV 2017 (Manuscript #10)
- TAVI-SMALL Investigators. Transcatheter Self-Expandable Valve Implantation for Aortic Stenosis in Small Aortic Annuli: The TAVI-SMALL Registry. JACC Int 2020 (Manuscript #19)
- Transcatheter Mitral Valve Replacement After Surgical Repair or Replacement: Comprehensive Midterm Evaluation of Valve-in-Valve and Valve-in-Ring Implantation From the VIVID Registry. Circ 2021 (Manuscript #26)
- Transcatheter Aortic Valve Replacement With the LOTUS Edge System: Early European Experience. JACC 2021 (Manuscript #28)
- Next-generation balloon-expandable Myval transcatheter heart valve in low-risk aortic stenosis patients. CCI 2021 (Manuscript #29)
- Predictors and Clinical Impact of Prosthesis-Patient Mismatch After Self-Expandable TAVR in Small Annuli. JACC Int 2021. (Manuscript #33)
- Sequential transcatheter aortic valve implantation due to valve dislodgement - a Portico valve implanted over a CoreValve bioprosthesis. RPC 2017 (Manuscript #44)
- Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era: A challenge to organization of the heart team. RPC 2017 (Manuscript #45)
- Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure. RPC 2020 (Manuscript #50)
- Ten-year survival of patients undergoing coronary angioplasty with first-generation sirolimus-eluting stents and bare-metal stents. RPC 2020. (Manuscript #53)
- Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI. RPC 2020 (Manuscript #54)
- Non-pharmacological treatment of refractory angina: The coronary sinus reducer, the new kid on the block. RPC 2021 (Manuscript #57)

Historically, balloon aortic valvuloplasty (BAV) was first proposed in 1986 by Alain Cribier for AoS patients who were not suitable for surgical treatment, as a useful, low-risk, palliative treatment for symptomatic relief. Despite the promising initial results - reduction of maximum and mean aortic gradients and improvement in functional capacity- its popularity waned due to the high rate of complications, early restenosis and long-term survival, resembling the natural course of untreated severe AoS. As such, in the TAVI era, multidisciplinary programs must be structured in such a way to provide a prompt response to patients, avoiding BAV as a palliative procedure, given that some complications remain important despite the acquired experience [13].

The actual TAVI story started in February 1989, when Henning Andersen thought of inserting a biological valve inside a large stent and to implant this using a 41 Fr introducer sheath, testing it in pigs. In the mid-1990s Alain Cribier, confronted with the high BAV restenosis rate, presented a similar idea to several companies. The first cadaver experiment was performed in 1994. The

first clinical TAVI happened on 16 April 2002 and the subsequent feasibility study, in 36 compassionate patients, from 2002 until 2005, showed a 30 days mortality rate of 20%, a "success rate" of 75%, and frequent paravalvular leakages. An introducer sheath size of 22 and 24 Fr was used. The THVs had high caliber, rigidity, were not repositionable or recapturable, and had no anti-reflux skirts. Since then, the technical solutions and training to carry out TAVI safely have made enormous progress. Several device iterations emerged progressively and slowly mitigated these limitations, specially the reduced delivery sheaths, currently ranging from 14 to 18 Fr, that impacted the vascular and bleeding complications [66,67].

In the initial generations of THV, device migration and embolization were also important events, especially in self-expanding valves, with a prevalence of valve dislocation of 3.2-3.9% that was reported in several series and in our center [12,15]. A VIV TAVI using a Portico that presented such innovative features was selected and reported in an embolized first generation CoreValve. This one was immobilized with a snare loop and a Portico valve was implanted with a good result a one year [12].

Paravalvular regurgitation (PVL) is one of the pioneering concerns of TAVI, as there is evidence of an impact on mortality and rehospitalization. Several solutions were launched either with a sealing skirt or increased radial force. The Lotus aortic valve system was designed as a mechanically expanding THV with an intra-annular design and both mechanisms, that were offset by a higher rate of new permanent pacemaker (PPM) implantation. The early experience with the valve was studied and, despite a short-term safety and efficacy, and very low rates of PVL the new PPM implantation was required in 30.8% among PPM-naive patients[31]. This preliminary result was later confirmed in other series and the device was removed from the market by the company, depicting the importance of collaborative investigation to detect hurdles in this competitive environment. Another THV, an alternative balloon expandable device, the MyVal was studied in a multicentric retrospective registry. The rate of moderate aortic regurgitation was 4%, with no cases of severe PVL. However, despite a good hemodynamic performance, 11 patients presented some degree of prosthesis-patient mismatch (range: 0.83–0.70 cm^2/m^2) and the highest residual mean gradient was 16.5 mmHg. In individuals presenting a small annulus size < 420 mm (40%), there was a 5% rate of moderate mismatch with no cases of severe PPM [61].

The issue of annulus size, prosthetic or native, has emerged in this context and is a pertinent example. In fact, there is a relationship of the smallest dimensions with the patient-prosthesis

disproportion. An international multicenter investigation was performed in 859 patients with annular perimeter <72 mm or area <400 mm^2 by MSCT, noting that pre-discharge gradients were slightly smaller in Corevalve Evolut R (8.1 mmHg, 95%CI 7.7 to 8.5 mmHg) and Evolut PRO (6.9 mmHg, 95% CI: 6.3 to 7.6 mmHg) compared to Symetis Acurate (9.6 mmHg, 95% CI: 8.9 at 10.2 mmHg) and Portico (8.9 mm Hg; 95% CI: 8.2 to 9.6 mmHg) groups (p<0.001)[57]. In the sub-study of self-expanding devices, encompassing 445 patients, severe PPM was independently associated with all-cause mortality. Post-dilation and valve oversizing protected against PPM occurrence and, conversely, the use of intra-annular valves yielded higher risk [58].

TAVI new-generation devices are paralleled by other relevant innovations in the field of embolic protection, closure devices and technical refinements that impact outcomes. Device implantation depth depends on delivery accuracy. It has been shown in vitro that the high position of the device is important for optimizing hemodynamics and reducing PPM in aortic ViV procedures. Twenty-eight implants were simulated with 3 different devices in vitro, in which a relationship was established between implantation depth and mean valve gradients (Corevalve Evolut: p <0.001; Edwards Sapiens XT: p = 0.01; Portico: p = 0.002) , as well as with effective orifice area -EOA (Corevalve Evolut: p <0.001; Edwards Sapiens XT: p = 0.02; Frame: p = 0.003) [39].

Globally, TAVI presents itself as a successful model, with extraordinary results, namely in the context of the national RNCI VaP, where, based on the VARC-2 criteria, the immediate implant success was rather high (90.1%). The combined safety endpoint occurred in 85.0% of patients. The median clinical follow-up duration was 259 days (IQR 96) with an overall 30-day mortality of 4.8%, decreasing progressively from 14,1% in 2011 to 3,8% in 2018 [37].

The operator's imagination and adaptability are valuable in the context of SHD. The failures of bioprostheses in aortic, mitral and tricuspid positions could be treated using valves originally developed for the aortic space. Although it is not always possible to have perfect solutions, in most cases an effective treatment can achieved with acceptable security, often not accessible by any other method [30,68].
The evaluation of devices in these extraordinary contexts, particularly at long-term, is important to build, in many cases, an approval by the scientific community and by regulatory authorities for new indications that were initially considered off-label [18,22,27,29].

9. Training and Certification

- In vitro evaluation of implantation depth in valve-in-valve using different transcatheter heart valves. EIJ 2016 (Manuscript #9)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- ESC Core Curriculum for the Cardiologist. EHJ 2020 (Manuscript #25)
- Trailing behind: limitations on transcatheter aortic valve implantation in Portugal. RPC 2013 (Manuscript #37)
- Position statement on transcatheter aortic valve implantation in Portugal. RPC 2013 (Manuscript #38)
- Sequential transcatheter aortic valve implantation due to valve dislodgement - a Portico valve implanted over a CoreValve bioprosthesis. RPC 2017 (Manuscript #44)

The clinical specialty of cardiology delivers expert care for patients presenting with heart and circulatory diseases. The ESC *Core Curriculum* for the Cardiologist outlines the clinical competencies required to practice, based on ESC clinical practice guidelines. And provides a framework for training, certification, continuous medical education and recertification. Although the *curriculum* by necessity includes sufficient knowledge of the sub-specialties to ensure that patients are referred appropriately for more advanced investigations and therapies, the expertise for cardiovascular interventions is covered by EAPCI *Core Curriculum* in Percutaneous Cardiovascular Interventions Cardiology [6,7]. The Training and Certification Committee of the EAPCI is currently working on the EAPCI Percutaneous Structural Heart Disease Core Curriculum that will address the specificities of the TAVI field.

The first TAVI procedures were performed using the anterograde and transseptal technique, due to the high caliber of the devices. Initial results were encouraging but showed a relatively high mortality, that discouraged widespread adoption of the technique. Technological evolution has made available THV with a lower profile, enabling its navigation through the arterial territory and the retrograde approach, reducing the complexity of procedures and allowing its expansion to most hemodynamic laboratories by structured proctoring programs [67].

In an effort to reduce the impact of this learning process, numerous educational methods focused on TAVI skills and procedures are offered to medical centers desiring a TAVI program. These teaching methods include dry laboratory sessions, training devices, animal models, and simulation. Albeit necessary and informative at early stages, an higher level of procedural and technical skills are needed for clinical practice, and thus, in an innovative way, models of medical proctoring aim to reduce the usual learning curves and spare complications.

The issue of vascular access and associated hemorrhagic complications constituted the first challenge of pioneer operators, requiring learning of peripheral vascular intervention techniques that were not mastered by most intervention cardiologists [68].

In the first generation of marketed THV, device migration and embolization were also main concerns. The causes included mismatch of the annulus and valve size, arrhythmias- which hinder stabilization of the valve during deployment - and accidents. The adoption of technical proctoring to independently assess MSCT scans and the use of more favorable projections to LVOT elongation played a relevant role in its control, which culminated in the appearance of THV with novel capabilities: the ability to be repositioned, recaptured, and redeployed [12].

Regardless of the operator's experience, throughout his career, there is a need for continuous education and access to training and simulation conditions that are deemed to improve the techniques used, as well as test the use of devices in challenging clinical scenarios and/or in anatomical models. For example, the treatment of degenerated bioprostheses, where 3D printed models are sometimes used to select the device and its implantation method [39].

Regulatory aspects and organizational requirements are critical to define the profile and performance of the center and, as such, the extent and quality of training in SHD. Any institution should be compliant with the recommendations of their national regulatory bodies, first. The APIC issued in 2013 the first position statement on transcatheter aortic valve implantation recommending that TAVI should only be performed in carefully selected patients in centers with a minimum annual volume of 50 procedures, in order to keep additional costs at an acceptable level and to maintain proficiency. The use of TAVI should be rigorously monitored, preferably through a national multicenter registry using the current VARC criteria to ensure quality and transparency [69].

Standardized guidelines for safe initiation of a TAVI program and clear methods to negotiate this learning curve have been generically reported by the EAPCI *Core Curriculum* in Percutaneous Cardiovascular Interventions Cardiology. This document determines the level of competence translating into interventional cardiology skills that are desirable for a trainee in interventional cardiology to achieve at the end of his/her [6]. SHD teachers and proctors should be recognized IC specialists, trained, and certified in the field, actively involved in the clinical and research activities of the local Heart Team. It is recommended to organize a formal environment that includes a supervisor, a mentor, a procedural Heart Team leader and multiple clinical

trainers. Early involvement of SHD trainee in scientific activity promotes education and training in the latest SHD achievements and highlights needs to address on a local level. Finally, the institutions must be standardized using reports of procedural characteristics, volume, and performance measures [6].

10. Pharmacological therapies

- Successful Clinical and Therapeutic Approach for Valve-in-valve Leaflet Thrombosis. REC 2018.(Manuscript #14)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- O meu doente não pode, não quer ou não cumpre a anticoagulação oral. Cruzo os dedos ou cruzo o septo? RPC 2020 (Manuscript #55)

Aortic stenosis is associated with a dismal prognosis and aortic valve intervention is the only treatment shown to improve survival. So far, no specific medical therapy could halt aortic stenosis progression, reduce its hemodynamic repercussions on left ventricular function or remodeling, and improve clinical outcomes.

Atrial fibrillation (AF) is a prevalent disease that affects up to 3% of the population and accounts for 1-3% of health care costs due to stroke, sudden death, heart failure, unplanned hospitalizations and other complications. A significant proportion of TAVI patients present AF and important efforts are made to reduce the rate of thrombotic complications because valve thrombosis and cerebral ischemic events post-TAVI are dreadful and remain significant, around 5% at 30 days. The antithrombotic treatments to prevent stroke carry a risk of life-threatening bleedings that reach a 10% rate, which in itself is associated with a 4 to 5 fold increase in adverse clinical outcomes [6,70]. An 87-year-old woman case was reported. She presented rheumatic valve disease and had undergone aortic, mitral and tricuspid biological prosthetic valve implantation in 2010. In 2016 a transapical mitral valve-in-valve procedure was performed with a 26 mm-Edwards Sapiens because of prosthesis degeneration with predominant intra-prosthetic regurgitation. She was in sinus rhythm and long-term clopidogrel antithrombotic regimen was recommended. She developed a prosthetic thrombosis that was successfully treated with a conservative strategy with unfractionated intravenous heparin and clopidogrel [24].
New insights regarding the drivers of TAVI-associated thrombosis, coupled with the ongoing development of novel antithrombotic, hold the potential to deliver newer, safer therapies to prevent post-TAVI thrombotic and bleeding complications. Possible solutions, in selected patients, are the use of embolic filters that protect cerebral circulation and left atrial appendage occlusion (LAAO), to block the anatomical origin of around 90% of the thrombi that cause stroke. Still, there is controversy around these therapies. The risk scores, CHA2DS2- VASc and HAS-BLED, which are recommended in the guidelines, even in the best circumstances, are not

particularly robust for predicting individual stroke and bleeding risk. And the use of LAAO lacks validation in randomized trials. Despite safe and effective compared to direct oral anti-coagulants (OAC) therapy in the medium term, LAAO is mainly supported by the pressing need for therapeutic alternatives to chronic OAC [71].

11. Outcomes

- Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis. REC 2012 (Manuscript #1)
- Implante Percutaneo de Válvula Aórtica: Seguridad y Eficácia del Tratamiento del Homoenxierto Aortico Disfuncionante. REC 2012 (Manuscript #2)
- The Ibero-American transcatheter aortic valve implantation registry with the CoreValve prosthesis. Early and long-term results. IJC 2013 (Manuscript #3)
- Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA 2014 (Manuscript #5)
- Neurologic complications after transradial or transfemoral approach for diagnostic and interventional cardiac catheterization: A propensity score analysis of 16,710 cases from a single centre prospective registry. CCI 2015 (Manuscript #6)
- Impact of complete revascularization in patients with ST-elevation myocardial infarction: analysis of a 10-year all-comers prospective registry. CAD 2016 (Manuscript #8)
- Transcatheter tricuspid valve-in-valve replacement: one-year results: Alternative to surgery in high-risk patients. HV 2017 (Manuscript #10)
- Portugal: coronary and structural heart interventions from 2010 to 2015. EIJ. 2017 (Manuscript #12)
- VIVID Registry. Mid-Term Valve-Related Outcomes After Transcatheter Tricuspid Valve-in-Valve or Valve-in-Ring Replacement. JACC 2019 (Manuscript #15)
- Impact of Transcatheter Aortic Valve Implantation on Kidney Function. ABC 2019 (Manuscript #17)
- EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions (2020): Committee for Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI). EIJ 2020 (Manuscript #22)
- Long-term outcomes after transcatheter aortic valve implantation in failed bioprosthetic valves.
- Transcatheter Mitral Valve Replacement After Surgical Repair or Replacement: Comprehensive Midterm Evaluation of Valve-in-Valve and Valve-in-Ring Implantation From the VIVID Registry. Circ 2021 (Manuscript #26)
- Impact of COVID-19 Pandemic on Mechanical Reperfusion for Patients With STEMI. JACC 2020 (Manuscript #27)
- Predictors of pacemaker implantation after TAVI in a registry including self, balloon and mechanical expandable valve. IJCVS 2021 (Manuscript #30)
- Surgical versus transcatheter aortic valve replacement in low-risk patients: a long-term propensity score-matched analysis. CCI 2021 (Manuscript #31)
- Gender Differences and Mortality Trends After Transcatheter Aortic Valve Implantation: A 10-Year Analysis From a Single Tertiary Center. JIC 2021 (Manuscript #32)
- Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves: The TRANSIT International Project. CCI 2021 (Manuscript #34)
- Late results (>10 years) of intracoronary beta brachytherapy for diffuse in- stent restenosis. RPC 2014. (Manuscript #40)
- Aortic valve replacement for severe aortic stenosis in octogenarians: patient outcomes and comparison of operative risk scores. RPC 2015 (Manuscript #41)
- Trends in percutaneous coronary intervention from 2004 to 2013 according to the Portuguese National Registry of Interventional Cardiology. RPC 2015 (Manuscript #42)
- Sequential transcatheter aortic valve implantation due to valve dislodgement - a Portico valve implanted over a CoreValve bioprosthesis. RPC 2017 (Manuscript #44)
- Advantages of a prospective multidisciplinary approach in transcatheter aortic valve implantation: Eight years of experience. RPC 2017 (Manuscript #46)
- Post-procedural N-terminal pro-brain natriuretic peptide predicts one-year mortality after transcatheter aortic valve implantation. RPC 2018 (Manuscript #47)
- Fifteen years of coronary intravascular ultrasound in percutaneous coronary intervention in Portugal. RPC 2019 (Manuscript #49)
- "A momentary lapse of opinion": The reader should be aware of the iatrogenic potential of this publication. RPC 2020 (Manuscript #52)

- Ten-year survival of patients undergoing coronary angioplasty with first-generation sirolimus-eluting stents and bare-metal stents. RPC 2020. (Manuscript #53)
- Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI. RPC 2020 (Manuscript #54)

The ultimate goal of any treatment is measured by the objective assessment of the patient outcomes. In the field of interventional cardiology, longitudinal evaluation of innovative devices is extraordinarily important to define peer approval and promote adoption by the scientific community and regulatory bodies [6]. In addition to approved indications, there is an initial path of novel treatments that get reported and, when considered off-label, require proper authorization and clinical and institutional monitoring.

The Portuguese National Registry of Interventional Cardiology (RNCI) of the Associação Portuguesa de Intervenção Cardiovascular (APIC, www.apic.pt) has reported trends in Portuguese interventional cardiology since 2004. From 2007 until 2013 there was an increase of, respectively, 34% and 65%, in diagnosis and PCI [81]. Between 2010 and 2015, a total of 73.977 PCIs and 780 TAVI were performed, including a fourfold increase in the last, reaching 29 per million population by 2015 [8]. From January 2007 to December 2018, 2346 consecutive patients underwent TAVI, with a mean EuroScore II 4,3%, age of 81±7 years and 53% female [37].

The Hospital de Santa Cruz original multidisciplinary program was thoroughly described and documented. The Heart Team prospectively assessed 473 patients and was able to appropriately select 214 candidates for TAVI or SAVR, using an original standardized approach, taking into account the risk of both invasive treatments [43].

- Regarding complications treatment, where individual case reports and novel approaches are important to share expertise. That was the case of a patient presenting decompensated heart failure refractory to medical treatment 1 month after TAVI due to severe PVL, requiring a device explantation performed by cardiac surgery [15]. And other cases of embolized devices [12];
- Regarding the initial experience in special subsets, as previously described, namely the degenerated aortic homografts [16,25,28], the TAVI in failed bioprosthetic surgical valves [17] and the chronic kidney disease (CKD) [67];
- Regarding the use of off-label techniques that require exceptional institutional, ethical, and regulatory authorizations. Such was the case of a transcatheter tricuspid valve-in-valve replacement executed through the right femoral vein, with the insertion of an aortic approved device through the inferior vena cava, in the tricuspid bioprosthesis (ViV) [18] ;
- Regarding the systematic institutional analysis, crucial to detect hurdles in practice and facilitate procedural enhancement. The gender differences [63], the role of proBNP [38], the conduction disturbances management [62] or the octogenarians options comparing TAVI and SAVR [10] depicted this goal;

- Regarding the long-term and very-long-term follow-up. A prospective longitudinal analysis demonstrated that gender differences only appeared after one-year, at a median follow-up of 23 months (IQ, 21 months), where females presented a better overall survival rates (70.3% vs 60.5% in men; p=0.01; log-rank p < 0.01) [63]. Moreover, some independent prognostic indicators are only evident at long-term follow-up, which in the TAVI area is certainly from 3 years beyond, namely in the importance of the size of the original failed valve at 5 years mortality, and the type of the transcatheter valve at reintervention after aortic ViV [25]. Or in the similar major results at 4,5 years in low-risk patients treated by either TAVI or SAVR [44];
- Regarding rare cases or urgent societal needs where special assets are needed. Large collaborative consortiums and/or permanent longitudinal databases, can provide a realistic data source of clinical practice. The results of the mitral valve-in-valve (ViV) and valve-in-ring (ViR) techniques [29], the degenerated TAVI treated by means of a second TAVI [19], the 10 years data in the ACROSS (Angiography and Coronary revascularization Registry of Santa Cruz Hospital DAP) database, the 15 years of ultrasound in PCI at RNCI are examples of exceptional information that helps to monitor long-term impact of ongoing clinical practice [26,27,53,73,74].
- Finally, as a complement of scientific evidence, raising awareness is another mainstay of improving patient outcomes. During the COVID-19 pandemic, patient access to the health system was a major concern and a collaborative publication on the treatment of patients with STEMI alerted to a 19% reduction in primary PCI procedures and a longer delay to treatment [75].

In summary, the TAVI environment shows the extensive, continuous, and evidence-driven development of a short and long-term assessment of patient outcomes that derives from and in many areas.

PUBLICATIONS (ABSTRACTS)

7. Publications (abstracts)

Manuscript#1

Hindawi Publishing Corporation
Case Reports in Cardiology
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Case Report

Surgical Bailout Therapy after Implantation of a Medtronic CoreValve Bioprosthesis

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Moderate-to-severe paraprosthesic leak causing hemodynamic deterioration and left ventricular remodeling can occur after transcatheter aortic valve implantation (TAVI). We present the case of a 75-year-old woman who underwent TAVI with a 26 mm CoreValve prosthesis complicated with an acute left ventricle dilatation due to a severe paravalvular leak. Patient was unresponsive to elective balloon post-dilatation, and therefore she was successfully treated with open-heart surgery to remove the malfunctioning CoreValve bioprosthesis and perform standard aortic valve replacement.

1. Introduction

Moderate-to-severe paraprosthesic leak causing hemodynamic deterioration and left ventricular remodeling can occur after transcatheter aortic valve implantation (TAVI) [1]. There are several percutaneous techniques already described to manage early implant failure [2]. Nevertheless, the surgical bailout therapy has not been described after TAVI using the Medtronic Core Valve bioprosthesis (Medtronic, Minneapolis, MN).

2. Case Report

A 75-year-old female with worsening exertional dyspnea and angina for the previous 10 months was referred for cardiology evaluation. She had several cardiovascular risk factors (hypertension, diabetes, hiperlipidaemia and a morbid obesity with a BMI of 40), chronic lung disease, and renal chronic insufficiency with a calculated creatinine clearance of 38 mL/min. On the transthoracic echocardiogram, a severe stenosis aortic was diagnosed with an aortic orifice area of 0,7 cm^2 and a systolic left ventricle dysfunction with an ejection fraction of 38%. Coronary angiography showed coronary arteries without lesions and good femoral accesses. The intraoperative transesophageal echocardiogram confirmed a heavy calcified aortic valve with an annulus of 21 mm. The transfemoral implantation of the 26 mm CoreValve prosthesis was complicated with acute moderate aortic leak (Figure 1) and moderate mitral regurgitation associated to a deep prosthesis implantation. Repositioning the prosthesis with a snair was performed to reduce the severity of mitral regurgitation with slight improvement (Figure 2). The postoperative course was uneventful, and the patient was discharged eight days later.

One month later the patient developed a progressive dyspnea and was readmitted with acute pulmonary edema. Transthoracic echocardiography evidenced a moderate-to-severe aortic paraprostesic leak (which occupies a quarter of the sewing ring, with a steep jet deceleration slope of 6,3 m/s^2 and a holodiastolic flow reversal in the descending thoracic aorta) [3] associated with a severe left ventricle dilatation and dysfunction (left ventricle diastolic dimensions in paraesternal long axis increased from 53 to 70 mm by M-mode tracing preprocedure and postprocedure, respectively). She performed angiotomography which suggests an adequate position prosthesis although underexpansion (Figure 3). For that reason a postdilatation with a Nucleus NuMED balloon

Manuscript #2

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Artículo original

Implante percutáneo de válvula aórtica: seguridad y eficacia del tratamiento del homoinjerto aórtico disfuncionante

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Estenosis valvular aórtica
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Homoinjerto aórtico

RESUMEN

Introducción y objetivos: El implante percutáneo de válvula aórtica, como tratamiento de la estenosis aórtica severa con elevado riesgo quirúrgico, está actualmente bien establecido. Pretendemos comunicar la experiencia en términos de seguridad y eficacia del implante percutáneo de válvula aórtica, sobre una serie de homoinjertos aórticos disfuncionantes.
Métodos: Presentamos la experiencia inicial acumulada en cuatro centros, sobre 5 pacientes portadores de un homoinjerto aórtico degenerado, todos con insuficiencia aórtica severa y rechazados para cirugía por un equipo multidisciplinario, sometidos a implante de una prótesis aórtica CoreValve®.
Resultados: Se incluyó a 3 varones y 2 mujeres, con una media de edad de 70 ± 3,5 años, severamente sintomáticos en clase funcional III o IV de la *New York Heart Association.* El procedimiento se llevó a cabo por vía femoral en todos los casos, y mediante sedación en 4 pacientes. El implante se realizó con éxito en todos los casos. Ningún paciente presentó complicaciones mayores durante el procedimiento o el ingreso, y en todos ellos se resolvió la deficiencia valvular. No hubo mortalidad hospitalaria ni durante el seguimiento. Todos los pacientes presentaron mejoría clínica en el seguimiento, con una disminución de al menos 2 grados en la escala de la *New York Heart Association.*
Conclusiones: En nuestra experiencia, el tratamiento de homoinjerto disfuncionante e insuficiencia aórtica se ha demostrado seguro y eficaz. El reto actual es trasladar los buenos resultados del implante percutáneo de válvula aórtica en la estenosis aórtica severa degenerativa del anciano a pacientes con alto riesgo quirúrgico y otras afecciones de la aorta. Es posible que en el futuro el implante percutáneo de válvula aórtica abarque cada vez mayor número de enfermedades aórticas y pacientes de menor riesgo quirúrgico.

Transcatheter Aortic Valve Implantation: Safety and Effectiveness of the Treatment of Degenerated Aortic Homograft

Keywords:
Aortic valve stenosis
Valvular prosthesis
Aortic homograft

ABSTRACT

Introduction and objectives: Percutaneous aortic valve implantation for patients with severe symptomatic aortic stenosis and a high surgical risk is currently well established. We report our experience in terms of safety and effectiveness of transcatheter aortic valve implantation in other clinical context like the degenerated aortic homografts.
Methods: We report our initial experience in four hospitals and five patients with degenerated aortic homograft and severe aortic regurgitation, refused for surgery for a heart team, that underwent percutaneous implantation of CoreValve® aortic prosthesis.
Results: We included three males and two females. The mean age was 70 (3.5) years. All patients were symptomatic in New York Heart Association class III or IV. Procedures were performed through one of the femoral arteries in all patients and under sedation in three patients. The implant was successfully carried out in all cases. There were no major complications during the procedure or admission and the valvular defect was solved in all cases. In-hospital and 30-days mortality was 0. All patients had clinical improvement during follow-up with a reduction in at less two grades in the New York Heart Association functional scale.
Conclusions: In our experience the treatment of degenerated aortic homografts and aortic insufficiency with transcatheter aortic valve implantation showed to be safe and effective. The current challenge is to

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Manuscript #3

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The Ibero-American transcatheter aortic valve implantation registry with the CoreValve prosthesis. Early and long-term results

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is the recommended therapy for patients with severe aortic stenosis who are not suitable candidates for surgery. The aim of this study was to describe early experience and long-term follow-up with the CoreValve self-expanding aortic prosthesis at 42 Ibero-American hospitals.
Methods: Multiple centre observational study including 1220 consecutive patients with symptomatic severe aortic stenosis who are not suitable candidates for surgery and underwent transcatheter aortic valve implantation with the self-expanding Medtronic CoreValve System between December 2007 and May 2012.
Results: The registry included 1220 consecutive patients with a mean age of 80.8 ± 6.3 years and a mean logistic euroSCORE of 17.8% ± 13%. The procedural success rate was 96.1%. Hospital mortality was 7.3% and combined end-point was 21.3%. Aortic regurgitation after TAVI was present in 24.5% (Sellers grade ≥ 2). The estimated 1-year and 2-year survival rates were 82.1% and 73.4% respectively. The following issues were significant independent risk factors for hospital mortality: acute kidney failure (odds ratio 3.55); stroke (odds ratio 5.72); major bleeding (odds ratio 2.64) and euroSCORE (odds ratio 1.02). Long-term predictors of mortality were diabetes mellitus (hazard ratio 1.59, 95% confidence interval 1.09–2.31), severe chronic obstructive pulmonary disease (hazard ratio 1.85, 95% confidence interval 1.85–2.88), and functional classes NYHA III–IV (hazard ratio 1.31, 95% confidence interval 1.01–1.70).
Conclusions: Transcatheter aortic valve implantation constitutes a safe and viable therapeutic option for high operative risk patients with severe aortic stenosis. Long-term prognosis is conditioned by associate comorbidities.

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[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Heart Valve Disease

Transcatheter Aortic Valve Replacement in Europe

Adoption Trends and Factors Influencing Device Utilization

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Montreal, Canada; Galway, Ireland; Rotterdam, the Netherlands; Bern and Basel, Switzerland; Massy, France; Milan, Italy; London and Belfast, United Kingdom; Copenhagen, Denmark; Wilrijk, Belgium; Lisbon, Portugal; Madrid, Spain; and Munich, Germany

Objectives The authors sought to examine the adoption of transcatheter aortic valve replacement (TAVR) in Western Europe and investigate factors that may influence the heterogeneous use of this therapy.

Background Since its commercialization in 2007, the number of TAVR procedures has grown exponentially.

Methods The adoption of TAVR was investigated in 11 European countries: Germany, France, Italy, United Kingdom, Spain, the Netherlands, Switzerland, Belgium, Portugal, Denmark, and Ireland. Data were collected from 2 sources: 1) lead physicians submitted nation-specific registry data; and 2) an implantation-based TAVR market tracker. Economic indexes such as healthcare expenditure per capita, sources of healthcare funding, and reimbursement strategies were correlated to TAVR use. Furthermore, we assessed the extent to which TAVR has penetrated its potential patient population.

Results Between 2007 and 2011, 34,317 patients underwent TAVR. Considerable variation in TAVR use existed across nations. In 2011, the number of TAVR implants per million individuals ranged from 6.1 in Portugal to 88.7 in Germany (33 ± 25). The annual number of TAVR implants performed per center across nations also varied widely (range 10 to 89). The weighted average TAVR penetration rate was low: 17.9%. Significant correlation was found between TAVR use and healthcare spending per capita ($r = 0.80$; $p = 0.005$). TAVR-specific reimbursement systems were associated with higher TAVR use than restricted systems (698 ± 232 vs. 213 ± 112 implants/million individuals ≥75 years; $p = 0.002$).

Conclusions The authors' findings indicate that TAVR is underutilized in high and prohibitive surgical risk patients with severe aortic stenosis. National economic indexes and reimbursement strategies are closely linked with TAVR use and help explain the inequitable adoption of this therapy. (J Am Coll Cardiol 2013;62:210–9) © 2013 by the American College of Cardiology Foundation

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Manuscript #5

Research

Original Investigation

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

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IMPORTANCE Owing to a considerable shift toward bioprosthesis implantation rather than mechanical valves, it is expected that patients will increasingly present with degenerated bioprostheses in the next few years. Transcatheter aortic valve-in-valve implantation is a less invasive approach for patients with structural valve deterioration; however, a comprehensive evaluation of survival after the procedure has not yet been performed.

OBJECTIVE To determine the survival of patients after transcatheter valve-in-valve implantation inside failed surgical bioprosthetic valves.

DESIGN, SETTING, AND PARTICIPANTS Correlates for survival were evaluated using a multinational valve-in-valve registry that included 459 patients with degenerated bioprosthetic valves undergoing valve-in-valve implantation between 2007 and May 2013 in 55 centers (mean age, 77.6 [SD, 9.8] years; 56% men; median Society of Thoracic Surgeons mortality prediction score, 9.8% [interquartile range, 7.7%-16%]). Surgical valves were classified as small (≤21 mm; 29.7%), intermediate (>21 and <25 mm; 39.3%), and large (≥25 mm; 31%). Implanted devices included both balloon- and self-expandable valves.

MAIN OUTCOMES AND MEASURES Survival, stroke, and New York Heart Association functional class.

RESULTS Modes of bioprosthesis failure were stenosis (n = 181 [39.4%]), regurgitation (n = 139 [30.3%]), and combined (n = 139 [30.3%]). The stenosis group had a higher percentage of small valves (37% vs 20.9% and 26.6% in the regurgitation and combined groups, respectively; *P* = .005). Within 1 month following valve-in-valve implantation, 35 (7.6%) patients died, 8 (1.7%) had major stroke, and 313 (92.6%) of surviving patients had good functional status (New York Heart Association class I/II). The overall 1-year Kaplan-Meier survival rate was 83.2% (95% CI, 80.8%-84.7%; 62 death events; 228 survivors). Patients in the stenosis group had worse 1-year survival (76.6%; 95% CI, 68.9%-83.1%; 34 deaths; 86 survivors) in comparison with the regurgitation group (91.2%; 95% CI, 85.7%-96.7%; 10 deaths; 76 survivors) and the combined group (83.9%; 95% CI, 76.8%-91%; 18 deaths; 66 survivors) (*P* = .01). Similarly, patients with small valves had worse 1-year survival (74.8% [95% CI, 66.2%-83.4%]; 27 deaths; 57 survivors) vs with intermediate-sized valves (81.8%; 95% CI, 75.3%-88.3%; 26 deaths; 92 survivors) and with large valves (93.3%; 95% CI, 85.7%-96.7%; 7 deaths; 73 survivors) (*P* = .001). Factors associated with mortality within 1 year included having small surgical bioprosthesis (≤21 mm; hazard ratio, 2.04; 95% CI, 1.14-3.67; *P* = .02) and baseline stenosis (vs regurgitation; hazard ratio, 3.07; 95% CI, 1.33-7.08; *P* = .008).

CONCLUSIONS AND RELEVANCE In this registry of patients who underwent transcatheter valve-in-valve implantation for degenerated bioprosthetic aortic valves, overall 1-year survival was 83.2%. Survival was lower among patients with small bioprostheses and those with predominant surgical valve stenosis.

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Author Video Interview at jama.com

Supplemental content at jama.com

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Group Information: The Valve-in-Valve International Data Registry Investigators are listed in eTable 1 in the Supplement.

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Manuscript #6

Catheterization and Cardiovascular Interventions 00:00–00 (2015)

Original Studies

Neurologic Complications after Transradial or Transfemoral Approach for Diagnostic and Interventional Cardiac Catheterization: A Propensity Score Analysis of 16,710 Cases From a Single Centre Prospective Registry

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Background and aim: Transradial approach (TRA) is being used increasingly as the preferential vascular access site for both diagnostic and interventional procedures. However, concerns have risen about the risk of clinically meaningful neurologic complications. We aimed to assess the association between the risk of stroke/transient ischemic attack (TIA) and the transradial (vs. transfemoral) approach. Methods and Results: Data from 16,710 cases included in a single centre prospective registry between January 2006 and November 2012 was analyzed. Radial procedures were considered as those in which the radial access was used either primarily ($n = 4,195$) or after conversion ($n = 36$). Potential cases with neurologic events were targeted by cross-referencing patients who underwent both cardiac catheterization and cranial-computed tomography (cranial-CT) during the same admission episode ($n = 67$). Procedure-related events were defined as a definitive non-CABG related stroke/TIA occurring within 48 hr of the procedure. TRA increased from 0.7% in 2006 to 75% in 2012. Total incidence of stroke/TIA was 0.16% and did not change over the study period ($P = 0.26$). There was no significant difference in stroke/TIA rates between groups (0.165% vs. 0.160%; $P = 1.0$). After correction for baseline differences and propensity score matching, TRA was not an independent predictor of stroke/TIA (OR 1.21; 95% CI 0.49–2.98 and 1.3; 95% CI 0.55–3.54, respectively). Results were consistent in pre-specified sub-groups according to age (≥65 y.o. vs. younger), gender, interventional vs. diagnostic and ACS vs. stable. Conclusion: Rates of documented stroke/TIA were low. Our observational study suggests that widening the use of the TRA is not associated with an increased risk of clinically relevant procedure-related neurologic complications.

Key words: percutaneous coronary intervention; coronary angiography; transradial; stroke

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Conflict of interest: Nothing to report.

L.R. and S.M. contributed equally to this work.

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Manuscript #7

Original Article

Predictors of Conversion from Radial Into Femoral Access in Cardiac Catheterization

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Abstract

Background: **Fewer bleeding complications and early ambulation make radial access a privileged route for cardiac catheterization. However, transradial (TR) approach is not always successful, requiring its conversion into femoral access.**

Objectives: **To evaluate the rate of conversion from radial into femoral access in cardiac catheterization and to identify its predictors.**

Methods: **Prospective dual-center registry, including 7632 consecutive patients undergoing catheterization via the radial access between Jan/2009 and Oct/2012. We evaluated the incidence of conversion into femoral access and its predictors by logistic regression analysis.**

Results: **The patients' mean age was 66 ± 11 years, and 32% were women. A total of 2969 procedures (38.4%) were percutaneous coronary interventions (PCI), and the most used first intention arterial access was the right radial artery (97.6%). Radial access failure rate was 5.8%. Independent predictors of conversion from radial into femoral access were the use of short introducer sheaths (OR 3.047, CI: 2.380-3.902; p < 0.001), PCI (OR 1.729, CI: 1.375-2.173; p < 0.001), female sex (OR 1.569, CI: 1.234-1.996; p < 0.001), multivessel disease (OR 1.457, CI: 1.167-1.819; p = 0.001), body surface area (BSA) ≤ 1.938 (OR 1.448, CI: 1.120-1.871; p = 0.005) and age > 66 years (OR 1.354, CI: 1.088-1.684; p = 0.007).**

Conclusion: **Transradial approach for cardiac catheterization has a high success rate and the need for its conversion into femoral access in this cohort was low. Female sex, older age, smaller BSA, the use of short introducer sheaths, multivessel disease and PCI were independent predictors of conversion into femoral access. (Arq Bras Cardiol. 2015; 104(5):401-408)**

Keywords: **Radial Access; Femoral Access; Cardiac Catheterization.**

Background

For the last decades, transfemoral approach in cardiac catheterization has been the preferred access for invasive cardiac procedures. However, recent evidence favors transradial approach in several observational and randomized trials. It has been shown that radial artery access decreases vascular complications with fewer access site bleeding complications, early patient ambulation, shorter length of hospital stay and lower hospital costs[1-8]. Recently, the large RIFLE study, on patients with ST elevation myocardial infarction (STEMI), has reported a statistically significant benefit from radial approach on cardiac mortality[9]. Despite its proven clinical benefit, many interventional cardiologists perceive that the decrease in vascular complications is balanced by technical difficulties and a longer learning curve, which might explain why the transradial approach is still underemployed[5,10]. On the other hand, when radial access fails, the most common alternative route is the femoral one[11,12].

In this study, we aimed to evaluate the rate of conversion from radial into femoral access in cardiac catheterization and to identify its clinical, demographic and procedural predictors.

Methods

Study design and patient population

In a prospective registry of 14750 consecutive patients from two centres, who underwent cardiac catheterization for diagnostic or interventional coronary procedures, between January 2009 and October 2012, we selected for the purpose of this analysis all consecutive patients in whom the first intention was to use the radial artery (n = 7664). Of these patients, we excluded those in whom the radial access failed, and the alternative choice was the contralateral radial (n = 26), the humeral (n = 4) and the cubital artery (n = 2) (Figure 1).

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Manuscript #8

122 Original research

Impact of complete revascularization in patients with ST-elevation myocardial infarction: analysis of a 10-year all-comers prospective registry

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Background **The benefit of complete revascularization (CR) during a primary percutaneous coronary intervention (PCI) in patients with multivessel disease (MVD) is still not clear. The aim of the present study was to evaluate the impact of CR in a nonselected population from an all-comers prospective registry of patients with ST-elevation myocardial infarction (STEMI) over a long period of time.**

Methods and results **Between 2004 and 2014, 671 noncardiogenic shock STEMI patients with MVD were included in the present study, of whom 522 were subjected to incomplete revascularization and 149 were subjected to CR. Patients in the CR group were younger [61 (SD 12) vs. 64 (SD 12.4) years old, $P = 0.001$], more often subjected to femoral access (79.4 vs. 67.1%, $P = 0.002$), and had a lower number of segments with lesion [2 (2.2) vs. 3 (3.4), $P = 0.001$]. The CR group tended to have a lower 1-year major adverse cardiac event (MACE) rate (17.8 vs. 25.7%; $P = 0.05$) that reached statistical significance at 2 years (19.4 vs. 28.5%, $P = 0.03$). The rates of the individual endpoints were not different between groups. Independent predictors of 2-year MACE were age, femoral access, and previous PCI. Index CR was associated with lower MACE (hazard ratio 0.5, 0.36–0.79). MACE-free survival was higher in the CR group throughout the 2 years of follow-up.**

Conclusion **In patients with STEMI and MVD undergoing culprit lesion PCI, preventive PCI in noninfarct coronary arteries with significant stenosis was associated with a lower risk of MACE compared with incomplete revascularization in this all-comers prospective registry.** *Coron Artery Dis* **27:122–127**

Coronary Artery Disease 2016, **27**:122–127

Keywords: complete index revascularization, multivessel disease, ST-elevation myocardial infarction

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Introduction

ST-segment elevation myocardial infarction (STEMI) remains a major cause of morbidity and mortality worldwide, and according to contemporary guidelines, timely reperfusion of the culprit lesion with a percutaneous coronary intervention (PCI) is considered the treatment of choice [1,2].

At angiography, 40–65% of STEMI patients have multivessel disease (MVD), which is associated with a poorer prognosis [3–7]. The best revascularization strategy, especially in terms of PCI of nonculprit arteries, is still not clear [7–11]. Until recently, except for patients in cardiac shock, PCI of nonculprit lesions during primary PCI was not recommended, but guidelines are mainly based on nonrandomized studies, susceptible to important biases [1,2,5, 12–14]. Recently, three randomized studies, Complete versus Lesion only Primary-PCI Trial (CvLPRIT), preventive angioplasty in myocardial infarction (PRAMI), and DANAMI3-PRIMULTI, suggested some benefit from complete revascularization (CR) [15–18].

The aim of the present study was to evaluate the potential clinical impact of CR in a nonselected population from an all-comers prospective registry of STEMI patients over a long period of time.

Methods

Population and design

The present analysis is based on the single-center Angiography and Coronary revascularization Registry of Santa Cruz Hospital (ACROSS Registry) in which demographic, clinical, angiographic, and procedure-related variables are prospectively collected using a dedicated lab-based computer database (Cardiobase; Infortucano, Lisbon, Portugal). This study was investigator driven and independent of any commercial funding. Between January 2004 and January 2014, all consecutive

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Manuscript #9

EXPERIMENTAL RESEARCH
INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

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In vitro evaluation of implantation depth in valve-in-valve using different transcatheter heart valves

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KEYWORDS

- aortic valve replacement
- circulatory *in vitro* studies
- haemodynamics
- heart valve prosthesis
- valve-in-valve

Abstract

Aims: Transcatheter heart valve (THV) implantation in failed bioprosthetic valves (valve-in-valve [ViV]) offers an alternative therapy for high-risk patients. Elevated post-procedural gradients are a significant limitation of aortic ViV. Our objective was to assess the relationship between depth of implantation and haemodynamics.

Methods and results: Commercially available THVs used for ViV were included in the analysis (CoreValve Evolut, SAPIEN XT and the Portico valve). THVs were implanted in small surgical valves (label size 19 mm) to simulate boundary conditions. Custom-mounted pulse duplicators registered relevant haemodynamic parameters. Twenty-eight experiments were performed (13 CVE, 5 SXT and 10 Portico). Ranges of depth of implantation were: CVE: –1.2 mm to 15.7 mm; SXT: –2.2 mm to 7.5 mm; Portico: 1.4 mm to 12.1 mm. Polynomial regression established a relationship between depth of implantation and valvular mean gradients (CVE: $p<0.001$; SXT: $p=0.01$; Portico: $p=0.002$), as well as with EOA (CVE: $p<0.001$; SXT: $p=0.02$; Portico valve: $p=0.003$). In addition, leaflet coaptation was better in the high implantation experiments for all valves.

Conclusions: The current comprehensive bench testing assessment demonstrates the importance of high device position for the attainment of optimal haemodynamics during aortic ViV procedures.

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Manuscript #10

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CASE REPORT

Transcatheter tricuspid valve-in-valve replacement: one-year results

Alternative to surgery in high-risk patients

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Abstract Although rheumatic heart disease is becoming uncommon in industrialized countries, its global burden is still significant. We report the case of a 70-year-old male with rheumatic heart disease, who underwent 4 previous heart valve replacement surgeries, and presented to our hospital with refractory heart failure (NYHA functional class IV) due to severe stenosis of a previously implanted tricuspid bioprosthesis. The Heart Team deemed the patient as inoperable/high-risk for surgery. As an alternative, a transcatheter tricuspid valve-in-valve replacement was decided upon and later executed through the right femoral vein, with the insertion of an Edwards SAPIEN XT 29 no. (Edwards Lifesciences, Irvine, CA, USA) through the inferior vena cava, towards the RV, followed by direct implantation in the tricuspid bioprosthesis (valve-in-valve), under rapid pacing, without complications. A substantial clinical and echocardiographic improvement was noted after the procedure and the patient was subsequently discharged in NYHA functional class II. These favourable outcomes persisted through the 1-year follow-up period. This case report adds to the current body of evidence that tricuspid valve implantation stands as a viable and reliable alternative in the treatment of degenerated bioprosthesis in high-surgical-risk patients.

Keywords Tricuspid valve · Bioprosthesis · Heart failure · Structural heart intervention

Introduction

Rheumatic heart disease (RHD) remains associated with a significant global cardiovascular burden [1]. Although aortic and mitral valves are usually the main focus of diagnostic and therapeutic concerns, tricuspid valve disease is not uncommon amongst these patients [2].

Until the last decade, heart surgery was the only viable treatment option for patients with heart failure (HF) due to valvular heart disease [3]. However, after several trials reported transcatheter valve implantation as a viable therapeutic approach for high-risk surgical patients presenting with symptomatic aortic stenosis [4–9], the procedure began to be performed in other clinical settings, namely in high-surgical-risk/inoperable patients with degenerated aortic and mitral bioprosthesis, with varying but generally positive outcomes [10–14]. Nevertheless, there is still an important call for additional data regarding the Heart Team clinical and evidence-based decision-making, procedural characteristics and follow-up of these patients.

Case report

We report the case of a 70-year-old male with a history of rheumatic heart disease, who initially underwent a double mitral and aortic bioprosthesis [Carpentier-Edwards

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Manuscript #11

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Transcatheter mitral valve interventions for mitral regurgitation, with special focus on MitraClip: The position of Spanish, Portuguese and Italian interventional societies

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ABSTRACT

Mitral regurgitation is a common valvular heart disease and its prevalence is expected to increase with population ageing. In the recent years we have witnessed the evolution of several transcatheter devices to correct mitral regurgitation in patients at high-risk for surgery. Most of the evidence of the safety and efficacy of this new therapy comes from MitraClip studies. However, new alternatives have emerged with promising results. The aim of this position paper is to review the current evidence regarding patient selection, expected results and timing for transcatheter mitral valve interventions from the perspective of three European interventional societies.

1. The necessity of transcatheter mitral valve interventions (TMVI)

Mitral regurgitation (MR) is the second most common symptomatic valvular disease worldwide [1]. The presence of MR after myocardial infarction or with dilated cardiomyopathy is associated with an increased risk of cardiac insufficiency and death [2–4].

Mitral valve (MV) surgery is the treatment of choice for patients with severe MR; however, 50% of patients [5] referred for MV surgery are not operated on, predominantly because of comorbidities, LV dysfunction or advanced age [6]. Noteworthy, the proportion of functional MR (FMR) patients undergoing surgical treatment is even lower [7], due to high surgical risk, the lack of clear survival benefit and the high recurrence rate of significant MR 1 year after surgery. Notwithstanding, patients with FMR when medically managed are burdened with substantial morbidity, mortality, and cost of care [8,9]. In this setting, catheter-based interventions have emerged to fill a large unmet need.

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2. Summary of current available devices for TMVI

In the last few years, important innovations have been developed in this field, with several percutaneous devices under investigation [10]. In Table 1 the most promising devices for TMVI are displayed. Some of them have gained approval for human use and have been tested in small clinical trials (Fig. 1). A detailed description of all these devices is beyond the scope of this position paper and their clinical application is still limited. We will focus in the device with the largest use to date in order to overview the role of TMVI in current clinical practice. However, one of the lessons learned from heart valve surgery is that a combination of diverse techniques addressing different mechanisms of MR may improve long-term outcomes [11] and we will foresee a place for combination therapy in early future.

2.1. Annuloplasty devices

Annuloplasty is the most common surgical repair performed to treat MR [12]. This technique is widely used as a stand-alone procedure to enhance MV coaptation in FMR or added to leaflet repair in degenerative MR in order to improve durability [11]. Based on prior large surgical experience, some percutaneous novel devices have tried to reproduced

Manuscript #12

PORTUGUESE ASSOCIATION OF CARDIOVASCULAR INTERVENTION

EuroIntervention 2017;13:Z55-Z58

Portugal: coronary and structural heart interventions from 2010 to 2015

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Abstract

The aim of the present paper is to report trends in Portuguese interventional cardiology from 2010 to 2015. We studied data from the prospective multicentre Portuguese National Registry of Interventional Cardiology (RNCI) to analyse percutaneous coronary intervention (PCI) procedures and structural heart interventions from 2010 to 2015. A total of 73,977 PCIs and 780 transcatheter aortic valve implants were performed during the study period. Since 2010 there has been a 60% increase in PCI procedures and a twofold increase in primary angioplasty rates reaching 316 per million population. Significant PCI trends were observed, notably the increase of radial access, a reduction in restenosis indications, as well as an increase in stent use, including DES, in imaging and in functional techniques. Importantly, there was a fourfold increase in the TAVI rates reaching 29 per million population.

Introduction

The aim of the present paper is to report trends in the percutaneous treatment of heart disease in Portugal, based on the description of the demographics and health system organisation and on the data analysis from the Portuguese National Registry of Interventional Cardiology (RNCI) of the Associação Portuguesa de Intervenção Cardiovascular (APIC, www.apic.pt).

We performed a transversal analysis regarding the 2015 cathlab status and studied the prospective multicentre data from the RNCI to analyse percutaneous coronary intervention (PCI) procedures and structural heart interventions from 2010 to 2015.

Demographics and organisation

The Portuguese population is 10.3 million and there is a total of 27 catheterisation laboratories, seven of them private. A total of 19 public hospitals operate 24h/7d and run the primary PCI (pPCI)

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Manuscript #13

ESC European Society of Cardiology

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ESC GUIDELINES

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries

Endorsed by: the European Stroke Organization (ESO)

The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS)

Authors/Task Force Members: Victor Aboyans* (ESC Chairperson) (France), Jean-Baptiste Ricco*[1] (Co-Chairperson) (France), Marie-Louise E. L. Bartelink (The Netherlands), Martin Björck[1] (Sweden), Marianne Brodmann (Austria), Tina Cohnert[1] (Austria), Jean-Philippe Collet (France), Martin Czerny (Germany),

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ESC Committee for Practice Guidelines (CPG) and National Cardiac Societies (NCS) document reviewers: listed in the Appendix

[1]Representing the European Society for Vascular Surgery (ESVS)

[2]Representing the European Stroke Organisation (ESO)

ESC entities having participated in the development of this document:
Associations: European Association of Preventive Cardiology (EAPC), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI).
Councils: Council for Cardiology Practice (CCP), Council on Cardiovascular Primary Care (CCPC), Council on Hypertension (CHT).
Working Groups: Atherosclerosis and Vascular Biology, Cardiovascular Pharmacotherapy, Cardiovascular Surgery, Peripheral Circulation, Thrombosis.

Manuscript #14

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Rev Esp Cardiol. 2018;xx(x):xxx–xxx

Image in cardiology

Successful Clinical and Therapeutic Approach for Valve-in-valve Leaflet Thrombosis

Exitoso abordaje clínico y terapéutico de trombosis en procedimiento valve-in-valve

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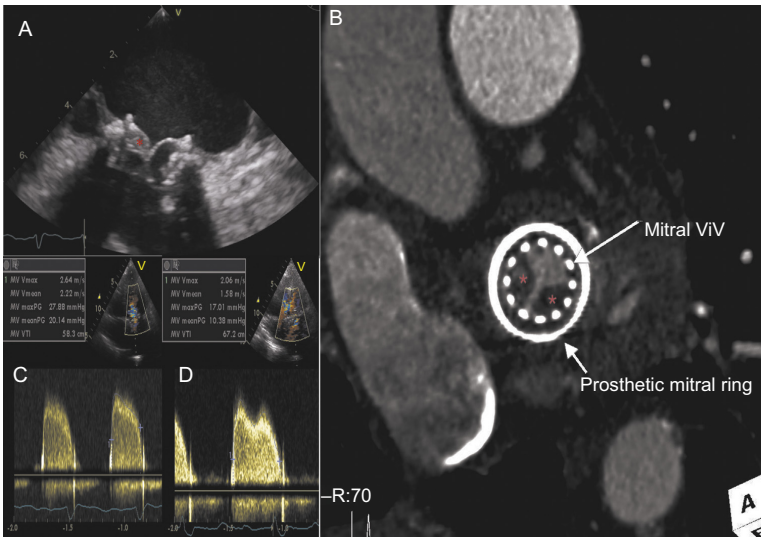

Figure.

An 87-year-old woman with rheumatic valve disease underwent aortic, mitral (Hancock II 27) and tricuspid biological prosthetic valve implantation in 2010.

In 2016, a transapical mitral valve-in-valve procedure (ViV; Edwards Sapien 26) was performed because of prosthesis degeneration with predominant intraprosthetic regurgitation. The patient was in sinus rhythm and a long-term clopidogrel antithrombotic regimen was started.

She was admitted in December 2017 with a 3-week history of exertional dyspnea and orthopnea. A transthoracic echocardiogram (TTE) revealed a severely obstructed mitral prosthesis (mean gradient of 20 mmHg and right ventricle-right auricle gradient of 96 mmHg). A transesophageal echocardiogram suggested the presence of a prosthetic thrombosis (asterisk), as hypoechoic material overlapped the atrial surface of the posterior leaflet (Figure A).

Restrictive motion of the prosthetic leaflets, covered by hypodense thrombotic material (asterisk), was also depicted by computed tomography (Figure B). Given the patient's hemodynamic stability and high surgical risk, a conservative strategy with unfractionated intravenous heparin and clopidogrel was attempted. The clinical course was favorable with a gradual increase in exercise tolerance and normalization of prosthetic gradients at the first month, confirmed by transthoracic echocardiography (Figure C and Figure D).

The incidence of transcathether heart valve thrombosis after mitral ViV procedures remains largely unknown and scarcely reported, with uncertain treatment and undefined antithrombotic regimens. It is particularly interesting in the era of the upcoming percutaneous mitral bioprosthesis. We found this case notable for its rarity and favorable outcome under anticoagulation and antiplatelet therapy. Complementary use of multimodality imaging improved our confidence in its diagnosis and the treatment strategy selected.

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Manuscript #15

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Mid-Term Valve-Related Outcomes After Transcatheter Tricuspid Valve-in-Valve or Valve-in-Ring Replacement

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ABSTRACT

BACKGROUND Transcatheter aortic and pulmonary valves have been used to treat stenosis or regurgitation after prior surgical tricuspid valve (TV) replacement or repair. Little is known about intermediate-term valve-related outcomes after transcatheter tricuspid valve replacement (TTVR), including valve function, thrombus, and endocarditis.

OBJECTIVES The authors sought to evaluate mid-term outcomes in a large cohort of patients who underwent TTVR after surgical TV repair or replacement, with a focus on valve-related outcomes.

METHODS Patients who underwent TTVR after prior surgical TV replacement or repair were collected through an international registry. Time-related outcomes were modeled and risk factors assessed.

RESULTS Data were collected for 306 patients who underwent TTVR from 2008 through 2017 at 80 centers; 52 patients (17%) had a prior history of endocarditis. Patients were followed for a median of 15.9 months after implantation (0.1 to 90 months), with 64% of patients estimated to be alive without TV reintervention or a valve-related event at 3 years. The cumulative 3-year incidence of death, reintervention, and valve-related adverse outcomes (endocarditis, thrombosis, or significant dysfunction) were 17%, 12%, and 8%, respectively. Endocarditis was diagnosed in 8 patients 2 to 29 months after TTVR, for an annualized incidence rate of 1.5% per patient-year (95% confidence interval: 0.45% to 2.5%). An additional 8 patients were diagnosed with clinically relevant valve thrombosis, 3 in the short term, 2 within 2 months, and 3 beyond 6 months. Only 2 of these 8 patients received anticoagulant therapy before thrombus detection ($p = 0.13$ vs. patients without thrombus). Prior endocarditis was not a risk factor for reintervention, endocarditis, or valve thrombosis, and there was no difference in valve-related outcomes according to TTVR valve type.

CONCLUSIONS TV dysfunction, endocarditis, and leaflet thrombosis were uncommon after TTVR. Patients with prior endocarditis were not at higher risk for endocarditis or other adverse outcomes after TTVR, and endocarditis occurred with similar frequency in different valve types. Though rare, leaflet thrombosis is an important adverse outcome, and further study is necessary to determine the appropriate level of prophylactic therapy after TTVR.
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Manuscript #16

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REVIEW PAPER

Usefulness of skeletal muscle area detected by computed tomography to predict mortality in patients undergoing transcatheter aortic valve replacement: a meta-analysis study

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Abstract
Measures of sarcopenia, such as low muscle mass measured from the readily available preoperative computed tomography (CT) images, have been recently suggested as a predictor of outcomes in patients undergoing transcatheter aortic valve replacement (TAVR). However, results of these studies are variable and, therefore, we performed a systematic review of current literature to evaluate sarcopenia as a predictor of outcome post TAVR. The search was carried out in electronic databases between 2008 and 2018. We identified studies that reported CT-derived skeletal muscle area (SMA) and survival outcomes post TAVR. Studies were evaluated for the incidence of early (≤ 30 days) and late all-cause mortality (> 30 days) post TAVR. Eight studies with 1881 patients were included (mean age of 81.8 years ± 12, 55.9% men). Mean body mass index was (28.2 kg/m^2 ± 1.1), mean Society of Thoracic Surgeons risk score (7.0 ± 0.6), and mean albumin level was (3.8 g/dL ± 0.1). Higher SMA was associated with lower long-term mortality [odds ratio (OR) 0.49, 95% confidence interval (CI) 0.28–0.83, p = 0.049], compared with low SMA. Also, higher SMA was associated with lower early mortality but was not statistically significant (OR 0.72; 95% CI 0.44–1.18; p = 0.285). CT-derived SMA provides value in predicting post-TAVR long-term outcomes for patients undergoing TAVR. This is a simple risk assessment tool that may help in making treatment decisions and help identifying and targeting high-risk patients with interventions to improve muscle mass prior to and following the procedures.

Keywords Transcatheter aortic valve replacement · Skeletal muscle area · Computed tomography · Frailty · Mortality

Introduction

The Society of Thoracic Surgeons (STS) score and European System for Cardiac Operative Risk Evaluation are frequently used as risk stratification tools before transcatheter aortic valve replacement (TAVR) in order to evaluate a patient's risk for such interventions [1]. In recent years, there was an increasing interest in frailty as a predictor of outcomes after surgical aortic valve replacement/TAVR, thus guiding risk stratification of those patients before the procedure [2]. Nevertheless, most of the proposed frailty indicators are difficult to measure objectively and are often estimated on the basis of subjective clinical judgment and questionnaires of patient functionality as well as relying heavily on physical performance tests which can be less feasible in very frail patients [2, 3]. In the aging population, frailty is often associated with sarcopenia, which is defined as an age-related disease described by a significant loss of muscle mass [4, 5]. Low

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Manuscript #17

Original Article

Impact of Transcatheter Aortic Valve Implantation on Kidney Function

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Abstract

Background: **Chronic kidney disease (CKD) is frequently present in patients with aortic valve disease. Decreased kidney perfusion as a consequence of reduced cardiac output may contribute to renal dysfunction in this setting.**

Objective: **Given the potential reversibility of kidney hypoperfusion after valve repair, this study aimed to analyze the impact of percutaneous transcatheter aortic valve implantation (TAVI) on kidney function.**

Methods: **We performed a retrospective analysis of 233 consecutive patients who underwent TAVI in a single center between November 2008 and May 2016. We assessed three groups according to their baseline estimated glomerular filtration rate (eGFR) (mL/min/1.73 m²): Group 1 with eGFR ≥ 60; Group 2 with 30 ≤ eGFR < 60; and Group 3 with eGFR < 30. We analyzed the eGFR one month and one year after TAVI in these three groups, using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula to calculate it.**

Results: **Patients from Group 1 had a progressive decline in eGFR one year after the TAVI procedure (p < 0.001 vs. pre-TAVI). In Group 2 patients, the mean eGFR increased one month after TAVI and continued to grow after one year (p = 0.001 vs. pre-TAVI). The same occurred in Group 3, with the mean eGFR increasing from 24.4 ± 5.1 mL/min/1.73 m² before TAVI to 38.4 ± 18.8 mL/min/1.73 m² one year after TAVI (p = 0.012).**

Conclusions: **For patients with moderate-to-severe CKD, kidney function improved one year after the TAVI procedure. This outcome is probably due to better kidney perfusion post-procedure. We believe that when evaluating patients that might need TAVI, this 'reversibility of CKD effect' should be considered. (Arq Bras Cardiol. 2019; 113(6):1104-1111)**

Keywords: **Aortic Valve Stenosis/complications;renal Insufficiency,Chronic; Calcinosis; Renal Dialysis; Diabetes Mellitus; Cardyomyopathies; Hypertension.**

Introduction

Since Bright[1] first described the association between chronic kidney disease (CKD) and heart disease in 1836, many epidemiological studies have confirmed and extended this finding.

With higher life expectancy, the prevalence of valvular heart disease, such as aortic valve disease, is increasing, and patients needing intervention are older and display multiple comorbidities.[2] Surgical intervention is the most effective therapeutic option, but transcatheter aortic valve implantation (TAVI) has become an important treatment choice for inoperable or high-risk patients.[2-4]

Many studies show poor short- and long-term outcomes in patients with CKD submitted to TAVI.[5,6] Other studies on this field focus on acute kidney injury (AKI) after TAVI, showing that AKI is not merely an independent predictor of adverse outcome but also predisposes to the development of CKD. Cases of AKI requiring dialysis have a poor prognosis (50% in-hospital mortality), and a significant proportion of patients progress to end-stage kidney disease.[7–9]

Aortic valve disease is frequently seen in CKD patients[10] due to progressive and accelerated leaflet calcification, a well-known complication of kidney failure. The key modulators in this field have not been totally identified, but might include calcification inhibitors (e.g., fetuin-A and matrix Gla protein), calcification promotors (e.g., hyperphosphatemia, calcium-phosphate product, parathyroid hormone), and leptin. On the other hand, long-standing aortic stenosis may contribute to CKD by impairing forward blood flow from the heart, causing chronic hypoperfusion and resulting in organ damage, and by increased renal venous pressure associated with right-sided heart failure.[11,12] Hypothetically, these pathological CKD mechanisms can be reversed after correction of aortic valve stenosis.

Little is known about the reversibility of CKD after aortic valve replacement. The dynamic changes in kidney function after TAVI have not been described and are not fully understood.

Given the potential reversibility of the pathological CKD mechanism after the correction of aortic valve disease, this study aimed at analyzing the variations in kidney function after TAVI.

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OPEN

Diagnostic accuracy of computed tomography angiography for the exclusion of coronary artery disease in candidates for transcatheter aortic valve implantation

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Coronary CT angiography (CTA) is currently considered a reliable method to exclude obstructive coronary artery disease (CAD) before valvular heart surgery in patients with low pretest probability. However, its role in excluding obstructive CAD before transcatheter aortic valve implantation (TAVI) is less well established. Single-center retrospective study where patients with severe symptomatic aortic stenosis underwent both CTA and invasive coronary angiography (ICA) as part of TAVI planning. CTA exams were conducted on a 64-slice dual source scanner, with a median interval of 45 days to ICA (IQR 25–75 [13–82]). In both tests, obstructive CAD was defined as a ≥50% stenosis in an epicardial vessel ≥2 mm diameter. Per-patient, per-vessel and per-proximal segment analyses were conducted, excluding and including non-evaluable segments. The study included 200 patients (120 women, mean age 83 ± 6 years). The prevalence of obstructive CAD on ICA was 35.5% (n = 71). On a per-patient analysis (assuming non-evaluable segments as stenotic), CTA showed sensitivity of 100% (95% CI, 95–100%), specificity of 42% (95% CI, 33–51%), and positive and negative predictive values of 48% (95% CI, 44–51%) and 100% (95% CI, 92–100%), respectively. CTA was able to exclude obstructive CAD in 54 patients (27%), in whom ICA could have been safely withheld. Despite the high rate of inconclusive tests, pre-procedural CTA is able to safely exclude obstructive CAD in a significant proportion of patients undergoing TAVI, possibly avoiding the need for ICA in roughly one quarter of the cases.

The prevalence and prognostic significance of coronary artery disease (CAD) among patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI) warrant the systematic evaluation of the coronary anatomy[1–3]. Cardiac computed tomography angiography (CTA) is usually performed before TAVI for procedure planning, but may also provide valuable information about the coronary arterial tree[4]. Despite several limitations in this setting, pre-procedural CTA may be sufficient to exclude significant CAD, thus avoiding the risks and costs of invasive coronary angiography (ICA)[5–11].

The purpose of this study was to evaluate the diagnostic performance of pre-procedural CTA for excluding significant CAD in patients with severe AS assessed for TAVI, and to determine the proportion of patients where ICA could safely be avoided.

Results

The baseline characteristics of the 200 selected patients with severe symptomatic AS are presented in Table 1.

Overall, 71 patients (35.5%) had obstructive CAD on ICA. These patients were more often male, had a higher prevalence of peripheral artery disease, higher coronary artery calcium (CAC) score values, and a higher

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Transcatheter Self-Expandable Valve Implantation for Aortic Stenosis in Small Aortic Annuli

The TAVI-SMALL Registry

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate and compare the outcomes of transcatheter self-expandable prostheses in patients with small annuli.

BACKGROUND Transcatheter aortic heart valves appear to have better performance than surgical valves in terms of prosthesis-patient mismatch, especially in patients with aortic stenosis with small aortic annuli.

METHODS TAVI-SMALL (International Multicenter Registry to Evaluate the Performance of Self-Expandable Valves in Small Aortic Annuli) is a retrospective registry of patients with severe aortic stenosis and small annuli (annular perimeter <72 mm or area <400 mm^2 on computed tomography) treated with transcatheter self-expandable valves (n = 859; Evolut R, n = 397; Evolut PRO, n = 84; ACURATE, n = 201; Portico, n = 177). Primary endpoints were post-procedural mean aortic gradient, indexed effective orifice area, and rate of severe prosthesis-patient mismatch.

RESULTS Pre-discharge gradients were consistently low in every group, with a slight benefit with the Evolut R (8.1 mm Hg; 95% confidence interval [CI]: 7.7 to 8.5 mm Hg) and Evolut PRO (6.9 mm Hg; 95% CI: 6.3 to 7.6 mm Hg) compared with the ACURATE (9.6 mm Hg; 95% CI: 8.9 to 10.2 mm Hg) and Portico (8.9 mm Hg; 95% CI: 8.2 to 9.6 mm Hg) groups ($p < 0.001$). Mean indexed effective orifice area was 1.04 cm^2/m^2 (95% CI: 1.01 to 1.08 cm^2/m^2) with a trend toward lower values with the Portico. No significant differences were reported in terms of severe prosthesis-patient mismatch (overall rate 9.4%; p = 0.134), permanent pacemaker implantation (15.6%), and periprocedural and 1-year adverse events. Pre-discharge more than mild paravalvular leaks were significantly more common with the Portico (19.2%) and less common with the Evolut PRO (3.6%) compared with the Evolut R (11.8%) and ACURATE (9%) groups.

CONCLUSIONS Transcatheter self-expandable valves showed optimal clinical and echocardiographic results in patients with small aortic annuli, although supra-annular functioning transcatheter heart valves seemed to slightly outperform intra-annular functioning ones. The role of transcatheter aortic valve replacement with self-expandable valves for the treatment of aortic stenosis in patients with small annuli needs to be confirmed in larger trials.
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Letters

TO THE EDITOR

The Spotlight Is on Secondary Access for TAVR

Radial Versus Femoral Revisited

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The evolution of transcatheter aortic valve replacement since its introduction in 2002 has been astonishing. Classically, contralateral ancillary femoral artery (FA) access was used. More recently, the radial artery (RA) has been proposed for angiography and iliac crossover (1).

Khubber et al. (2) described an innovative approach, reporting their experience with ipsilateral FA secondary access. In a consecutive cohort of patients, 1,007 (83.4%) had contralateral secondary FA access, and 201 (16.6%) had ipsilateral access. The investigators hypothesized that ipsilateral FA access might improve patient comfort, facilitate bailout interventions by having access to the distal lumen, and avoid the need for an iliac crossover, which is switching from a routine technique to a bailout intervention.

The small sample size of the ipsilateral group precludes drawing definitive conclusions. However, it is reassuring to note that vascular complications are equally rare in both groups—10.7% with contralateral access and 8.4% with ipsilateral access—and bailout interventions were successfully performed (2).

The investigators acknowledge that RA access constitutes a viable alternative, although noting that the adoption of cerebral protection devices could be a limitation. Current protection devices use the right RA, leaving the left RA available for angiography and staged bailout peripheral interventions with dedicated equipment (3).

With decreasing rates of vascular complications, the advantage of FA access for peripheral interventions might be overshadowed by lower vascular complication rates and improved patient comfort with RA access (4). This debate revisits the discussion of arterial access in percutaneous coronary intervention (5). Prospective randomized trials are needed to address the pros and cons of each strategy.

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REPLY: The Spotlight Is on Secondary Access for TAVR

Radial Versus Femoral Revisited

We would like to thank Dr. Felix-Oliveira and colleagues for bringing up a very important alternative for contralateral access. The idea of using the radial artery as an alternative access site for crossover is appealing, and the initial data from a small number of patients (N = 46) showed no difference in major vascular and bleeding complications between the 2 techniques (1). As appropriately pointed out, the limitation of this approach is the need to use right radial access for the only currently Food and Drug Administration-approved embolic protection device.

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WILEY

ORIGINAL STUDIES

Transcatheter aortic valve implantation (TAVI) in cardiogenic shock: TAVI-shock registry results

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Abstract

Objectives: Aim of this study is to evaluate safety, feasibility, and mid-term outcome of transcatheter aortic valve implantation (TAVI) in cardiogenic shock (CS).

Background: Balloon aortic valvuloplasty in patients with severe aortic valve stenosis (SAS) complicated by CS is indicated but associated with a grim prognosis. TAVI might be a more reasonable treatment option in this setting but data are scant.

Methods: From March 2008 to February 2019, 51 patients with severe aortic valvulopathy (native SAS or degenerated aortic bioprosthesis) and CS treated by TAVI in 11 European centers were included in this multicenter registry. Demographic, clinical, and procedural data were collected, as well as clinical and echocardiographic follow-up.

Results: The mean age of our study population was 75.8 ± 13, 49% were women, and mean Society of Thoracic Surgeons (STS) score was 19 ± 15%. Device success was achieved in 94.1%, with a 5% incidence of moderate/severe paravalvular leak. The 30-day events were mortality 11.8%, stroke 2.0%, vascular complications 5.9%, and acute kidney injury 34%. Valve Academic Research Consortium-2 early safety endpoint was reached in 35.3% of cases. At 1-year of follow-up, the mortality rate was 25.7% and the readmission for congestive heart failure was 8.6%.

Conclusions: TAVI seems to be a therapeutic option for patients with CS and SAS or degenerated aortic bioprosthesis in terms of both safety and efficacy at early and long-term follow-up.

KEYWORDS

aortic stenosis, aortic valve disease, cardiogenic shock, transcatheter aortic valve implantation

Manuscript #22

EAPCI CORE CURRICULUM

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2020 EAPCI Core Curriculum for Percutaneous Cardiovascular Interventions

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KEYWORDS

• miscellaneous

Abstract

The proposed 2020 Core Curriculum for Percutaneous Cardiovascular Interventions aims to provide an updated European consensus that defines the level of experience and knowledge in the field of percutaneous cardiovascular intervention (PCI). It promotes homogenous education and training programmes among countries, and is the cornerstone of the new EAPCI certification, designed to support the recognition of competencies at the European level and the free movement of certified specialists in the European Community. It is based on a thorough review of the ESC guidelines and of the EAPCI textbook on percutaneous interventional cardiovascular medicine. The structure of the current core curriculum evolved from previous EAPCI core curricula and from the "2013 core curriculum of the general cardiologist" to follow the current ESC recommendations for core curricula. In most subject areas, there was a wide - if not unanimous - consensus among the task force members on the training required for the interventional cardiologist of the future. The document recommends that acquisition of competence in interventional cardiology requires at least two years of postgraduate training, in addition to four years devoted to cardiology. The first part of the curriculum covers general aspects of training and is followed by a comprehensive description of the specific components in 54 chapters. Each of the chapters includes statements of the objectives, and is further subdivided into the required knowledge, skills, behaviours, and attitudes.

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ESC European Society of Cardiology

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FASTTRACK CLINICAL RESEARCH

Long-term outcomes after transcatheter aortic valve implantation in failed bioprosthetic valves

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Cardiovascular Revascularization Medicine

Low rate of invasive coronary angiography following transcatheter aortic valve implantation: Real-world prospective cohort findings

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ABSTRACT

Aim: To evaluate the real need for coronary access after transcatheter aortic valve implantation (TAVI).
Methods and results: Prospective observational single center registry, including 563 consecutive patients that underwent TAVI between April 2008 and November 2018, with both self and balloon expandable valves in a tertiary European center. Mean age was 82.4 ± 6.9 years, 53.3% were female, 16% had previous history of CABG, 33% of previous PCI and 16.6% of MI. Twenty four percent of the patients were revascularized within one year before TAVI in preparation for the procedure. Median STS Score was 4.82 (IQ 2.84).
In a median follow up of 24 months (IQ 21.5), 18 patients (3.2%) were identified as potentially in need for ICA: 9 (1.6%) in the setting of stable coronary artery disease and 9 (1.6%) for an acute coronary syndrome.
A total of 11 PCI were performed in 9 patients, with a complete success rate of 63.6%. Procedures that were unsuccessful or partially unsuccessful were due to the inability to cross the stent or the drug eluting balloon through the valve struts or misplacement within the coronary artery due to lack of catheter's support.
Conclusion: In this population, a strategy of previous guideline guided revascularization before transcatheter aortic valve implantation was associated with a low rate of myocardial infarction and repeated need of coronary access, with a scattered distribution over time. Assuring future access to coronary arteries in patients at increased risk may depend on the revascularization strategy rather than device selection.

1. Introduction

It is known that coronary artery disease is prevalent among patients with severe aortic stenosis, ranging from 70% in intermediate and high risk patients to 30% in low risk patients [1–3]. Transcatheter aortic valve implantation (TAVI) procedures are increasing at a high rate in Europe with approximately 180,000 patients annually being considered potential TAVI candidates in the European Union and in Northern-America, a number that could increase up to 270,000 with the widespread of indications to low-risk patients [4]. Revascularization strategies before TAVI differ [5,6] and concerns about future coronary intervention influence strategy and device selection.

With the high prevalence of coronary artery disease, the lowering age of patients and the increasing life expectancy after TAVI it is expected that acute coronary syndromes may occur, with reported rates as high as 10% at two years [7–9]. Intraprocedural need for coronary access is a major concern and coronary ostial obstruction due to valve

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CCTA, coronary computed tomography angiography; CKD, chronic kidney disease; DES, drug eluting stent; ICA, invasive coronary angiography; LVEF, left ventricular ejection fraction; LAD, left anterior descending artery; LCX, left circumflex coronary artery; LM, left main; MI, myocardial infarction; NSTEMI, non ST segment elevation myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; PAP, pulmonary artery pressure; RCA, right coronary artery; SHID/SAP, stable angina pectoris; SOV, sinus of Valsalva; STEMI, ST segment elevation myocardial infarction; STJ, sinotubular junction; TAVI, transcatheter aortic valve implantation; TF, transfemoral; VCROSS, Valve Catheter Restorative Operation on Santa Cruz hospital; ViV, valve-in-valve.

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ESC Report

ESC Core Curriculum for the Cardiologist

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Circulation

ORIGINAL RESEARCH ARTICLE

Transcatheter Mitral Valve Replacement After Surgical Repair or Replacement

Comprehensive Midterm Evaluation of Valve-in-Valve and Valve-in-Ring Implantation From the VIVID Registry

Editorial, see p 117; Article see p 178

Matheus Simonato, MD
Danny Dvir, MD

BACKGROUND: Mitral valve-in-valve (ViV) and valve-in-ring (ViR) are alternatives to surgical reoperation in patients with recurrent mitral valve failure after previous surgical valve repair or replacement. Our aim was to perform a large-scale analysis examining midterm outcomes after mitral ViV and ViR.

METHODS: Patients undergoing mitral ViV and ViR were enrolled in the Valve-in-Valve International Data Registry. Cases were performed between March 2006 and March 2020. Clinical endpoints are reported according to the Mitral Valve Academic Research Consortium (MVARC) definitions. Significant residual mitral stenosis (MS) was defined as mean gradient ≥10 mm Hg and significant residual mitral regurgitation (MR) as ≥ moderate.

RESULTS: A total of 1079 patients (857 ViV, 222 ViR; mean age 73.5±12.5 years; 40.8% male) from 90 centers were included. Median STS-PROM score 8.6%; median clinical follow-up 492 days (interquartile range, 76–996); median echocardiographic follow-up for patients that survived 1 year was 772.5 days (interquartile range, 510–1211.75). Four-year Kaplan-Meier survival rate was 62.5% in ViV versus 49.5% for ViR (P<0.001). Mean gradient across the mitral valve postprocedure was 5.7±2.8 mm Hg (≥5 mm Hg; 61.4% of patients). Significant residual MS occurred in 8.2% of the ViV and 12.0% of the ViR patients (P=0.09). Significant residual MR was more common in ViR patients (16.6% versus 3.1%; P<0.001) and was associated with lower survival at 4 years (35.1% versus 61.6%; P=0.02). The rates of Mitral Valve Academic Research Consortium–defined device success were low for both procedures (39.4% total; 32.0% ViR versus 41.3% ViV; P=0.01), mostly related to having postprocedural mean gradient ≥5 mm Hg. Correlates for residual MS were smaller true internal diameter, younger age, and larger body mass index. The only correlate for residual MR was ViR. Significant residual MS (subhazard ratio, 4.67; 95% CI, 1.74–12.56; P=0.002) and significant residual MR (subhazard ratio, 7.88; 95% CI, 2.88–21.53; P<0.001) were both independently associated with repeat mitral valve replacement.

CONCLUSIONS: Significant residual MS and/or MR were not infrequent after mitral ViV and ViR procedures and were both associated with a need for repeat valve replacement. Strategies to improve postprocedural hemodynamics in mitral ViV and ViR should be further explored.

The full author list is available on page 114.

Key Words: heart valve disease ■ hemodynamics ■ mitral valve ■ mitral valve insufficiency ■ mitral valve stenosis

Sources of Funding, see page 115

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Impact of COVID-19 Pandemic on Mechanical Reperfusion for Patients With STEMI

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ABSTRACT

BACKGROUND The fear of contagion during the coronavirus disease-2019 (COVID-19) pandemic may have potentially refrained patients with ST-segment elevation myocardial infarction (STEMI) from accessing the emergency system, with subsequent impact on mortality.

OBJECTIVES The ISACS-STEMI COVID-19 registry aims to estimate the true impact of the COVID-19 pandemic on the treatment and outcome of patients with STEMI treated by primary percutaneous coronary intervention (PPCI), with identification of "at-risk" patient cohorts for failure to present or delays to treatment.

METHODS This retrospective registry was performed in European high-volume PPCI centers and assessed patients with STEMI treated with PPPCI in March/April 2019 and 2020. Main outcomes are the incidences of PPCI, delayed treatment, and in-hospital mortality.

RESULTS A total of 6,609 patients underwent PPCI in 77 centers, located in 18 countries. In 2020, during the pandemic, there was a significant reduction in PPCI as compared with 2019 (incidence rate ratio: 0.811; 95% confidence interval: 0.78 to 0.84; $p < 0.0001$). The heterogeneity among centers was not related to the incidence of death due to COVID-19. A significant interaction was observed for patients with arterial hypertension, who were less frequently admitted in 2020 than in 2019. Furthermore, the pandemic was associated with a significant increase in door-to-balloon and total ischemia times, which may have contributed to the higher mortality during the pandemic.

CONCLUSIONS The COVID-19 pandemic had significant impact on the treatment of patients with STEMI, with a 19% reduction in PPCI procedures, especially among patients suffering from hypertension, and a longer delay to treatment, which may have contributed to the increased mortality during the pandemic. (Primary Angioplasty for STEMI During COVID-19 Pandemic [ISACS-STEMI COVID-19] Registry; NCT04412655). (J Am Coll Cardiol 2020;76:2321–30) © 2020 by the American College of Cardiology Foundation.

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Manuscript #28

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Transcatheter Aortic Valve Replacement With the LOTUS Edge System

Early European Experience

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate the short-term safety and efficacy of transcatheter aortic valve replacement (TAVR) with the LOTUS Edge system.

BACKGROUND The LOTUS Edge system was commercially re-released in April 2019. The authors report the first European experience with this device.

METHODS A multicenter, single-arm, retrospective registry was initiated to evaluate short-term clinical outcomes. Included cases are the first experience with this device and new implantation technique in Europe. Clinical, echocardiographic, and computed tomographic data were analyzed. Endpoints were defined according to Valve Academic Research Consortium-2 and were site reported.

RESULTS Between April and November 2019, 286 consecutive patients undergoing TAVR with the LOTUS Edge system at 18 European centers were included. The mean age and Society of Thoracic Surgeons score were 81.2 ± 6.9 years and 5.2 ± 5.4%, respectively. Nearly one-half of all patients (47.9%) were considered to have complex anatomy. Thirty-day major adverse events included death (2.4% [n = 7]) and stroke (3.5% [n = 10]). After TAVR, the mean aortic valve area was 1.9 ± 0.9 cm^2, and the mean transvalvular gradient was 11.9 ± 5.7 mm Hg. None or trace paravalvular leak (PVL) occurred in 84.4% and moderate PVL in 2.0%. There were no cases of severe PVL. New permanent pacemaker (PPM) implantation was required in 25.9% among all patients and 30.8% among PPM-naive patients.

CONCLUSIONS Early experience with the LOTUS Edge system demonstrated satisfactory short-term safety and efficacy, favorable hemodynamic data, and very low rates of PVL in an anatomically complex cohort. New PPM implantation remained high. Further study will evaluate if increasing operator experience with the device and new implantation technique can reduce the incidence of PPM implantation. (J Am Coll Cardiol Intv 2021;14:172–81)

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ORIGINAL STUDIES

WILEY

Next-generation balloon-expandable Myval transcatheter heart valve in low-risk aortic stenosis patients

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Abstract

Objectives: We aimed to describe hemodynamic performance and clinical outcomes at 30-day follow-up of the balloon-expandable (BE) Myval transcatheter heart valve (THV) in low-risk patients.

Background: The results of the next-generation BE Myval THV in low-risk aortic stenosis (AS) patients are still unknown.

Methods: Retrospective registry performed in nine European centers including patients with low predicted operative mortality risk according to Society of thoracic surgeons (STS) and European system for cardiac operative risk evaluation (EuroSCORE-II) scores.

Results: Between September 2019 and February 2021, a total of 100 patients (51% males, mean age 80 ± 6.5 years) were included. Mean STS score and EuroSCORE-II were 2.4 ± 0.8% and 2.2 ± 0.7%, respectively. Intermediate sizes were used in 39% (21.5 mm: 8%, 24.5 mm: 15%, 27.5 mm: 15%). There were no cases of valve embolization, coronary artery occlusion, annulus rupture, or procedural death. A definitive pacemaker implantation was needed in eight patients (8%). At 30-day follow-up aortic valve area (0.7 ± 0.2 vs. 2.1 ± 0.6 cm^2) and mean aortic valve gradient (43.4 ± 11.1 vs. 9.0 ± 3.7 mmHg) improved significantly ($p < 0.001$). Moderate aortic regurgitation occurred in 4%. Endpoints of early safety and clinical efficacy were 3 and 1%, respectively.

Conclusions: Hemodynamic performance and 30-day clinical outcomes of the BE Myval THV in low-risk AS patients were favorable. Longer-term follow-up is warranted.

Abbreviations: AR, aortic regurgitation; AS, aortic stenosis; BE, balloon-expandable; ES, European System for Cardiac Operative Risk Evaluation version II (EuroSCORE II); SE, self-expandable; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve; VARC-2, Valve Academic Research Consortium 2.

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ORIGINAL PAPER

Predictors of pacemaker implantation after TAVI in a registry including self, balloon and mechanical expandable valves

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Abstract
The need for permanent pacemaker implantation (PPMI) is a burdensome complication of transcatheter aortic valve implantation (TAVI). The aim of our study was to evaluate different anatomical, clinical, electrocardiographic, and procedural variables associated with the development of conduction abnormalities after TAVI across the entire device spectrum. Single-center prospective cohort of consecutive patients who underwent TAVI since March 2017. Final cohort was studied to detect areas of calcium within aortic valve characterized by leaflet sector and region. Membranous septum (MS) length was assessed throughout a modified coronal view. Device selection and positioning were performed according to the operator criteria. Device selection and positioning were performed according to the operator criteria. From the 273 patients included, 57 underwent PPMI (20.8%). Univariate analysis determined right bundle branch block (RBBB), QRS duration, MS length and calcium within LVOT of non-coronary cuspid as independent predictors. After multivariable logistic regression, both RBBB (OR 6.138; 95% CI 1.23–30.73, $P=0.027$) and MS length (OR 0.259; 95% CI 0.164–0.399, $P<0.005$) emerged as statistically significant. As a model, they could predict PPMI in 88.7%, independently of which valve used. Youden index analysis yielded 7.69 mm as the optimal cut-off with a negative and positive predictive value of 94.7 and 71.9%, respectively. In our experience, both RBBB pattern and short membranous septum (<8 mm) were strongly and independently associated with new permanent pacemaker implantation, regardless of the device type. Our findings suggest that this simple evolved measure of MS length may guide device selection and implantation technique and facilitate early discharge.

Keywords Diagnostic testing · TAVI · Pacemaker · Cardiovascular computed tomography · Complications

Abbreviations

AVC	Aortic-valvular complex
AV	Atrioventricular
BEV	Balloon expandable valve
ICD	Implantable cardioverter-defibrillator
CT	Computed tomography
MS	Membranous septum
MEV	Mechanically expandable valve
MSCT	Multislice computed tomography
PPMI	Permanent pacemaker implantation
RBBB	Right bundle branch block
SEV	Self-expandable valve
TAVI	Transcatheter aortic valve implantation
THV	Transcatheter heart valve
SD	Standard deviation
ViV	Valve-in-valve

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Background

The occurrence of high degree atrioventricular conduction disturbances after transcatheter aortic valve implantation (TAVI) and the subsequent need of permanent pacemaker implantation (PPMI), is a present limitation that has not

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ORIGINAL STUDIES

WILEY

Surgical versus transcatheter aortic valve replacement in low-risk patients: A long-term propensity score-matched analysis

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Abstract

Background: Recent studies suggest the use of transcatheter aortic valve implantation (TAVI) as an alternative to surgical aortic valve replacement (SAVR) in lower risk populations, but real-world data are scarce.

Methods: Single-center retrospective study of patients undergoing SAVR (between June 2009 and July 2016, $n = 682$ patients) or TAVI (between June 2009 and July 2017, $n = 400$ patients). Low surgical risk was defined as EuroSCORE II (ES II) < 4% for single noncoronary artery bypass graft procedure. TAVI patients were propensity score-matched in a 1:1 ratio with SAVR patients, paired by age, New York Heart Association class, diabetes mellitus, chronic obstructive pulmonary disease, atrial fibrillation, creatinine clearance, and left ventricular ejection fraction < 50%.

Results: A total of 158 patients (79 SAVR and 79 TAVI) were matched (mean age 79 ± 6 years, 79 men). TAVI patients had a higher incidence of permanent pacemaker implantation (0% vs. 19%, $p < 0.001$) and more than mild paravalvular leak (4% vs. 18%, $p = 0.009$), but comparable rates of stroke, major or life-threatening bleeding, emergent cardiac surgery, new-onset atrial fibrillation, and need for renal replacement therapy. Hospital length-of-stay and 30-day mortality were similar. At a median follow-up of 4.5 years (IQR 3.0–6.9), treatment strategy did not influence all-cause mortality (HR 1.19, 95% CI 0.77–1.83, log rank $p = 0.43$) nor rehospitalization (crude subdistribution HR 1.56, 95% CI 0.71–3.41, $p = 0.26$). ES II remained the only independent predictor of long-term all-cause mortality (adjusted HR 1.40, 95% CI 1.04–1.90, $p = 0.029$).

Abbreviations: AF, atrial fibrillation; AS, aortic stenosis; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; ES II, EuroSCORE II; HR, hazard ratio; IQR, interquartile range; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PPM, permanent pacemaker; PVL, paravalvular leak; RCT, randomized clinical trial; RRT, renal replacement therapy; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium; 95% CI, 95% confidence interval.

Manuscript #32

Original Contribution

Gender Differences and Mortality Trends After Transcatheter Aortic Valve Implantation: A 10-Year Analysis From a Single Tertiary Center

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Abstract

Aim. To evaluate gender differences and mortality trends in a population undergoing transcatheter aortic valve implantation (TAVI) and to analyze the correlates to all-cause mortality at follow-up. **Methods.** The study comprises a prospective cohort of 592 TAVI patients (53.4% female) treated between 2008 and 2018. Mortality differences between genders at different timepoints were assessed according to log rank test. Predictors of all-cause mortality at follow-up were identified using a univariate model and were then analyzed through multivariate Cox proportional hazard models. **Results.** Compared with female patients, males were younger (81 ± 7.5 years vs 84.3 ± 5.3 years) and presented more comorbidities. Twelve female and 8 male patients (3.5%) died in the first 30 days after TAVI. Despite a higher Society of Thoracic Surgeons (STS) score in women, all-cause mortality rates at 30 days and 1 year were comparable. At long-term follow-up, female patients demonstrated better survival rates, despite a higher number of periprocedural complications. Correlates identified in men were the presence of diabetes and previous history of coronary artery bypass grafting, New York Heart Association class III/IV, pulmonary artery systolic pressure, and non-transfemoral access. None of these variables remained significant in the multivariable analysis. In females, only peripheral artery disease was associated with mortality. Shock and need for renal replacement were predictors of mortality in both genders, as was heart failure readmission after discharge. STS score was also shown to correlate with long-term mortality in both genders. **Conclusion.** Despite a higher STS score in women, 30-day mortality was not significantly different from men, while women present better clinical outcomes at long-term follow-up.

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Key words: aortic stenosis, gender differences, TAVI mortality, transcatheter aortic valve implantation

Aortic stenosis is the most common valvular heart disease in developed countries, and its impact on public health and healthcare resources is expected to increase due to the aging population.[1]

Transcatheter aortic valve implantation (TAVI) is now an alternative to conventional cardiac surgery therapy for patients presenting symptomatic aortic stenosis in all settings of risk. In the European countries, predicted numbers point to 114,757 TAVI candidates annually and 58,556 in North America.[2]

Percutaneous valve treatment offers substantial reductions in mortality and improvement in quality of life compared with medical therapy[3,4] and has shown at least similar long-term outcomes compared with surgical aortic valve replacement (SAVR)[5-7] even in patients presenting low surgical risk.[8-10] Current mortality in TAVI trials with new-generation valves ranges from 1% to 2.4%[8,9] vs 3.5% in SAVR[11] in patients at low surgical risk, and 10%[12] in TAVI vs >12% in SAVR patients at high risk.[13] Long-term follow-up of TAVI cases from real-world tertiary European centers is not available, particularly in cohorts in which female patients are the majority. Female gender has been associated with higher operative mortality after SAVR,[14] yet previous reports are

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Predictors and Clinical Impact of Prosthesis-Patient Mismatch After Self-Expandable TAVR in Small Annuli

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ABSTRACT

OBJECTIVES The aim of this study was to define predictors of prosthesis-patient mismatch (PPM) and its impact on mortality after transcatheter aortic valve replacement (TAVR) with self-expandable valves (SEVs) in patients with small annuli.

BACKGROUND TAVR seems to reduce the risk for PPM compared with surgical aortic valve replacement, especially in patients with small aortic annuli. Nevertheless, predictors and impact of PPM in this population have not been clarified yet.

METHODS Predictors of PPM and all-cause mortality were investigated using multivariable logistic regression analysis from the cohort of the TAVI-SMALL (International Multicenter Registry to Evaluate the Performance of Self-Expandable Valves in Small Aortic Annuli) registry, which included patients with severe aortic stenosis and small annuli (annular perimeter <72 mm or area <400 mm^2 on computed tomography) treated with transcatheter SEVs: 445 patients with (n = 129) and without (n = 316) PPM were enrolled.

RESULTS Intra-annular valves conferred increased risk for PPM (odds ratio [OR]: 2.36; 95% confidence interval [CI]: 1.16 to 4.81), while post-dilation (OR: 0.46; 95% CI: 0.25–0.84) and valve oversizing (OR: 0.53; 95% CI: 0.28–1.00) seemed to protect against PPM occurrence. At a median follow-up of 354 days, patients with severe PPM, but not those with moderate PPM, had a higher all-cause mortality rate compared with those without PPM (log-rank p = 0.008). Multivariable Cox regression confirmed severe PPM as an independent predictor of all-cause mortality (hazard ratio: 4.27; 95% CI: 1.34 to 13.6).

CONCLUSIONS Among patients with aortic stenosis and small aortic annuli undergoing transcatheter SEV implantation, use of intra-annular valves yielded higher risk for PPM; conversely, post-dilation and valve oversizing protected against PPM occurrence. Severe PPM was independently associated with all-cause mortality.
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Manuscript #34

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves

The TRANSIT International Project

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BACKGROUND: Transcatheter aortic valve replacement (TAVR) has determined a paradigm shift in the treatment of patients with severe aortic stenosis. However, the durability of bioprostheses is still a matter of concern, and little is known about the management of degenerated TAV. We sought to evaluate the outcomes of patients with a degenerated TAV treated by means of a second TAVR.

METHODS: The TRANSIT is an international registry that included cases of degenerated TAVR from 28 centers. Among around 40 000 patients treated with TAVR in the participating centers, 172 underwent a second TAVR: 57 (33%) for a mainly stenotic degenerated TAV, 97 (56%) for a mainly regurgitant TAV, and 18 (11%) for a combined degeneration. Overall, the rate of New York Heart Association class III/IV at presentation was 73.5%.

RESULTS: Valve Academic Research Consortium 2 device success rate was 79%, as a consequence of residual gradient (14%) or regurgitation (7%). At 1 month, the overall mortality rate was 2.9%, while rates of new hospitalization and New York Heart Association class III/IV were 3.6% and 7%, respectively, without significant difference across the groups. At 1 year, the overall mortality rate was 10%, while rates of new hospitalization and New York Heart Association class III/IV were 7.6% and 5.8%, respectively, without significant difference across the groups. No cases of valve thrombosis were recorded.

CONCLUSIONS: Selected patients with a degenerated TAV may be safely and successfully treated by means of a second TAVR. This finding is of crucial importance for the adoption of the TAVR technology in a lower risk and younger population.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT04500964.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: bioprosthesis ■ heart failure ■ transcatheter aortic valve replacement

See Editorial by Barbanti and Costa

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Manuscript #35

Original Article

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Percutaneous vs surgical axillary access for transcatheter aortic valve implantation: the TAXI registry

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PDF **Supplementary Materials**

BACKGROUND: Transcatheter aortic valve implantation (TAVI) is an established management strategy for severe aortic valve stenosis. Percutaneous axillary approach for TAVI holds the promise of improving safety without jeopardizing effectiveness in comparison to surgical access. We aimed at appraising the comparative effectiveness of percutaneous vs surgical axillary approaches for TAVI.
METHODS: We performed an international retrospective observational study using de-identified details on baseline, procedural, and 1-month follow-up features. Valve Academic Research Consortium (VARC)-3 criteria were applied throughout. Outcomes of interest were clinical events up to 1 month of follow-up, compared with unadjusted and propensity score-adjusted analyses.
RESULTS: A total of 432 patients were included, 189 (43.8%) receiving surgical access, and 243 (56.2%) undergoing percutaneous access. Primary hemostasis failure was more common in the percutaneous group (13.2% vs 4.2%, p<0.001), leading to more common use of covered stent implantation (13.2% vs 3.7%, p<0.001). Irrespectively, percutaneous access was associated with shorter hospital stay (-2.6 days [95% confidence interval: -5.0; -0.1], p=0.038), a lower risk of major adverse events (a composite of death, myocardial infarction, stroke, type 3 bleeding, and major access-site related complication; odds ratio=0.44 [0.21; 0.95], p=0.036), major access-site non-vascular complications (odds ratio=0.21 [0.06; 0.77], p=0.018), and brachial plexus impairment (odds ratio=0.16 [0.03; 0.76], p=0.021), and shorter hospital stay (-2.6 days [-5.0; -0.1], p=0.038).
CONCLUSIONS: Percutaneous axillary access provides similar or better results than surgical access in patients undergoing TAVI with absolute or relative contraindications to femoral access.

KEY WORDS: Access; Aortic stenosis; Axillary; Transcatheter aortic valve implantation; Transcatheter aortic valve replacement

Manuscript #36

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Original article

Iberian experience with PASCAL transcatheter edge-to-edge repair for mitral valve regurgitation

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Mitral valve insufficiency
Transcatheter edge-to-edge repair
Pascal device
Cardiac catheterization
Heart failure

ABSTRACT

Introduction and objectives: The PASCAL system is a novel device for transcatheter mitral valve repair based on the edge-to-edge concept. The unique features of this device might have a relevant impact on the repair outcomes. There are few data on clinical outcomes in real-life registries. The aim of this study was to report the early Iberian experience (Spain and Portugal) of the PASCAL system.
Methods: Procedural and 30-day outcomes were investigated in consecutive patients with symptomatic severe mitral regurgitation (MR) treated with the PASCAL system at 10 centers. Primary efficacy endpoints were technical success and degree of residual MR at discharge. The primary safety endpoint was the rate of major adverse events (MAE) at 30 days.
Results: We included 68 patients (age, 75 [68-81] years; 38% women; EuroSCORE II 4.5%). MR etiology was degenerative in 25%, functional in 65%, and mixed in 10%. A total of 71% of patients were in New York Heart Association (NYHA) functional class ≥ III. Technical success was achieved in 96% and independent capture was used in 73% of procedures. In the treated population, MR at discharge was ≤ 2+ in 100%, with no in-hospital deaths. At 30 days, the MAE rate was 5.9%, the all-cause mortality rate was 1.6%, 98% were in NYHA functional class ≤ II, and 95% had MR ≤ 2+ ($P < .001$).
Conclusions: Transcatheter mitral valve repair with the PASCAL system was safe and effective, with high procedural success and low rates of MAE. At 30 days, MR was significantly reduced, with a significant improvement in functional status.

Experiencia ibérica con PASCAL para la reparación percutánea borde a borde en insuficiencia mitral

Palabras clave:
Insuficiencia mitral
Reparación percutánea borde a borde
Dispositivo PASCAL

RESUMEN

Introducción y objetivos: PASCAL es un dispositivo novedoso de terapia mitral transcatéter basada en la reparación borde a borde. Algunas características únicas podrían tener un impacto relevante en sus resultados. Hay pocos datos sobre los resultados clínicos en registros de la vida real. El objetivo de este estudio es publicar la experiencia ibérica precoz (centros de España y Portugal) del sistema PASCAL.
Métodos: Se incluyó prospectivamente a los pacientes tratados consecutivamente de insuficiencia mitral (IM) grave sintomática en 10 centros. El objetivo primario de eficacia fue el éxito técnico y el grado de regurgitación al alta. El objetivo primario de seguridad fueron los eventos adversos mayores (MAE) a 30 días.

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COMENTÁRIO EDITORIAL

Na cauda do cometa. Limitações para implantação de válvulas aórticas percutâneas transcatéter em Portugal

Trailing behind: Limitations on transcatheter aortic valve implantation in Portugal

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Disponível na Internet a 29 de março de 2013

As válvulas aórticas percutâneas (VAP) transcatéter constituem uma inovação terapêutica sem paralelo na última década cardiológica. Desde a primeira válvula desenvolvida por Andersen em 1989 passaram duas décadas até ao primeiro estudo aleatorizado. Aos 24 meses de seguimento observou-se um decréscimo absoluto de mortalidade de 51% sob terapêutica médica para 31% após implantação de VAP[1–4]. Após a primeira implantação humana por Cribier em 2002, Webb introduziu a via retrógrada em 2005 e Walther a via transapical em 2006, verificando-se um crescimento meteórico da técnica desde então[5–7]. Este rápido progresso permitiu alcançar uma mortalidade aos 30 dias situada entre os 6,5 e os 9,7%[8–10], ainda em trajetória descendente, traduzida igualmente em ganhos significativos na qualidade de vida[11,12].

Na Europa há assimetrias consideráveis no acesso ao tratamento transcatéter desta patologia grave, com destaque para a realidade portuguesa[13,14]. A prevalência da estenose aórtica aumenta com a idade, pelo que, considerando uma prevalência de 3,4% de estenose aórtica nos 924 000 portugueses com mais de 75 anos, haverá cerca de 32 000 portadores de estenose grave, sendo 75% sintomáticos (n = 24 000)[15]. Admitindo que são elegíveis para VAP cerca de 40% dos doentes considerados inoperáveis e 80% dos doentes de alto risco, conclui-se que existem 4600 indivíduos nestas circunstâncias[16]. Os dados portugueses evidenciam que, nos últimos 5 anos, foram realizados 265 procedimentos, correspondentes a 5% dos candidatos.

Portugal apresenta a menor taxa anual de implantes por milhão de habitantes da União Europeia, 7 *versus* uma média 45. A adoção das recomendações conjuntas de 2012 de cardiologistas, cardiologistas de intervenção e cirurgiões para a doença valvular pode vir a reduzir este desfasamento paradigmático da mudança que estamos a viver[17]. Relativamente à estenose aórtica, há três áreas em que estas orientações revelam especial importância:

1. No rastreio e diagnóstico, que deve ser mais preciso e atempado:
   a. ao nível dos doentes e da medicina familiar, designadamente na valorização das queixas muito comuns nestas idades, tais como o dispneia de esforço, a astenia e as tonturas;
   b. no diagnóstico ecocardiográfico, viciado pela não realização de Doppler em muitos casos.
2. Nas indicações terapêuticas apropriadas, favorecendo a implantação cirúrgica ou percutânea de próteses em detrimento da terapêutica médica isolada:
   a. pela referenciação adequada pelos cardiologistas, podendo incluir estenoses valvulares aórticas graves que surgem em doentes que parecem «assintomáticos» e especialmente aqueles que têm demasiadas comorbilidades que limitam a sua qualidade de vida e/ou inibem a referenciação para a substituição valvular[18];

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POSITION STATEMENT

Position statement on transcatheter aortic valve implantation in Portugal☆

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KEYWORDS
Aortic stenosis;
Transcatheter aortic valve implantation;
Recomendations;
Consensus;
Experts;
Working group

Abstract
Objective: To evaluate the clinical indications and guidelines for transcatheter aortic valve implantation (TAVI) and to propose adaptations for its use in Portugal.
Methods and Results: The working group analyzed the epidemiology of aortic stenosis and current clinical recommendations in the light of current evidence, taking into consideration their own experience in Portugal.

The evidence shows that TAVI significantly reduces mortality in patients with severe aortic stenosis considered unsuitable for surgery. This technique has a comparable safety profile, efficacy and quality of life improvement to conventional surgery in patients with high surgical risk, when carefully selected by multidisciplinary teams.

TAVI procedures should be performed within multidisciplinary programs in centers with on-site cardiac surgery by experienced teams treating no fewer than 50 cases per year in order to maintain proficiency.

The technique is little used in Portugal, with seven implantations/year per million population, a seventh of the European average and the lowest rate in Europe.

From a societal standpoint, it is important to evaluate clinical outcomes and analyze the incremental cost involved in order to define the situations in which the technique is appropriate and should be used.

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REVISTA PORTUGUESA DE CIRURGIA CARDIO-TORÁCICA E VASCULAR

CIRURGIA CARDIO-TORÁCICA

VÁLVULA AÓRTICA PERCUTÂNEA TRANSAPICAL: 5 ANOS DE EXPERIÊNCIA

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Trabalho galardoado com o Prémio Nacional Machado Macedo no decurso da XVª Reunião da Sociedade Portuguesa de Cirurgia Cardio-Torácica e Vascular, Santa Eulália, Algarve, Novembro de 2013

Resumo

Objectivos: A implantação de próteses valvulares transcatéter (VAP) por via transapical é uma terapêutica aceite para a estenose aórtica grave de alto risco para a cirurgia convencional. Reportam-se os resultados clínicos iniciais da técnica num centro de referência.

Métodos: Realizámos um estudo prospectivo longitudinal de centro único incluindo 54 doentes consecutivos (idade média 79±7,5 anos, 59% masculinos) submetidos, entre novembro 2008 e outubro 2013, a implantação de VAP Edwards Sapien por via transapical.

A indicação foi estenose aórtica nativa em 83% (gradiente médio=49±18,3mmHg e área=0,7cm^2), 11% doença aórtica e em 3 doentes próteses valvulares biológicas degeneradas, estando 65% em classe III/IV NYHA. As principais comorbidades eram doença coronária em 56% (status pós-cirurgia coronária em 37%), diabetes (37%), doença arterial periférica (31%) e insuficiência renal crónica (24%). O Euroscore logístico do grupo foi 19,8±11,2 e o Euroscore II 5,5%±3,5 com score STS mortalidade 5,1±3,7 e STS morbilidade 23,7±7,6.

Resultados: Análise seguindo os critérios VARC-2 (Valve Academic Research Consortium), com mortalidade aos 30 dias de 5,6%; EAM peri-procedimento 7,4%; acidente vascular cerebral incapacitante 1,9%; hemorragia grave 14,8%; complicações vasculares major 5,6%; implantação de pacemaker 11%. Utilizou-se circulação extra corporal não planeada em 5 casos e ocorreu disfunção protésica em 4 doentes (deslocamento de válvula em 2 casos). A mediana do internamento foi de 8,0 dias, com re-hospitalização em 12,2% dos casos. Os *endpoints* compostos VARC-2 foram: sucesso do dispositivo=90,7%; segurança precoce=75,9% e eficácia clínica após 30 dias=83,7%.

Conclusão: A abordagem transapical constituiu uma terapêutica eficaz para doentes de alto risco para a cirurgia convencional.

Summary

Transapical aortic valve replacement: A 5-years experience

Objectives: Transcatheter aortic valve replacement (TAVR) by transapical approach is accepted for severe aortic stenosis in patients with high risk for conventional surgical therapy. Herein is reported the initial clinical results of this technique in a reference center.

Methods: We conducted a longitudinal prospective single center study including 54 consecutive patients (mean age 79±7.5 years, 59% male) who underwent, between November 2008 and October 2013, TAVR with Edwards Sapien valves throught transapical approach.

The etiology was native aortic stenosis in 83% (mean gradient=49±18,3mmHg and area=0,7cm2), 11% aortic disease and 3 patients had degenerated biological valvular prostheses, being 65% in class III / IV NYHA. The major comorbidities were

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ORIGINAL ARTICLE

Late results (>10 years) of intracoronary beta brachytherapy for diffuse in-stent restenosis☆

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KEYWORDS
Beta radiation;
Brachytherapy;
Restenosis;
Coronary disease

Abstract
Introduction: Until the development of drug-eluting stents (DES), diffuse in-stent restenosis (ISR) was the main limitation of bare-metal stents in percutaneous coronary intervention (PCI). Among the different treatments available, intracoronary brachytherapy (BT) emerged as one of the most promising, although it was almost abandoned with the increasing use of DES.
Objective: To assess the Portuguese experience with $^{90}Sr/^{90}Y$ beta brachytherapy for the treatment of diffuse ISR regarding long-term (>10 years) major adverse cardiac events (MACE) and angiographic restenosis.
Methods: This single-center, retrospective, observational study included 12 consecutive patients treated between January and June 2001, mean age 58.6±9.9 years (range 43–77 years), 11 male. All had chronic stable angina, 75% had dyslipidemia, 58% had hypertension, 50% had peripheral arterial disease, 42% had diabetes and 50% had multivessel disease. Recurrent ISR was present in half of the patients and 11 had normal left ventricular function. After balloon dilatation, BT was performed using an $^{90}Sr/^{90}Y$ (Novoste Beta-Cath™) beta radiation source. All patients remained under dual antiplatelet therapy until scheduled nine-month follow-up angiography. Patients were followed for the occurrence of death (all-cause and cardiovascular), non-fatal myocardial infarction (MI), revascularization, stent thrombosis and angiographic restenosis. MACE were defined as the combined incidence of cardiac death, MI and urgent target vessel revascularization.
Results: In all cases there was both clinical and angiographic success. In a mean follow-up of 10.9±2.5 years, 19 events occurred in seven patients: death in three (25%), only one cardiac

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ELSEVIER

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ORIGINAL ARTICLE

Aortic valve replacement for severe aortic stenosis in octogenarians: Patient outcomes and comparison of operative risk scores

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KEYWORDS
Aortic valve surgery;
Aortic stenosis;
Octogenarians;
Risk assessment;
EuroSCORE;
STS score

Abstract
Introduction and Aim: Isolated aortic valve replacement (AVR) in octogenarians is associated with increased operative risk, due to higher prevalence of associated risk factors and other comorbidities, making outcome prediction essential. We sought to analyze operative mortality and morbidity and to compare the predictive accuracy of the logistic European System for Cardiac Operative Risk Evaluation score (EuroSCORE) I, EuroSCORE II and Society of Thoracic Surgeons (STS) score in this population.
Methods: We retrospectively enrolled 106 consecutive octogenarians with symptomatic severe aortic stenosis undergoing isolated AVR in a large-volume single center between January 2003 and December 2010 and calculated surgical risk scores.
Results: Mean logistic EuroSCORE I, EuroSCORE II and STS score were 14.6±11, 4.4±3.1 and 4.0±2.4%, respectively. Mean operative mortality was 5.7% (six patients). Two (1.9%) patients suffered an ischemic stroke, three (2.8%) required temporary hemodialysis and five (4.7%) had a permanent pacemaker implanted. Five (4.7%) required rethoracotomy. No myocardial infarction or sternal wound infection was observed. Calibration-in-the-large showed overestimation of operative mortality with logistic EuroSCORE I (p=0.036), whereas EuroSCORE II (p=1.0) and STS (p=1.0) showed good calibration. C-statistic values were 0.877 (95% CI 0.800–0.933) for logistic EuroSCORE I, 0.792 (95% CI 0.702–0.864) for EuroSCORE II and 0.702 (95% CI 0.605–0.787) for STS, without statistically significant differences.

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ARTIGO ORIGINAL

Evolução da intervenção coronária percutânea entre 2004-2013. Atividade em Portugal segundo o Registo Nacional de Cardiologia de Intervenção

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EDITORIAL COMMENT

Risk assessment in percutaneous coronary intervention and appropriate use criteria: Manual or automatic?☆

Avaliação do risco e uso apropriado da intervenção coronária percutânea. Portagem manual ou via verde eletrónica automática?

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Available online 17 February 2016

Coronary artery disease is the leading cause of death in developed countries. Percutaneous coronary intervention (PCI) alleviates patients' symptoms and in many cases reduces mortality in settings of cardiac decompensation, particularly acute coronary syndromes (ACS).[1]

In the thirty years since PCI was introduced in Portugal, its indications have widened following improvement in techniques and results, and now include more complex and higher-risk situations. Advances have been seen in drug-eluting stents, adjuvant therapy, arterial access, imaging and understanding of the underlying physiology.[2]

The benefits of PCI must be weighed against the risk associated with intervention, which depends on clinical and angiographic variables. The ability to predict the outcome for a patient before and after PCI is extremely useful, in order to assess individual risk, to counsel patients and their families, and to plan revascularization strategies.[3–5] It also helps in identifying opportunities to improve quality and in comparing results between centers and operators.

The main requirements for cardiovascular risk scores are accessibility, ease and speed of use, ability to integrate with the institution's computer systems, and low cost. Risk scores must be validated, ideally for both short-term and long-term application (up to five years).

Most existing risk scores for PCI have significant limitations. The most widely used in interventional cardiology is the SYNTAX score, both the original and the updated clinical SYNTAX score, which are referred to in the European guidelines but can be complex and laborious to calculate, while the EuroSCORE II uses clinical variables and is easy to calculate. Both have been the subject of extensive external validation.[6–11] A variety of other interesting risk scores have been developed, but with limited applicability and external validation (especially in European populations), and with outcome restricted to in-hospital adverse events.[12]

The article by Timóteo et al. in this issue of the *Journal* is timely, specifically addressing these limitations and analyzing the role of risk scores derived from populations with ACS.[13] It concludes that the Global Registry of Acute Coronary Events (GRACE) score is to be preferred to the Mayo Clinic risk score (MCRS) and the National Cardiovascular Data Registry (NCDR) risk score for predicting in-hospital mortality in Portuguese patients undergoing PCI, mainly for ST-elevation myocardial infarction (STEMI).

The study population was large, reflecting the experience of a reference center between January 2005 and October 2013.

The proportion of STEMI was high (70.9%), which explains the demographic and clinical differences between this population and others, both Portuguese and non-Portuguese, used to derive risk scores, which had a lower prevalence of comorbidities that are generally associated with greater clinical complexity.[14–16]

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CASE REPORT

Sequential transcatheter aortic valve implantation due to valve dislodgement - a Portico valve implanted over a CoreValve bioprosthesis

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KEYWORDS
Severe aortic stenosis;
Transcatheter aortic valve implantation complications;
Valve dislocation

Abstract Transcatheter aortic valve implantation (TAVI) has become an important treatment in high surgical risk patients with severe aortic stenosis (AS), whose complications need to be managed promptly.

The authors report the case of an 86-year-old woman presenting with severe symptomatic AS, rejected for surgery due to advanced age and comorbidities. The patient underwent a first TAVI, with implantation of a Medtronic CoreValve®, which became dislodged and migrated to the ascending aorta. Due to the previous balloon valvuloplasty, the patient's AS became moderate, and her symptoms improved. After several months, she required another intervention, performed with a St. Jude Portico® repositionable self-expanding transcatheter aortic valve. There was a good clinical response that was maintained at one-year follow-up.

The use of a self-expanding transcatheter bioprosthesis with repositioning features is a solution in cases of valve dislocation to avoid suboptimal positioning of a second implant, especially when the two valves have to be positioned overlapping or partially overlapping each other.

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COMENTÁRIO EDITORIAL

Valvuloplastia aórtica de balão na era das válvulas aórticas percutâneas. Um desafio à dimensão organizativa dos programas multidisciplinares

Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era: A challenge to organization of the heart team

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A intervenção por valvuloplastia aórtica de balão (VAoB) foi introduzida por Cribier em 1986 e sofreu um recrudescimento na era das válvulas aórticas percutâneas (VAP)[1,2]. Devido ao treino e evolução técnica do procedimento, a VAoB é hoje em dia mais segura, com uma mortalidade periprocedimento de 2,2%, uma mortalidade hospitalar de 7,1% e taxas de acidentes cerebrovasculares de 1,1%, de insuficiência aórtica *major* de 1,1% e de complicações vasculares *major* de 7,0%. Isto apesar dos doentes atuais serem mais complexos e dos resultados hemodinâmicos permanecerem modestos[3,4].

Perante a alternativa da VAP, o principal desafio contemporâneo da VAoB prende-se com a dimensão organizativa dos programas multidisciplinares para a estenose aórtica, que constitui a principal doença valvular nos países desenvolvidos. Atualmente, existem em Portugal cerca de um milhão de indivíduos com mais de 75 anos, apresentando cerca de 3,4% uma estenose aórtica grave, sendo sintomáticos cerca de 75%[5]. Destes 25 000 portugueses, cerca de 4500 terão indicação para implantação de uma VAP por alto risco ou inoperabilidade, segundo as recomendações sobre a doença valvular[6–8]. O registo nacional de VAP apresenta, desde 2007 a 2015, cerca de 850 implantes, tendo sido realizados 300 no último ano. Embora não haja registo nacional de cirúrgica cardíaca, estima-se que em 2015 tenham sido realizadas cerca de 2000 cirurgias valvulares aórticas, simples ou com pontagem (CVAo). Como tal, o *ratio* VAP/CVAo é de 1:6, enquanto muitos países da Europa estão no 1:1[5,9].

A pressão assistencial tem subido e os programas multidisciplinares de válvulas percutâneas (VaP) têm que se adaptar ao enorme acréscimo de volume e aos doentes que não são primordialmente para VAP. Assim, as grandes questões atuais são:

1. **A avaliação *fasttrack***: a capacidade de se organizar a avaliação clínica e complementar principal em apenas duas ou três sessões (consulta de cardiologia e cirurgia, análises, angio CT, ecocardiograma com eventual transesofágico, cateterismo com eventual angioplastia);
2. **As indicações para VAoB em 2017**: as recomendações atuais nos adultos (classe IIb, da *European Society of Cardiology* e do *American College of Cardiology/American Heart Association*) não refletem a evolução dos resultados na era das VAP[8,10]. Dado que potencialmente muitas das complicações se replicam quando se faz inicialmente a VAoB e mais tarde a VAP, há que refletir em que condições é aceitável sujeitar o doente ao risco acrescido:
   a. Uma VAoB será apenas aceitável em caso de paleação de sintomas graves (uso por compaixão); ou como ponte paliativa devida a uma comorbilidade grave, seja temporária ou tenha ela um prognóstico indefinido e/ou uma expetativa de longevidade

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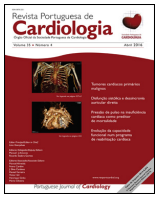

ORIGINAL ARTICLE

Advantages of a prospective multidisciplinary approach in transcatheter aortic valve implantation: Eight years of experience

Cátia Costa[a,b,*], Rui Campante Teles[a,g], João Brito[a], José Pedro Neves[c], Henrique Mesquita Gabriel[a], Miguel Abecassis[c], Regina Ribeiras[a], João Abecasis[a,g], Tiago Nolasco[c], Maria da Conceição Furstenau[d], Nélson Vale[a], António Tralhão[a], Sérgio Madeira[a], João Mesquita[a], Carla Saraiva[e], Rita Calé[a,f], Manuel Almeida[a,g], Ana Aleixo[g], Miguel Mendes[a]

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KEYWORDS
Severe aortic stenosis;
Transcatheter aortic valve implantation;
Surgical aortic valve replacement;
Heart team;
Standardization

Abstract
Introduction: Aortic stenosis is the most prevalent type of valvular disease in Europe. Surgical aortic valve replacement (SAVR) is the standard therapy, while transcatheter aortic valve implantation (TAVI) is an alternative in patients at unacceptably high surgical risk. Assessment by a heart team is recommended by the guidelines but there is little published evidence on this subject. The purpose of this paper is to describe the experience of a multidisciplinary TAVI program that began in 2008.
Methods: The heart team prospectively assessed 473 patients using a standardized approach. A total of 214 patients were selected for TAVI and 80 for SAVR. Demographic, clinical and procedural characteristics and long-term success rates were compared between the groups.
Results: TAVI patients were older than the SAVR group (median 83 vs. 81 years), and had higher surgical risk scores (median EuroSCORE II 5.3 vs. 3.6% and Society of Thoracic Surgeons score 5.1 vs. 3.1%), as did the patients under medical treatment only. These scores were unable to assess multiple comorbidities. Patients' outcomes were different between the three groups (mortality with SAVR 25% vs. TAVI 37.6% vs. conservative therapy 57.6%, p=0.001).

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ORIGINAL ARTICLE

Post-procedural N-terminal pro-brain natriuretic peptide predicts one-year mortality after transcatheter aortic valve implantation

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KEYWORDS
Transcatheter aortic valve replacement;
Aortic valve stenosis;
N-terminal pro-BNP;
Prognosis

Abstract
Introduction: Natriuretic peptides are ubiquitously used for diagnosis, follow-up and prognostic assessment in various heart conditions. N-terminal pro-brain natriuretic peptide (NT-proBNP) correlates with aortic stenosis severity, however its significance after transcatheter aortic valve implantation (TAVI) is not well established.
Aim: We aimed to assess the prognostic value of NT-proBNP at one year in patients undergoing TAVI.
Methods: This single-center retrospective analysis included 151 patients in whom both baseline and one-month post-procedure NT-proBNP were measured, from 206 consecutive patients undergoing TAVI between November 2008 and December 2014. The best cut-off values of both baseline and one-month post-TAVI NT-proBNP for one-year mortality were determined by receiver operating characteristic curve analysis. Independent predictors of one-year mortality were assessed by Cox regression.
Results: The areas under the curve of baseline and post-procedural NT-proBNP for one-year mortality were 0.60 and 0.72, with the best cut-off values of 1350 and 2500 pg/ml, respectively. Atrial fibrillation, procedure-related major bleeding, baseline NT-proBNP higher than 1350 pg/ml, post-procedural NT-proBNP higher than 2500 pg/ml, higher creatinine and Society of Thoracic Surgeons score, and lower left ventricular ejection fraction were associated with one-year mortality. Only post-procedural NT-proBNP was independently and negatively associated with one-year survival (HR 5.9, 95% CI 1.6-21.7, p=0.008).

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ORIGINAL ARTICLE

Comparison of multiparametric risk scores for predicting early mortality after transcatheter aortic valve implantation

João Carmo[a,*], Rui Campante Teles[a], Sérgio Madeira[a], António Ferreira[a], João Brito[a], Tiago Nolasco[b], Pedro de Araújo Gonçalves[a], Henrique Mesquita Gabriel[a], Luís Raposo[a], Nelson Vale[a], Regina Ribeiras[a], Miguel Abecasis[b], Manuel de Sousa Almeida[a], José Pedro Neves[b], Miguel Mendes[a]

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Received 1 June 2017; accepted 13 September 2017
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KEYWORDS
Aortic stenosis;
Transcatheter aortic valve implantation;
Risk scores;
Early mortality

Abstract
Introduction: Surgical risk scores are widely used to identify patients at high surgical risk who may benefit from transcatheter aortic valve implantation (TAVI). A multiparametric TAVI mortality risk score based on a French registry (FRANCE-2) has recently been developed. The aim of our study was to compare the 30-day mortality prediction performance of the FRANCE-2, EuroSCORE II and STS scores.
Methods: We retrospectively studied 240 patients from a single-center prospective registry who underwent TAVI between January 2008 and December 2015. All scores were assessed for calibration and discrimination using calibration-in-the-large and ROC curve analysis, respectively.
Results: The observed mortality was 5.8% (n=14). The median EuroSCORE II, STS and FRANCE-2 scores were 5.0 (IQR 3.2-8.3), 5.1 (IQR 3.6-7.1) and 2.0 (IQR 1.0-3.0), respectively. Discriminative power was greater for EuroSCORE II (C-statistic 0.67) and STS (C-statistic 0.67) than for FRANCE-2 (C-statistic 0.53), but this was not statistically significant (p=0.26). All scores showed adequate calibration.
Conclusions: All scores showed modest performance in early mortality prediction after TAVI. Despite being derived from a TAVI population, FRANCE-2 was no better than surgical risk scores in our population.

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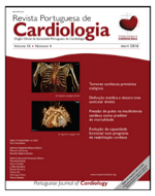

ARTIGO ORIGINAL

Quinze anos de ecografia intravascular coronária em intervenção coronária percutânea em Portugal

Rui Azevedo Guerreiro[a,*], Renato Fernandes[a], Rui Campante Teles[b,c], Pedro Canas da Silva[d], Hélder Pereira[e], Rui Cruz Ferreira[f], Marco Costa[g], Filipe Seixo[h], Pedro Farto e Abreu[i], João Luís Pipa[j], Luís Bernardes[k], Francisco Pereira Machado[l], José Palos[m], Eduardo Infante de Oliveira[n,o], Henrique Cyrne Carvalho[p], João Carlos Silva[q], Graça Caires[r], Dinis Martins[s], José Baptista[t], João Calisto[u], Rui Pontes dos Santos[v], Fernando Matias[w], João Costa[x], Paulino Sousa[y], Vasco Gama Ribeiro[z], António Fiarresga[f,o], João Brum da Silveira[p,aa] , em nome dos investigadores do Registo Nacional de Cardiologia de Intervenção-PCI

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CASE REPORT

Innovative transapical-transfemoral loop approach: First case of CoreValve implantation in a 19-mm Mitroflow during double valve-in-valve procedure

Rui Campante Teles[a], **Daniel Nascimento Matos**[a,*], **Miguel Abecasis**[b], **João Mesquita**[a], **Regina Ribeiras**[a], **José Pedro Neves**[b], **Manuel Almeida**[a], **Miguel Mendes**[a]

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Received 19 July 2017; accepted 8 October 2017

KEYWORDS
Aortic valve;
Mitral valve;
Bioprosthesis;
Valve-in-valve;
Heart failure;
Structural heart intervention

Abstract An 80-year-old woman with rheumatic valve disease and two previous cardiac surgeries was admitted for heart failure exacerbation. The patient presented stenotic aortic 19-mm Mitroflow and mitral 31-mm Carpentier-Edwards bioprostheses, and was deemed inoperable due to frailty and prohibitive surgical risk. The heart team decided on a compassionate double valve-in-valve procedure, with transfemoral implantation of a 23-mm aortic CoreValve Evolut R and transapical implantation of a 29-mm mitral Edwards SAPIEN 3. During the procedure, after extreme difficulty in retrograde crossing of the aortic valve, a transapical-transfemoral loop was successfully performed. The procedure was without complications and the patient was discharged in NYHA class II with normally functioning valves.

PALAVRAS-CHAVE
Válvula aórtica;
Válvula mitral;
Bioprótese;
Válvula-em-válvula;
Insuficiência cardíaca;
Intervenção estrutural cardíaca

Abordagem inovadora por ansa transapical-femoral: primeiro caso de implantação de Corevalve em Mitroflow 19 durante procedimento *valve-in-valve*

Resumo Uma mulher de 80 anos com valvulopatia reumática e duas cirurgias cardíacas prévias foi internada por insuficiência cardíaca agudizada. A doente apresentava estenose de biopróteses Mitroflow 19 em posição aórtica e Carpentier-Edwards 31 em posição mitral, sendo considerada inoperável devido a fragilidade e a risco cirúrgico proibitivo. A *Heart Team* decidiu por um duplo procedimento *valve-in-valve compassionate*: implantação de Corevalve Evolut R 23 em posição aórtica via transfemoral e de Edwards Sapiens 3 29 em posição mitral

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LETTER TO THE EDITOR

Caring for cardiac patients amidst the SARS-CoV-2 pandemic: The scrambled pieces of the puzzle

O doente cardiovascular durante a pandemia SARS-CoV2: As peças separadas do puzzle

The SARS-CoV-2 (COVID-19) pandemic is disrupting modern societies. By April 12, 2020, more than 1.5 million people had been infected and 114 197 had died worldwide as a result of SARS-CoV-2 infection.[1] The first case in Portugal was reported on March 2. National authorities then established and upgraded contingency measures culminating with the declaration of a state of emergency, for only the second time in almost 50 years of Portuguese democracy. By April 12, a total of 16 585 cases had been confirmed in Portugal; 504 individuals (3.0% of those confirmed as infected) had succumbed to COVID-19 and 228 (1.4%) were in the intensive care unit (ICU).[2]

Portuguese health system workers have been preparing for the expected rise in demand for emergency room (ER) visits and admissions to wards and the ICU. Medical departments and equipment have been adapted and

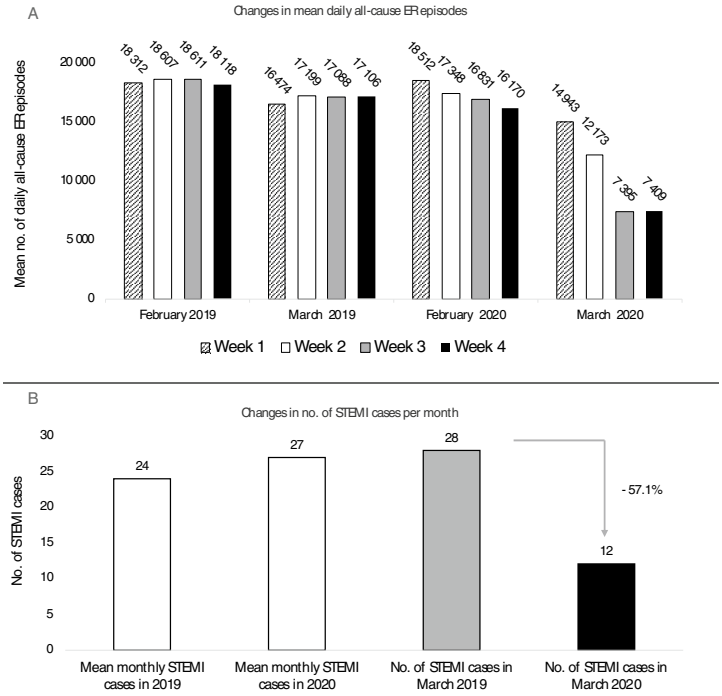

Figure 1 (A) Mean number of daily all-cause emergency room (ER) episodes in Portugal according to week number in February 2019, March 2019, February 2020, and March 2020; (B) number of admissions for ST-elevation myocardial infarction (STEMI) in a public sector tertiary hospital in Portugal, showing mean monthly STEMI admissions for all of 2019 and for January and February 2020 and total STEMI admissions in March 2019 and March 2020.

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EDITORIAL COMMENT

''A momentary lapse of opinion'': The reader should be aware of the iatrogenic potential of this publication

«Um lapso de opinião momentâneo»: O leitor deve estar consciente do potencial iatrogénico desta publicação

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Available online 23 August 2020

Aortic stenosis is the most frequent native valve disease in Europe, and as the elderly population increases, together with the high prevalence of comorbidities and the extension of indications to low-risk patients, the number of individuals requiring transcatheter aortic valve replacement (TAVR) is likely to increase substantially.[1–3]

Frailty, dependence and comorbidities affect the lives of some of these patients, raising the question whether the intervention justifies the economic cost. High-quality American and European analyses of TAVR have shown generally acceptable cost-effectiveness, with the higher cost of the procedure being offset by the considerable benefits in quality of life and survival. It is, however, important to examine the specifics at a national level, since large differences have been observed between countries.[4–8]

The article by Fontes-Carvalho et al. of the Centro Hospitalar de Vila Nova de Gaia in this issue of the *Journal*[9] points to the need to assess the cost-effectiveness and economic impact of the adoption of new technologies before their dissemination in clinical practice. In this case the time for this objective has passed, which since these authors are well respected I would suggest should be put down to a momentary lapse of opinion. In fact it is now 18 years since the first TAVR procedure was performed, and it was the Gaia Hospital group that introduced it to the Iberian peninsula in 2007.

The article is of interest because it assesses health technology in structural interventional cardiology from a national viewpoint. On the basis of detailed data from 2017 from a single center, it sets out to estimate the potential impact of expanding the indications for TAVR in three hypothetical scenarios, concluding that public expenditure on this treatment is likely to grow considerably. The authors suggest a centralized approach to the management of the required economic and clinical resources, as well as optimization of the procedure itself.

There are two questions that this study raises in 2020.

The first question is whether economic considerations are paramount for a technique that is considered the first-line treatment for high-risk patients and for which good evidence is emerging for low-risk individuals. The answer is no, for the following reasons:

a) Firstly, since 2017, not only has there been an increase of 33% in the number of TAVR procedures, but in line with

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ORIGINAL ARTICLE

Ten-year survival of patients undergoing coronary angioplasty with first-generation sirolimus-eluting stents and bare-metal stents

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KEYWORDS
Sirolimus-eluting stent;
Bare-metal stent;
Coronary intervention;
Coronary disease

Abstract
Introduction: Compared to bare-metal stents (BMS), drug-eluting stents reduce stent restenosis and improve subsequent revascularization rates. The impact on patients' survival has been the subject of debate.
Objective: To assess the long-term (10-year) survival of patients undergoing percutaneous coronary intervention (PCI) with first-generation sirolimus-eluting stents (SES) in comparison with BMS.
Methods: In a single-center registry, 600 consecutive patients who underwent successful PCI with SES between April 2002 and February 2003 were compared to 594 patients who underwent PCI with BMS between January 2002 and April 2002, just before the introduction of SES. Clinical and procedural data were collected at the time of intervention and 10-year survival status was assessed via the national life status database.
Results: All baseline characteristics were similar between groups except for smaller stent diameter (2.84±0.38 vs. 3.19±0.49 mm; p<0.001), greater stent length (18.50±8.2 vs. 15.96±6.10 mm; p<0.001) and higher number of stents per patient (1.95 vs. 1.46, p<0.001) in the SES group. Overall five- and 10-year all-cause mortality was 9.6% (n=110) and 22.7% (n=272), respectively. The adjusted HR for 10-year mortality in patients undergoing PCI with SES was 0.74 (95% CI 0.58-0.94; p=0.013), corresponding to a relative risk reduction of 19.8%. Other than PCI with BMS, older age, chronic kidney disease, chronic obstructive pulmonary disease and lower ejection fraction were independent predictors of 10-year mortality.

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ORIGINAL ARTICLE

Short and long-term clinical impact of transcatheter aortic valve implantation in Portugal according to different access routes: Data from the Portuguese National Registry of TAVI

Cláudio Guerreiro[a], Pedro Carrilho Ferreira[b], Rui Campante Teles[c,d,*], Pedro Braga[a], Pedro Canas da Silva[b], Lino Patrício[e], João Carlos Silva[f], José Baptista[g], Manuel de Sousa Almeida[c,d], Vasco Gama Ribeiro[h], Bruno Silva[i], João Brito[c,d], Eduardo Infante Oliveira[b], Duarte Cacela[e], Sérgio Madeira[c,d], João Silveira[j]

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Available online 28 November 2020

KEYWORDS
Severe aortic valvular disease;
TAVI;
Heart failure

Abstract
Introduction: The Portuguese National Registry of Transcatheter Aortic Valve Implantation records prospectively the characteristics and outcomes of transcatheter aortic valve implantation (TAVI) procedures in Portugal.
Objectives: To assess the 30-day and one-year outcomes of TAVI procedures in Portugal.
Methods: We compared TAVI results according to the principal access used (transfemoral (TF) vs. non-transfemoral (non-TF)). Cumulative survival curves according to access route, other procedural and clinical variables were obtained. The Valve Academic Research Consortium-2 (VARC-2) composite endpoint of early (30-days) safety was assessed. VARC-2 predictors of 30-days and 1-year all-cause mortality were identified.

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EDITORIAL COMMENT

My patient cannot or will not comply with oral anticoagulation. Do I cross my fingers or cross the septum?☆

O meu doente não pode, não quer ou não cumpre a anti-coagulação oral. Cruzo os dedos ou cruzo o septo?

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Atrial fibrillation (AF) is a prevalent disease that affects up to 3% of the population and accounts for 1–3% of health care costs due to stroke, sudden death, heart failure, unplanned hospitalizations and other complications.[1–3]

Once non-valvular AF is diagnosed, a multidisciplinary and multifaceted approach is required, including acute management, treatment of underlying and concomitant conditions, rate and rhythm control, and prevention of the most feared complication, stroke. The tendency for blood pooling in the left atrium and left atrial appendage (LAA) due to AF was first reported in 1996, and although oral anticoagulation with vitamin K antagonists and direct oral anticoagulants (DOACs) has significantly reduced stroke risk, up to 40% of patients with AF are untreated, due to intolerance, bleeding, or other contraindications.[1,4,5]

Left atrial appendage occlusion (LAAO) aims to perform complete mechanical blockage of the LAA, which is the anatomical origin of around 90% of the thrombi that cause stroke. The two main trials comparing LAAO with warfarin, PROTECT AF and PREVAIL, demonstrated that closure is non-inferior for the prevention of ischemic stroke and is superior for the prevention of cardiovascular and all-cause mortality.[2,5,6] However, the randomized clinical trials were restricted to a single device and did not include patients who were intolerant to anticoagulation. Percutaneous LAAO, like AF ablation, has not been properly assessed in randomized trials with the standard current comparator, DOACs, in terms of major cardiovascular events. There have, of course, been large observational studies that suggest a reduction in stroke risk compared with risk estimates such as the CHA_2DS_2-VASc score. These studies often included patients who were only prescribed antiplatelet agents or took no antiplatelet or anticoagulant agents at all following the implantation procedure.[6] Furthermore, there is no evidence that the presence of peri-device leak is associated with subsequent thromboembolic events, although these

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ORIGINAL ARTICLE

Adoption and patterns of use of invasive physiological assessment of coronary artery disease in a large cohort of 40 821 real-world procedures over a 12-year period

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KEYWORDS
Coronary physiology;
Fractional flow reserve;
Instantaneous wave-free ratio;
Coronary artery disease;
Adoption

Abstract
Introduction and Objectives: Use of invasive physiological assessment in patients with coronary artery disease varies widely and is perceived to be low. We aimed to examine adoption rates as well as patterns and determinants of use in an unselected population undergoing invasive coronary angiography over a long time frame.
Methods: We retrospectively determined the per-procedure prevalence of physiological assessment in 40 821 coronary cases performed between 2007 and 2018 in two large-volume centers. Adoption was examined according to procedure type and patient- and operator-related variables. Its association with relevant scientific landmarks, such as the release of clinical trial results and practice guidelines, was also assessed.
Results: Overall adoption was low, ranging from 0.6% in patients undergoing invasive coronary angiography due to underlying valve disease, to 6% in the setting of stable coronary artery disease (CAD); it was 3.1% in patients sustaining an acute coronary syndrome. Of scientific landmarks, FAME 1, the long-term results of FAME 2 and the 2014 European myocardial revascularization guidelines were associated with changes in practice. Publication of instantaneous wave-free ratio (iFR) trials had no influence on adoption rates, except for a higher proportion of iFR use. In 42.9% of stable CAD patients undergoing percutaneous coronary intervention

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ARTIGO DE REVISÃO

Tratamento não farmacológico da angina refratária. Dispositivo de redução do seio coronário, uma nova alternativa terapêutica

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PALAVRAS-CHAVE
Dispositivo de redução do seio coronário;
Terapia antianginosa não farmacológica;
Angina refratária;
Doença coronária

Resumo A angina refratária define-se como a persistência de sintomas superior a três meses apesar da terapêutica médica otimizada e revascularização. É uma entidade em crescimento, resultado da melhoria do prognóstico da doença coronária com a terapêutica farmacológica e com as técnicas de revascularização contemporâneas. A mortalidade a longo prazo enquadra-se no espetro prognóstico da doença estável assintomática, contudo interfere com a qualidade de vida do doente e tem um impacto significativo nos sistemas de saúde.

Múltiplos alvos terapêuticos têm sido investigados, contudo, a maioria com resultados dececionantes. Muitas das técnicas foram abandonadas por ausência de eficácia, problemas de segurança e limitações tanto logísticas como económicas à sua implantação.

Esta revisão incide essencialmente sobre o dispositivo de redução do seio coronário, cuja evidência, embora ainda escassa, é promissora relativamente à segurança e eficácia na redução dos sintomas anginosos e na melhoria da qualidade de vida. Para além do seu efeito terapêutico, é uma opção virtualmente acessível a todos os serviços de cardiologia de intervenção.

KEYWORDS
Coronary sinus reducer device;
Non-pharmacological antianginal therapy;

Non-pharmacological treatment of refractory angina: The coronary sinus reducer, the new kid on the block

Abstract Refractory angina is defined as persistent angina (≥3 months) despite optimal medical and interventional therapies. It is increasing in frequency, due to the success of current medical and interventional therapies in improving the prognosis of coronary artery disease.

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KEY RESULTS, SUMMARY AND CLINICAL IMPLICATIONS

8. Key Results, Summary and Clinical Implications

Transcatheter aortic valve interventions are the reflex of contemporary longevity and modern medicine. Their expansion became a reference model in the evolution of contemporary cardiology and cardiac surgery, inducing changes that are transposed to other structural heart disease intervention areas. . The current work illustrates the systematic approach that was set in place to meet patient needs as well as to support and stimulate the institutional and national progress in this area (Figure)

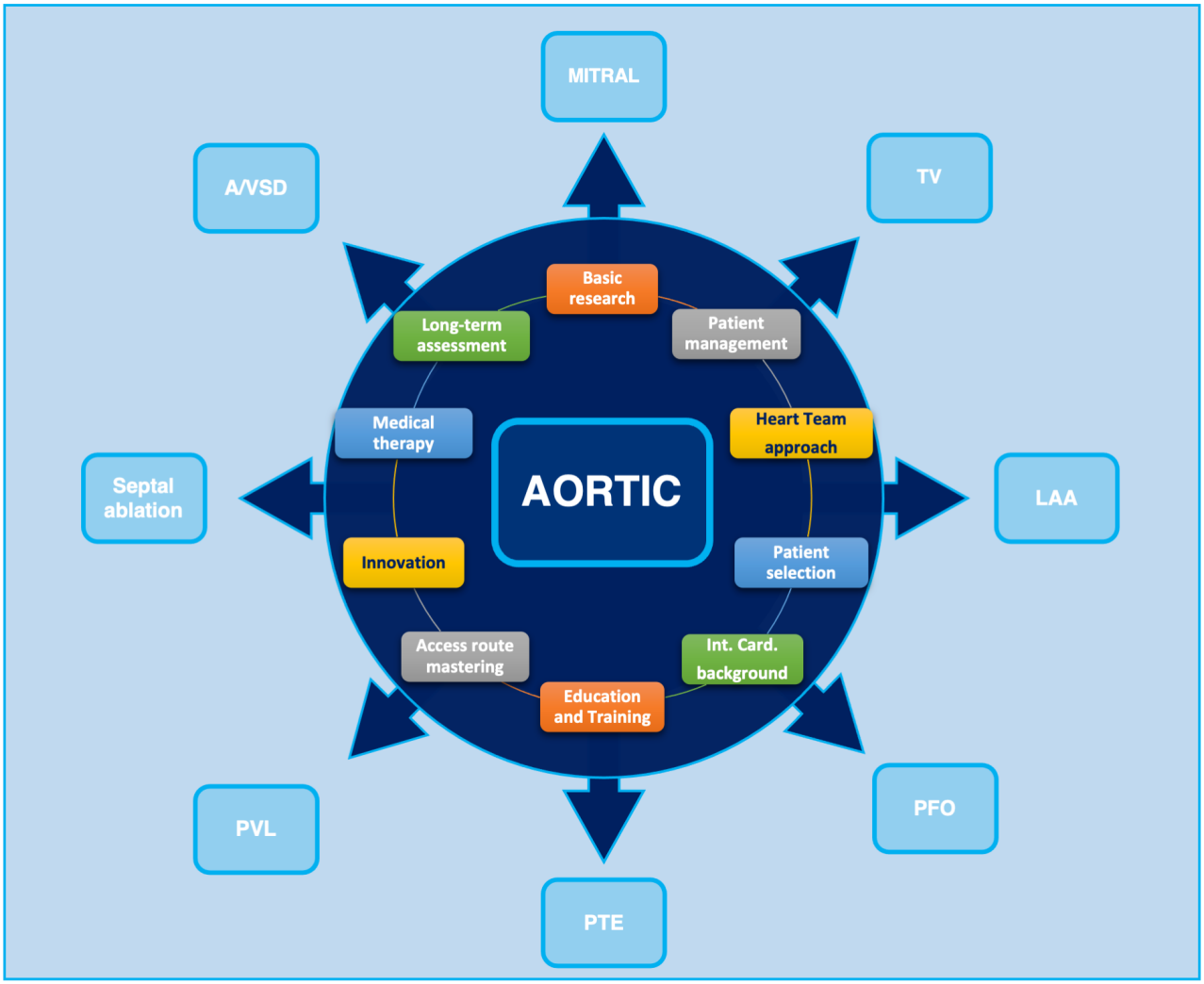

Figure: **Influence transcatheter aortic valve interventions in structural heart disease.** *Legend: tricuspid valve (TV), paravalvular regurgitation (PVL), atrial/ventricular septal defect (A/VSD), patent foramen ovale (PFO), left atrial appendage occlusion (LAA) and pulmonary thromboembolism (PTE).*

1. **Basic research has a key role** in interventional techniques, as depicted by the use of biomarkers in our population (proBNP) and bench simulation (THV precise depth delivery).
2. **A comprehensive management of comorbidities is essential**. The use of simple tools, like sarcopenia at MSCT, helps guiding clinical decision-making as well as potential nutritional and exercise interventions.
3. **The multidisciplinary team is the pillar to assess patients**. Risk stratification scores (EuroScore II) are valid, and low risk aortic valve interventions (TAVI or SAVR) are comparable, in our population. Some profiles deserve studies due to their prevalence and consequences in procedural planning, namely adverse access routes, CAD, CRF and conduction disturbances.
4. Because **the access route has a major impact on the clinical outcomes**, it is relevant to acknowledge that primary and secondary arterial access and closure devices evidence, locally and at the national level, good short-term safety in the SHD field.
5. **The TAVI periprocedural results are influenced by distinct subsets** that must be considered: the VIV procedural safety and efficacy, the PPM determinants, the post-TAVI coronary access management, the renal function response, the cardiogenic shock results, the low-risk patient options, the gender differences and the octogenarians.
6. Aortic stenosis is associated with a dismal prognosis and aortic valve intervention is the only treatment shown to improve survival. Importantly, **a significant proportion of TAVI patients present AF that is related to valve thrombosis and cerebral ischemic events** post-TAVI. If a patient develops prosthetic thrombosis they can be successfully treated with a conservative strategy with unfractionated intravenous heparin and clopidogrel.
7. **A solid background on coronary interventions, peripheral artery disease and management of any procedural complications is needed to embark on TAVI**. Similarly, the Heart Team organization and technical skills learned in the aortic field matured, expanded and proved extremely useful to treat other valvular diseases, despite the distinct specifics of each domain. We reported cases describing mitral and tricuspid valve-in-valve (ViV) transcatheter interventions in such high risk or compassionate patients.
8. Since balloon aortic valvuloplasty (BAV) and earlier THV generations, several technical and training solutions were implemented to carry out TAVI safely, paralleled by innovations in the field of embolic protection, closure devices and practical refinements that impact outcomes. Such progress was present at national registry level. **Device iteration is relevant,** as demonstrated by the first repositionable device and, later, a new balloon expandable valve. Technical improvements regarding implantation depth and in patients with small annular areas, improved the hemodynamic profile.
9. In an effort to **guide the learning and training process**, the EAPCI *Core Curriculum* in Percutaneous Cardiovascular Interventions Cardiology was published in 2020. This document determines the level of competence translating into interventional cardiology skills that is desirable for a trainee, recommends the formal environment and the involvement in scientific activity.
10. **The objective assessment of the patient outcomes, particularly long-term, is critical** in the field of interventional cardiology and extraordinarily important to define peer approval and adoption by the scientific community and regulatory bodies. The TAVI

continuous program monitoring by a prospective registry, the VCROSS, presents favorable short and long-term results of TAVI, namely the low mortality rate at 30 days.

Resumo

As válvulas aórticas percutâneas (TAVI) são o reflexo do aumento da longevidade e da medicina moderna. A sua expansão constitui um modelo de referência na evolução da cardiologia e da cirurgia cardíaca contemporâneas, induzindo alterações que são transpostas para outras áreas de intervenção em cardiopatias estruturais.

O trabalho atual ilustra a abordagem sistemática que foi implementada para dar resposta às necessidades dos doentes, bem como apoiar e estimular o progresso institucional e nacional nesta área.

1. ***A pesquisa básica tem um papel fundamental*** *nas técnicas de intervenção, como retratado pelo uso de biomarcadores em nossa população (proBNP) e simulação de bancada (precisão do implante em profundidade).*

2. ***É essencial uma abordagem abrangente das comorbidades****. O uso de ferramentas simples, como a sarcopenia no MSCT, ajuda a orientar a tomada de decisão clínica, bem como as potenciais intervenções nutricionais e de reabilitação.*

3. ***A equipe multidisciplinar é o pilar de avaliação dos doentes****. As pontuações de estratificação de risco (EuroScore II) são válidas e as intervenções valvulares aórticas em doentes de baixo risco (TAVI ou SAVR) são comparáveis, na nossa população. Alguns perfis merecem estudos particulares devido à sua prevalência e consequências no planeamento do procedimento, nomeadamente as vias de acesso não transfemoral, a CAD, a insuficiência renal e os distúrbios de condução.*

4. Considerando que ***a via de acesso tem grande impacto nos resultados clínicos****, o estudo as vias alternativas – primárias e secundárias – e os dispositivos de encerramento evidenciam, local e nacionalmente, boa segurança a curto prazo no campo da intervenção estrutural.*

5. ***Os resultados peri-procedimento da TAVI são influenciados por subgrupos distintos que devem ser considerados****: a segurança e eficácia do procedimento VIV, os determinantes do PPM, o manejo do acesso coronário pós-TAVI, a evolução da função renal, os resultados no choque cardiogénico, os doentes de baixo risco, as diferenças de género e os octogenários.*

6. A estenose aórtica está associada a um prognóstico grave e a intervenção valvular aórtica é o único tratamento que demonstrou melhorar a sobrevida. ***É importante ressalvar que uma proporção significativa de pacientes com TAVI apresenta FA que se relaciona com a trombose valvular e eventos isquémicos cerebrais pós-TAVI.*** *Se um doente desenvolver trombose protésica, ele pode ser tratado com sucesso com uma estratégia conservadora com heparina intravenosa não fracionada e clopidogrel.*

7. ***É necessária uma base sólida em intervenções coronárias, doença arterial periférica e gestão de complicações peri- procedimento para dominar a TAVI****. Da mesma forma, a organização do Heart Team e as técnicas aprendidas na área aórtica são amadurecidas, ampliadas e revelam-se extremamente úteis para o tratamento de outras valvulopatias, apesar das especificidades distintas de cada domínio. Relatamos casos descrevendo intervenções transcatéter de válvula em válvula mitral e tricúspide (ViV) em doentes de alto risco ou uso por compaixão.*

8. Desde a valvuloplastia aórtica por balão (VAB) e gerações anteriores da THV, várias soluções técnicas e de treino foram implementadas para realizar a TAVI com segurança e eficácia, paralelamente com as inovações no campo da proteção embólica, dos dispositivos de encerramento e melhorias na técnica do operador. Esse progresso foi patente no registo nacional. ***A iteração dos dispositivos é impactante****, como demonstrado pelo primeiro dispositivo reposicionável e, posteriormente, uma nova válvula expansível por balão. Melhorias técnicas quanto à profundidade de implantação e em doentes com pequenas áreas anulares para reduzir o perfil hemodinâmico.*

9. ***De molde a harmonizar e orientar o processo de educação e treino, o Currículo Básico da EAPCI em Intervenções Cardiovasculares Percutâneas foi publicado em 2020****. Este documento estabelece os níveis de competência que são desejáveis para um estagiário, recomendando o ambiente formal e a envolvimento na atividade científica.*

10. ***A avaliação objetiva dos resultados dos doentes, particularmente a longo prazo, é fundamental no campo da cardiologia de intervencão*** *e extraordinariamente importante para definir a aprovação pelos pares e adoção pela comunidade científica e órgãos reguladores. O programa de monitorização contínua da TAVI por um registo prospetivo, o VCROSS, apresenta resultados favoráveis do TAVI a curto e a longo prazo, designadamente a baixa taxa de mortalidade em 30 dias.*

CONCLUSION AND FUTURE PERSPECTIVES

9. Conclusion and future perspectives

The transcatheter aortic valve interventions are an established treatment that improve clinical outcomes.

Their expansion became a reference model that intersected and changed the entire cardiology spectrum.

This dissertation illustrates and documents the fundamentals of systematic research, organization, strategic planning, continuous innovation, critical appraisal and long-term responsibilities in the field of structural heart diseases.

It is a rewarding and endless task, that keeps expanding to other cardiovascular areas.

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