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Skirt in TAVI: a toll-free packaging

Falda en la TAVI — un embalaje sin peaje

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The article signed by García-Guimarães et al.¹ recently published in REC: Interventional Cardiology is a living example of how a technical modification of a percutaneous device already being used with good clinical outcomes can have a significant impact not only from the standpoint of the parameters of technical results but also from the clinical viewpoint. Over the past 20 years of development of valves for transcatheter aortic valve implantation (TAVI) procedures we have witnessed a gradual technological progression where 2 different concepts—self-expanding valves and balloon-expandable valves—have initially achieved encouraging clinical outcomes in high-risk or inoperable patients.¹,²,³ This successful trajectory is partly due to the interest for developing and improving early and successive TAVI devices. The trials conducted among high-risk patients already found a higher rate of paravalvular leak after TAVI compared to surgical repair. As a matter of fact, it was a common event very much associated with a greater need for pacemaker implantation after TAVI in the early self-expandable valves.

Conceptually this is something that could have been expected since there is no native valve resection or washout of the calcium remaining in the leaflets or the annulus. The need for permanent pacemaker implantation increases due to the implicit mechanism of mechanical fixation due to pressure to the valve annulus and its adjacent structures. We should mention that both phenomena can be inversely associated, that is, the more annular overexpansion we have, the more chances of atrioventricular block and vice versa with paravalvular leak. If we accept that the clinical impact of residual leak—with disparate evidence available—⁴ can be associated with different degrees categorized as mild, all design changes and those associated with the implantation technique used aim at reducing its rate and severity.

The nature and mechanisms involved with paravalvular regurgitation are obviously different compared to the native valve, which is why several authors propose more categories, and a modification of the analysis technique of transthoracic echocardiography after implantation. This aims at the proper detection of different degrees of paravalvular regurgitation with some potential adverse prognostic effect.⁷ The fact of the matter is that the development of TAVI devices mostly aims at reducing the degree of paravalvular leak without compromising the rate of new pacemaker implantation after TAVI, that is, without changing the degree of pressure to the native annulus. Therefore, the «skirts» surrounding the metal structure of the devices where they come into contact with the annulus are not only here to stay but come in longer lengths and have more morphological variations. The history of ACURATE neo (Boston Scientific Corporation, United States) would be a good example of how a modified skirt that is 60% longer can have a benefit that, though may seem spurious, is really a breakthrough with a potential clinical benefit like García-Guimarães et al. proved.¹

Although the study has some limitations associated with its nature like comparing 2 different, non-homogeneous historic cohorts, it demonstrates something that operators who have tried different models have already confirmed in our routine clinical practice: the segment packaging in contact with the annulus has reduced the rates of leak in TAVI. Also, it proves that designing a device should be a positively toll-free packaging: the ACURATE neo² valve reduces paravalvular leak without compromising the rate of pacemaker implantation as another similar study that compared 2 consecutive cohorts with the 2 consecutive models of Accurate neo already demonstrated.⁸

In the process of developing new devices for TAVI we have learned to study the size of aortic anulli with the computed tomography (CT) scan much better and be more accurate when adapting the size of the device that should be implanted. More technical options have come up regarding the size of the valve have become available too regarding the size of the valve, its measurement, implantation height, and even the need for pre or postdilation. The impact of each one of these factors could be statistically figured out, although this is not an easy task between 2 different historic cohorts.

If we conduct an in-depth study of what it means to assess aortic valves with the CT scan, especially the capacity to predict the rate of paravalvular leak after TAVI, we’ll find some contradictions along the way. Although the degree or spread of calcification can seem the culprits of paravalvular regurgitation, not everything is so clear or linear. This confusion can be attributed to the different ways valvular calcium can impact the sealing of the valve based on the type (balloon-expandable or self-expanding), specific design (with or without skirt, among other), size selected, and procedural technical issues (implantation height). In the studies of coronary calcification assessed via CT scan there is variability in the technique used to quantify coronary calcium (CT without contrast or coronary computed tomography angiography [CCTA]) and the methods of analysis.

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The standard method to quantify coronary calcium includes a baseline study often before the injection of the iodinated contrast material needed to perform the cardiac and aortic CCTA. When this baseline determination is lacking, the calcium quantification used in the article signed by García-Guimarães et al. includes a dichotomic detection threshold based on the opacification obtained in the outflow tract of CCTA images; an easy method with an acceptable correlation that was homogeneously applied to both cohorts.

The size of the valve selected, implantation height, and the distribution of calcium both in the annulus and left ventricular outflow tract may have shared some protagonism in this study and on this regard. Sealing limitations with TAVI compared to surgical aortic valve replacement may still persist for some time despite the advances made with the former. However, the supravalvular position of coaptation and the worse profile of the bare-metal stents vs surgical valve can be favorable assets for TAVI regarding the study of long-term durability.

Finally, although for the time being there is not a cause-effect correlation, it’s striking to see that the group with more residual leak in the aforementioned study and others also shows more bleeding at follow-up. It is obvious that since they’re historic cohorts, this could be due to other factors involved in the learning curve and the development of the technique like vascular access treatment or use of drugs that may affect bleeding. It could also be that the leak has deleterious rheological effects like some studies have already suggested.

We should say that although there’s always a toll to pay with new packagings, this doesn’t seem to be the case.

**CONFLICTS OF INTEREST**

B. García del Blanco is a proctor for Edwards, and has declared to have received funding for counselling jobs for Medtronic, and Boston Scientific. H. Cuéllar Calabria declared no conflicts of interest whatsoever.

**REFERENCES**

The structural heart disease (r)evolution.
TAVI et al., where and how?

La (r)evolución del intervencionismo cardiaco estructural.
TAVI et al., ¿dónde y cómo?

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Two decades of transcatheter aortic valve implantation (TAVI) changed the history of contemporary medicine and became a reference model in cardiovascular disease. Percutaneous structural heart disease (SHD) therapies emerged to treat the entire heart valve and vessel spectrum, as well as congenital or acquired wall and muscular defects.

(r)evolution happened back in 2002 with Alain Cribier’s human aortic valve disease percutaneous milestone treatment. A progressive and impressive range of therapeutic alternatives for patients grew parallel to the population’s longevity given the most prevalent etiology of aortic stenosis is degenerative. In fact, cardiovascular diseases remain the leading causes of death and hospitalization and represent an enormous clinical and public health burden, which disproportionately affects older adults. The World Health Organization expects octogenarians to quadruple up to 396 million by 2050. Although rheumatic heart disease has become rare in industrialized countries, its overall burden is still significant. It comes as no surprise that complex patients who can benefit from combined valvular procedures are increasingly common.

The TAVI impact on cardiology and cardiac surgery surpassed the clinical field and imposed a restructure as the path taken in aortic valve disease is transposed, progressively, to other structural clinical areas, namely mitral, tricuspid, and acute stroke prevention.

WHAT’S THE STORY?

Initially, safety and efficacy were the main requirements for TAVI, same as for any other cardiovascular technique. Mortality and complications were important from a clinical point of view resulting in prolonged admissions and increased hospital costs. Intensive use of imaging and general anesthesia were the default procedure for most. Patient selection became the concern and frailty assessment, risk stratification, futility, and the imponderables were the main issues. Bench simulation provided relevant information while studies and registries depicted the actual TAVI expression across countries. Progressive, innovative techniques and devices led to cautious simplified protocols that run parallel to image expertise replication in the non-aortic space, especially in the mitral valves. Patient subgroups were the main topic, namely the history of cardiac valve surgery –aortic, mitral, and tricuspid– as well as octogenarians. The economic burden of incremental cost on health economics emerged as a concern, as well as device selection, hybrid techniques, alternative access routes, and standardized approaches for complications. Concomitant medical therapy and longevity were also captured.

Therefore, the field of aortic procedures expanded, grew, and consolidated. TAVI procedures became daily routine with hands-on training for fellows. The need for preparing interventional cardiologists for this area became clear, which was reflected in industry proctoring programs and by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) Core Curriculum. Simultaneously, expansion to other SHD areas like percutaneous mitral and tricuspid valve procedures, left atrial appendage and valve leak closures emerged from this maturity as a natural (r) evolution in the field of SHD.

WHAT DID WE LEARN?

Aortic valve procedures reflect, first, contemporary longevity and modern medicine. Their expansion constitutes a role model in cardiology and cardiac surgery by inducing changes adopted in other SHD areas.

Several SHD procedures have the extraordinary ability to ameliorate heart failure, prevent and treat thromboembolic diseases, and improve survival. We should recognize and acknowledge the common features that bring their current prestige, success, and expansion. Among immense factors, the following may be considered the most relevant:

– Basic research
– Comprehensive patient management
– Multidisciplinary approach
– Patient and subset selection
– Access route mastering
– Interventional cardiology background
Progress is endless and these are valuable assets to guide the next steps (figure 1).

**WHAT DOES THE FUTURE LOOK LIKE?**

Physicians, caretakers, industry, and policy makers conquered a huge responsibility in the field of SHD.

To match societal and patient’s expectations, the interventional cardiologist needs a holistic approach:

- To define the role of SHD interventional cardiologists. As a medical cardiologist who manages patients from diagnosis to follow-up of SHD and performs percutaneous procedures in this domain. As members of heart teams that interact closely with other cardiologists, cardiac surgeons, and other medical specialties, nurses, paramedics, and other healthcare professionals. All these considerations are based on the EAPCI Core Curriculum of 2020 and on the upcoming EAPCI Core Curriculum on percutaneous SHD procedures (submitted for publication).

- To harmonize SHD interventional cardiology practice. Data from health surveys, administrative records, cohort studies, and registries show persisting geographic inequity across Europe. The EAPCI certification that includes a national mutual recognition system, attempts to validate a proper level of knowledge and practice to protect patients from undergoing interventional cardiology procedures performed by unqualified professionals and set up a European standard for competency and excellence in this field.

- To perform TAVI in centers without permanent onsite cardiac surgery by establishing straight-forward protocols that provide patient safety and ensure that both operators and hospitals are committed to high quality outcomes. Though TAVI in centers without permanent onsite cardiac surgery is not endorsed at present, the dramatic growth of candidates outpaced the efforts, prompting increased waiting times with negative and severe clinical consequences. Models should include an optimal heart team around the patient from periodic visiting teams to an overall exchange partnership.

- To promote and assess quality of care by adopting standardized data definitions for the quantification of quality of care and outcomes. Recently, the EuroHeart methodology reached consensus on a set of variables, 93 categorized as mandatory (level 1) and 113 as additional (level 2) based on their clinical importance and feasibility. That facilitates quality improvement, observational research, registry-based randomized trials, benchmarking and post-marketing surveillance of devices, and pharmacotherapies.
To expand SHD procedures to low-risk and/or younger patients who present distinct challenges in their stratification, comorbidities, clinical presentation, anatomy, and potential longevity supported by recent trials. Also, by promoting responsible research and enhancing patient-centered solutions.14

To develop awareness regarding valvular heart disease since it is not commonly acknowledged by the population and because aortic, mitral, and tricuspid valves present overlapping functions, and differences regarding diagnostic and therapeutic methods. The EAPCI Valve for Life initiative detects barriers, identifies stakeholders, and implements strategic plans to overcome difficulties in different areas.15

To provide the referral network a simple, expeditious, and efficient articulation from the patient and the referring physician perspective by deploying and/or developing dedicated information technology solutions for treatment pathways and reshaping the future cardiovascular department (eg, by fusion or rotative leadership between cardiology and surgery).

CONCLUSION

In conclusion, percutaneous SHD procedures are highly demanding and rewarding. Lessons from the past are precious and interventional cardiology must use them wisely as access and volume are increasing significantly. A comprehensive approach is warranted to face this surge.

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CONFLICTS OF INTEREST

R. Campante Teles declared no conflicts of interest associated with this manuscript.

REFERENCES


Paravalvular leak with ACURATE neo and neo2: a comparative study with calcium quantification

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ABSTRACT

Introduction and objectives: Moderate or severe paravalvular leak (PVL) following transcatheter aortic valve implantation (TAVI) has been associated with worse outcomes. Aortic valve (AV) calcification is a strong predictor of PVL. ACURATE neo (Boston Scientific Corporation, United States) is a self-expanding transcatheter heart valve to treat degenerative aortic stenosis. We evaluated PVL after ACURATE neo and neo2 implantation, and the role of AV calcification.

Methods: We analyzed patients referred for TAVI with ACURATE neo and neo2 from a large volume tertiary center. All cardiac computed tomography scans were analyzed using 3Mensio Structural Heart software (Pie Medical Imaging, The Netherlands). The volume of AV calcium was quantified using contrast-enhanced cardiac computed tomography series. The 30-day clinical and echocardiographic data were prospectively recorded.

Results: We included 165 patients referred for TAVI with ACURATE (neo = 87; neo2 = 78). Median age was 82 years-old, 65% were women with a median EuroSCORE II of 4.7 [IQR, 2.4-6.1]. Patients in the neo group showed a larger amount of total AV calcium (320 mm $^3$ vs 200 mm $^3$; $P = .0305$). We found no significant inter-group differences regarding clinical outcomes both in-hospital or at 30-days. At 30-days, the rate of PVL $\geq$ mild (61% vs 34%; $P < .001$) and $\geq$ moderate (15.9% vs 5.4%; $P = .0365$) were higher in the neo group. After propensity score matching adjusted by the total amount of AV calcium, neo2 was associated with a lower risk of PVL $\geq$ mild (OR, 0.35, 95%CI, 0.18-0.69; $P = .003$), and $\geq$ moderate (OR, 0.16; 95%CI, 0.03-0.74; $P = .019$).

Conclusions: TAVI with ACURATE neo2 vs neo is associated with a lower risk of any degree of PVL and a reduced risk of PVL $\geq$ moderate. After adjusting for AV calcium volume, ACURATE neo2 was still associated with a lower risk of PVL.

Keywords: Transcatheter aortic valve implantation. Transcatheter heart valve. Paravalvular leak.

Fuga paravalvular tras implante de ACURATE neo y neo2: estudio comparativo con cuantificación de calcio

RESUMEN

Introducción y objetivos: La fuga paravalvular (FPV) moderada o grave tras el implante percutáneo de válvula aórtica (TAVI) se ha asociado a peores resultados. La calcificación de la válvula aórtica constituye un importante factor predictivo de FPV. ACURATE neo (Boston Scientific Corporation, Estados Unidos) es una válvula cardíaca transcatéter autoexpandible para el tratamiento de la estenosis aórtica degenerativa. Se evaluó la presencia de FPV tras el implante de ACURATE neo y neo2, así como el papel de la calcificación de la válvula aórtica.

Métodos: Se analizaron pacientes intervenidos de TAVI con ACURATE neo y neo2 de un hospital terciario de alto volumen. Todas las tomografías computarizadas cardíacas se analizaron con el software 3Mensio Structural Heart (Pie Medical Imaging, Países Bajos). El volumen de calcio aórtico se cuantificó mediante tomografía computarizada cardíaca con contraste. Se registró prospectivamente la evolución clínica y ecocardiográfica a 30 días.

Resultados: Se incluyeron 165 pacientes intervenidos de TAVI con ACURATE [neo = 87; neo2 = 78]. La mediana de edad fue de 82 años, el 65% eran mujeres y la mediana de EuroSCORE II fue de 4.7 [rango intercuartílico, 2.4-6.1]. Los pacientes del grupo con neo presentaban una mayor cantidad de calcio total aórtico [320 frente a 200 mm $^3$; $p = 0,0305$]. No se hallaron diferencias significativas entre los grupos en cuanto a los resultados clínicos tanto durante el ingreso como a los 30 días. A los 30 días, la tasa de FPV $\geq$ leve (61 frente a 34%; $p < 0,001$) y de FPV $\geq$ moderada (15,9 frente a 5,4%; $p = 0,0365$) fue más alta en el grupo con neo.

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Transcatheter aortic valve implantation (TAVI) has become an increasingly popular therapeutic option in patients with degenerative severe aortic stenosis in the entire spectrum of estimated procedure-related risks.\(^1,2\) Compared to surgical aortic valve replacement, transcatheter heart valves (THV) have to deal with a higher risk of paravalvular leak (PVL), a matter of especial concern replacement, transcatheter heart valves (THV) have to deal with a higher risk of paravalvular leak (PVL), a matter of especial concern.

In addition, the presence of residual moderate or severe PVL following TAVI has been associated with an increased risk of short- and long-term mortality.\(^3,5\) The prognostic role of mild PVL is still controversial, still some studies have also shown worse outcomes in patients with mild compared with none or trace PVL.\(^3\) Former studies have identified the presence and distribution of calcium in the aortic valve (AV) as a predictor of residual PVL after TAVI.\(^6,7\) In addition, left ventricular outflow tract (LVOT) calcification has also been associated with a higher risk of residual PVL.\(^8\) ACURATE neo (Boston Scientific Corporation, United States) is a self-expanding THV indicated for the treatment of AS. However, early data with ACURATE neo showed a higher rate of moderate or severe PVL compared to other self-expanding THV.\(^8\) Its last iteration, the ACURATE neo2, added an inner and outer pericardial skirt, potentially capable of reducing the rate of PVL.

The aim of this study was to compare the rate of PVL at 30-days after ACURATE neo and neo2 THV implantation, and analyze the role of aortic calcium volume in the development of significant PVL after ACURATE neo and neo2 THV implantation.

METHODS

We selected patients from our prospective TAVI registry referred for TAVI with ACURATE neo and neo2 in our center, a large volume tertiary hospital and reference center for structural heart procedures. In all cases, the decision to perform TAVI over surgical replacement was agreed by the heart team based on the patients’ characteristics, comorbidities, and estimated risk scores. Per site protocol, 30-day follow-up clinical visits, and follow-up transcatheter echocardiograms were scheduled in all the patients. Due to the COVID-19 outbreak in the Netherlands that started back in March 2020 some of the 30-day follow-up visits were performed via telephone call. All transthoracic echocardiograms were performed by an experienced imaging cardiologist in THV evaluation following current clinical guidelines on the evaluation of PVL after TAVI.\(^10\) Consequently, PVL was classified as none/trace, mild, moderate, and severe following the Valve Academic Research Consortium definitions regarding AV clinical research (VARC-3) recommendations.\(^10\) Data on baseline admission, demographics, clinical, and procedural characteristics, in-hospital events, and 30-day follow-up were prospectively collected and managed using REDCap (Research Electronic Data Capture), a secure, web-based software platform designed to support data capture for research studies. The study received the approval of the local research ethics committee (St. Antonius Hospital, Nieuwegein, The Netherlands). Informed consent for this study was waived due to its retrospective and observational design.

Event definitions

For both in-hospital and 30-day adverse events, the last published VARC-3 definitions regarding AV clinical research were followed.\(^10\)

Cardiac computed tomography calcium analysis

The 3Mensio Structural Heart software version 10.3 (Pie Medical Imaging, Bilthoven, The Netherlands) was used for all cardiac computed tomography (CCT) analyses. All CCT scans were independently analysed by 1 operator experienced in THV sizing and specific training in 3Mensio software. In the early cases, our CCT protocol for TAVI evaluation did not include non-contrast-enhanced series. Therefore, non-contrast-enhanced series were unavailable for a significant number of patients. Thus, we decided to evaluate calcium volume using contrast-enhanced series. We followed the method recently described by Angelillis et al. that showed a good correlation with Agatston score as measured in non-contrast-enhanced scans.\(^11\) In short, this method for calcium volume estimation modifies the Hounsfield Units threshold depending on the average found in the LVOT. In highly contrasted LVOT (> 300 HU) the threshold used was 850. Regarding low contrasted LVOT (< 300 HU), the threshold was set at 450. After the aortic annulus identification [baseline plane], the ‘calcium scoring tool’ included in the software was used to estimate the aortic volume. The aortic box displayed a 15 mm length from the baseline plane to the aortic root. All calcium on the aortic wall and/or the coronary arteries was carefully identified and excluded from the volume estimate. The estimate of LVOT calcium volume was performed too. For this, a 10 mm-long box was included from the baseline plane to the LVOT. All calcium associated with the anterior mitral leaflet was identified and excluded from the estimated volume. To analyze the impact of the valve size, and the prosthesis to annular size, the cover index

**CONCLUSIONS**: El TAVI con ACURATE neo2, en comparación con neo, se asocia a un menor riesgo de cualquier grado de FPV y a un menor riesgo de FPV ≥ moderada. Tras el ajuste por volumen de calcio aórtico, ACURATE neo2 se asocia a un menor riesgo de FPV.
was calculated \[(100 \times [\text{valve diameter} - \text{CCT perimeter-derived annulus diameter in systole}] / [\text{valve diameter}])\] following the previous description established by Kim et al.\(^{12}\)

**Statistical analysis**

Quantitative variables were expressed as mean ± standard deviation or median [interquartile range]. The Kolmogorov-Smirnov test was used to evaluate the adjustment to normality. Categorical variables are expressed as numbers (percentage). The Student t test or the Mann-Whitney U test were used to compare continuous variables. Pearson's chi-square test was used for categorical variables. Predictors of binary PVL were analyzed using logistic regression. Test for a trend across a categorical variable was performed using the nptrend command (STATA). Two propensity score matching models (1:1 matching) were estimated, the first model adjusted for the total amount of LVOT calcium according to the CCT too. A second model matched patients with 30-day clinical follow-up (98%) to patients with 30-day transthoracic echocardiogram (95%). The amount of calcium in the non-coronary and left coronary cusps of the aortic valve was more frequently seen in the neo2 group (99% vs 92%; \(P = .0434\)) driven by differences in the total amount of calcium in the non-coronary and left coronary cusps \((154 \text{ mm}^3 \text{ vs } 98 \text{ mm}^3; P = .0149; 86 \text{ mm}^3 \text{ vs } 37 \text{ mm}^3; P = .0335\) respectively). We found no inter-group differences in the quantification of calcium in the LVOT. However, the presence of any amount of calcium in the LVOT was more frequently seen in the neo group \((61\% \text{ vs } 41\%); P = .0107\). No differences were reported in the cover index between groups with a median of 6.8% [IQR, 4.4-8.5] oversize in the overall cohort.

Data on procedural characteristics and in-hospital evolution are shown on table 3. All cases were performed via transfemoral access. The first 8 cases from the neo group were performed under general anaesthesia while the remaining cases from both groups were performed under local anaesthesia. There was a non-significant trend towards a lower use of the small 23 mm ACURATE in the neo2 group \((43\% \text{ vs } 22\%); P = .0523\). Predilatation was more common in the neo group \((99\% \text{ vs } 92\%); P = .0434\), and postdilatation in the neo group \((43\% \text{ vs } 22\%); P = .0046\). We found no differences in the presence of residual PVL ≥ moderate on angiography immediately after implantation \((7\% \text{ vs } 5\%); P = .6346\). Regarding in-hospital outcomes, only 1 patient died at the index admission due to sepsis 59 days after TAVI. A total of 3 patients suffered a stroke without inter-group differences being reported. There was a non-significant trend towards a higher bleeding risk in the neo group \((18\% \text{ vs } 12\%); P = .2203\) without any differences being reported in the rates of major or life-threatening bleeding. The rate of permanent pacemaker implantation was 7.3% without any inter-group differences.

**RESULTS**

A total of 167 patients were referred for TAVI with ACURATE at our center from October 2017 through December 2021. Of those, a total of 89 patients were referred for TAVI with an ACURATE neo from October 2017 through October 2020. A total of 78 patients were referred for TAVI with ACURATE neo2 from November 2020 through December 2021. In 2 patients from the ACURATE neo group, preoperative CCT information was not available and both patients were eventually excluded from the analysis. A 30-day clinical follow-up was available in 158 patients \(96\%\), information regarding the presence of PVL at 30-days by transthoracic echocardiogram was available in 156 patients \(95\%\). The study flowchart is shown on figure 1.

The cohort baseline characteristics are shown on table 1. We found no differences in the distribution of age, sex, and cardiovascular risk factors between the groups \(\text{median age, 82 years-old; } 65\%,\text{ female}\). There were not significant inter-group differences regarding risk estimate with EuroSCORE II \(4.2 \text{ vs } 4.8; P = .5371\). A third of the patients had atrial fibrillation, and a fourth had been treated with previous percutaneous coronary intervention, and 9% with previous coronary artery bypass graft with no inter-group differences. Almost 2 thirds of the patients had functional New York Heart Association class III-IV before intervention while 17% showed systolic dysfunction (left ventricular ejection fraction < 50%) by transthoracic echocardiogram.

Main data of the CCT analysis is shown on table 2. We found no differences in the aortic annulus mean diameter, area or perimeter between the groups. Regarding calcium analysis, patients from the neo group showed a larger amount of estimated total calcium in the AV \((320 \text{ mm}^3 \text{ vs } 200 \text{ mm}^3; P = .0305)\) driven by differences in the amount of calcium in the non-coronary and left coronary cusps \((154 \text{ mm}^3 \text{ vs } 98 \text{ mm}^3; P = .0149; 86 \text{ mm}^3 \text{ vs } 37 \text{ mm}^3; P = .0335\) respectively). We found no inter-group differences in the quantification of calcium in the LVOT. However, the presence of any amount of calcium in the LVOT was more frequently seen in the neo group \((61\% \text{ vs } 41\%); P = .0107\). No differences were reported in the cover index between groups with a median of 6.8% [IQR, 4.4-8.5] oversize in the overall cohort.
Median length of stay was 2 days [IQR, 2-4]. Half of the patients were discharged on aspirin with patients in the neo group being more frequently treated with dual antiplatelet therapy at discharge (41% vs 10%; \( P < .001 \)). A total of 40% of the cohort were discharged with oral anticoagulation.

Information on 30-day follow-up is also shown on Table 3. One-month clinical follow-up information was available in 158 patients. We found no differences in the rates of death, myocardial infarction, and stroke between the groups. However, there was a trend towards a higher bleeding risk in patients from the neo group (22% vs 12%; \( P = .0986 \)). Regarding the follow-up echocardiogram, we found no differences in mean and peak AV gradients between the groups (mean, 7 ± 3 mmHg vs 8 ± 4 mmHg; \( P = .3160 \); peak 14 ± 6 mmHg vs 15 ± 7 mmHg; \( P = .3365 \)) with good performance in both groups regarding aortic gradients. The rate of PVL ≥ mild at 30 days was significantly higher in the neo vs neo2 group (61% vs 34%; \( P < .001 \)). Also, the rate of PVL ≥ moderate was also significantly higher in the neo group (15.9% vs 5.4%; \( P = .0365 \)) compared to the last THV generation.

A crude analysis showed a significant univariate relationship between neo2 vs neo with a lower rate of both PVL ≥ mild (OR, 0.33; 95%CI, 0.17-0.63; \( P = .001 \)) and ≥ moderate (OR, 0.30; 95%CI, 0.10-0.98; \( P = .045 \)) at 30-day follow-up. A trend analysis showed a significant correlation between the AV calcium quartile and the presence of PVL ≥ mild (Q₁, 37%; Q₂, 38%; Q₃, 54%; Q₄, 63%; \( P \)-value for trend = .012). This analysis failed to show any significant correlations between the AV calcium quartile and PVL ≥ moderate (\( P = .125 \)). However, Q₄ showed a significantly higher rate of PVL ≥ moderate on binary comparison (Q₄ vs Q₁-3, 20% vs 7.8%; \( P = .0322 \)). A trend analysis showed a no significant correlation between the cover index and the presence of PVL ≥ mild (\( P = .961 \)) or ≥ moderate (\( P = .596 \)). Figure 2 illustrates a case of moderate PVL in a severely calcified AV after ACURATE neo implantation.

After propensity score matching adjusted for the total amount of AV calcium (71 pairs), the use of neo2 vs neo was associated with a lower risk of PVL ≥ mild (OR, 0.35; 95%CI, 0.20-0.69; \( P = .003 \)) and ≥ moderate (OR, 0.16; 95%CI, 0.03-0.74; \( P = .019 \)) at follow-up. An alternative propensity score matching model adjusted for the total amount of LVOT calcium was also used (71 pairs). In this model, the use of neo2 vs neo was also associated with a lower risk of PVL ≥ mild (OR, 0.39; 95%CI, 0.20-0.78; \( P = .008 \)) and showed a non-significant trend towards a lower risk of PVL ≥ moderate at follow-up (OR, 0.33; 95%CI, 0.10-1.08; \( P = .066 \)).

**DISCUSSION**

Our study analyzed consecutive cases referred for TAVI with ACURATE THV technology in a large volume tertiary center. The main findings of our study are a) the rate of PVL ≥ moderate was dramatically reduced with the use of the ACURATE neo2 compared...
to its former version; and b) this reduced residual PVL seen with the ACURATE neo2 was not determined by differences in the degree of calcification in the AV.

The ACURATE neo THV received the CE marking back in 2014 for the management of degenerative severe aortic stenosis. Despite early registries showed a good performance of this technology, clinical trials that compared it to other balloon-expandable and self-expandable THVs showed worse results. In the SCOPE-I trial, TAVI with ACURATE neo did not meet non-inferiority criteria compared to the SAPIEN 3 (Edwards Lifesciences, Irvine, CA, United States) with differences mainly driven by a higher rate of moderate or severe PVL with ACURATE (9% vs 3%). In the SCOPE-2 trial, TAVI with ACURATE neo failed to reach the non-inferiority margin compared to the CoreValve Evolut THV (Medtronic, United States) regarding mortality or stroke at 12 months. In this study, once again, the use of ACURATE was associated with aortic stenosis can persist after TAVI in patients associated with dual antiplatelet therapy compared to aspirin alone for most of our neo2 cohort were more commonly treated with P2Y12 inhibitors and risk of PVL with ACURATE THV technology. In our study, we found that, compared to neo, the neo2 TVH was associated with a lower risk of any degree of PVL and a decreased risk of PVL ≥ moderate. Moreover, propensity score matching analysis allowed us to ascertain that the lower risk of PVL seen with neo2 was independent of the AV calcium estimate.

However, we also have some additional findings that are worth discussing. We found a trend towards a higher rate of bleeding with neo compared to neo2, both in-hospital and at 30-day follow-up. This can be potentially explained by baseline differences in the antithrombotic treatment between both groups. Patients from the neo cohort were more commonly treated with P2Y12 inhibitors and dual antiplatelet therapy. Nevertheless, current evidence, adopted for most of our neo2 cases, has demonstrated a higher bleeding risk associated with dual antiplatelet therapy compared to aspirin alone in patients referred for TAVI.10-12 Our data also seem to support these findings. Alternatively, acquired von Willebrand syndrome associated with aortic stenosis can persist after TAVI in patients

### Table 2. Computed tomography analysis

<table>
<thead>
<tr>
<th></th>
<th>Global cohort N = 165</th>
<th>ACURATE neo N = 87</th>
<th>ACURATE neo2 N = 78</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cover index (oversizing) %</strong></td>
<td>6.8 [4.4-8.5]</td>
<td>6.8 [3.7-8.4]</td>
<td>6.9 [5.2-9]</td>
<td>.1769</td>
</tr>
<tr>
<td><strong>Calcium quantification</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total calcium volume at the AV, mm³</td>
<td>266 [100-566]</td>
<td>320 [123-896]</td>
<td>200 [90-377]</td>
<td>.0305</td>
</tr>
<tr>
<td>Total calcium volume at the LVOT, mm³</td>
<td>1 [0-29]</td>
<td>4 [0-34]</td>
<td>0 [0-22]</td>
<td>.2897</td>
</tr>
<tr>
<td>Calcium volume at the NCC-LVOT, mm³</td>
<td>0 [0-5]</td>
<td>0 [0-6]</td>
<td>0 [0-0]</td>
<td>.5474</td>
</tr>
<tr>
<td>Calcium volume at the RCC-AV, mm³</td>
<td>0 [0-0]</td>
<td>0 [0-0]</td>
<td>0 [0-0]</td>
<td>.8615</td>
</tr>
<tr>
<td>Calcium volume at the LCC-AV, mm³</td>
<td>0 [0-3]</td>
<td>0 [0-7]</td>
<td>0 [0-0]</td>
<td>.3521</td>
</tr>
<tr>
<td>Any calcium at the LVOT</td>
<td>85 (52)</td>
<td>53 (61)</td>
<td>32 (41)</td>
<td>.0107</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%) or mean ± standard deviation or median [interquartile range].

AV, aortic valve; LCC, left coronary cusp; LVOT, left ventricle outflow tract; NCC, non-coronary cusp; RCC, right coronary cusp.
The higher rate of PVL associated with neo compared to neo2 may explain, by itself, our finding of a trend towards a higher risk of bleeding in the neo cohort. We are aware that the learning curve seen with the ACURATE device may have altered our results. We found a higher AV calcium volume estimate in neo vs neo2 cases. Our early experience with the neo device may lead interventional cardiologists involved in the
heart team to be more prone to selecting a different THV (with a lower estimated risk of PVL) in patients with a high degree of AV calcification. Also, despite being high in both groups (92% and 99%, respectively), the rate of predilatation was significantly higher in the neo2 group, even when this group showed a lower amount of estimated AV calcium, which confirms the impact the learning curve has on device implantation. We should mention that this procedural step can be of special relevance to avoid residual PVL, especially in a THV as the ACURATE one that has a lower radial force. However, the benefits seen with neo2 reducing the risk of any degree of PVL, even after adjusting for AV calcification, seem to exceed what could be justified by these 2 potential biases. The different postdilatation rates reported may be explained by the fact that operators more commonly identified and attempted to correct an angiographically significant PVL immediately after THV implantation in the neo vs neo2 group.

Limitations

Among the limitations of this study are those regarding its non-randomized observational design. The current study is limited by its small sample size and for being a single-center experience. A strict methodology for CCT calcium volume estimate was followed, and clinical and echocardiographic information was prospectively recorded. However, the degree of PVL at 30-day follow-up and adverse outcomes were not independently assigned but based on clinical reports. Current standards to estimate AV calcium are based on the analysis of non-contrast-enhanced CCT. However, we applied a method for calcium volume estimate based on contrast enhanced CTT as this was the only method that allowed us to analyze our oldest cases since, at that time, non-contrast-enhanced series were not part of our pre-TAVI CCT protocol. Finally, our report is limited by a short-term follow-up. Longer clinical follow-up is needed to assess clinical outcomes, and the prognostic implication of residual PVL.

Impact on the routine daily practice

With data from our real-world registry, compared to its former iteration, TAVI with ACURATE neo2 is associated with a lower risk of residual PVL. These results were not affected by differences in the total amount of calcium in the AV detected by CCT.

CONCLUSIONS

Compared to ACURATE neo, TAVI with ACURATE neo2 THV was associated with a lower risk of any degree of PVL, as well as a
lower risk of PVL > moderate. After adjusting for AV calcium volume, ACURATE neo2 was still associated with a lower risk of PVL compared to ACURATE neo THV.

**FUNDING**

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**AUTHORS’ CONTRIBUTIONS**

M. García-Guimarães, M.J. Swaans, and L. Timmers contributed to the study idea and design. M. García-Guimarães acquired data, performed the analysis, and drafted the manuscript. D.-J. Van Ginkel contributed to data acquisition. B.J. Rensing, J.M. Ten Berg, U. Sonker, T.L. de Kroon, and R.H. Heijmen made a critical revision of its intellectual content. All authors give their final approval to this version for publication.

**CONFLICTS OF INTEREST**

L. Timmers is a proctor and a member of Boston Scientific advisory board. M.J. Swaans received lecturer fees from Boston Scientific. The remaining authors did not declare any conflicts of interest whatsoever.

**WHAT IS KNOWN ABOUT THE TOPIC?**

- Presence of significant PVL following TAVI is associated with worse clinical outcomes. Aortic valve calcification is a strong predictor of PVL after TAVI. ACURATE neo is a self-expanding transcatheter heart valve for the management of degenerative aortic stenosis. Its last iteration, the ACURATE neo2, aims to reduce the incidence of residual PVL.

**WHAT DOES THIS STUDY ADD?**

- In our study with data from a real-world TAVI registry, compared to its former ACURATE neo, ACURATE neo2 was associated with a lower risk of residual PVL. Also, these results were not affected by differences in the total amount of calcium detected in the aortic valve as evaluated by cardiac computed tomography.

**SUPPLEMENTARY DATA**

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000369.

**REFERENCES**

Right atrium: a good ally in left ventricular pacing during transcatheter aortic valve implantation

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ABSTRACT

Introduction and objectives: Rapid ventricular pacing reduces cardiac output by providing stability during transcatheter aortic valve implantation (TAVI). Our objective is to assess the efficacy and safety profile of left ventricular pacing through the high-support guidewire used for implantation and a guidewire located in the right atrium (RA) functioning as an anode.

Methods: Left ventricular pacing is performed by connecting the external end of a Safari 2 pre-shaped guidewire located in the left ventricle to the cathode of a temporary pacemaker, and the anode to the body of an Emerald guidewire inserted into the RA using a diagnostic Judkins Right catheter (via ultrasound-guided femoral venous access). Pacemaker was programmed with maximum output (20 V) and null sensitivity.

Results: A total of 62 selected patients (median 79.4 ± 6.5 years old) underwent transfemoral TAVI using the pacing technique described (25 patients the SAPIEN 3 Ultra; 13 the Navitor, 9 the ACURATE neo2, 14 the Evolut PRO+, and 1 patient the Myvalve). Procedure was successful in all cases (there was 1 capture failure due to pacemaker programming). Two patients required a temporary and permanent pacemaker due to high-grade atrioventricular block. No vascular complications from venous access were documented, not even from the RA guidewire. Procedural time did not increase significantly, and the median length of stay after implantation was 2 days.

Conclusions: In our series, left ventricular pacing using the RA-positioned wire as the anode proved to be effective and safe without increasing procedural time significantly. This procedure also provides the advantage of being able to use the central venous access for possible emergency temporary pacemaker implantation.

Keywords: Aortic stenosis. Transcatheter aortic valve implantation. Left ventricular pacing. Right atrium. Femoral venous access.

Aurícula derecha: un buen aliado en la estimulación ventricular izquierda durante el implante percutáneo de válvula aórtica

RESUMEN

Introducción y objetivos: La estimulación ventricular rápida reduce el gasto cardiaco, proporcionando estabilidad durante el implante percutáneo de válvula aórtica (TAVI). Nuestro objetivo fue evaluar la eficacia y la seguridad de la estimulación ventricular izquierda a través de la guía de alto soporte utilizada para el implante y una guía situada en la aurícula derecha (AD) que actúa como ánodo.

Métodos: La estimulación ventricular izquierda se realiza conectando el extremo externo de una guía Safari2 preformada situada en el ventrículo izquierdo al cátodo de un marcapasos temporal, y el ánodo al cuerpo de una guía Emerald insertada en la aurícula mediante un catéter Judkins Right diagnóstico a través de un acceso venoso femoral [punción ecoguiada]. El marcapasos se programa con salida máxima (20 V) y sensibilidad anulada.

Resultados: Se realizó TAVI transfemoral a 62 pacientes seleccionados (mediana de edad: 79.4 ± 6.5 años) utilizando la técnica de estimulación descrita [25 SAPIEN 3 Ultra, 13 Navitor, 9 ACURATE neo2, 14 Evolut PRO+ y 1 Myvalve]. Con éxito en todos los casos [hubo 1 fallo de captura atribuido a la programación del generador del marcapasos]. Dos pacientes necesitaron marcapasos transitorio y definitivo posterior por bloqueo auriculoventricular completo durante el procedimiento. No se documentaron complicaciones vasculares derivadas del acceso venoso ni del posicionamiento de la guía en la AD. No aumentaron de manera significativa el tiempo del procedimiento ni la fluoroscopia. La mediana de estancia hospitalaria tras el implante fue de 2 días.

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INTRODUCTION

Twenty years have passed since A. Cribier performed the first transcatheter aortic valve implantation (TAVI) in humans. Since 2002 and up until today, the studies published have demonstrated the non-inferiority of TAVI compared to surgical aortic valve replacement in high-risk [PARTNER 1A], moderate- [PARTNER 2 and SURTAVI] and low-surgical risk patients [PARTNER 3 and Evolut Low Risk]. Also, the PARTNER 3 demonstrated the superiority of transfemoral TAVI over surgical aortic valve implantation.

Over the past few years, the implantation technique has become easier thanks to procedural standardization, the operators’ experience, the technological evolution of the devices, and the tendency to perform minimalist approaches, thus reducing complications and allowing faster patient recovery times.

Rapid ventricular pacing necessary to reduce the cardiac output and promote stability during balloon valvuloplasty, valve deployment or postdilation have traditionally been performed through temporary pacemaker implantation into the right ventricle (RV). A way to simplify the procedure and reduce cost that has proven safe and effective is to perform pacing through a high-support guidewire located at left ventricular (LV) level that is connected to the cathode (negative electrode) of the generator of temporary pacemaker using crocodile clips. On the other hand, the anode (positive electrode) of the generator of the temporary pacemaker is placed in the LV (of XS or S size based on the ventricular size).

This study is a different take on the left ventricular pacing technique where the guidewire inserted into the right atrium (RA) acts as an anode. Its efficacy and safety profile, and advantages compared to conventional traditional techniques available will be assessed here.

METHODS

This is single-center, prospective, and observational registry of patients with severe aortic valvular heart disease treated with transfemoral TAVI from November 2021 through September 2022. In patients with baseline conduction disorders involving a higher risk of high-degree atrioventricular block (AVB) during or after the procedure (complete right bundle branch block, selected cases of bifascicular block or bradycardia left to the operator’s criterion), the pacing method used was temporary pacemaker implantation into the RV via jugular vein at the beginning of the procedure. In patients with low risk of AVB regardless of the type of valve implanted (balloon-expandable or self-expanding), rapid ventricular pacing was performed using a high-support guidewire of LV location. The use of a needle inside the subcutaneous cellular tissue or a guidewire into the RA as the anode was left to the operator’s criterion.

Description of the technique

After crossing the aortic valve with a straight guidewire and a diagnostic AL-1 catheter, the former is exchanged for a high-support Safari2 pre-shaped guidewire (Boston Scientific, United States) that is placed in the LV (of XS or S size based on the ventricular size). This guidewire is routinely used in our center for valve implantation purposes. The guidewire external border connects to the negative electrode (cathode) of the generator of the temporary pacemaker using crocodile clips. On the other hand, the anode (positive electrode) of the generator of the temporary pacemaker connects the same way to the body of a 0.035 in guidewire inserted into the RA via femoral venous access (an ultrasound-guided puncture is performed in all cases followed by femoral 6-Fr introducer sheath at this level).

The 0.035 in guidewire used is the Emerald (Cordis, Switzerland) with atraumatic J-shape tip in its distal border—common in our cath lab—for catheter exchange purposes. Across its entire trajectory it is covered by a diagnostic Judkins Right (JR) catheter that acts as an electric insulator during pacing to avoid damaging the vascular structures that run through the guidewire and conduct the electrical charge towards the region of interest except for the guidewire distal border that should remain in close contact with the walls of the RA (figure 2).

This guidewire could also be inserted via jugular venous access. However, in our own experience, femoral vein cannulation is a safe, quick, and easy technique interventional cardiologists have become more familiar with.

Once these connections have been made, the generator of the pacemaker is programmed with the maximum energy output allowed (20-25 V) and cancelled sensitivity. Proper capture is, then, checked. Also, when performing rapid pacing, arterial pressure falls < 50 mmHg. Finally, overpacing is performed at 120 bpm to

Conclusions: En nuestra serie, la estimulación ventricular izquierda utilizando como ánodo la guía situada en la AD ha demostrado ser una técnica eficaz y segura, sin aumentar significativamente el tiempo de procedimiento, y además aporta la ventaja de disponer de acceso venoso central para un posible marcapasos transitorio urgente.


Abbreviations


A. Abril Molina et al. REC Interv Cardiol. 2023;5(3):178-184
180 bpm depending on each case. We should mention that inadequate positioning of the guidewire into the RA can lead to failed captures, which is why checking its location prior to pacing is advised.

**Criteria for temporary pacemaker implantation**

In cases when the patient develops high-degree AVB—both persistent and transient—during the procedure, a temporary pacemaker is implanted at the cath lab using the femoral venous access previously cannulated. In cases of complete AVB without ventricular escape rhythm at < 30 bpm or with a higher escape rhythm but poor hemodynamic tolerance, left ventricular pacing is maintained while the high-support guidewire remains in the LV and a needle is inserted in the skin as an anode until an electrocatheter of temporary pacemaker is implanted into the RV via femoral access. The femoral introducer sheath is maintained in cases of CLBBB (complete left bundle branch block) with de novo QRS complex > 150 ms or transient alternating bundle-branch block. Otherwise, it is removed when the procedure has been completed. Also, mechanical compression is performed at this level (figure 3).

After TAVI, the patient is admitted to the intermediate coronary care unit where cardiac rhythm is monitored for, at least, 24 hours following the 2021 ESC guidelines recommendations on cardiac pacing regarding cardiac monitorization, HV interval measurement or definitive pacemaker implantation. At our center, there is an X-ray room in the cardiology ward. Therefore, if temporary pacemaker implantation is required, it is swiftly implanted by the cardiologist at the intermediate coronary care unit or the cardiologist on call.

**Statistical analysis**

Standard descriptive statistics was used for the patients’ baseline and procedural characteristics, and clinical results. Continuous variables are expressed as mean ± standard deviation or median ± interquartile range based on the sample normal distribution. Categorical variables are expressed as percentages. All statistical analyses were performed using the statistical software package SPSS V25 (IBM, United States).

**RESULTS**

A total of 130 patients were treated with TAVI during the time included in this analysis. Rapid ventricular pacing was performed in 62 cases (58 severe aortic stenoses and 4 pure severe aortic failures)
Conduction disorders after transcatheter aortic valve implantation

Complete AVB was described in 2 patients during the procedure [1 Evolut PRO+ [Medtronic, United States], and 1 Navitor [Abbott, United States]]. One of them had a baseline electrocardiogram with a narrow QRS complex (100 ms), and an image of incomplete right bundle branch block with a complete AVB after the valvuloplasty. The second patient showed no conduction disorders at baseline [PR, 120 ms; QRS, 90 ms], and a complete AVB after valvular deployment. Left ventricular pacing was performed in both with the Safari® pre-shaped guidewire (using a needle inserted into the subcutaneous cellular tissue connected to the positive electrode of the generator of the pacemaker) until the insertion of an electrocautery into the RV via femoral venous access previously cannulated, without complications to eventually implant a definitive pacemaker 24 hours later due to persistent high-degree AVB.

A total of 24.2% of the cases (15 patients) developed CLBBB after valve implantation. In 9 patients [14.5%], bundle branch block was temporary and resolved at the cath lab or a few hours after the procedure. However, one of them developed a complete AVB 24 hours after the procedure (seen during monitorization with telemetry), and another one was readmitted 5 days after valve implantation due to the presence of a symptomatic complete AVB (recurrent syncopes), which is why, in both cases, a definitive pacemaker was implanted (both patients with self-expanding valves). In the remaining cases, the CLBBB was persistent [12.3%]: in 1 patient, the width of the QRS complex narrowed down from 130 ms to 120 ms during admission (4 days of monitorization), 3 patients had previously been treated with a valve-in-valve procedure and, for 5 days of admission and monitorization, they kept the same width of the QRS complex without any other conduction disorders being reported. Also, in 2 patients the HV interval was measured due to a persistent QRS complex of 140 ms and 150 ms [HV interval, 55 mm and 58 ms, respectively]. Therefore, they were all discharged from the hospital without the need for definitive pacing while none of them required definitive pacemaker implantation at follow-up.

We should mention that, in this cohort of patients, balloon-expandable valves had a rate of definitive pacemaker implantation of 0%.

In the 3 patients with baseline CLBBB (2 of them with first-degree AVB) no changes to the baseline electrocardiograms were seen or conduction disorders during monitoring were reported. No definitive pacing has been required at follow-up either.

The low rate of pacemaker implantation in this cohort [6.5%] within the first 30 days after TAVI despite the fact that 58% of the devices were self-expanding valves is mainly attributed to patient selection since, like we already said, in cases with baseline conduction disorders including a high risk of high-degree AVB after TAVI, pacing is performed through temporary pacemaker implantation since the beginning of the procedure. In our entire series of patients, the rate of pacemaker implantation within the first 30 days after TAVI over the past year was 15.5% [being the rate of self-expanding valves implanted over the past 12 months, 69%].

Procedural success, and major adverse cardiovascular events

The rates of immediate procedural success [according to the VARC-3 standard definition], 30-day procedural success, in-hospital mortality, and cardiovascular and 30-day mortality since discharge were 95.2%, 93.5%, 3.2% [2 patients], and 0%, respectively. It was necessary to implant a second valve in 1 patient due to the supra-annular position of the first valve [ACURATE neo2 [Boston Scientific, United States] and then a SAPIEN 3 Ultra. In the emergency procedures performed the immediate and 30-day success rates were 100%.
No neurological adverse events were reported in this cohort at 30 days (in 2 cases a Sentinel device (Boston Scientific, United States) was used for cerebral protection) or coronary occlusions after TAVI. The rate of grade ≥ III major aortic regurgitation after TAVI was 0%.

No femoral venous access-related complications or due to the position of the guidewire into the RA were reported. In 98.3% of the cases, the femoral artery was closed with a collagen-based MANTA vascular closure device. A covered stent was required in 2 patients due to failed device closure. On the other hand, acute arterial ischæmia occurred in 1 patient with severe peripheral arteriopathy.

The mean x-ray and procedural times were 19 ± 3 min and 48 ± 10 min, respectively without significant differences among the 3 types of pacing described. The median length of stay after TAVI was 2 days following all cases a minimalist approach.

Results regarding the procedure immediate success and mortality are similar with the 3 pacing techniques mentioned without higher rates of valve embolization, need for a second valve or significant aortic regurgitation after the procedure in cases where left ventricular pacing was performed using the guidewire located at the RA as the anode. In our overall series of TAVI, the rate of cardiac tamponade due to RV perforation by the electrophysiology insertion for temporary pacemaker implantation was 1.9%.

DISCUSSION

Rapid ventricular pacing reduces the preserved cardiac output, thus providing the necessary stability for valve deployment. Failed ventricular captures during overpacing is associated with a risk of valve embolization or malapposition with potentially devastating
consequences, which is why it is essential to achieve effective overpacing.

Traditionally, ventricular pacing has been performed by inserting a temporary pacemaker into the RV. The standard electrocatheter used for transient pacing has a rigid electrode in its distal end that increases the risk of myocardial perforation. There are other electrodes more commonly used today during TAVI that come with a small balloon in their distal border and are less traumatic. However, since they are softer and more flexible, their implantation is often more challenging and their position less stable, which increases procedural and fluoroscopy times, and the risk of failed capture during overpacing.

Back in 2007, ventricular pacing was described for the first time through a guidewire of LV location in a series of pediatric patients with congenital severe aortic stenosis. It proved to be a safe and effective technique with a lower rate of vascular complications, shorter procedural times, and less expensive compared to the systematic implantation of a temporary pacemaker electrode.

Back in 2019, the EASY TAVI was published. It was the first randomized clinical trial to compare the 2 aforementioned pacing techniques that proved that left ventricular pacing (using, in all cases, a needle inserted into the patient’s skin as the anode) had a similar efficacy, simplified the procedure, and reduced time, fluoroscopy times, costs, and complications (with a higher rate of cardiac tamponade due to RV perforation by the pacemaker catheter). However, the study was only conducted in patients with balloon-expandable valves (SAPIEN 3) in whom the risk of high-degree AVB is lower compared to self-expanding valves.

At our center, the rate of self-expanding valve implantation is high (69% over the past year), which is associated with a higher risk of high-degree AVB and, therefore, definitive pacemaker implantation. Therefore, left ventricular pacing using a guidewire placed in the RA as the anode (positive electrode) is a very effective technique to have a vascular access available since the beginning of the procedure. Therefore, in case of high-degree AVB, temporary pacemaker implantation is often performed quickly to avoid the systematic implantation of an electrocatherer into the RV, thus reducing procedural costs and the rate of complications. On the other hand, in balloon-expandable valves where failed captures during overpacing could jeopardize the immediate success of the procedure, this technique has worked optimally.

We should mention the fact that temporary pacemaker implantation since the beginning of the procedure conditions a lower threshold to keep after leaving the cath lab, thus increasing the risk of infectious, vascular, thromboembolic or cardiac complications and delaying the start of patient mobilization. In cases of left ventricular pacing and RA guidewire, the temporary pacemaker is only kept after leaving the cath lab in the 2 patients with high-degree AVB during implantation. However, in the cohort of patients with temporary pacemaker implantation right from the start, 88.9% [32 patients] have the cath lab with a temporary pacemaker on that was kept for nearly 24 hours. Finally, 37% of these patients [13] had an indication for definitive pacing.

Regarding the use of femoral venous access, we should mention that it comes with some disadvantages regarding the jugular vein. Basically, it’s a less direct access towards the RV, less aseptic, and limits the patient’s mobility until definitive pacemaker implantation. However, the cannulation of the femoral vein is an easy-to-do, safe, and fast technique for interventional cardiologists who are often not that used to jugular venous access that is often cannulated by the assisting anesthesiologist. Less experienced operators can have issues too. In our case, femoral venous puncture was ultrasound-guided in all the cases, and the rate of complications at this level was 0%, being the introducer sheath withdrawn at the end of the procedure in all the patients who did not require a temporary pacemaker or a central venous catheter. In cases that required definitive pacing, the pacemaker was implanted after 24 hours, which reduces complications and minimizes the patient’s mean length of stay.

There is only 1 single-center, observational study in the medical literature available with prospective recruitment of patients and retrospective analysis where left ventricular pacing was performed with a high-support guidewire for valve implantation (Safari) plus a standard guidewire inserted into the inferior vena cava (without introducer sheath) in 226 non-selected patients treated with TAVI from March 2017 through September 2018 [27.4%, CoreValve; 16.4%, SAPIEN; 56.2%, ACURATE neo]. The efficacy of pacing was 99.1% (2 patients required temporary pacemaker implantation due to failed captures with the guidewire). Additionally, in 7.6% of the patients a temporary pacemaker had to be implanted due to conduction disorders during the procedure. Vascular complications occurred in 2.7% of the patients, and the rate of definitive pacemaker implantation was 14%.

One of the main differences with our study is the previous selection of cases at our center being patients with a low baseline risk of developing AVB after TAVI those who benefit the most from pacing with a high-support guidewire into the LV. On the contrary, temporary pacemaker implantation should be considered right from the beginning of the procedure in the presence of baseline conduction disorders that increase the risk of high-degree AVB (mainly complete right bundle branch block). Since there are higher chances of definitive pacing, jugular venous access can be used in these patients for the advantages already mentioned. On the other hand, the technical differences are the insertion of the guidewire into the RA instead of the inferior vena cava—which allows us to check its position at all time to minimize possible failed captures—the fact that the guidewire is covered with a diagnostic catheter that works as an insulator, use a femoral introducer sheath to speed up electrocatheter implantation into the RV, if necessary, and the availability of a central venous catheter during the procedure.

In conclusion, our study proves the efficacy and safety of the pacing technique described in our population of patients treated with transfemoral TAVI with satisfactory results, fewer temporary pacemakers implanted over the past year, and lower procedural cost without complications associated with femoral venous access or guidewire placement into the RA.

Limitations

The study main limitation is that it is an observational, single-center study with a small sample of patients describing all the results obtained since the technique was first used in our center, initially performed by 2 operators and in very selected cases. However, currently, the pacing technique described has been included in the routine interventional clinical practice of our cath labs.

CONCLUSIONS

In our own experience, left ventricular pacing using the needle placed in the RA as the anode has proven a very safe and effective technique in patients with low risk of AVB due to TAVI without increasing procedural time significantly. This technique cuts the costs associated with the systematic use temporary pacemaker. Also, it provides a venous access fully available since the start
WHAT IS KNOWN ABOUT THE TOPIC?

– Rapid ventricular pacing is necessary to reduce the cardiac output and provide stability during TAVI. Therefore, traditionally, a transvenous temporary pacemaker has been placed in the RV. However, its systematic use increases procedural risk, fluoroscopy time, and above all, total cost. Therefore, left ventricular pacing performed through a high-support guidewire used for implantation simplifies the procedure, has proven safe, and has a similar efficacy.

WHAT DOES THIS STUDY ADD?

– This article showed a change to the left ventricular pacing technique in which a high-support guidewire located at the LV was used (connected to the negative electrode of a temporary pacemaker) plus a guidewire placed in the RA (connected to the positive electrode). In our own experience, it is a safe and effective technique without significant differences in procedural or fluoroscopy time with respect to the traditional way of guidewire-driven LV pacing. Also, it provides us with a venous access fully available right from the start of the procedure to facilitate quick electrocatheter implantation into the RV in cases of high-degree AVB.
Spanish cardiac catheterization in congenital heart diseases registry. Second official report from the ACI-SEC and the GTH-SECPCC (2021)

Fernando Ballesteros Tejerizo, Félix Coserría Sánchez, Xavier Freixa, Ignacio J. Amat-Santos, Enrique Balbacid Domingo, Pedro Betrián Blasco, Roberto Blanco Mata, José Ignacio Carrasco, María Jesús del Cerro Marín, Marta Flores Fernández, Alfredo Gómez Jaume, Miguel José Navalón Pérez, Soledad Ojeda Pineda, Fernando Rueda Núñez, Joaquín Sánchez Gila, Ricardo Sanz-Ruiz, and Juan Ignacio Zabala Argüelles

ABSTRACT

Introduction and objectives: This is the 2021 annual activity report from the Interventional Cardiology Association of the Spanish Society of Cardiology (ACI-SEC), and the Interventional Working Group of the Spanish Society of Pediatric Cardiology (GTH-SECPCC). Methods: All Spanish centers with cath lab capabilities and interventional activity in congenital heart diseases were invited to participate. Data were collected online, analyzed by an external company, and ACI-SEC and GTH-SECPCC members. Results: A total of 16 centers participated—15 public and 1 private—including 34 cath labs with experience in congenital heart diseases, 7 of them (20.5%) exclusively dedicated to pediatric patients. A total of 1094 diagnostic studies (4.5% more than 2020) and 1353 interventional catheterizations (5.8% more than 2020) were registered. The most common procedures were atrial septal defect closure (336 cases), pulmonary branch artery angioplasty (231 cases), and percutaneous closure of the patent ductus arteriosus (228 cases). Interventional procedures were considered successful in 95% of the cases with rates of major procedural complication and in-hospital mortality of 2.7% and 0.2%, respectively. Conclusions: This is the second Spanish Cardiac Catheterization in Congenital Heart Diseases Registry report. A significant increase of diagnostic and interventional procedures was reported with a special increase of percutaneous valve implantation, ductus arteriosus closure, and aortic angioplasty. Most interventional techniques continue to demonstrate excellent safety and efficacy outcomes.

Keywords: Congenital heart disease. Cardiac catheterization. Atrial septal defect. Percutaneous valve implantation.
Registro español de intervencionismo en cardiopatías congénitas. II Informe oficial de la ACI-SEC y el GTH-SECPCC (2021)

RESUMEN

Introducción y objetivos: La Asociación de Cardiología Intervencionista de la Sociedad Española de Cardiología (ACI-SEC) y el Grupo de Trabajo de Hemodinámica de la Sociedad Española de Cardiología Pediátrica y Cardiopatías Congénitas (GTH-SECPCC) presentan su informe anual de actividad hemodinámica en cardiopatías congénitas correspondiente al año 2021.

Métodos: Se invitó a participar a los centros españoles con laboratorio de hemodinámica y actividad intervencionista en cardiopatías congénitas. La recogida de datos fue telemática y su análisis lo efectuó una empresa externa junto con miembros de la ACI-SEC y el GTH-SECPCC.

Resultados: Participaron 16 centros (15 públicos y 1 privado) que acumulan 34 salas de hemodinámica con actividad en cardiopatías congénitas; 7 (20,5%) de ellas con dedicación exclusiva a pacientes pediátricos. Se registraron 1,094 estudios diagnósticos (5,1% más que en 2020) y 1,553 cateterismos intervencionistas (6,4% más que en 2020). Las técnicas más frecuentes fueron el cierre de comunicación interauricular (336 casos), la angioplastia de ramas pulmonares (231 casos) y el cierre de ductus (228 casos). Respecto al año anterior se incrementaron significativamente las técnicas de implantación de válvulas percutáneas (29,3%), cierre de ductus (20,6%) y angioplastia aórtica (12,8%). La tasa de éxito en los procedimientos intervencionistas fue del 95%, con una tasa de complicaciones mayores del 2,7% y una mortalidad intrahospitalaria del 0,2%.

Conclusiones: Este trabajo es la segunda publicación del Registro Español de Intervencionismo en Cardiopatías Congénitas. Se ha constatado un aumento significativo de los procedimientos diagnósticos y terapéuticos, destacando el incremento en la implantación de válvulas percutáneas, el cierre de ductus y la angioplastia aórtica. La mayoría de las técnicas intervencionistas siguen demostrando excelentes datos de seguridad y eficacia.


INTRODUCTION

The collaborative effort which was initiated in 2019 by the Interventional Cardiology Association of the Spanish Society of Cardiology and the Interventional Working Group of the Spanish Society of Pediatric Cardiology (GTH-SECPCC) has reactivated and continued the management and improvement of a Spanish registry of interventional procedures in patients with congenital heart diseases of all ages. The previous report that included the activity from 2020 was the first one to be published.2

The current report, analyzed in this article dealing with the activity displayed in 2021, assesses for the very first time, the progression of volume and results of transcatheter procedures to treat congenital heart diseases in our country. It also assesses the implementation of hemodynamic techniques across different age groups. Its publication confirms the collaboration and commitment from both organizations to improve and consolidate it, as well as the dissemination of its outcomes.

METHODS

Data presented here come from an online, unaudited, voluntary, and retrospective registry that is updated on a yearly basis. All hospitals already participating in the Registry of Hemodynamics and Interventional Cardiology of the ACI-SEC, and all pediatric hospitals represented in the GTH-SECPCC were asked to participate. The study period goes from January 1, 2021 to December 31, 2021. Data mining was conducted via telematic format accessible for every participant center through the ACI-SEC official website.2

An external company—Tride Madrid, Spain—managed and analyzed the registry results, with help from members of the GTH-SECPCC and the ACI-SEC board of directors. After data cleaning, deputation, and analysis, discordant values or out of tendency at a given center were confirmed with the investigator responsible at such center.

Due to the methodological characteristics of the study, and since it is an activity registry only, it did not require the approval of the corresponding ethics committee, and informed consents were not deemed necessary.

RESULTS

Resources and infrastructure

Back in 2021, participation included 16 hospitals, 15 from the public system and 1 private center [annex 1]. A total of 34 cath labs with experience the management of congenital heart diseases were included, 7 of which had bi-plane systems, and 14 the possibility to perform rotational angiography. Only 7 (20.8%) were meant for pediatric patients only. Regarding the number of days per month dedicated to performing interventional procedures to treat congenital heart diseases in each center, a median of 7 days [4-18] was reported. In 13 centers (81.2%), 24-hour emergency hemodynamic monitoring was provided for patients with congenital heart disease including patients under 18 years old.

Regarding the amount of medical personnel available, a total of 56 interventional cardiologists with dedication to this activity were included, 27 (52%) and 29 (48%) of whom treated adult and pediatric patients, respectively.

Diagnostic procedures

A total of 1094 diagnostic studies were performed, which is a 5.1% increase in the activity displayed compared to the previous year.
Distribution per age range was: 50 (4.6%) cardiac catheterizations were performed in patients under 1 month old, 117 (10.7%) in patients between 1 month and 1 year, 497 (45.4%) in patients between 1 and 18 years, and 430 (39.3%) in patients over 18 years. A total of 93 (8.5%) were categorized as emergency procedures.

Regarding morbidity, a total of 6 (0.5%) cases of severe complications were reported: 4 vascular and 2 severe hemodynamic instabilities, 1 of which was of anaphylactic etiology. No mortality associated with this type of cardiac catheterizations was reported.

Interventional procedures

A 6.4% increase in the activity reported was seen compared to the previous year: a total of 1553 therapeutic cardiac catheterizations grouped into 13 different categories was reported with the following age distribution: 133 (8.6%) procedures in patients under 1 month, 182 (11.7%) in patients between 1 month and 1 year, 821 (52.9%) in patients between 1 and 18 years, and 417 (26.9%) in patients over 18 years.

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## Table 1. Number of interventional procedures performed and distribution by age group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Fetal</th>
<th>&lt; 1 month</th>
<th>1 month to 1 year</th>
<th>1 to 18 years</th>
<th>&gt; 18 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional procedures</td>
<td>1553</td>
<td>0</td>
<td>133 (8.6)</td>
<td>182 (11.7)</td>
<td>821 (52.9)</td>
<td>417 (26.9)</td>
</tr>
<tr>
<td>Congenital aortic valvuloplasty</td>
<td>45</td>
<td>0</td>
<td>13 (28.9)</td>
<td>10 (22.2)</td>
<td>22 (48.9)</td>
<td>0</td>
</tr>
<tr>
<td>Congenital pulmonary valvuloplasty</td>
<td>104</td>
<td>0</td>
<td>33 (31.7)</td>
<td>30 (28.8)</td>
<td>26 (25.0)</td>
<td>15 (14.4)</td>
</tr>
<tr>
<td>Congenital mitral valvuloplasty</td>
<td>1</td>
<td>–</td>
<td>0</td>
<td>0</td>
<td>1 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary angioplasty</td>
<td>108</td>
<td>–</td>
<td>5 (4.6)</td>
<td>4 (3.7)</td>
<td>56 (51.9)</td>
<td>43 (39.8)</td>
</tr>
<tr>
<td>Pulmonary branch angioplasty</td>
<td>231</td>
<td>–</td>
<td>1 (0.4)</td>
<td>31 (13.4)</td>
<td>150 (64.9)</td>
<td>49 (21.2)</td>
</tr>
<tr>
<td>Aortic angioplasty</td>
<td>123</td>
<td>–</td>
<td>5 (4.1)</td>
<td>32 (26.0)</td>
<td>57 (46.3)</td>
<td>29 (23.6)</td>
</tr>
<tr>
<td>Other angioplasties</td>
<td>119</td>
<td>–</td>
<td>15 (12.6)</td>
<td>18 (15.1)</td>
<td>51 (42.9)</td>
<td>35 (29.4)</td>
</tr>
<tr>
<td>Closure of atrial septal defect/foramen ovale</td>
<td>336</td>
<td>–</td>
<td>–</td>
<td>2 (0.6)</td>
<td>161 (47.9)</td>
<td>173 (51.5)</td>
</tr>
<tr>
<td>Closure of ductus arteriosus</td>
<td>228</td>
<td>19</td>
<td>(8.3)</td>
<td>30 (13.2)</td>
<td>157 (68.9)</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td>Closure of ventricular septal defect</td>
<td>27</td>
<td>–</td>
<td>–</td>
<td>3 (11.1)</td>
<td>18 (66.7)</td>
<td>6 (22.2)</td>
</tr>
<tr>
<td>Other occlusions</td>
<td>80</td>
<td>–</td>
<td>1 (1.3)</td>
<td>8 (10.0)</td>
<td>55 (68.8)</td>
<td>16 (20.0)</td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>26</td>
<td>–</td>
<td>1 (3.8)</td>
<td>1 (3.8)</td>
<td>18 (69.2)</td>
<td>6 (23.1)</td>
</tr>
<tr>
<td>Atrial septostomy and transseptal puncture</td>
<td>54</td>
<td>–</td>
<td>31 (57.4)</td>
<td>5 (9.3)</td>
<td>17 (31.5)</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Transcatheter aortic valve implantation</td>
<td>75</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>32 (42.7)</td>
<td>43 (57.3)</td>
</tr>
</tbody>
</table>

* In this case, data were not collected separately < 1 month and 1 month to 1 year, which is why the value corresponds to < 1 year.
* In the closure of ductus arteriosus, groups are premature (fetal), < 6 months (< 1 month), 6 months to 1 year (1 month to 1 year).
* Data collected as patients < 18 years, which is why the value corresponds to < 18 years.

Data are expressed as no. or percentage (%).
Pulmonary branch angioplasty entailed 231 procedures. The age group with the largest number of dilatations performed was patients between 1 and 18 years with 150 (64.9%) cases. In 206 (89.1%) cardiac catheterizations, the proximal branches were dilated while in the remaining ones peripheral arteries (lobar-segmental) were dilated. Regarding the angioplasty technique used, conventional balloon dilatation was used in 120 (51.9%) cardiac catheterizations, stenting in 106 (45.8%), and cutting balloon dilatation only in 5 (21%).

A total of 123 aortic angioplasties were reported, which is a 12.8% increase compared to the previous year. Also in this category, the age group that accumulated more cases was the 1 to 18 years group with the largest number of dilatations performed was patients between 1 and 18 years with 150 (64.9%) cases. In 206 (89.1%) cardiac catheterizations, the proximal branches were dilated while in the remaining ones peripheral arteries (lobar-segmental) were dilated. Regarding the angioplasty technique used, conventional balloon dilatation was used in 120 (51.9%) cardiac catheterizations, stenting in 106 (45.8%), and cutting balloon dilatation only in 5 (21%).

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Table 2. Efficacy summary reported of all interventional procedures

<table>
<thead>
<tr>
<th>Interventional procedure</th>
<th>N</th>
<th>Successful</th>
<th>Ineffective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital aortic valvuloplasty</td>
<td>45</td>
<td>40 (88.9)</td>
<td>5 (11.1)</td>
</tr>
<tr>
<td>Congenital pulmonary valvuloplasty</td>
<td>104</td>
<td>95 (91.3)</td>
<td>9 (8.7)</td>
</tr>
<tr>
<td>Congenital mitral valvuloplasty</td>
<td>1</td>
<td>1 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary angioplasty</td>
<td>108</td>
<td>104 (96.3)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Pulmonary branch angioplasty</td>
<td>231</td>
<td>216 (93.5)</td>
<td>15 (6.5)</td>
</tr>
<tr>
<td>Aortic angioplasty</td>
<td>123</td>
<td>120 (97.6)</td>
<td>3 (2.4)</td>
</tr>
<tr>
<td>Other angioplasties</td>
<td>119</td>
<td>113 (95.0)</td>
<td>6 (5.0)</td>
</tr>
<tr>
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<td>10 (3.0)</td>
</tr>
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<td>228</td>
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<td>17 (77.3)</td>
<td>5 (22.7)</td>
</tr>
<tr>
<td>Other occlusions</td>
<td>80</td>
<td>80 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>28</td>
<td>23 (88.5)</td>
<td>3 (11.5)</td>
</tr>
<tr>
<td>Atrial septostomy and transseptal puncture</td>
<td>54</td>
<td>53 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Transcatheter aortic valve implantation</td>
<td>75</td>
<td>63 (84.0)</td>
<td>12 (16.0)</td>
</tr>
</tbody>
</table>

Total | 1553 | 1469 (95.0) | 77 (5.0)

* Percentages estimated on 331 reported.
* Percentages estimated on 22 reported.
* Percentages estimated on 53 reported.
* Percentages estimated on 1546 reported.

Data are expressed as no. or percentage (%).

Within the "other occlusion procedures" category, a total of 106 catheterizations were performed with a 24.5% drop in the volume of procedures performed compared to the previous year. Data on the type of occlusion used were reported in 76 (95%) cases like closure of systemic-to-pulmonary artery collateral vessels in 46 (60.5%), closure of venous collaterals in 10 (13.1%), closure of surgical fistulae in 7 (9.2%), and closure of coronary fistulae in 6 (7.8%). The most widely used materials were occluders (37.5%) followed by coil systems (25%), and particles (16.2%).

Atrial septostomy

In this category a total of 54 procedures were reported, which is a 20.6% drop compared to the previous year. Regarding imaging guidance, the echocardiography was used in 21% of the cases, fluoroscopy guidancecin 34.6%, and both techniques combined in 44.2%. A total of 32 (56.1%) procedures were balloon atrial septostomies [Rashkind procedure]. Also, 13 procedures were reported with radiofrequency assisted septal perforation, 9 with needle perforation, and 10 with septal stenting.

Transcatheter aortic valve implantation

A total of 75 procedures were reported, which is a 29.3% increase compared to 202. Up to 43 (57.3 %) cardiac catheterizations were performed in patients over 18 years old. Transcatheter implantation was the rule in all the cases. A total of 63 valves were implanted in the pulmonary position, 10 in the tricuspid position, and 2 in the mitral position.
DISCUSSION

2021 can be considered the year we came back from the COVID-19 pandemic. In this year’s report, the Spanish Registry of Hemodynamic and Interventional Cardiology Activity confirms this recovery compared to 2020. It is especially interesting to see the increased number of structural heart and congenital procedures performed among the adult population reaching all-time maximum levels of activity.\(^3\)\(^4\)

This tendency that demonstrates activity has come back can also be seen in this year’s report thanks to comparison with the data available from the 2019-2021 Spanish Cardiac Catheterization in Congenital Heart Diseases Registry (figure 1). It shows a 6.4\% overall increase of most interventional procedures performed, especially those associated with closure of ductus arteriosus, transcatheter aortic valve implantation, and aortic angioplasty.

Diagnostic catheterization also increased its volume up to 5.1\% reaching 1094 procedures performed, which is a 41.3\% of the overall cardiac catheterizations reported by the registry. These data confirm the relevance of these procedures in the management of patients with congenital heart disease across all age ranges despite the evolution of imaging modalities.

The overall number of interventional procedures reported was 1553. A total of 73.2\% were performed in patients < 18 years old, which shows the predominance of pediatric activity in this registry. However, 2 techniques accumulated the highest percentage of cases in the segment of patients > 18 years: the closure of atrial septal

### Table 3. Distribution of major complications and death across the different interventional procedures performed

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Major complications</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital aortic valvuloplasty</td>
<td>45</td>
<td>5 (11.1): 1 mitral rupture, 1 thrombosis of arterial access, 3 cardiac arrests</td>
<td>0</td>
</tr>
<tr>
<td>Congenital pulmonary valvuloplasty</td>
<td>104</td>
<td>4 (3.8): 1 pulmonary perforation requiring emergency surgery, 1 thrombosis of arterial access, 2 cardiac arrests</td>
<td>0</td>
</tr>
<tr>
<td>Congenital mitral valvuloplasty</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary angioplasty</td>
<td>108</td>
<td>3 (2.8): 2 embolizations (1 requiring surgery), 1 pleural effusion requiring drainage</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary branch angioplasty</td>
<td>231</td>
<td>4 (1.7): 2 vascular dissections, 1 pulmonary hemorrhage, 1 ischemia</td>
<td>0</td>
</tr>
<tr>
<td>Aortic angioplasty</td>
<td>123</td>
<td>6 (4.9): 4 vascular dissections, 1 cardiac arrest, 1 death</td>
<td>1</td>
</tr>
<tr>
<td>Other angioplasties</td>
<td>119</td>
<td>1 death (0.8)</td>
<td>1</td>
</tr>
<tr>
<td>Closure of atrial septal defect/foramen ovale</td>
<td>336(^a) (331)</td>
<td>8 (2.4): 3 embolizations requiring surgery, 5 embolizations not requiring surgery</td>
<td>0</td>
</tr>
<tr>
<td>Closure of ductus arteriosus</td>
<td>228</td>
<td>2 (0.9): 1 arterial pseudoaneurysm, 1 Moderate TR in PTNB</td>
<td>0</td>
</tr>
<tr>
<td>Closure of ventricular septal defect</td>
<td>27(^b) (22)</td>
<td>4 (18.2): 1 embolization requiring surgery, 1 embolization not requiring surgery, 1 atrioventricular block, 1 rupture of the device delivery system that required surgery</td>
<td>0</td>
</tr>
<tr>
<td>Other occlusions</td>
<td>80</td>
<td>1 (1.3): 1 embolization not requiring surgery</td>
<td>0</td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>26</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Atrial septostomy and transseptal puncture</td>
<td>54(^c) (53)</td>
<td>2 (3.8): 1 severe arrhythmia, 1 cardiac arrest</td>
<td>0</td>
</tr>
<tr>
<td>Transcatheter aortic valve implantation</td>
<td>75</td>
<td>6 (8.0): 1 embolization requiring surgery, 1 embolization not requiring surgery, 1 dissection of pulmonary conduit, 1 coronary thrombosis, 1 perforation of pulmonary lobar artery, 1 death</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>1553(^d) (1546)</td>
<td>42 (2.7):</td>
<td>3 (0.2)</td>
</tr>
</tbody>
</table>

\(^a\) Percentages estimated on 331 reported.
\(^b\) Percentages estimated on 22 reported.
\(^c\) Percentages estimated on 53 reported.
\(^d\) Percentages estimated on 1546 reported.

Data are expressed as no. or percentage (%).
defect (51.5%), and transcatheter aortic valve implantation (57.3%). The analysis of data from the 2021 Spanish Registry of Hemodynamic and Interventional Cardiology Activity reveals, once again, the limitation of this report to show the true volume of interventional activity displayed in adult patients with congenital heart disease. Some techniques like the closure of atrial septal defect, the closure of ductus arteriosus or transcatheter pulmonary valve implantation are still underestimated. Conversely, the scarce fetal interventional activity displayed in Spain can be seen in the lack of cases reported despite evidence of its true value and effectiveness in certain prenatal settings of aortic stenosis, pulmonary atresia with intact ventricular septum or hypoplastic left heart syndrome.

The overall data and results of the different interventional techniques available show efficacy and mortality rates of 95% and 0.2%, respectively with just 3 deaths associated with these procedures. These data are very similar to those reported the year before and still consistent with those expected according to different international studies. The rate of serious adverse events, however, has increased significantly (2.7%) with up to 42 major complications compared to the 2% reported back in 2020. Embolizations of different materials still gather the largest number of events reported (19% of the total). Still, they have not gone up as opposed to vascular complications and episodes of hemodynamic instability with associated cardiac arrest that have increased. The improved registry data collection and depuration process could partly explain this increased morbidity reported. Still, it will be interesting to see its evolution in future reports.

Some changes introduced in the registry design have also improved information on some interventional techniques. The "pulmonary angioplasty" has split into 2 separate categories: a category including angioplasties of pulmonary conduits or right ventricular native tracts, and a category including pulmonary branch dilatations. Therefore, the overall increase of cases has been very significant (71%). However, this methodological change does not allow any comparisons with previous years. Also, it has allowed us to know new technical details associated with these procedures: the anatomical concentration of most angioplasties on the proximal segments of pulmonary arteries (89.9%) could explain the scarce use of cutting balloons in this category since it would be more suitable to treat resistant peripheral stenoses rather than conventional dilatations. Within aortic angioplasties, the brand-new reporting of data on the anatomical setting of dilatations allowed to confirm that angioplasties of ascending or abdominal aorta are extremely rare, most cases being dilatations of aortic arch or isthmus (94.5%).

Regarding valvuloplasties, their volume has remained almost unchanged compared to the previous year being most of them performed in patients < 1 year. In aortic valvuloplasty, the high rate of serious events reported (11.1%) is surprising although with no associated mortality, as well as the 89.9% efficacy rate that also worsens a little bit the previous results confirming its status as a high-risk technique, especially in the neonatal setting. Nonetheless, its role as therapeutic option vs repair surgery is still strong and consistent with the medical literature available to this date.

The closure of atrial septal defect is again the interventional procedure most widely used according to the registry, although with a slight 10% drop compared to the previous year. The use of intracardiac ultrasound and balloon measurements as support techniques...
of closure procedures is still scarce. The development of new devices confirms the strength of this technique while the arrival of new materials could reduce potential morbidities in the mid- and the long-term.\textsuperscript{11,12}

The closure of ductus arteriosus has increased its volume by 20\% being very significant the increased number of cases reported in premature patients (8.3\% of the total). Therefore, the margin for growth of this technique in this group of pediatric patients seems evident. In the meantime, other studies are being published on the strength of this procedure compared to the surgical closure option.\textsuperscript{13} We should mention that this is one of the techniques with better efficacy results and lower rates of complications, which reveals the maturity of its implantation in our country.

Same as in former reports, the least effective technique reported (77.3\%) is the closure of ventricular septal defect that still has a high rate of complications (18\%) whose volume keeps dropping significantly. These data confirm its technical difficulty and scarce implantation in our setting. However, the introduction of new closure devices like the adoption of a few technical modifications to the traditional approach could be a paradigm shift supported by recent reports from Spanish interventional working groups.\textsuperscript{14,15}

Another technique that is expanding significantly is transcatheter aortic valve implantation; however, its increase (29\%) is almost exclusively associated, with patients > 18 years. The data reported on its efficacy (84\%) and rate of complications (8\%) reflect how this technique has grown in our setting with the corresponding learning curve. Regarding the anatomical substrate of implantation, the tricuspid position has reached a significant 13\% overall, being implantations in the mitral position exceptionally rare. The availability of new clinically validated valves\textsuperscript{16} is still improving transcatheter treatment options for patients with a dysfunctional right ventricular outflow tract (the group that benefited the most from this procedure).

**Limitations**

The deficient estimate of interventional procedures in patients > 18 years can be considered the main weakness of this registry. The number of participant centers, though representative of the pediatric activity displayed, is still scarce and does not show the actual activity displayed to treat congenital heart disease in the adult population in our country. Fixing this limitation will be the main goal of future registries.

From the methodological standpoint, the parameters of success of certain interventional procedures were not reported, thus assuming the uniformity of criterion of all participants. Furthermore, the scarce information collected on certain techniques like transcatheter aortic valve implantation can diminish the impact of the results obtained. The wider use of this procedure and the addition of new procedures of special interest —like interventional procedures of congenital aortic valve disease— should be considered in future iterations of the registry.

**CONCLUSIONS**

A significant increase in the activity displayed in both cardiac catheterizations and most interventional procedures was reported throughout 2021. A significant increase was seen in the use of procedures like transcatheter aortic valve implantation, closure of ductus arteriosus, and aortic angioplasty. Diagnostic catheterization still plays a key role in the management of patients with congenital heart disease across all age ranges. The safety and efficacy results of most interventional techniques are similar to those reported by the best international registries.

Participation in this registry of a larger number of centers with interventional activity in congenital heart disease will help us achieve a more realistic approach to its true dimension in the years to come.

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**AUTHORS’ CONTRIBUTIONS**

All authors contributed substantially to data mining, and the manuscript critical review process. F. Ballesteros Tejerizo, F. Coserría Sánchez, and X. Freixa also designed and drafted the manuscript.

**CONFLICTS OF INTEREST**

S. Ojeda Pineda is an associate editor of *REC: Interventional Cardiology*; the journal’s editorial procedure to ensure the impartial handling of the manuscript has been followed. The remaining authors declared no conflicts of interest whatsoever.

**WHAT IS KNOWN ABOUT THE TOPIC?**

- Cardiac catheterization is the cornerstone in the management of patients with congenital heart disease.
- Numerous interventional techniques available that apply in this field across all age ranges from fetal to the adult age.
- Knowledge on the degree of implantation of all these techniques in our country and the results reported is still limited.
- The availability of a national registry of pediatric transcatheter procedures and adult congenital procedures is essential for patients, families, and health professionals involved.

**WHAT DOES THIS STUDY ADD?**

- A significant increase of activity was reported during 2021 being transcatheter aortic valve implantation, closure of ductus arteriosus, and aortic angioplasty the techniques that have grown the most.
- Procedures most performed are the closure of atrial septal defect, angioplasty of pulmonary branches, and the closure of ductus arteriosus.
- Data on the safety and efficacy profile of most techniques are consistent with the results published in the medical literature available to this date.
- Device embolization leads the list of complications associated with the procedures described. Also, vascular complications, and episodes of hemodynamic instability have increased with associated cardiac arrests during cardiac catheterization.
ANNEX 1

Centers participating in the Spanish Cardiac Catheterization in Congenital Heart Diseases Registry (in alphabetical order)

- Complexo Hospitalario Universitario, A Coruña, Spain
- Hospital Clínico Universitario de Valladolid, Valladolid, Spain
- Hospital Regional Universitario de Málaga (Materno-Infantil), Málaga, Spain
- Hospital Universitario de Cruces, Barakaldo, Bizkaia, Spain
- Hospital Universitario 12 de Octubre (Instituto Pediátrico del Corazón), Madrid, Spain
- Hospital Universitario Gregorio Marañón, Madrid, Spain
- Hospital Universitario La Paz, Madrid, Spain
- Hospital Universitario y Politécnico La Fe, Valencia, Spain
- Hospital Universitario Ramón y Cajal, Madrid, Spain
- Hospital Universitario Reina Sofia, Córdoba, Spain
- Hospital Universitario Son Espases, Palma de Mallorca, Spain
- Hospital Universitario Vall d’Hebron, Barcelona, Spain
- Hospital Universitario Virgen de la Arrixaca, Murcia, Spain
- Hospital Universitario Virgen de las Nieves, Granada, Spain
- Hospital Universitario Virgen del Rocio, Sevilla, Spain
- Hospital Vithas 9 de Octubre, Valencia, Spain

REFERENCES


Fluoroscopic and tomographic correlation for aortic annulus measurements in transcatheter aortic valve implantation: “follow the right cusp” rule

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ABSTRACT

Introduction and objectives: Coronary computed tomography angiography (CCTA) has become the gold standard to measure the size of the aortic annulus and better select the size of transcatheter heart valves (THV) in patients undergoing transcatheter aortic valve implantation (TAVI). However, in selected cases, CCTA may not be feasible. Angiographic aortic annulus (AAA) measurements during TAVI may be an alternative and should be evaluated for precision regarding the proper selection of THV sizes. We sought to investigate the correlation between AAA and CCTA measurements for the proper selection of balloon-expandable valve (BEV) sizes in patients undergoing TAVI.

Methods: Patients undergoing TAVI with BEV and high-quality CCTA were included. AAA measurements were obtained in the standard 3-cusp view after aortic root aortography. Angiographic distance between non- and left coronary cusps were compared to CCTA annulus measurements. Endpoints were diagnostic tests and correlations between angiographic and CCTA measurements, and the composite endpoint of the V ARC-3-defined efficacy (technical success, correct position, and intended performance), and safety profile (multiple valves, valve embolization, pacemaker implantation, and more than moderate valvular regurgitation).

Results: Regarding the Sapien family of THV, aortography-based distance measurements showed a correlation of 0.528 ($P < .01$), 0.451 ($P < .01$), and 0.579 ($P < .01$) for 23 mm, 26 mm, and 29 mm valves with CCTA-based distance measurements. No difference was seen regarding the V ARC-3-defined efficacy (94.2% vs 96.0%; $P = .60$) and safety profile (90.9% vs 91.9%; $P = .84$) among cases showing discordant and concordant pairs of measurements.

Conclusions: AAA measurement showed a moderate diagnostic test and Spearman’s correlation coefficient compared to CCTA-based annulus assessment for perioperative THV size selection. This strategy could potentially enable TAVI in patients in whom access to preoperative CCTA is not available.

Keywords: non-coronary cusp, left coronary cusp, aortography, angiographic aortic annulus measurements, transcatheter aortic valve implantation.
Métodos: Se incluyeron pacientes de TAVI con prótesis de balón expandible y angio-TC de alta calidad. Las mediciones del AAA se obtuvieron de la angiografía de la raíz aórtica en proyección de 3 cúspides. Se comparó la distancia angiográfica entre la cúspide izquierda y no coronaria con las mediciones de angio-TC. Se evaluaron la prueba diagnóstica y la correlación entre las medidas angiográficas y de angio-TC, así como la eficacia (éxito técnico, posición correcta y desempeño intencionado) y la seguridad (múltiples válvulas, embolización, implante de marcapasos e insuficiencia valvular moderada o mayor) definida por VARC-3.

Resultados: Para válvulas con balón expandible de 23 mm, la distancia en la aortografía tuvo una correlación de 0,528 (p < 0,01) comparada con las mediciones de angio-TC; para las de 26 mm, la correlación fue de 0,451 (< 0,01), y para las de 29 mm fue de 0,579 (< 0,01). No hubo diferencia en cuanto a eficacia (84,2 frente a 96,0%; p = 0,60) y seguridad (90,9 frente a 91,9%; p = 0,84) entre casos con medidas concordantes y discordantes.

Conclusions: Las mediciones del AAA mostraron un moderado valor de prueba diagnóstica y de correlación Spearman en comparación con el angio-TC para elegir el tamaño de la válvula cardíaca percutánea. Esta estrategia podría permitir un TAVI en situaciones en que la angio-TC no esté disponible.


INTRODUCTION

During transcatheter aortic valve implantation (TAVI), coronary computed tomography angiography (CCTA) remains the key factor to determine the characteristics of the aortic valve and predetermine the size of annular valve prior to the selection of specific transcatheter heart valves [THV].1,2 Several CCTA protocols were described to achieve reproducible and reliable aortic annulus measurements.3-6 At the same time, transathoracic and transesophageal echocardiographic measurements were used to determine the aortic valve annular size showing good correlation with the gold standard of direct surgical and CCTA-based measurements.7 However, CCTA showed better image quality acquisition, detailed evaluation of the aortic annulus, and other useful anatomicies for transfemoral TAVI (aorto-iliac-femoral vessels)7 making CCTA the default strategy for preoperative planning.

Adequate THV size selection is an important factor to prevent patient-prosthesis mismatch and reduce the risk of over- and under-sizing and, hence, the increased risk of all-cause-mortality and unplanned repeat reintervention.8,9 While CCTA has been established as the gold standard method for annular sizing pre-TAVI implantation,4 an associated risk between radiation exposure and cancer, and contrast media and nephropathy has also been described.10,11 Furthermore, in selected cases, CCTA may not be feasible prior to TAVI following emergency clinical indications and/or the patients’ unstable conditions.

Aortography-only annular measurement was described as an efficient technique to determine the size of aortic annulus and select the size of the THV.12,13 Based on the standard 3-cusp view, the angiographic determination of anatomical dimensions with contrast media (and/or balloon-sizing) can facilitate the identification of proper annular size when CCTA-based sizing is not available.14-17 Aortography-based measurements have been shown to correlate with direct anatomical preoperative aortic annulus measurements.13 Against this background, we sought to investigate whether angiographic aortic valve annular measurements between the non-coronary [NCC] and left coronary cusp [LCC] correlate with CCTA-based measurements to facilitate proper size selection of the THV in a retrospective, all-comers, single-center cohort of patients undergoing TAVI.

METHODS

Study population

This retrospective, observational analysis evaluated all consecutive patients undergoing transfemoral TAVI following heart team evaluation at the German Heart Center cardiovascular disease unit in Munich, Germany. Transfemoral TAVI was performed using a minimalistic approach16 in all cases, while THV size selection was left to the operator’s discretion based on size chart, CCTA measurements, anatomical factors including calcium distribution and severity, aortic valve annular size, coronary height, and disease.

All patients with native tricuspid calcified aortic valve disease, and available high-quality CCTA for TAVI were included in this study. Procedural information was obtained from a customized database and screened for all patients treated from January 2014 through December 2021 at the German Heart Center in Munich, Germany. During this period, a total of 2500 transfemoral TAVI cases were performed using commercially available balloon-expandable (1865) and self-expanding (635) THVs. Only those who received the SAPIEN 3 or the SAPIEN 3 Ultra [Edwards Lifesciences, United States] balloon-expandable valves [BEV] were included in this analysis.

The study was performed in full compliance with the principles set forth in the Declaration of Helsinki, and all patients gave their written informed consent to undergo the procedure. Ethical approval was obtained from the Technical University of Munich ethical committee under registry no. OBSERVATVI [#525/17]. CCTA measurements were performed before THV implantation. Angiographic aortic valve annular measurements between the NCC and LCC were performed offline and documented in the database. The baseline clinical and procedural characteristics (including size of the implanted THV and angiographic aortic regurgitation after implantation), and test lab results were obtained from registry data or the
clinical records, as appropriate. Regarding the Valve Academic Research Consortium 3 (VARC-3) defined safety and efficacy profile, in-hospital and discharge follow-up was monitored and registered. A 30-day follow-up was established via telephone call, hospital visits or follow-up letter.

Coronary computed tomography angiography measurements

CCTA was analyzed by 1 experienced cardiologist (HA) while a second experienced cardiologist (JM) analyzed a sample of 40 cases to determine inter-observer variability. Using multi-slice computed tomography reconstruction, quantitative measures of the aortic valve annular size (minimum, maximum and mean diameter, perimeter, and area) were obtained based on predefined protocols using 3-Mensio software (Pie Medical Imaging, The Netherlands). In summary, the 3 hinge points of the aortic cusps were detected and selected. After proper identification of the 3 hinge points, the aortic annulus was seen in automatic multiplanar reconstruction. Annular measurements were obtained 0.5 mm below the hinge points, and the aortic valve annular contour was traced to calculate the perimeter-derived area and diameter (figure 1A). To define the direct one-planar measurement between the NCC and the LCC on the CCTA, a straight line between the red (LCC) and yellow (NCC) hinge points was used to determine length (figure 1B,C). The most appropriate THV size was selected based on size chart recommendations and anatomical considerations (figure 1D). CCTA-based measurements and calculations were used to determine the proper THV size according to commercial size charts supplied by the manufacturer. The mean diameter and area of the aortic annulus were used to select the THV size [23 mm, 26 mm, and 29 mm] and then coded as a binary variable for each size category; when only 1 measurement was within the proposed range for a specific THV size based on the manufacturer’s size chart [within the gray zone], the area was used to decide the final THV size.

Aortographic measurements

All procedures were performed by experienced TAVI operators using a monoplane digital flat panel detector X-ray system (Allura Xper FD 10 C, Royal Philips, The Netherlands) in a dedicated hybrid cath lab. All fluoroscopic 3-cusp view images were analyzed after completion of the procedure and images with distance measurements saved. Angiographic measurements were obtained offline from the angiographic aortic root injection (native annulus without the implanted THV) using a 5-Fr pigtail catheter placed in the right coronary cusp in the standard 3-cusp view. The distance between the NCC and LCC hinge points was measured by experienced cardiologists (HA and JM) using dedicated Phillips...
software (figure 2A-H). Angiographic measurements were performed after automatic (based on calibration factor determined by the software) and manual (using the 5-Fr catheter as reference calibration factor) calibration to determine the distance in millimeters.

Endpoints

Endpoints were the correlation between angiographic and CCTA measurements of the distance between the NCC and the LCC. The rates of the VARC-3-defined efficacy (technical success, correct position, and intended performance using VARC-3 definitions) and safety profile (multiple valves, valve embolization, pacemaker implantation, and more than moderate valvular regurgitation using VARC-3 definitions) in patients with concordant and discordant measurements between angiographic and CT-based measurements were also analyzed.

Rates of in-hospital complications defined as conversion to surgery, perioperative death, life-threatening bleeding, major and minor bleeding, major and minor vascular complications, and in-hospital mortality in patients with concordant and discordant measurements were reported. The 30-day mortality rate, chronic heart failure, stroke, valve dysfunction, aortic mean gradient, and aortic regurgitation were reported too.

Statistical analysis

Categorical variables were expressed as frequencies and proportions and compared using the chi-square test or Fisher’s exact test, as appropriate. Continuous data were tested for normality with the Shapiro-Wilk test and expressed as mean (± standard deviation) or median [interquartile range (IQR)] as appropriate, and then compared, respectively, using the unpaired t test or the Mann-Whitney U test.

The study population was divided into derivation (n = 1256), and validation cohort (n = 40 cases). The study group of interest was obtained from the derivation cohort (n = 393). In the derivation cohort, selection of specific THV sizes (23 mm, 26 mm, and 29 mm) based on the gold standard CCTA assessment was categorized as a binary variable and then compared to the THV size selection derived from aortography. Subsequently, logistic regression analysis was performed using the binary variable from the CCTA-based THV selection as a dependent variable while aortographic distance measurements were considered an independent variable. Afterwards, the receiver operating characteristic (ROC) curve was analyzed to identify optimal cut-off criteria (distance in mm, Youden’s index) and determine individual diameter ranges based on aortographic distance measurements of each category of THV sizes. The lowest value from the smallest THV and the highest value from the largest THV was determined using the 25th and 75th IQR, respectively, taken from the distribution of the derivation population. The suggested THV size was derived using aortography with manual or automatic calibration. Sensitivity, specificity, positive, and negative predictive values, as well as positive and negative likelihood were used to determine diagnostic accuracy index. Bland-Altman plots were used to test correlation between the CT NCC-LCC and the NCC-LCC aortography with manual calibration and NCC-LCC aortography with automatic calibration.

Inter- and intra-observer analysis using intraclass correlation coefficient (with absolute agreement) and Pearson correlation coefficient for dichotomized data were performed in a sample of 40 cases between the 2 independent cardiologists.

To perform internal validation, previously established cut-off values to determine THV size by aortography were applied in a separate
cohort of 40 patients (validation cohort) and compared using the gold standard CCTA-based sizing determination.

Pairs of sizing results based on angiography and CCTA were generated as a study group of interest and classified as concordant or discordant after comparison using the chi square test or Fischer’s exact test, unpaired t test or the Mann-Whitney U test, as appropriate. Statistical analysis was performed using IBM SPSS Statistics software package (version 27, IBM Corporation, United States). All tests were 2-sided at the 0.05 significance level.

RESULTS

After exclusion, 1256/2500 (50.2%) patients who received a BEV were evaluated in the validation cohort (figure 3). Aortography-based diameter measurements were feasible in 393 of these patients (15.7%) (study group of interest).

Baseline and CCTA characteristics are shown on table 1. The median age of the entire population was 81 (77-85) years, 34.3% female, with a left ventricular function of 60% [47-60], and a median EuroScore II of 3.74 [2.14-6.24].

Procedural characteristics are shown on table 2. Procedural time, fluoroscopic dose, and fluoroscopic time were 48 min [38-59], 919 [444-1712] cGys/cm², and 10.9 min [8.2-14.7], respectively. Technical success was achieved in 95.4% of the cases. Regarding in-hospital complications [table 3], there rates of major bleeding events, major vascular complication, and in-hospital mortality were 16.1%, 14.6%, and 1.5%, respectively.

No differences were reported regarding the efficacy [94.2% vs 96%; P = .60] and safety profile [90.9% vs 91.9%; P = .84] between discordant and concordant pairs of tomographic and angiographic measurements using aortography with manual calibration, respectively (table 4).

A moderate correlation was seen between CCTA-based assessment and aortographic THV size determination: 23 mm, 26 mm, and 29 mm THV sizes were associated with Spearman’s correlation coefficients of 0.528 [P < .01], 0.451 [P < .01], and 0.579 [P < .01], respectively. For more details, see tables 1-3 of the supplementary data.
The suggested angiographic cut-off values for each THV size are shown on table 5. In brief, the best diameter range for selecting 23 mm BEVs was 18.46 mm to 22.55 mm; for 26 mm THVs the best diameter range was 21.55 mm to 24.55 mm while for 29 mm THVs the best diameter range was ≥ 24.25 mm to < 28.50 mm.

The intra- and inter-observer intraclass correlation coefficients were 0.931 (95%CI, 0.869-0.963; \(P < .01\)), and 0.902 (95%CI, 0.814-0.948; \(P < .01\)), respectively (see table 4 of the supplementary data). The CT NCC-LCC distance and NCC-LCC showed an intraclass correlation coefficient of 0.885 (95%CI, 0.834-0.920; \(P < .01\)) (figure 4).

The values obtained were tested and compared with the validation cohort (\(n = 40\)) showing moderate-to-good diagnostic test analysis with a good Spearman’s correlation coefficient [0.711 (95%CI, 0.506-0.840; \(P = < .01\)], and moderate diagnostic accuracy [table 5 of the supplementary data]. The validation cohort of 40 patients is shown on tables 6 to 10 of the supplementary data.

The 30-day follow-up is shown on table 6. There was no difference in 30-day mortality between discordant and concordant tomographic and angiographic measurements [1.7% vs 2.6%; \(P = .73\)]. There was no difference at 30 days regarding the mean gradient [11 [10-16] vs 12 [10-15] mmHg; \(P = .76\)], and more than moderate aortic regurgitation (3.2% vs 1.1%; \(P = .34\)) using aortography with manual calibration between discordant and concordant tomographic and angiographic measurements, respectively.

### Table 1. Baseline characteristics (continued)

<table>
<thead>
<tr>
<th>Balloon-expandable valve (N = 393)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Perimeter, mm</td>
<td>79 (74-84)</td>
</tr>
<tr>
<td>Visual estimate of the severity of valve calcification</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>80 (20.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>185 (47.3)</td>
</tr>
<tr>
<td>Severe</td>
<td>126 (32.2)</td>
</tr>
<tr>
<td>Visual estimate of the severity of annular calcification</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>55 (14.1)</td>
</tr>
<tr>
<td>Mild</td>
<td>268 (68.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>67 (17.1)</td>
</tr>
<tr>
<td>Severe</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Visual estimate of the severity of LVOT calcification</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>223 (57)</td>
</tr>
<tr>
<td>Mild</td>
<td>145 (37.1)</td>
</tr>
<tr>
<td>Moderate</td>
<td>23 (5.9)</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%), mean ± standard deviation or mean [interquartile range]. Ao, aortic; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass graft; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society angina grading scale; CCTA, coronary computed tomography angiography; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MI, myocardial infarction; mg/dL, milligrams per deciliter; mL/min, milliliters per minute; mm², square millimeters; mmHg, millimeters of mercury; NYHA, New York Heart Association functional classification; PAD, peripheral artery disease; PCC, percutaneous coronary intervention; sPAP, systolic pulmonary artery; TIA, transient ischemic attack; %, percentage.

### Table 2. Procedural characteristics

<table>
<thead>
<tr>
<th>Balloon-expandable valve (N = 393)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective</td>
<td>389 (99.5)</td>
</tr>
<tr>
<td>Need for intubation</td>
<td></td>
</tr>
<tr>
<td>Prophylactic</td>
<td>5 (1.3)</td>
</tr>
<tr>
<td>Emergency</td>
<td>8 (2)</td>
</tr>
<tr>
<td>Use of ECMO</td>
<td></td>
</tr>
<tr>
<td>Prophylactic</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Emergency</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Use of cerebral protection device</td>
<td>16 (4.1)</td>
</tr>
<tr>
<td>Size of the valve implanted</td>
<td></td>
</tr>
<tr>
<td>23 mm</td>
<td>118 (30.2)</td>
</tr>
<tr>
<td>26 mm</td>
<td>207 (52.9)</td>
</tr>
<tr>
<td>29 mm</td>
<td>66 (16.9)</td>
</tr>
<tr>
<td>THV implanted</td>
<td></td>
</tr>
<tr>
<td>SAPIEN 3</td>
<td>95 (24.3)</td>
</tr>
<tr>
<td>SAPIEN 3 Ultra</td>
<td>296 (75.7)</td>
</tr>
<tr>
<td>Predilatation</td>
<td>166 (42.5)</td>
</tr>
<tr>
<td>Postdilatation</td>
<td>54 (13.8)</td>
</tr>
<tr>
<td>Contrast media, mL</td>
<td>139 [110-172]</td>
</tr>
<tr>
<td>Fluoroscopic time, min</td>
<td>10.9 [8.2-14.7]</td>
</tr>
<tr>
<td>Fluoroscopic dose, cGys/cm²</td>
<td>919 [444-1712]</td>
</tr>
<tr>
<td>Procedural time, min</td>
<td>48 [38-59]</td>
</tr>
<tr>
<td>Technical success</td>
<td>373 (95.4)</td>
</tr>
<tr>
<td>Procedural success</td>
<td>384 (98.2)</td>
</tr>
<tr>
<td>Intended performance</td>
<td>380 (97.2)</td>
</tr>
<tr>
<td>Correct position</td>
<td>389 (99.5)</td>
</tr>
<tr>
<td>Multiple valves</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Access site complications</td>
<td>18 (4.6)</td>
</tr>
<tr>
<td>THV embolization</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>5 (1.3)</td>
</tr>
<tr>
<td>Annular rupture</td>
<td>3 (0.8)</td>
</tr>
<tr>
<td>Coronary impairment</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Procedural CPR</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Procedural mortality</td>
<td>3 (0.8)</td>
</tr>
<tr>
<td>Angiographic AR ≥ moderate</td>
<td>5 (1.3)</td>
</tr>
<tr>
<td>Postoperative mean gradient, mmHg</td>
<td>9 [5-10]</td>
</tr>
<tr>
<td>Days at the ICU</td>
<td>1 [1-1]</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%), mean ± standard deviation or mean [interquartile range]. AR, aortic regurgitation; cGys/cm², centiGrays per square centimeters; CPR, cardiac pulmonary resuscitation; ECMO, extra corporeal membrane oxygenator; ICU, intensive care unit; THV, transcatheter heart valve; min, minutes; mL, milliliters; mm, millimeters.
Table 3. In-hospital complications

<table>
<thead>
<tr>
<th></th>
<th>Balloon-expandable valve (N = 393)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life-threatening bleeding</td>
<td>11 (2.8)</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>63 (16.1)</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>65 (16.6)</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>57 (14.6)</td>
</tr>
<tr>
<td>Minor vascular complications</td>
<td>80 (20.5)</td>
</tr>
<tr>
<td>TIA</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Major stroke</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>5 (1.3)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3 (0.8)</td>
</tr>
<tr>
<td>New pacemaker implantation</td>
<td>26 (6.6)</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>6 (1.5)</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%). TIA, transient ischemic attack.

Table 4. Procedural complications in concordant and discordant valve sizes using manual and automatic calibration in aortography vs CCTA (N = 393)

<table>
<thead>
<tr>
<th></th>
<th>All (N = 393)</th>
<th>Discordant (N = 121)</th>
<th>Concordant (N = 272)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical success</td>
<td>386 (98.2)</td>
<td>118 (97.5)</td>
<td>268 (98.5)</td>
<td>.44a</td>
</tr>
<tr>
<td>Correct position</td>
<td>391 (99.5)</td>
<td>120 (99.2)</td>
<td>271 (99.6)</td>
<td>.52a</td>
</tr>
<tr>
<td>Intended performance</td>
<td>382 (97.2)</td>
<td>117 (96.7)</td>
<td>265 (97.4)</td>
<td>.74a</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple valves</td>
<td>1 (0.3)</td>
<td>0 (0)</td>
<td>1 (0.4)</td>
<td>&gt; .99c</td>
</tr>
<tr>
<td>THV embolization</td>
<td>1 (0.3)</td>
<td>0 (0)</td>
<td>1 (0.4)</td>
<td>&gt; .99c</td>
</tr>
<tr>
<td>New pacemaker implantation</td>
<td>27 (6.9)</td>
<td>9 (7.4)</td>
<td>18 (6.6)</td>
<td>.83d</td>
</tr>
<tr>
<td>AR &gt; moderate after valve implantation</td>
<td>5 (1.3)</td>
<td>2 (1.7)</td>
<td>3 (1.1)</td>
<td>.64d</td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>4 (1.0)</td>
<td>1 (0.8)</td>
<td>3 (1.1)</td>
<td>&gt; .99d</td>
</tr>
<tr>
<td>Procedural mortality</td>
<td>3 (0.8)</td>
<td>1 (0.8)</td>
<td>2 (0.7)</td>
<td>&gt; .99d</td>
</tr>
<tr>
<td>Life-threatening bleeding</td>
<td>11 (2.8)</td>
<td>5 (4.1)</td>
<td>6 (2.2)</td>
<td>.32e</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>64 (16.3)</td>
<td>20 (16.5)</td>
<td>44 (16.2)</td>
<td>&gt; .99e</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>66 (16.8)</td>
<td>16 (13.2)</td>
<td>50 (18.4)</td>
<td>.24e</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>58 (14.8)</td>
<td>17 (14)</td>
<td>41 (15.1)</td>
<td>.87e</td>
</tr>
<tr>
<td>Minor vascular complications</td>
<td>81 (20.6)</td>
<td>22 (18.2)</td>
<td>59 (21.7)</td>
<td>.50e</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>6 (1.5)</td>
<td>2 (1.7)</td>
<td>4 (1.5)</td>
<td>&gt; .99e</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%). AR, aortic regurgitation; CCTA, coronary computed tomography angiography; no., number; %, percentage.

Discussion

This single-center, retrospective, observational study investigated the correlation and diagnostic accuracy between angiographic and tomographic measurements to determine THV size according to 1 single angiographic measurement between the NCC and the LCC in patients treated with BEV.

Regarding this objective, the most salient findings are a) angiographic aortic valve annular size determination based on distance measurements between the NCC and LCC is reproducible; b) diagnostic accuracy between CCTA-based and angiography-based aortic valve annular size determination is of moderate strength [table 5 of the supplementary data]; and c) internal validation of previously established diameter ranges for angiography-based aortic valve annular size determination revealed moderate diagnostic accuracy.

We found a moderate overall diagnostic accuracy and correlation between angiographic and CCTA measurements to determine aortic valve annular size for THV selection. The use of angiography only measurements may expand the minimalistic TAVI approach in scenarios where CCTA is not an option or is unavailable.

The gold standard method to size the aortic annulus is direct surgical measurement, which is impossible in the TAVI setting. Hereby, several non-invasive reproducible methods have been used to determine the aortic valve annular size. 1,5-7,20 However, the CCTA has been established as the gold standard diagnostic tool to determine aortic valve annular size dimensions due to its outstanding reproducibility. Before CCTA was established as the actual gold standard method, angiographic measurements were used demonstrating good correlation with direct perioperative measurements in patients undergoing surgical aortic valve replacement. 13 The comparison of transesophageal echocardiography and CCTA and direct perioperative measurements reported by Wang et al. 12 showed a moderate correlation. Our study showed moderate diagnostic accuracy and correlation between angiographic and tomographic measurements to determine THV size. Similar results were previously tested in a small sample size of 50 patients where 60% of the valves were properly sized with fair-to-moderate agreement between angiography- and CCTA-guided selections. 12 This provides evidence that angiography measurements could potentially be used in scenarios where CCTA is not available or its application is of increased risk.

Radiation exposure during CCTA assessment

It has been shown that TAVI-related imaging studies can potentially increase radiation exposure by some 15.4 to 79 mSv [millisieverts] with the TAVI procedure alone accounting for an effective dose of 26.9 ± 8 mSv and a dose-area product of 2006.3 ± 1152.2 cGy·cm² [centiGray·centimeters²]. This radiation exposure is associated with a 70% and 50% increased risk of lung cancer-related death in women and men, respectively, and a 12% to 21%, and 23% to 33% risk of leukemia in women and men, respectively. 11 We should mention that our study population experienced lower procedural radiation exposure [919 [444-1712] cGy·cm²] during TAVI including aortic valve annular sizing that may reduce radiation-associated risk of cancer. Using intraoperative low-dose radiation protocols can achieve equal
efficacy in TAVI patients same as standard protocols without compromising safety, thus reducing radiation exposure and its associated risk. Additionally, the use of balloon-sizing combined with our proposed angiographic measurements may increase accuracy when determining the necessary THV size. Specifically, when the aortography annular measurement falls near the cut-off value between 2 different THV sizes, balloon-sizing can be used to confirm the use of the larger or smaller device. Although the additional use of balloon-sizing could increase radiation exposure due to additional imaging acquisition, the use of low-dose radiation protocol can reduce this risk without impacting the final result.

**Contrast media-associated nephropathy**

Besides the benefits of mitigating radiation-associated risks, contrast media-associated nephropathy remains a critical concern in patients undergoing TAVI. Chronic kidney disease is present in around 38% of patients with aortic valve stenosis, 55%, 30%, and 15% of whom show mild, moderate, and severe chronic kidney disease. The use of contrast media can exacerbate acute kidney injury after its administration in patients with moderate-to-severe chronic kidney disease (from 2% to 17%) with a higher estimated 5-year mortality rate.

Previous studies have demonstrated the safety and efficacy profile of TAVI compared to surgical aortic valve replacement across all ranges of surgical risk. Against this background, our data suggest that using aortography is safe to facilitate THV size selection in selected indications. In cases where aortography THV sizing was concordant with CCTA determined THV size, the safety and efficacy outcomes reported compared favorably to studies published in similar risk categories of patients.
Table 6. 30-day follow-up comparing concordant vs discordant measurements using balloon-expandable valve

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 393)</th>
<th>Discordant (N = 121)</th>
<th>Concordant (N = 272)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>9 (2.3)</td>
<td>2 (1.7)</td>
<td>7 (2.6)</td>
<td>.72</td>
</tr>
<tr>
<td>CHF</td>
<td>24 (6.1)</td>
<td>8 (6.6)</td>
<td>16 (5.9)</td>
<td>.82</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (0.5)</td>
<td>0 (0)</td>
<td>2 (0.7)</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Valve dysfunction</td>
<td>8 (2)</td>
<td>2 (1.7)</td>
<td>6 (2.2)</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>60 (60-60)</td>
<td>60 (57-60)</td>
<td>60 (50-60)</td>
<td>&lt; .01</td>
</tr>
<tr>
<td>Mean gradient, mmHg</td>
<td>12 (10-15)</td>
<td>11 (10-16)</td>
<td>12 (8.8-15)</td>
<td>.76</td>
</tr>
<tr>
<td>AR &gt; moderate, (n = 279)</td>
<td>5 (1.8)</td>
<td>3 (3.2)</td>
<td>2 (1.1)</td>
<td>.33</td>
</tr>
<tr>
<td>NYHA ≥ III, (n = 345)</td>
<td>18 (5.2)</td>
<td>5 (4.6)</td>
<td>13 (5.5)</td>
<td>.80</td>
</tr>
</tbody>
</table>

Data are expressed as no. (%), mean ± standard deviation or mean (interquartile range). AR, aortic regurgitation; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; mmHg, millimeters of mercury; NYHA, New York Heart Association functional class. 

WHAT IS KNOWN ABOUT THE TOPIC?

- Little has been investigated in relation to the implementation of aortography as a diagnostic test to determine aortic valve annular size.
- Former studies used aortography to determine balloon size in valvuloplasty treatment in the pre-TAVI era.
- Aortography has been used in the TAVI era as a method to determine annular plane and for valve delivery purposes.

WHAT DOES THIS STUDY ADD?

- Implementation of aortography in addition to coronary computed tomography angiography (CCTA) may help us decide the size of the valve where gray zones areas are seen on the CCTA.
- Aortography measurements are reproducible and give moderate accuracy to decide the size of the valve in cases where CCTA is not available, and patients must be treated immediately.

CONCLUSIONS

Angiographic aortic valve annular measurements are reproducible and show moderate correlations and diagnostic accuracy compared to CCTA measurements when selecting the proper BEV THV size. This technique may be appropriate in situations when CCTA is not available, when high radiation exposure needs to be avoided, for patients in critical condition, and to reduce the risk of contrast-induced nephropathy. This strategy could potentially advance the minimalistic TAVI approach in selected patients.

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None whatsoever.

AUTHORS’ CONTRIBUTIONS

H. A. Álvarez-Covarrubias: conceptualization, methodology, formal analysis, investigation, resources, and original drafting of the manuscript. M. Kasel: conceptualization, original drafting of the manuscript, and editing. J.M. Michel: original drafting of the manuscript, and formal analysis. S. Cassese: visualization, investigation: S. Kufner: supervision, and data curation. C. Duesmann, C. Pellegrini, T. Rheude, and N. P. Mayr: resources, and data curation. H. Schunkert: supervision, drafting and revision of the manuscript, and visualization editing. A. Kastrati: supervision, visualization, drafting and revision of the manuscript, and editing. E. Xhepa: drafting of the manuscript, supervision, and formal analysis. G. Borrroyo-Sánchez, and M. Joner: conceptualization, drafting and revision of the manuscript, and project administration.

CONFLICTS OF INTEREST

M. Kasel reports being a proctor and consultant for Edwards Life-sciences, but totally unrelated to this study; J. M. Michel reports a being proctor for Boston Scientific, but totally unrelated to this study; S. Cassese having received grants from Abbott Vascular, Boston Scientific, and SIS Medical AG, consulting fees from SIS Medical AG, and speaker fees from Abiomed, Astra Zeneca, SIS Medical AG, and Teleflex, but totally unrelated to this study; S. Kufner reports having received speaker and consultant fees from AstraZeneca, Bristol Myers Squibb, Bentley, and Translumina, but totally unrelated to this study; C. Pellegrini reports having received a grant from Else-Kröner Fresenius Memorial Stipendium, but totally unrelated to this study; T. Rheude reports having received lecturer fees from SIS Medical AG, and Astra Zeneca, but totally unrelated to this study; H. Schunkert reports having received consulting, honoraria, and speaker fees from AMGEN, Daiichi-Sankyo, MSD SHARP&DOHME, Astra Zeneca, Bayer Vital, Boehringer-Ingelheim, Novartis, Servier, and Synlab, but totally unrelated to this study; A. Kastrati reports a patent number PCT/EP2021/053116, and participation on the Data Safety Monitoring Board of the DSMB-TARGET Trial, but totally unrelated to this study; E. Xhepa reports having received lecturer and speaker fees from Astra Zeneca, Boston Scientific, and SIS Medical AG, and support for attending meetings from Abbott Vascular, but totally unrelated to this study; G. Borrroyo reports being former president of the Asociación Nacional de Cardiólogos de México from 2020 through 2022; M. Joner reports having received grants from Boston Scientific, Cardiac Dimensions, Edwards Lifesciences, Infraredx, consulting fees from Biontronik, TriCare, Veryan and Shockwave, and lecturer and speaker fees from Abbott Vascular, Biontronik, Boston Scientific, Edwards Lifesciences, Cardiac Dimensions, Astra Zeneca, Recor Medical, and Shockwave, but totally unrelated to this study; the remaining authors declared no conflicts of interest whatsoever. This manuscript is part of the Masters and PhD program in medical sciences of Universidad Nacional Autónoma de México (UNAM).
Efficacy of virtual reality reducing anxiety during CTO revascularization: the ReViCTO trial design

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ABSTRACT

Introduction and objectives: Percutaneous coronary interventions (PCI) of chronic total occlusions (CTO) are long procedures where many patients suffer moderate-to-high level anxiety and pain. Virtual reality (VR) has proven capable of reducing procedural pain and anxiety in many medical procedures. The objective of this study is to demonstrate that the use of VR during CTO PCI reduces anxiety and pain compared to conventional routine clinical practice.

Methods: Randomized, controlled, open-label, superiority trial clinical trial with 2 parallel arms including 58 patients with a scheduled CTO PCI randomized on a 1:1 ratio to VR during the procedure or conventional management. In both arms, the administration of anxiolytic drugs will be left to the lead operator’s discretion and based on the degree of anxiety or pain perceived. The remaining actions for the management of pre- and perioperative anxiety will be identical in both arms. The primary endpoint will be the maximum level of anxiety perceived by the patient. Secondary endpoints will be the level of patient-perceived pain, the need for intraoperative anxiolytic drug therapy, dose of drug administered, and satisfaction with the VR goggles.

Results: The results of this study will add significant knowledge on the utility of VR regarding anxiety reduction in CTO PCIs.

Conclusions: The ReViCTO trial is the first randomized clinical trial to use VR during a PCI CTO. Its results will show the utility of this technology to reduce anxiety and pain in PCIs performed on CTOs.

Trial design registered at ClinicalTrials.gov (Identifier: NCT05458999).

Keywords: Chronic total coronary occlusion. Virtual reality. Anxiety.

Eficacia de la realidad virtual en la reducción de la ansiedad en la revascularización de las OTC: diseño del ensayo ReViCTO

RESUMEN

Introducción y objetivos: Las intervenciones coronarias percutáneas (ICP) de oclusiones totales crónicas (OTC) son procedimientos largos en los que muchos pacientes sufren ansiedad y dolor. La realidad virtual (VR) ha demostrado reducir el dolor y la ansiedad en muchos procedimientos médicos. Nuestro objetivo es demostrar que el uso de la realidad virtual durante la ICP de OTC reduce la ansiedad y el dolor en comparación con la práctica convencional.

Métodos: Ensayo clínico aleatorizado, controlado, abierto y de superioridad con 2 grupos paralelos en el que 58 pacientes con una ICP de OTC programada serán aleatorizados 1:1 al uso de realidad virtual frente al tratamiento convencional. La administración de fármacos ansiolíticos será a criterio del operador principal y en función del grado de ansiedad o dolor percibido. El resto de las acciones para el tratamiento de la ansiedad serán idénticas en ambos grupos. El objetivo primario será el nivel máximo de ansiedad percibido por el paciente. Los objetivos secundarios serán el nivel de dolor percibido por el paciente, la necesidad de tratamiento farmacológico ansiolítico, la dosis de fármaco administrada y la satisfacción con la realidad virtual.

Resultados: Los resultados de este estudio añadirán conocimientos importantes sobre la utilidad de la realidad virtual en la reducción de la ansiedad en los procedimientos de ICP de OTC.

Conclusiones: El ensayo ReViCTO es el primer ensayo clínico aleatorizado que utiliza la realidad virtual durante la ICP en OTC. Sus resultados mostrarán la utilidad de esta tecnología para reducir la ansiedad y el dolor en esta intervención.

Diseño del ensayo registrado en ClinicalTrials.gov [Identificador: NCT05458999].

Palabras clave: Oclusión total crónica. Realidad virtual. Ansiedad.
INTRODUCTION

Chronic total coronary occlusions (CTO) are diagnosed in up to 15% of patients with coronary artery disease undergoing coronary angiography.1 Percutaneous coronary interventions (PCI) of CTOs are one of the greatest challenges we face in interventional cardiology due to the complexity of these procedures and the increased risk of complications.2 Over the past few decades, advances in techniques and devices have made it possible to obtain better results while reducing the associated complications.3,4 Anxiety and pain during these procedures are often treated with oral benzodiazepines plus opioids or IV benzodiazepines upon request during the procedure. The possibility of performing these procedures without anesthesia or sedation avoids the risks associated with these therapies. On the contrary, it submits the patient to pain and anxiety during the procedure. Several factors such as long procedures, patient immobility (especially in biradial access), and monotonous and hostile environments (operating rooms or cath labs) influence patient anxiety. Virtual reality (VR) has been successfully used in several clinical settings such as transcatheter aortic valve implantation6 or atrial fibrillation ablation7 to reduce intraoperative anxiety. There is no evidence on the use of VR reducing perioperative patient anxiety during PCI, specifically in CTO PCI. Compared to standard PCI, this procedure could benefit even further from VR due to its longer duration, use of double arterial access, and possibility of triggering ischemia and chest pain.

The objective of this study is to determine whether the use of a VR system in PCI on CTOs decreases the level of anxiety and pain during CTO procedures compared to conventional management.

METHODS

Overall study design

The Decreasing patient anxiety during revascularization of chronic total coronary occlusions using virtual reality glasses (ReViCTO) trial (ClinicalTrials.gov Identifier: NCT05458999) was designed as a randomized, controlled, open-label, superiority clinical trial with 2 parallel arms (procedural use of VR goggles vs conventional management) with a primary endpoint of maximum level of anxiety perceived by the patient measured through the visual analogue scale of anxiety (VASA).

The study will be conducted in full compliance with the principles set forth in the Declaration of Helsinki (1996) and the International Conference on Harmonization Good Clinical Practice Guideline. The study protocol was approved by the Clinical Research Ethics Committee (CREC) of Hospital Clínico Universitario de Valencia, Spain. All patients signed an informed consent form. The study is registered at clinicaltrials.gov [NCT05458999]. The World Health Organization minimum standard list of items for clinical trials are listed in table 1 of the supplementary data. This protocol follows the SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials.8

Study setting and eligibility criteria

The trial will be conducted at Hospital Clínico Universitario de Valencia, Spain, a reference teaching hospital on interventional cardiology that treats nearly 800 000 patients both from rural and metropolitan areas. Since this is a preliminary study it is designed as a single-center trial. All procedures will be performed by a team of 2 interventional cardiologists experienced in CTO revascularization. Patient enrolment started back in December 2021. On Dec. 25th 2022, 25 patients had already been enrolled in the study (43% of the target population). Patients with visual impairment, dementia, language barriers or any situations that would prevent the use of VR glasses will be excluded. Inclusion and exclusion criteria are listed in table 1. All patients must meet all the inclusion criteria and none of the exclusion criteria.

Assignment of interventions

Each patient will be randomized on a 1:1 ratio to the intervention [use of VR goggles during the CTO procedure] or the control arm [routine clinical practice]. Given the small sample size estimated, permuted block randomization was used to guarantee an equal number of participants per arm.9 Random sequence was computer generated using blocks with a size unknown to the investigators until the end of recruitment. Patient enrolment and arm assignment will be performed by the investigators. Allocation concealment will be ensured using a web application that assigns a unique identification number and the assigned arm once the patient has been recruited for the trial. This system prevents changes to the identification number or arm deleting patients after randomization. Because of the nature of the trial no masking or blinding will be applied at any level.

Participant timeline

Since there is no follow-up, this study has a very simple timeline. Upon arrival to the cath lab, all patients scheduled for elective CTO PCI will be screened and checked to see if they meet all the inclusion criteria and none of the exclusion criteria. If they don’t meet these criteria, they will be considered a screening failure and will not participate in the study. If all criteria are met by the patients, the investigators will need to obtain their written informed consent right before patients arrive at the cath lab. The functioning

Abbreviations


Table 1. Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Age &gt; 18 years</td>
<td>Unable to or unwilling to give informed consent</td>
</tr>
<tr>
<td>Elective percutaneous coronary intervention on chronic total coronary occlusion</td>
<td>Visual impairment</td>
</tr>
<tr>
<td>Physical and mental ability to wear virtual reality glasses</td>
<td>Dementia</td>
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<td></td>
<td>Language barrier (unable to communicate fluently in Spanish or English)</td>
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<td></td>
<td>Any other situations that would prevent the use of virtual reality glasses</td>
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Abbreviations

of the trial will be explained orally and reading of the informed consent will be offered allowing enough time, if necessary. Patients will be randomized to wear VR goggles or to the control arm. During the PCI, all measures regarding anxiety will be applied regardless of the allocation arm. Also, all drug therapies administered will be registered by the study nurse. After the procedure, the patient’s perceived anxiety and pain will be assessed by the study nurse, this being the end of the trial for the patient (figure 1).

Data collection

Demographics, the past medical history, preoperative (indication for revascularization, blood tests, left ventricular ejection fraction...), and perioperative variables (arterial access, radiation dose, maximum level of anxiety [VASA], and visual analogue scale of pain [VASP] perceived by the patient measured through visual analogue scale, nausea, and dizziness during the procedure) will be collected (table 2 of the supplementary data).

Clinical variables will be collected from the local and regional electronic clinical data system and asked directly to the patient when lacking. Blood test results will be collected from the local laboratory system using the last available determination. Echocardiographic and magnetic resonance imaging data will be collected from the local electronic clinical data system. The Seattle Angina Questionnaire, VASA, VASP, the presence of nausea or dizziness, overall satisfaction with the procedure, and overall satisfaction will be assessed by the study nurse and included in a dedicated form (table 3 of the supplementary data). All these data will be transferred to a dedicated database in 1 single local computer. This database is designed with range check for numerical variables to prevent erroneous data entry. Also, the database will check for duplicates when entering the hospital identification number. All data will be stored in a database kept in a dedicated computer with no Internet connection to avoid unwanted leaks or stolen information. The investigators will have access to this database only.

Trial intervention

Eligible patients will be randomized to the intervention (VR goggles) or the control arm (routine clinical practice).

Virtual reality goggles

A commercial Oculus Quest 2 VR goggle system [Meta Platforms, Inc., United States] will be used. The viewing consisted of using the capabilities of the VR goggles to recreate a 2D playback that simulates the size of a large-format movie screen. Using Netflix video streaming system [Netflix Inc. United States], the documentary series “Our Planet” [Silverback Films, United Kingdom]10 will be played for all patients starting with chapter 1, and sequentially and automatically playing the following chapters. Before the procedure, the patient will be informed on the VR goggle system-based operation, possible side effects (nausea or dizziness), and the possibility to remove it at any time. Before the arterial puncture, the VR goggle system will be put on and checked for proper functioning. It will be removed before removing arterial introducers, when the patient wishes to do so or if serious complications occur. During the procedure, the patient’s general condition will be checked every 30 min.

The system will be prepared following these steps: 1) drawing the security perimeter with the controller; 2) starting the Netflix application; 3) selecting the “Void Theater” option; 4) searching for the documentary series “Our Planet” and playing the first episode; 5) adjusting the screen size with the controller; 6) selecting travel mode; 7) putting the VR goggles on the patient (figure 2); 8) asking the patient if he can watch and hear correctly. If not, the VR goggles should be repositioned.

Control arm

The comparator chosen is the current clinical practice with no VR goggles. A possible comparator using a VR goggle with no content was discarded because of the high chances of claustrophobia or mental discomfort.

Both arms will receive drugs upon request to reduce perceived pain and anxiety. In both arms, anxiolytic drugs [morphine chloride or midazolam at 1 mg boluses] will be administered by the circulating nurse if the patient explicitly expresses the need for such treatment or if external signs of anxiety or pain (agitation, complaints...) are observed. The last decision on treatment administration will be left to the lead operator. The remaining actions for the management of pre- and perioperative anxiety will be identical in both arms. Preoperative anxiolytic treatment was not routinely administered to all patients, only upon the patient’s request.

Endpoints

The primary endpoint will be to assess changes to the maximum level of anxiety perceived by the patient during the procedure.
58 patients (29 in each arm) were estimated. Next, the significance level of differences ≥ 2 in VASA assuming a normal distribution, alpha (α) and beta (β) was descriptive of clinically significant differences. To detect differences, a chi-square test will be used if quantitative variables don’t follow a normal distribution.

The primary endpoint (VASA), VASP, and dosage of drugs will be compared in both arms using the Student t test. The use or non-use of drugs during the procedure, the presence or absence of dizziness or nausea will be compared using Fisher’s exact test or the chi-square test. Subgroup analyses will be performed based on sex, age, and previous experience with new technologies.

All statistical tests will be bilateral and considered significant if P < .05. Statistical analyses will be performed with R Core Team (2020) statistical software package (R Foundation for Statistical Computing, Austria).

**DISCUSSION**

CTOs are present in up to 20% of the patients with coronary artery disease. These numbers increase parallel to age (up to 40% in diabetics or patients with heart failure). In the past, most of these patients were referred for revascularization surgery due to poorly successful PCIs in this kind of lesions. Over the past few decades, several advances have been made regarding devices and the usage of new materials, organization, and concentration of complex procedures in reference centers. Also, increased operator experience has led to a high success rate of 90%, and a very low rate of severe complications with the corresponding increase in the number indications for PCI CTO.

Although PCIs are a common and relatively low risk procedure, many patients undergoing these treatments experience anxiety (up to 37% in some populations). Anxiety involves feelings of fear, tension or panic or the prospect that something unpleasant is about to happen. State anxiety may be more clinically relevant for patients undergoing PCI because it is transient in nature and amenable to clinical procedures. Patients undergoing PCI have multiple sources of anxiety including their own concerns. These concerns can include fear of discomfort, uncertainty, and fear associated with survival that can be more distressing than chest pain itself.

PCI CTO creates more anxiety for the patients compared to other interventional procedures for several reasons. In the first place, double access with high-calibre sheaths is frequently used, even biradial. Repeated access punctures with consequently an increased pain and limited patient mobility contributes to more discomfort and higher anxiety levels. Secondly, the duration of the procedure is long, and can be up to 3 to 4 hours more in some special scenarios. Being exposed to immobility in a monotone and hostile scenario for such a long time is a reasonable cause for anxiety. Thirdly, cath labs are often strange environments for the patient with machinery and equipment that may be frightening for him at first. Furthermore, discussion with the treating team, the use of terms unfamiliar to the patient or the existence of beeps and alarms can make the patient think that something bad might happen to him, thus increasing the levels of anxiety. Fourthly, patients undergoing elective PCI CTO usually undergo, at best, at least, 1 invasive coronary angiography, and commonly up to several coronary interventions including failed CTO revascularization attempts. Previous procedures could be remembered as painful or stressful and anticipation anxiety could appear. Stress and anxiety associated with...
needle-related procedures may lead to needle phobia,25 which could also contribute to a high level of anxiety. Fifthly, chest pain is an important factor of procedural anxiety during CTO PCI, and it occurs in a large number of patients. For example, with retrograde approaches, the flow of collateral branches on which the CTO-related myocardial territory is completely dependent is interrupted due to their occupation by the guidewire or microcatheter, thus causing ischemia and pain. Therefore, there is a potential high anxiety level in patients undergoing CTO PCI that depends on multiple factors and mechanisms that feed from one another.

At the end of the 20th century, it was noted that both behavioral and pharmaceutical interventions should be used to manage pain during medical procedures.26 Distraction techniques may be effective reducing the patients’ pain during various invasive procedures because pain involves both physical stimuli and emotional responses. Studies have shown that various distraction techniques like music, massage, breathing exercises, and behavioral therapy can effectively reduce the feeling of pain and stress symptoms during painful procedures.27,28

VR is a computer-generated simulation of the physical world that allows people to experience it in a realistic way. VR goggles achieve visual and auditory semi-isolation that, together with the images projected, evade the patient while act on environmental and emotional factors of anxiety. VR has proven superior to other distraction methods such as television, listening to music or playing games.29,30 VR has been used to relieve anxiety and pain in patients undergoing several kinds of procedures as needle-related interventions,31 burn wound debridement,32,33 physical therapy,34 dental procedures,35 colonoscopy,36 minor surgical procedures,37 nasal endoscopy38 or chemotherapy.39 A total of 4 randomized clinical trials have been conducted to study the level of anxiety experienced by adults undergoing different medical procedures like hysterectomy,39 labor,40 and colonoscopy.36 The studies used various measurement tools such as the VAS scale from 0 to 10, the 5-point Likert scale 0-5, and the State-Trait Anxiety Inventory.

Experiences with VR in interventional cardiology during procedures are scarce. Back In 2020, Bruno et al.6 used a randomized clinical trial to prove the that the use of a VR-based system was safe and feasible during TAVI and that VAS score was reduced by 3 points with the use of VR without impacting nausea or vomiting. Almost all patients said they would use this technology in a similar setting. It is remarkable that this study population was an old population (mean age, 83 years) without previous experience with VR and limited experience with new technologies. This shows that even in a population not used to new technologies that could be expected to reject or not tolerate VR goggles, its use was tolerated and effective. Moreover, this study found that it was important not only that patients accepted the new technology, but also that interventional cardiologists approved it. At first, their reaction went from full support to slight rejection. Those who hesitated to use this new approach thought that their interaction with the patient during the procedure might be limited. However, over time, when they saw that this was not the case, acceptance increased. Similarly, Roxburgh et al.7 tested the utility of VR in patients undergoing atrial fibrillation ablation in an observational study of 48 patients. They showed that VR reduced perceived pain during the procedure and that VR can be easily incorporated into the standard procedure workflow. As far as we know, no studies have ever been conducted on the use of VR during PCI CTO.

Most studies on VR technology have been observational and not standardized, which complicates comparing results and drawing solid conclusions. Additionally, currently, no guidelines or consensus have ever been published on how to incorporate VR technology to cardiac procedures.41 To address these challenges, an expert taskforce from the international scientific community may be useful to identify evidence gaps, set priorities, standardize research protocols, and create guidelines to implement VR technology in heart procedures.

Limitations

Some limitations should be taken in account in this clinical trial. First, the open-label nature of the trial could lead to bias favorable to the RV group due to the lack of blinding and potential for patients and investigators to influence the outcomes. The entire staff will be warned on this possible bias and advised to prevent it before each procedure. Second, some uncontrolled confounding factors may play a role in the differences seen in the administration of drug therapy between RV and the control groups. We will try to prevent or, at least, mitigate this treatment only if the patient explicitly wishes to do so or if outward signs of anxiety or pain are observed. Third, the results of this trial should be interpreted and applied with caution to other scenarios due to the single-center nature of this trial. Fourth, the primary and secondary endpoints of anxiolytic treatment needed could be closely correlated. Our objective is to determine whether the use of VR goggles decreases anxiety. However, it could happen that both groups have similar levels of anxiety and a greater need for anxiolytic treatment (which is a surrogate of increased anxiety, on the one hand, that could also expose patients to a higher risk of adverse effects, on the other). The choice of the primary and secondary endpoints of anxiety and need for anxiolytic treatment allows us to explore this possibility. Finally, the drug therapy of anxiety was not protocolized but left to the operator's discretion.

CONCLUSIONS

The ReViCTO trial is the first randomized clinical trial ever designed to evaluate the use of VR during CTO PCI. Results will show the utility of this technology reducing anxiety and pain in PCI CTO.

FUNDING

None whatsoever.

AUTHORS’ CONTRIBUTIONS

A. Fernández-Cisnal, and G. Miñana: study idea or design, data curation, analysis, and interpretation, drafting, and final approval of the version submitted for publication. B. Silla, J.M. Ramón, E. Valero, and S. García-Blas: data curation, analysis, and interpretation, revision of the manuscript regarding significant intellectual content, and final approval of the version submitted for publication. J. Núñez, V. Bodí, and J. Sanchis: data analysis and interpretation, revision of the manuscript regarding significant intellectual content, and final approval of the version submitted for publication. A. Fernández-Cisnal, and G. Miñana agree to take full responsibility for all aspects of the manuscript, and investigate and resolve all questions regarding the accuracy and truthfulness of the study as a whole.

CONFLICTS OF INTEREST

J. Núñez received fees for participating in the advisory boards and educational activities from Astra Zeneca, Boehringer-Ingelheim, NovoNordisk, Bayer, and Novartis. J. Sanchis received speaker fees from Abbott Vascular, and Prosmedica. G. Miñana received speaker fees from Abbott Vascular, and Prosmedica. G. Miñana received speaker fees from Abbott Vascular, and Prosmedica.
WHAT IS KNOWN ABOUT THE TOPIC?
– CTO PCI is one of the greatest challenges for interventional cardiology due to the complexity of these procedures and the increased risk of complications.
– Several factors like long procedures, patient immobility, and the presence of a monotonous and hostile environment influence patient anxiety, which is usually treated with benzodiazepines and opioids upon request during the procedure.
– Virtual reality has been successfully used in several clinical settings reducing intraoperative anxiety. There is no evidence that the use of VR reduces perioperative patient anxiety during CTO PCI.

WHAT DOES THIS STUDY ADD?
– The ReViCTO trial is the first randomized clinical trial ever conducted to use VR during PCI CTO. Its results will show the utility of this technology reducing anxiety and pain in PCI CTO.
– Primary endpoint will be to assess changes to the maximum level of anxiety perceived by the patient.
– Secondary endpoints will be a) changes to the maximum level of pain during the procedure; b) differences in the need for intraoperative anxiolytic drug therapy; and c) overall satisfaction with the VR goggles.

SUPPLEMENTARY DATA
Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000370.

REFERENCES


Debate. Cerebral embolic protection systems in TAVI: there is some supportive evidence

A debate. Sistemas de protección cerebral en procedimientos de TAVI: existe cierta evidencia a favor

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Servicio de Cardiología, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria San Carlos (IdiSSC), Madrid, Spain

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https://doi.org/10.24875/RECICE.M23000384

QUESTION: Do you think that there is, currently, any evidence behind the use of cerebral protection devices in transcatheter aortic valve implantation (TAVI)?

ANSWER: Former studies described that, during TAVI, loose debris like arterial wall fragments, thrombi, valve tissue, and foreign bodies often enters the circulation.1 These particles are the aftermath of the device making its way through the aorta towards the aortic annulus, the positioning and displacement of a calcified stenotic valve between the new valve stent and the aortic wall, and further manipulations to optimize results (postdilatation). To this date, numerous studies have been published on the safety and efficacy profile of these cerebral protection devices (CPD). Specifically, 4 randomized clinical trials have been published associated with the SENTINEL [Boston Scientific Corp., United States]: MISTRAL-C,2 CLEAN TAVI,3 SENTINEL,4 and PROTECTED TAVR5 we can talk about later on. The MISTRAL-C trial used cerebral magnetic resonance imaging to demonstrate a significant reduction in the number of patients with multiple cerebral lesions (20% vs 0%; P = .03) and less cognitive impairment (4% vs 27%; P = .017). Similarly, the CLEAN TAVI trial also reported fewer novel lesions and of a smaller volume without any differences being reported in the number of clinical events in the group that used CPD. These studies demonstrated fragments being captured in almost in 100% of the cases. Several metanalyses6-13 also confirm these results regarding the number and volume of cerebral lesions described, and even some show lower rates of strokes in the DPC group.10,12,13 Therefore, we not only have the visual in situ demonstration of the particles being captured in the baskets following implantation, but also scientific evidence that CPD are effective capturing fragments released during TAVI that can land in cerebral circulation, thus lowering the number of cerebral lesions found on the magnetic resonance imaging during the procedure. However, whether capturing such particles with the device has a clear clinical benefit for its widespread use is still to be elucidated.

Q.: What do you make of the PROTECTED TAVR trial?

A.: The PROTECTED TAVR5 was a multicenter randomized trial that included a total of 3000 patients treated with TAVI and randomized on a 1:1 ratio to undergo the procedure with or without a CPD (control group). The study primary endpoint was to assess the rate of strokes 72 hours after TAVI or before discharge, whatever came first, and the difference was not significant between the 2 groups (absolute difference, −0.6%; relative difference, −20.7%). However, in 1 of the 15 secondary endpoints, the rate of disabling strokes dropped significantly in the CPD group (0.5% vs 1.3% in the control group). The number needed to treat to prevent an disabling stroke was 125 patients. This study has its pros and cons. Its main strength is that neurological examinations were conducted before and after TAVI, and events were adjudicated by an independent event adjudication committee.14 However, these examinations were not always conducted by expert neurologists. Also, no imaging modalities were systematically performed on all the patients, thus leading to misdiagnosed asymptomatic strokes. We should mention that hemorrhagic strokes were also included. However, they were only found in 2 patients from each group. The study main weakness is that the size of the sample was estimated to have a rate of strokes of 4%. However, the actual rate of strokes of the control group was much lower than expected (2.9%). A reason that may explain the low rate of strokes reported in the control group is the risk profile of the patients included. In this study, the Society of Thoracic Surgeons (STS) mean score in the control group was 3.4 ± 2.8. Also, over 50% of the patients included in both groups had STS scores < 3 meaning that they were low-risk patients. The results of the PROTECTED TAVR trial do not provide scientific evidence for the systematic use of cerebral protection devices. However, we should mention that, across the years, the improvements made in both the TAVI implantation technique and the design of the devices used haven’t reduced the rate of strokes significantly.15 It’s plain to see that the rate of strokes of the different studies conducted drops because the risk profile of the patients included is better. However, if the SENTINEL device eventually manages to reduce the rate of disabling strokes in low-risk patients, we’d be reducing the occurrence of one of the most dreaded complications for patients treated with TAVI both due...
to the increased mortality associated and the greater morbidity it adds on the patient who, on many occasions, becomes disabled. However, not everything has been said and done in this field. The results of the BHF Protect TAVI randomized clinical trial are still pending. It is still recruiting patients and will include twice the number of patients since the size of the sample was estimated for a rate of strokes in the control group of 3%, something more in tune with the actual rate of patients treated with TAVI. There are still unsolved issues like what impact CPD have on patients with high risk of stroke and whether the protective effect of CPD treating asymptomatic cerebral lesions is associated with the patients’ cognitive function in both the mid- and long-term.

Q.: Are you for a widespread use of cerebral protection devices or do you think that some patients are more eligible than others?

A.: To this date, with the results currently available, there is no robust scientific evidence backing the systematic use of CPD in patients treated with TAVI. I think that those who would benefit the most from this kind of devices are individuals with a higher risk of stroke like patients with previous strokes, renal injuries, bicuspid aortic valves, severe aortic valve calcification and valve-in-valve procedures, porcelain aorta, and young patients. Also, patients with thrombi in the left atrial appendage or fibroelastoma or loose material dependent on the aortic leaflets or ascending aorta that could embolize during predilation or valve implantation. 

Q.: What are the main differences of the devices currently available?

A.: The 2 devices currently available in Spain are the SENTINEL and the TriGUARD (Keystone Heart Ltd, Israel). The main differences between the 2 are:

- Access route: the SENTINEL devices always uses a 6-Fr right radial access, and the TriGUARD a 8-Fr access route.

- The degree of protection of supraaortic trunks: the SENTINEL device protects the brachiocephalic trunk and the left carotid artery only sparing the left subclavian artery. However, the TriGUARD device protects all 3 supraaortic trunks.

- Anatomical limitations regarding implantation: the SENTINEL device requires brachiocephalic trunk and left carotid artery diameters of 9 mm to 15 mm and 6.5 mm to 10 mm, respectively, and no tortuosity or severe stenosis in the 3 cm from the ostia of the vessels. Also, there are certain anatomical variants of supraaortic trunks that, though rare, would contraindicate its use. Therefore, a computed tomography scan including supraaortic trunks is advised to measure and assess the anatomy and see if device implantation is feasible. Regarding the TriGUARD, the anatomical limitations are iliac artery and abdominal artery diameters > 3.7 mm and > 10 mm, respectively, a distance < 76 mm from the femoral head up to 3 cm to 4 cm beyond the brachiocephalic trunk [this measurement complies with almost 100% of the population in our country], and the so-called «security gap» consisting of a distance > 65 mm between the aortic annulus and the ostium of the brachiocephalic trunk to make sure that the device does not interfere with TAVI.

- The SENTINEL device captures particles in its filter baskets while the TriGUARD does not. Instead, it steers them towards the descending aorta.

- Finally, another significant difference is that the TriGUARD device does not protect the coronary arteries from the radial access. If there is risk of coronary occlusion during TAVI, 2 different ipsilateral femoral accesses plus the therapeutic one should be used. This is not the case with the SENTINEL device because the left radial access can be used, if necessary.

**FUNDING**
None whatsoever.

**CONFLICTS OF INTEREST**
None reported.

**REFERENCES**

Debate. Cerebral embolic protection systems in TAVI: there is not enough evidence available

A debate. Sistemas de protección cerebral en procedimientos de TAVI: no existen evidencias suficientes

Pedro Luis Martín Lorenzo*
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QUESTION: Is there, currently, enough clinical evidence to recommend the use of cerebral protection in transcatheter aortic valve implantation (TAVI)?

ANSWER: Transcatheter aortic valve implantation (TAVI) has become the treatment of choice of severe aortic stenosis in patients with some degree of surgical risk involved. Perioperative stroke is a serious complication associated with a dramatic reduction of the patient's quality of life and, occasionally, with a lower mid-term survival rate. Although the rate of clinical stroke is relatively low (between 2% and 7%, according to the different series published), rates of silent cerebral infarction after TAVI of up to 70% have been described, which has been associated with the appearance of progressive cognitive decline at follow-up. To prevent these adverse events from happening, different cerebral embolic protection devices (CEPD) have been created over the past few years. However, despite several randomized clinical trials conducted, no proven net clinical benefit has been confirmed regarding lower rates of clinical stroke. In the DEFLECT III trial using the Triguard device [Keystone Heart Ltd., Israel], Lansky et al. obtained a successful CEPD implantation rate of 88.9% without any differences being reported regarding the safety endpoint, and a tendency towards more new-onset brain injuries (26.9% vs 11.5%) but with less neurological deficit (8.1% vs 15.4%) in the device group. The MISTRAL-C4 trial on the Sentinel device [Claret Medical Inc., United States] did not achieve its primary endpoint and found no significant differences in the percentage of patients with new-onset brain injuries in both groups. That same year, the CLEANTAVID trial on imaging modality-guided Sentinel devices before and after the procedure, confirmed the presence of fewer and smaller brain injuries in the CEPD group (242 mm² vs 527 mm²; P < .001). However, no significant differences were found regarding fewer clinical strokes. The SENTINEL IDE trial published back in 2017 met its safety endpoint [100% technical success rate]. However, no significant differences were found regarding clinical events [major adverse cardiovascular and cerebrovascular events: 7.3% vs 9.9%; P = .40] or volume of new-onset brain injuries (103 mm² vs 178 mm²; P = .33). However, a lower rate of early stroke (3% vs 8.2%; P = .05) was reported in the CEPD group. More recently, the REFLECT II trial on the Triguard 3 device showed a non-significant higher rate of bleeding and major vascular complications associated with TAVI in the CEPD group. Also, no significant differences were found in the efficacy endpoint between both groups [30-day rate of mortality or stroke, worsening of the NIHSS score, and presence of new-onset brain injuries on diffusion-weighted magnetic resonance imaging between the second and fifth days]. Finally, in the anticipated PROTECTED TAVR trial the authors concluded that the use of the Sentinel device [Boston Scientific, United States] during TAVI via femoral approach did not have a significant impact on the rate of perioperative stroke. Therefore, in light of the results obtained from different studies published so far, there is not enough clinical evidence to support the routine use of CEPD during TAVI.

Q.: What do you make of the PROTECTED TAVR trial?

A.: Although the SENTINEL IDE trial showed a secondary endpoint of fewer clinical strokes within the first 72 hours after the procedure (3% vs 8.2%; P = .05), it lacked the statistical power needed to assess this variable. To confirm this hypothesis, the PROTECTED TAVR clinical trial was conducted. This is a prospective and multicenter study that randomized 3000 patients with severe aortic stenosis who were going to be treated with TAVI via femoral access into 2 groups: the Sentinel CEPD group or the control group. The primary efficacy endpoint was the occurrence of a clinical stroke within the first 72 hours after the procedure or until hospital discharge whatever came first. Cerebral imaging modalities were spared only for patients with neurological deficits after TAVI. The rate of clinical stroke was 2.6% [2.3% in the CEPD group vs 2.9% in the control group; P = .30]. The rate of non-disabling stroke was 1.7% in the CEPD group compared to 1.5% in the control group [P = .67] while the rate of disabling stroke was 0.5% of the CEPD group vs 1.3% in the control group [P = .02]. The device efficacy and safety rates were 94.4% and 99.9%, respectively. Therefore, after a detailed analysis of the study, we can conclude that there is no significant benefit associated with the use of CEPD to reduce the rate of clinical stroke after TAVI. No subgroups of patients were identified either who could benefit from their use. Although the review of the outcomes of the current debate is evident.
safety profile of the device appears excellent, the associated financial cost and the low benefit derived from it with a number needed to treat regarding total stroke and disabling stroke of 166 and 125 patients, respectively, make the routine use of CEPD in TAVI ill-advised. It seems obvious that both the etiology and pathophysiology of stroke in this context are multifactorial. Therefore, we should not expect that devices that only act as a barrier mechanism will significantly reduce these types of events that occur not only during TAVI but also within the next 72 hours following the procedure. Additionally, the greater experience gained by interventional cardiology units, the precision of imaging techniques, the thorough analysis of each case before the procedure, the progressive reduction of device profiles, and the decreasing complexity of the implantation technique are all factors that could contribute to reduce the rate of stroke associated with TAVI.

Q.: Do you consider the use of cerebral protection devices in some kind of patients or in no patients at all?

A.: To this date, scientific evidence has not yet been able to establish which subgroup of patients eligible for TAVI may have a higher risk of having a stroke and, therefore, would benefit more from the use of CEPD. Although factors associated with the procedure that could increase the risk of stroke during TAVI have been described (pre- or postdilatation maneuvers, valve-in-valve procedures, smaller native aortic valve areas, higher valve gradients, severe valve calcification, bicuspid valve morphology, aortic atheromatous disease), it remains controversial since former studies have shown that several of these factors don’t seem to predispose to having a stroke after TAVI. Makkar et al.10 found no statistically significant differences regarding the morphology of bicuspid or tricuspid valve between the rates of mortality (0.9% vs 0.8%; P = .55) and stroke (1.4% vs 1.2%; P = .55) at 30 days in a series of low surgical risk patients. In the PROTECTED TAVR trial11 no significant differences were seen either regarding the use of CEPD in the subgroup analyses including the variables age, sex, STS-PROM (Society of Thoracic Surgeons Predicted Risk Of Mortality) surgical risk score, surgical risk assessed by the heart team, bicuspid or non-bicuspid morphology of the aortic valve, degree of aortic annular calcification, past medical history of coronary artery disease, peripheral arterial disease, stroke, previous valve-in-valve procedure, use of balloon-expandable valves, pre- and postdilatation.

Personally, I would say that patients with significant atheromatous disease in the ascending and thoracic aorta, and those undergoing valve-in-valve procedures with aggressive postdilatation maneuvers (annular fracture) could be subgroups where the use of DPEC could reduce the rate of perioperative stroke. It seems necessary to keep on conducting in-depth retrospective studies on potential predisposing factors thoroughly in patients who have suffered a stroke with or without clinical implications after TAVI before establishing subgroups of higher risk of stroke during implantation.

Q.: Are there any evidence-based differences regarding the type of devices used?

A.: Currently, we have 2 DPEC available with CE marking: the Sentinel and the Triguard 3. The former, on which we have more clinical experience, consists of 2 connected nitinol filters that independently seal the brachiocephalic trunk and the left carotid artery for particles ≥ 140 μm. The system is advanced from the right radial artery using a 6-Fr delivery catheter mounted over a 0.014 in guidewire. The Triguard 3 consists of a self-positioning nitinol structure arranged as a net that is advanced over a 0.035 in exchange guidewire via femoral artery using an 8-Fr delivery catheter. As a potential advantage over its competitor, it protects all 3 vessels (including the left subclavian artery too), thus preventing the passage of particles ≥ 145 μm. Similarly, its design allows us to advance a pigtail catheter through the same introducer without having to cannulate additional vascular accesses. Recently, the results of the PROTEMBO C trial11 on the ProtEmbo device [Protembis GmbH, Germany] have been published. This device consists of a 38 mm × 70 mm self-expanding nitinol mesh inserted via left radial or brachial artery through a 6-Fr catheter mounted over a 0.014 in guidewire. With it we can protect all 3 cerebral vessels by capturing particles ≥ 60 μm. In the 37 patients finally included in the study, the device implantation success rate was 94.5%. Only 1 thalamic stroke was documented in a patient in whom the DPEC was removed prematurely due to significant interaction while TAVI was being performed. Regarding subclinical strokes, diffusion-weighted magnetic resonance imaging found a mean volume of new-onset lesions of 210 mm³ (undetected in 97% of the patients with lesions with volumes > 350 mm³). Currently, no studies comparing the different DPEC available today have been conducted so there is no evidence to recommend the use of 1 device to the detriment of the others. Perhaps the emergence of DPEC with high device implantation success rates, no associated vascular complications, and protection of all 3 major cerebral vessels, preventing the passage of smaller particles could contribute to reducing the rate of perioperative stroke.

FUNDING
None whatsoever.

CONFLICTS OF INTEREST
P.L. Martin Lorenzo is a proctor for Myval [Meril Life].

REFERENCES
Complex venous disease in transcatheter left atrial appendage closure

Enfermedad venosa compleja en el cierre percutáneo de orejuela izquierda

David Martí Sánchez,*, Alfonso Suárez Cuervo, Juan Duarte Torres, Diego Rodríguez Torres, Miguel Ángel Sastre Perona, and Noelia Alonso Gómez

To the Editor,

In left atrial appendage closure (LAAC), venous access is often predictable. These are 2 cases of venous disease found during LAAC and the alternatives proposed for its resolution. Both patients gave their informed consent for publication purposes. In case #1, an 88-year-old man who was a pacemaker carrier, with permanent atrial fibrillation, ventricular dysfunction, and non-surgical sacral fracture was referred for LAAC due to recurrent hemorrhages.

Through previous ultrasound-guided venous puncture a trans-septal system was advanced that experienced significant resistance in the iliac curvature, difficult torsion at the right atrium, and loss of driving force in the fossa ovalis (figure 1, videos 1-4 of the supplementary data). Transseptal puncture was achieved through the rigid section of a 0.014 in angioplasty guidewire by exchanging the flexible section and advancing the sheath towards the pulmonary vein. Afterwards, it was exchanged for a 14-Fr sheath, and the pigtail catheter was mounted over the high-support guidewire. However, significant resistance during retraction and rotation maneuvers was reported. Nevertheless, it was successfully placed in the left atrial appendage and several angiographies were performed. During pigtail catheter withdrawal, resistance was very significant with evidence of severe torsion following the previous lumbosacral surgery. Since it was impossible to advance the device due to damage to the distal border or recanalize the sheath with a 0.035 in guidewire the procedure was stopped. Computed tomography (CT) scan revealed the presence of lateral deviation and elongation of the inferior vena cava bifurcation with endofibrosis at this level and loss of cleavage plane with the sacrum, posterior compression of the right common iliac vein, and horizontalization of the left common iliac vein. Conservative treatment was decided.

In case #2, a 74-year-old man with permanent atrial fibrillation, on hemodialysis, prostate cancer, and an old right pelvic fracture was referred for LAAC due to recurrent hemorrhages in arteriovenous fistula.

During ultrasound-guided venous puncture, a large caliber common femoral vein with flow inside was reported. Since the Teflon-coated guidewire could not be advanced antegradely, an angiography documented the presence of iliofemoral deep venous thrombosis [figure 2, videos 5-8 of the supplementary data]. Procedure went on via left access using a BRK-1 XS needle [Abbott Vascular, United States] by pre-shaping a secondary curve of additional 15º to 20º while the guidewire was being manipulated and elevated to prevent needle deformation. Given the limited contact with the septum, the rigid section of an angioplasty guidewire was required to perform the puncture. A pigtail catheter, and a high-support guidewire were used to bring the 14-Fr sheath closer to the left atrial appendage. A 31 mm Watchman FLX device [Boston Scientific, United States] was successfully implanted The CT scan confirmed the presence of chronic deep venous thrombosis at right common iliac vein level.

Venous damage is one of the most dreaded complications of lumbo-sacral surgery. May-Turner syndrome of posterior location [iliac vein compression due to incorrect alignment following spinal instrumentation] has been described by analogy with the anterior location one due to right common iliac artery crossing. In addition, lower limb fractures can become complicated with deep venous thrombosis and eventually trigger chronification in a third of the cases. The growing prevalence of this plethora of clinical signs and symptoms requires knowing different alternatives to complete structural heart procedures [table 1].

In case #1, the CT scan revealed the presence of an inelastic right axis, high risk of venous fracture, and extreme elongation and horizontalization of the left axis to an extent that all lower limb procedures were ill-advised. Although procedures have been performed via upper’ or transhepatic access,* experience on this regard is very limited. Case #2 illustrates the possibility of left access in patients without extreme elongation or iliofemoral axis horizontalization. As a last resort, epicardial approaches can be used. However, operators should be aware of the need for an associated transseptal access [hybrid procedures] or thoracotomy.

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AUTHORS’ CONTRIBUTIONS

All the authors participated in the management of the patients, collection of clinical information, drafting, and critical review of the manuscript.

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Figure 1. Limited contact pressure of transseptal system (A), and difficult maneuverability of the pigtail catheter (B) due to the severe torsion of the delivery catheter (C). Procedure stopped due to the impossibility of advancing a new device or guidewire (D, E). Computed tomography scan (F) of a compressed right iliac vein (asterisk) between the fracture and the homolateral common iliac artery. Presence of endofibrosis (arrows) and lack of cleavage plane between the left common iliac vein and the sacrum.

Table 1. Technical resources to perform left atrial appendage closure in the presence of elongation, calcification, tortuosity or venous obstruction

<table>
<thead>
<tr>
<th>Stage of the procedure</th>
<th>Maneuver proposed</th>
</tr>
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<tbody>
<tr>
<td>Suspected venous disease</td>
<td>Past medical history of trauma/vertebral or pelvic surgery or venous thromboembolic disease</td>
</tr>
<tr>
<td></td>
<td>Ultrasound-guided access (hypoplasia, increased caliber due to venous hypertension, collateral circulation)</td>
</tr>
<tr>
<td></td>
<td>Computed tomography scan (venous stage) and specialized assessment</td>
</tr>
<tr>
<td>Correction of tortuosity, and increased passive support</td>
<td>Work on a larger caliber introducer sheath like the ones used for transcatheter valve implantation (anticipate risk of venous lesion and possibilities of transcatheter repair)</td>
</tr>
<tr>
<td>Transseptal puncture</td>
<td>Pre-shaping of the needle additional curve</td>
</tr>
<tr>
<td></td>
<td>Needle with additional sharpening (XS series)</td>
</tr>
<tr>
<td></td>
<td>Sequential use of the rigid and flexible parts of the angioplasty guidewire</td>
</tr>
<tr>
<td></td>
<td>SafeSept system</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency or electrocautery needle</td>
</tr>
<tr>
<td>System crossing through the septum</td>
<td>Greater support guidewires</td>
</tr>
<tr>
<td></td>
<td>Septal dilatation with balloon or dilators like the ones used for transcatheter mitral valvuloplasty</td>
</tr>
<tr>
<td>Navigation through left atrium and placement into the left atrial appendage</td>
<td>Use of flexible, deflectable or pre-shapable sheaths</td>
</tr>
<tr>
<td></td>
<td>Additional support with a catheter of a larger caliber (≥ 6-Fr), and a high-support guidewire inside</td>
</tr>
<tr>
<td>Impossibility of lower access route</td>
<td>Upper limb access with deflectable sheath</td>
</tr>
<tr>
<td></td>
<td>Epicardial closure (eg, stapling or clips)</td>
</tr>
<tr>
<td></td>
<td>Anticoagulation at lower doses compared to the standard ones</td>
</tr>
</tbody>
</table>

Figure 2. Venography reveals the presence of a complete obstruction that triggered change to left access route (A). Note the unusual position and limited support of both the transseptal puncture needle (B) and the delivery catheter (C). The increased support provided by the rigid guidewire to the 6-Fr pigtail catheter facilitated sheath placement and device release (D, E). The CT scan (F) revealed the presence of an oversized right common iliac vein with hyperdensities inside.
To the Editor,

This is the case of a 62-year-old man who presented to the emergency department with signs of an acute neurological syndrome. He remained under regular monitoring due to spastic paraparesis. The patient’s past medical history also included dyslipidemia, active smoking, former alcohol abuse, and psoriasis. His routine medications included daily aspirin 150 mg, and simvastatin 20 mg. Due to severe worsening of his neurological status, he was admitted for further evaluation. After careful clinical evaluation, diagnosis of cerebellar and pyramidal syndrome in the neurosyphilis setting was achieved. Penicillin was started. During hospitalization, cerebral magnetic resonance imaging revealed the presence of a massive hernia at C4-C5 causing significant spinal cord compression. Decompressive surgery was advised. During hospitalization, he complained of chest pain. The ECG showed signs of sinus rhythm with sustained diffuse ST-segment depression and ST-segment elevation in aVR and V1. The transthoracic echocardiography showed a severely impaired left ventricular ejection fraction with severe hypokinesia of the apex, anterior, posterior, and lateral walls. The aortic root was mildly enlarged, but no flaps were seen. Due to refractory chest pain and progressively worsening hypotension, the patient was given unfractionated heparin (5000 IU) and underwent an emergency coronary angiography that revealed the presence of critical left main coronary artery ostial stenosis [videos 1 and 2 of the supplementary data]. No further lesions were identified. Due to the complexity of the lesion, percutaneous angioplasty under left ventricular assist device was advised. It was necessary to make a multidisciplinary decision due to the patient’s condition.

Due to the patient’s unstable and worsening hemodynamic condition, a coronary angioplasty using a drug-eluting stent was decided and successfully performed [figure 1, and figure 2]. Before the angioplasty was performed, the patient was given a loading dose of ticagrelor 180 mg. The procedure was backed by intracoronary ultrasound (IVUS), which showed good stent positioning and expansion at the end of the procedure [minimum in-stent area of 16 mm²] [videos 3 and 4 of the supplementary data]. No signs of coronary artery dissection were reported. After the procedure, the patient was pain-free, and blood pressure levels came back to normal. The transcatheter echocardiography was repeated, and confirmed a mildly dilated aortic root [40 mm to 41 mm] with apparent posterior wall thickening. The left ventricle was not dilated. The left ventricular ejection fraction was 30%-35% with an apical akinetic area, and anterior, lateral, and posterior walls. The right ventricular function was normal. No significant valvular disease, pericardial effusion or intracardiac masses were reported.

A thoracic computerized tomography scan showed multiple atheromatous aortic calcifications and significant wall thickening, which correlated to aortitis phenomena of syphilitic etiology. The patient remained on dual antiplatelet therapy and completed his antibiotic cycle with penicillin. The patient had favorable cardiovascular progression with gradual improvement of the left ventricular function and was discharged to the neurosurgery unit after 7 days. At 1 month, ticagrelor was withdrawn, and the patient underwent neurosurgery. His neurological recovery was uneventful and after 6 months, left ventricular function was normal.

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Although cardiovascular signs have been previously described in the medical literature as well-known complications of syphilis, this case illustrates a particularly rare cardiac complication in the modern era.1-3 A possible sign of syphilitic aortitis is ostial coronary narrowing that can lead to an acute myocardial infarction, most cases being identified post-mortem.1 The underlying mechanism can be associated with atherosclerotic plaques, inflammatory phenomena, and/or calcium protrusion to the coronary arteries.1-3 High level of suspicion and the proper clinical setting were essential to achieve diagnosis and further treatment.1 Other differential diagnoses can be questioned like ankylosing spondylitis, temporal arteritis, and Takayasu’s arteritis since they can cause ascending aortitis.2,3

This case underlines the complexity of treating ostial lesions of left main coronary artery especially in situations where coronary obstruction seems to be conditioned by calcifications at ascending aorta, aortic root or aortitis level. Displacement of calcium in the aorta can lead to critical obstructions that, in the emergency setting, can complicate percutaneous revascularization or make it unfeasible. The absence of left ventricular assist devices and the close availability of cardiac surgery in our hospital made this scenario frightening and difficult to manage in the acute phase. Former studies have reported angioplasties in patients with left main coronary artery ostial stenosis, most requiring left ventricular assist devices to support the angioplasty of left main coronary artery.4-6 Fortunately for the patient, emergence angioplasty was possible with favorable cardiovascular progression. The patient’s written informed consent was obtained.

FUNDING
None whatsoever.

AUTHORS’ CONTRIBUTIONS
R. Flores, F. Mané, C. Braga, and C. Oliveira treated the patient. R. Flores drafted the manuscript, and F. Mané, C. Braga, and C. Oliveira reviewed it.

CONFLICTS OF INTEREST
None reported.

SUPPLEMENTARY DATA
Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000375.

REFERENCES
Transfemoral valve-in-MAC implantation due to severe radiation-induced mitral stenosis

Implante de valve-in-MAC transfemoral en estenosis mitral grave por radioterapia

Mikel Maeztu,a,* Lara Ruiz, a Leire Andraka, a Mariano Larman, b Garikoitz Lasa, c and Jesús Roberto Sáezd

To the Editor,

This is the case of a 57-year-old man with a past medical history of thoracic radiation in his adolescence in the context of Hodgkin’s lymphoma. The patient also has unclassified interstitial lung disease and endoarthritic goitre with tracheal displacement creating a difficult airway. Back in 2014, the patient was diagnosed with chronic coronary syndrome and complete percutaneous revascularization of right coronary artery was achieved. The echocardiograms revealed the presence of severe mitral valve stenosis due to valve calcification without signs of rheumatic disease, preserved systolic function, and severe pulmonary hypertension.

The patient started showing progressive signs of heart failure, and aortic valve replacement was indicated. Given the evidence of porcelain aorta, transcatheter aortic valve implantation (TAVI) was decided using a 23 mm Edwards SAPIEN valve [Edwards Lifesciences, United States] under deep sedation via femoral access. No complications were reported at discharge.

Follow-up in the valve clinic showed progressive worsening of dyspnea (New York Heart Association [NYHA] class III). Additional tests confirmed the progression of mitral stenosis. The transthoracic (TTE) and transesophageal (TEE) echocardiography confirmed the presence of extensive mitral annular calcification (MAC) causing severe mitral stenosis (mean gradient, 15 mmHg) without regurgitation, mild right ventricular dilatation with preserved function, and estimated systolic pulmonary artery pressure > 60 mmHg. The valve was working properly.

The case was reassessed, and the possibility of transcatheter biological aortic valve implantation in the mitral position was considered given the surgical and anesthetic risks involved. The feasibility study of the procedure assessed using the 3mensio Structural Heart system (Pie Medical Imaging, The Netherlands) revealed the presence of mitral annular calcification with a circumferential extension of 298º, no calcification in the medial commissure, anteroposterior and intercommissural diameters of 24.5 mm and 33 mm, respectively, and a inner area of 646 mm². These measurements were considered eligible for the 29 mm Edwards SAPIEN valve implantation.

In the simulation, estimating the neo-left ventricular outflow tract (LVOT) area [340 mm²] was particularly relevant, considered low risk for LVOT obstruction [figure 1]. The results and the echocardiographic images obtained proved the case eligible for valve implantation in mitral annular calcification, also known as valve-in-MAC via transfemoral access. The patient was informed of the high complexity and morbidity and mortality associated with the procedure, with long-term results still unknown to this date.

The procedure was performed back in March 2022 with the patient presenting to the cath lab with clinical data of heart failure. Under general anesthesia and intubation with a fiberoptic bronchoscope, a conventional TEE probe was advanced uneventfully. Under TEE and fluoroscopy guidance, a transseptal puncture was performed via venous femoral. Afterwards, the left atrium was accessed with an Agilis Nxt catheter [Abbott Laboratories, United States], and the mitral valve was crossed using a conventional J-tip guidewire. With back-up from a 7-Fr coronary guide catheter, 2 Safari high-support guidewires [Boston Scientific, United States] were placed into the left ventricle. The interatrial septum was dilated using a 12 mm angioplasty balloon, and a 29 mm Edwards SAPIEN 3 valve was advanced until it was eventually placed inside the mitral orifice, and then properly aligned.
Once its proper position was confirmed, the valve was implanted under pacemaker stimulation that remained in the desired position without paravalvular leak (figure 2). The immediate postoperative mean diastolic mitral gradient was 8 mmHg. The main complication was complete atrioventricular block that persisted after the procedure. The patient was uneventfully extubated in the cath lab.

The postoperative period was uneventful, and the signs of congestion seen at admission were resolved. Episodes or paroxysmal atrial fibrillation episodes were reported, and a definitive DDD pacemaker was implanted due to persistent atrioventricular block. The patient was discharged after staying 20 days at the hospital on anticoagulant therapy with acenocoumarol.

Periodic clinical follow-up was performed 2, 6, and 9 months after the procedure. The patient remained in NYHA functional class I with a mean diastolic mitral gradient of 8 mmHg. Pulmonary artery systolic pressure dropped significantly, and no LVOT obstruction was seen.

The use of valve-in-MAC via transfemoral venous access is a novel technique in Spain that has not been widely explored until now. However, in this case, the 9-month follow-up outcomes were good regarding quality of life and improvement of hemodynamic parameters.

A clinical trial [NCT03539458] currently in the pipeline is analyzing the use of valves specifically designed for transcatheter mitral valve implantation in patients with mitral annular calcification and severe mitral regurgitation. However, no clinical trials on the management of patients with mitral annular calcification and severe mitral stenosis have ever been conducted. In a series of cases including 23 procedures, a 17% mortality rate and a high rate of complications at 30 days were seen in patients undergoing a similar transcatheter procedure as the one described in this case report. Therefore, it is necessary to move forward in the design of techniques that may result in good short- and long-term technical and clinical outcomes for this specific group of patients.

The patient gave his verbal consent for the publication of this study.

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AUTHORS’ CONTRIBUTIONS
All the authors contributed equally to the drafting and review process of the manuscript.
CONFLICTS OF INTEREST

None reported.

REFERENCES


Impact of ischemic preconditioning on the radial artery vasomotor function

Influencia del preacondicionamiento isquémico en la función vasomotora de la arteria radial

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To the Editor,

Transcatheter radial access is the usual approach to perform a coronary angiography. The advantages of this access come with certain inherent limitations like radial spasm, endothelial dysfunction associated with the insertion of the introducer sheath, nonocclusive radial artery injuries, and postoperative artery occlusions.\(^1\) Ischemic preconditioning (IPC) is an experimental phenomenon with confirmed protective effects by applying ischemia-reperfusion cycles to different target organs even at a distance.\(^2\) We suggest that IPC may be relevant to prevent radial spasm, nonocclusive radial artery injuries, and arterial occlusion post-catheterization.

This is a small pilot study of patients scheduled for diagnostic or therapeutic coronary angiography. After the radial artery catheterization we performed:

1. An optical coherence tomography (OCT) of the radial artery after the administration of an anti-spasmodic cocktail.
2. An IPC protocol or sham procedure through randomization.
3. An OCT of the radial artery after the protocol.
4. An OCT after the procedure was completed.

The PAI protocol consists of inflating the blood pressure cuff to 200 mmHg 3 times for 5 min with 5 min of rest between each ischemic cycle. The sham protocol is the same but here the cuff is inflated up to 10 mmHg only.

The OCT (LightLab Imaging Inc, Abbott Vascular, United States) was performed by 2 independent observers and included qualitative [the presence of nonocclusive radial artery injuries [intimal and intima-media dissections, white or red thrombus, and atherosclerotic plaques]] and quantitative analyses (volumetric analysis that measured the lumen contour frame by frame). A total arterial volume was generated for each of the 3 sequences with the same number of frames that were consistent with the same anatomical sections. The volume difference after the protocol was estimated relative to the baseline volume, and the minimum diameter, minimum lumen area, and percent maximum stenosis were determined for each sequence. In radial spasm by OCT the percent variation of the area using the proximal and distal areas as the reference [baseline, postoperative, and final] was analyzed frame by frame. Radial spasm was defined as a sudden decrease of the vessel area (> 50%) compared to the reference areas associated with greater media thickness (> 20% of baseline value). The study of atherosclerosis was conducted on the baseline OCT sequence and included 11 measurements every 5 mm. The intimal area, media area, and the corresponding maximum intima-media thickness were measured. In addition, the intimal thickness, intima-media ratio, and lumen stenosis were estimated as well.\(^3\)

After being approved by the ethics committee, 30 patients were randomized on a 1:1 ratio to IPC or the sham procedure. Both the baseline characteristics and the procedural outcomes are shown on Table 1. The analysis found a significant increase of the mean postoperative values of arterial volume compared to the baseline sequence. However, no differences were reported between the IPC and the sham group [total arterial volume \(P = .176\); total arterial volume adjusted for body surface area \(P = .199\)]. (Figure 1) The presence of spasm after the intervention or at the end of the procedure was greater in the sham compared to the IPC group (40% \(6\) vs 6.7% \([1]\); \(P = .08\)) yet not statistically significant. None of the patients had clinical spasm. No differences were seen in the onset of nonocclusive radial artery injuries (IPC, 20% \([3]\); sham procedure, 20% \([3]\)). No artery occlusions were seen at 30 days.

Table 1. Baseline characteristics and procedural outcomes

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<tr>
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<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>IPC</td>
<td>15</td>
<td>62.40</td>
<td>15.57</td>
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<tr>
<td></td>
<td>Sham</td>
<td>15</td>
<td>62.93</td>
<td>9.15</td>
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<td>BSA (m²)</td>
<td>IPC</td>
<td>15</td>
<td>2.03</td>
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<td>15</td>
<td>1.98</td>
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<td>SAP (mmHg)</td>
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<td>DAP (mmHg)</td>
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<td>15</td>
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<td>Sham</td>
<td>15</td>
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<tr>
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<td>Baseline minimum diameter (mm)</td>
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BSA, body surface area; DAP, diastolic arterial pressure; IPC, ischemic preconditioning; post, postoperative; SAP, systolic arterial pressure; SD, standard deviation.

IPC had no effect on volume, the appearance of nonocclusive radial artery injuries or radial artery occlusion. However, a tendency was seen towards fewer radial spasms on the OCT.

This study greatest limitation was its small sample size, which could lead to low statistical power, and failure to detect significant differences when they actually exist.
Despite being a widely studied phenomenon in the cath lab, IPC has shown modest results in large-scale trials. A better understanding of the underlying mechanisms is deemed necessary to overcome the confounding and interaction factors, but also caution is advised, given its poor results in the real-world.

**Figure 1.** Total arterial volume variation between baseline (pre) and postoperative (post) sequences. There is an increased volume in both the sham and ischemic preconditioning (IPC) groups without statistically significant differences between the 2.

**REFERENCES**

non-coronary sinus with a significant shunt across it (figure 1B, C and video 2 of the supplementary data). There were no images suggestive of infective endocarditis and repeated blood cultures remained negative for any bacterial growth. A computed tomography scan confirmed the findings, although mitral annuloplasty triggered metal artifacts, thus hindering 3D reconstruction. The individual was considered a high-risk patient for surgical reintervention by the heart team, and was initially treated with drugs. However, despite the optimal medical therapy he was readmitted twice within the following 3 months. Therefore, interventional management of the fistula was decided. The patient gave his written informed consent.

A percutaneous approach was attempted under general anesthesia using retrograde access via right femoral artery. The initial angiography performed using a 6-Fr right Judkins (Medtronic, United States) guiding catheter showed a large flow of contrast from the non-coronary sinus to the left atrium (figure 2A and video 3 of the supplementary data). Afterwards, a Sion Blue (Asahi Intecc, Thailand) wire was placed into the left atrium and the right Judkins guiding catheter advanced into the atrium to be used as a delivery system. A 6 mm Amplatzer Duct Occluder II (Abbott, United States) was successfully deployed with simultaneous angiographic (figure 2B and video 4 of the supplementary data) and transoesophageal echocardiography (figure 2C, D and videos 5 and 6 of the supplementary data) confirmation of almost complete fistula closure. Although the patient was previously on anticoagulant therapy due to permanent atrial fibrillation, empirical combination therapy adding aspirin 100 mg was prescribed for 6 months. The 6-month follow-up was uneventful, and the patient remained in functional class I with no residual shunt on the 2D echocardiography performed at 1 month.

Aorta-atrial fistulas are a rare condition being cardiac surgery a recognized cause.1 Among them, fistulas between the Ao-LA are very unusual, and occurrence is much more common after aortic compared to coronary artery bypass graft surgery. To this date, no cases have ever been associated with mitral valve repairs.1 The abnormal flow between the aorta and the left atrium often leads to volume overload and signs and symptoms of heart failure.2 Early recognition and diagnosis of this severe condition relies on its echocardiographic characterization being the transoesophageal echocardiography the imaging modality of choice regarding diagnosis. Combination with 3D imaging modalities is highly advised, when available either transoesophageal echocardiography or computed tomography scan as they allow spatial orientation and high anatomical definition for procedural planning.3 Evaluation can also include cardiac magnetic resonance imaging or cardiac catheterization to additionally assess shunt quantification.4

Due to the low incidence rate of aorta-atrial fistulas, treatment strategies depend on the underlying disease, and interventions are based on expert opinions and consensus among the treating physicians. Nevertheless, closure of the fistula is highly advised in symptomatic patients.5 Although surgery is the standard treatment, percutaneous closure can be considered in high-risk patients with favorable angiographic characteristics like location in the non-coronary sinus or fistulas of small diameters.1 In the absence of specific percutaneous material, the off-label use of an Amplatzer Duct Occluder II device with simultaneous echocardiographic and fluoroscopy guidance is an amenable option as described in our case and isolated cases in

![Figure 1. Transthoracic (A) and transoesophageal echocardiography (B, C) showing a high-velocity jet shunting from the non-coronary sinus of Valsalva towards the left atrium.](image1)

![Figure 2. A: Basal aortography with left atrium filling through the fistula (arrow). D: No contrast passage after Amplatzer Duct Occluder II deployment (arrow). E, F: Amplatzer device positioned with no shunt on the color Doppler ultrasound and 3D transoesophageal echocardiography view.](image2)
the medical literature available. Further antiplatelet/anticoagulant therapy after device implantation is advised although evidence regarding the optimal antithrombotic regimen and duration remains empirical.

In conclusion, although rare, aorto-atrial fistulas are a severe complication that can lead to refractory heart failure. Closure of the fistulous tract is often advised. Evidence on this regard is scarce and mostly based on case reports or case series. More data is needed to better define optimal therapeutic strategies in this scenario.

FUNDING

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AUTHORS’ CONTRIBUTIONS

All the authors contributed equally to this work.

CONFLICTS OF INTEREST

None whatsoever.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000387.

REFERENCES


Provoked exercise desaturation in patients with patent foramen ovale, infrequent or underdiagnosed?

Desaturación provocada por el ejercicio asociada a foramen, ¿infrecuente o infradiagnosticada?

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To the Editor,

The patent oval foramen (PFO) is present in nearly 1 out of every 4 people, and for the vast majority of them, it has no clinical implications. In others, however, it can trigger strokes, migraines or the orthostatic decompression or desaturation syndrome (known as platypnea-orthodeoxia syndrome). An even rarer presentation of PFO that can occur in the adult age is exercise-induced desaturation, which has been described in very few literature reviews and with a term not fully coined.

This is the case of a 79-year-old woman with a past medical history of hypertension and diabetes referred to the cardiac rehabilitation unit due to dyspnea and poor functional capacity. The patient had previously undergone various tests including transthoracic echocardiography, pulmonary function tests, computed tomography pulmonary angiography, and coronary catheterization, all of which showed no significant findings. The physical examination revealed oxygen saturation levels around 98%, blood test results were normal, and N-terminal pro-brain natriuretic peptide levels, 255 pg/mL.

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At the office, she complained of exertional dyspnea that had just appeared after walking from the waiting room to the office. Then, a pulse oximeter was placed on her, and she was told to go for a walk. Oxygen saturation progressively dropped down to 87%, and symptoms relapsed. However, they quickly normalized with rest even in an upright position. The treadmill exercise stress testing revealed the presence of significant saturation changes during exercise [values between 88% and 96%] followed by a sudden increase of ventilation, ventilatory equivalents (VE/VCO₂, VE/VO₂), a quick drop of end-tidal carbon dioxide pressure (PETCO₂), and a sudden increase of end-tidal oxygen pressure (PETO₂) (figure 1A,C,E; Wasserman plots 1, 6, and 9, respectively).

The presence of a shunt was suspected, and a transesophageal echocardiography was performed that revealed a large PFO (a 15 mm tunnel and a 3 mm to 5 mm separation) with bidirectional shunt whose right-to-left flow increased significantly with the Valsalva maneuver (figure 2 and video 1 of the supplementary data).

After diagnosis of a variant of the platypnea-orthodeoxia syndrome known as PFO related exercise-induced desaturation, the right heart catheterization confirmed the absence of pulmonary hypertension and then the percutaneous closure of the defect using an Occlutech ASD 13 device with a 28.5 mm left disc. The patient was discharged the next day.

Two weeks later, she joined the cardiac rehabilitation unit, where the new treadmill exercise stress testing conducted [figure 1B,D,F] confirmed the patient’s improved functional capacity and without desaturation.

PFO related exercise-induced desaturation is a rare and likely underdiagnosed condition that requires a high level of suspicion.

Figure 1. Comparison of multiple treadmill exercise stress testing performed at the cardiology unit. A, C, and E: test conducted before closing the foramen. B, D, and F: test conducted after closure with a device. PETCO₂, end-tidal carbon dioxide pressure; PETO₂, end-tidal oxygen pressure; VE/VCO₂, ventilatory equivalent for carbon dioxide; VE/VO₂, ventilatory equivalent for oxygen.
Listening to and interacting with the patient is key to be able to diagnose this condition as it allows us to see, in situ, the drop of oxygen saturation that is indicative of a shunt. Without thorough history-taking and physical examination of the patient, we will be blind in our diagnostic process.

Exercise-induced desaturation should be considered in the presence of both exertional dyspnea and desaturation with exercise. However, to achieve diagnosis, a pulse oximeter should be put on the patient who should also be told to go for a walk. This is not a common practice though. Confirmation comes through an echocardiogram that shows the right-to-left shunt through the PFO.

Very few series have been published on this condition being the study conducted by Devendra et al. worth mentioning. They reported a series of 10 cases where closure of the PFO resolved the shunt and exercise-induced desaturation, which improved the patients’ functional capacity.

The mechanisms involved in right-to-left shunting in PFO related exercise-induce desaturation are still not fully understood. However, several may be involved to varying degrees of significance in each patient. During exercise, terrestrial gravity and muscular effort change the anatomical arrangement of the chest cavity, viscera, blood vessels, and filling pressures of the different cardiac chambers. In cases of diagnostic uncertainty, exercise right heart catheterization can be useful to screen for other causes of right ventricular failure like early pulmonary vasculopathy or changes to the diastolic dysfunction that can compromise cardiac output after closure.

Patients who develop PFO related exercise-induce desaturation may remain asymptomatic for years. However, as they age, pressure or anatomical changes (chest cavity changes, interatrial septum modification or aortic dilatation/elongation, among others) may redirect blood flow from the vena cava towards the PFO. This facilitates the passage of deoxygenated blood from the right atrium to the left cavities even in the absence of a significant pressure difference.

The use of a device to close the atrial septal defect was decided because the PFO tunnel intermittently detached widely, leaving a wide trajectory. Similarly, the goal here was to make sure that the diameter of discs would adapt, as closely as possible, to the length of the septum, allowing them to embrace the septal aneurysm almost in its entirety and reduce device mobility after implantation.

This case is an example of the significant clinical impact that follows the occurrence of this condition and demonstrates that the percutaneous closure of the PFO is a safe and effective strategy.

The patient’s written informed consent and authorization was obtained to publish both figures and videos.

FUNDING
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AUTHORS’ CONTRIBUTIONS
V. Juárez, O. González, and C. Contreras drafted the manuscript preliminary version and selected the figures. A. Castro, A. Jurado, and S. Jiménez conducted the manuscript critical review by providing comments in later changes and reviewed its final version.

CONFLICTS OF INTEREST
None reported.

SUPPLEMENTARY DATA
Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECIC.M23000388.

REFERENCES
Role of transseptal approach during TAVI in a patient with uncrossable severe bicuspid aortic stenosis

Papel del acceso transeptal en TAVI en un paciente con estenosis aórtica sobre válvula bicúspide incruzable

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CASE PRESENTATION

This is the case of an 82-year-old man with a past medical history of permanent atrial fibrillation, chronic obstructive pulmonary disease, and stable Alzheimer’s disease admitted due to heart failure.

Transthoracic echocardiography revealed the presence of bicuspid aortic valve with severe aortic stenosis (maximum gradient, 76 mmHg; mean gradient, 48 mmHg), and a normal left ventricular ejection fraction (60%). During the examination, the coronary angiography documented the presence of proximal and middle right coronary artery severe stenosis treated with dual drug-eluting stent implantation. The baseline cardiac computer tomography angiography showed a bicuspid aortic valve type 1 with a noncoronary right calcified raphe and a 778.5 mm² area (Figure 1).

After Heart Team discussion, transcatheter aortic valve implantation (TAVI) with balloon-expandable was decided. A 29 mm SAPIEN 3 Ultra valve (Edwards Lifesciences; United States) was scheduled. The patient’s informed consent was obtained. A 16-Fr Edward sheath was inserted via right femoral arterial access, a 7-Fr pigtail catheter was placed into the ascending aorta via left femoral arterial access, and 6-Fr left femoral venous access was used for ventricular pacing lead placement.

Figure 1. Computed tomography images. Left: valve measurements. Right: valve reconstruction. LC, left coronary; NC, noncoronary; RC, right coronary; VR, volume rendered.
All attempts to cross the aortic valve proved ineffective following its severe calcification and complex anatomy despite many different catheters and wires were used by 3 different interventional cardiologists with great experience in TAVI in a center with a volume of 125 procedures each year. Given the numerous unsuccessful attempts made, a bailout solution was needed.

**FUNDING**

None whatsoever.

**AUTHORS’ CONTRIBUTIONS**

J. Martínez-Sole, S. Lozano-Edo, and J. Sanz-Sánchez designed, drafted the manuscript, and were involved in the manuscript final approval. F. Ten-Morro, L. Andrés-Lalaguna, and J.L. Díez-Gil designed the study, conducted the manuscript critical review, and approved its final version for publication.

**CONFLICTS OF INTEREST**

None reported.

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Role of transseptal approach during TAVI in a patient with uncrossable severe bicuspid aortic stenosis. How would I approach it?

_Papel del acceso transeptal en TAVI en un paciente con estenosis aórtica sobre válvula bicúspide incruzable. ¿Cómo lo haría?_

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https://doi.org/10.24875/RECICE.M22000310
https://doi.org/10.24875/RECICE.M22000312

**HOW WOULD I APPROACH IT?**

The authors present a case of retrogradely uncrossable aortic valve for transcatheter aortic valve implantation (TAVI). This happens with the valve introducer sheath in the femoral artery, and the remaining catheterized accesses. Therefore, a solution to implantation is needed since 1 of the basic steps is missing.

There are 3 situations when crossing a stenosed aortic valve can become especially difficult even for an experienced operator: one is stenosed surgical aortic valves where the ascending aorta is poorly dilated compared to the artificial valve. In this situation, building the latter prevents proper catheter alignment. Another situation is critical aortic stenosis due to small opening orifice. The third situation is bicuspid valves, as it is the case here, with an often dilated ascending aorta or a too vertical valvular plane that complicate maneuvers with the guide catheter. Also, because the bicuspid opening being eccentric often complicates steering the guidewires and the catheters through the valvular orifice.

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If we exhaust all retrograde crossing possibilities with different catheters and guidewires, the only option left is antegrade access from the left ventricle (LV) through transseptal catheterization. The use of antegrade access for implantation purposes has already been described in the history of structural heart procedures since it was used for the first TAVI back in 2002. Afterwards, it was abandoned due to the high rate of complications and ease of implantation via retrograde transfemoral access. Anyways, some authors still advocate for this access for the lack of better options.

I would perform the procedure using the right femoral vein since it is easier to perform the transseptal access and shorten the procedure since the retrograde access has already been tried for a while; the left femoral vein—already catheterized—is also valid. Currently, transseptal procedures are performed with much safety through transesophageal echocardiography (TEE) guidance. Once the ultrasound-guided right femoral vein has been punctured, a 0.032 in guidewire is advanced across the superior vena cava through which a sheath is advanced for transseptal puncture, often a 63 cm 8-Fr Schwartz SLO (Abbott Vascular, United States). The guidewire is removed and a Brokenburg BRK-1 X5 needle is advanced (Abbott Vascular, United States) up to 0.5 cm of the tip of the SLO catheter. At this point, the TEE is performed. At our center—since all procedures are performed under conscious sedation—we would proceed to increase sedation with a bolus of midazolam and use a TEE microprobe that is better tolerated and provides enough imaging for the puncture or else a conventional TEE probe. We will slide from the superior vena cava until the oval fossa and perform the puncture at halfway. Once in the left atrium we direct the transseptal sheath towards the left superior pulmonary vein leaving the 0.032 in guidewire inside. We remove the transseptal sheath and advance a medium curl deflectable Agilis NxT catheter (Abbott Vascular, United States) mounted on it. Once in the left atrium, dilator and guidewire are removed and deflected to bring the catheter closer to the mitral valve. The right anterior oblique view gives us an idea as to where the mitral valve is. Then, the Agilis is turned towards it. A 4-Fr Glidecath multipurpose hydrophilic diagnostic catheter (Terumo Europe, Belgium) is advanced through it until the apex. It bends while being advanced thanks to the Agilis catheter often pointing to the LV outflow tract. A 260 cm J-shaped tip conventional 0.035 in guidewire is advanced until the valve is crossed. Then it’s advanced through the ascending aorta until the abdominal aorta. If crossing is difficult with the multipurpose catheter, a JR4 catheter or a hydrophilic guidewire can be used. From the right femoral artery and through the TAVI introducer, a 6-Fr JR4 catheter we advance a Gooseneck snare of 20 mm-to-25 mm in diameter. The guidewire is captured and then removed through the artery. Therefore, a venoarterial loop has been created. We’ll remove the guidewire as much as possible through the arterial side. From there, we’ll advance the 6-Fr JR4 guide catheter until the LV and loosen up the tension of the loop so that the catheter can be accommodated towards the LV apex. Then, the guidewire is slowly removed from the venous side while keeping the JR4 inside the LV and the high-support guidewire is advanced from the femoral artery. I would keep the Agilis catheter inside the left atrium until to secure the TAVI guidewire into the LV. From that moment onwards, the procedure follows the transfemoral implantation conventional steps.

FUNDING

None whatsoever.

CONFLICTS OF INTEREST

None reported.

REFERENCES

Role of transseptal approach during TAVI in a patient with uncrossable severe bicuspid aortic stenosis.

Case resolution

Papel del acceso transeptal en TAVI en un paciente con estenosis aórtica sobre válvula bicúspide incruzable. Resolución

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CASE RESOLUTION

Bicuspid aortic valve (BAV) is the most common congenital cardiac anomaly since it affects approximately 1% of the population. Transcatheter aortic valve implantation (TAVI) has become the treatment of choice of aortic stenosis in high to moderate risk surgical patients.1 Initially, the presence of BAV was considered as an exclusion criterion for TAVI. However, with the development of new generation devices, TAVI for BAV has become a feasible treatment strategy given its good clinical outcomes.2 Nevertheless, BAV still represents a challenging clinical scenario the scientific community is still learning about. Therefore, heart team evaluation is key to decide the most suitable valve replacement strategy in patients with BAV.

To solve the challenge previously described a second procedure was scheduled with general endotracheal anesthesia. The patients' informed consent was obtained. Under biplanar fluoroscopic and transesophageal guidance, transseptal puncture was performed using a 7-Fr Mullins Sheath (Medtronic, Inc., United States). A long stiff J-tip guidewire (Terumo, Japan) and a 5-Fr Judkins Right JR 4 catheter (Boston Scientific, United States) were advanced towards the left atrium, left ventricle, and stenotic aortic valve. The antegrade approach was used to access the descending thoracic aorta.

The Terumo guidewire was snared using a 35 mm Gooseneck snare and then externalized from the left common femoral arterial sheath creating an arteriovenous loop (figure 1). The exchange guidewire was then extracted via right femoral arterial sheath, and an Amplatz Left AL1 catheter (Boston Scientific, United States) was advanced to facilitate the insertion of the Safari guidewire (Boston Scientific, United States) into the left ventricle.

Conventional retrograde aortic valvuloplasty with a 25 mm balloon (Edwards Lifesciences, United States) under pacing at 180 bpm was performed. However, the crossing of the prosthesis through the aortic valve was unsuccessful [video 1 of the supplementary data] due to the valve severe calcification. Therefore, using the same transseptal access (the transseptal sheath was left into the left atrium if the antegrade system was eventually needed), an additional valvuloplasty with a 25 mm noncompliant Atlas balloon (Bard Peripheral Vascular, United States) was performed. This caused massive aortic regurgitation with hemodynamic impairment. However, it allowed crossing the prosthesis (overexpanded SAPIEN 3 Ultra 29 mm by adding 4 mL of extra volume due to an extremely large annulus) that was successfully implanted [video 2 of the supplementary data]. After releasing the valve, the ascending aortogram demonstrated optimal valve position with mild paravalvular leak [video 3 of the supplementary data]. Immediate clinical improvement was observed after TAVI. Postoperative echocardiography confirmed the presence of mild paravalvular leak and normal transvalvular flow (Vmax, 1.8 m/s).

Progressive clinical improvement was observed during hospitalization. However, on day 21 after TAVI the patient developed aspiration pneumonia that led to his death.

The importance of this case is that given this progressive expansion towards younger and lower-risk patients,3 those with BAV are often treated with TAVI. However, the singular anatomy of the BAV adds complexity to the technical challenges associated with TAVI.

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As it was shown in the case presented here, patients with BAV disease undergoing TAVI represent a challenging scenario compared to tricuspid aortic disease. Uncrossable aortic valve during TAVI is not a common clinical scenario with an incidence rate of 0.37% in our case series. The presence of a highly calcified and asymmetric raphe between the noncoronary and the right cusp added to the presence of an extremely large annulus resulted in a technically arduous procedure. A hybrid transeptal strategy using the antegrade crossover technique ought to be considered in selected cases to improve the rate of technical success in patients with challenging anatomies in whom retrograde valve crossing is not possible.

FUNDING
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AUTHORS’ CONTRIBUTIONS
J. Martínez-Sole, S. Lozano-Edo, and J. Sanz-Sánchez designed, drafted the manuscript, and were involved in the manuscript critical review and final approval. F. Ten-Morro, L. Andrés-Lalaguna, and J.L. Díez-Gil designed the study, conducted the manuscript critical review, and approved its final version for publication.

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None whatsoever.

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REFERENCES
Percutaneous treatment of post-traumatic pulmonary artery pseudoaneurysm

Tratamiento percutáneo de seudoaneurisma postraumático de arteria pulmonar

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This is the case of a 68-year-old woman admitted due to polytrauma following a fall from a great height. While on mechanical ventilation she shows signs of self-limited hemoptysis without hemodynamic impairment. Several computed tomography (CT) scans reveal the presence of a 20 mm × 15 mm × 15 mm pseudoaneurysm at right upper lobe branch level without any data of active bleeding or erosion, but presence of progressive growth (5 mm) in 3 successive CT scans performed within 5 days (figure 1, arrows). Given the risk of rupture, percutaneous coronary intervention is attempted to seal the pseudoaneurysm. All the corresponding informed consents were obtained.

The angiography confirms the presence of the pseudoaneurysm including the bifurcation of 2 lobar branches (figure 2A, arrow; video 1 of the supplementary data) unsuitable for sealing with coils or intravascular plug and without a clear proper landing zone for stenting, which is why it is decided to implant a covered stent towards the upper subdivision to isolate it. Using a Judkins right 4 catheter (Launcher, Medtronic, United States) selective catheterization is achieved by advancing a 0.035 in guidewire. Afterwards, a 7-Fr Destination sheath (Terumo, Japan) is advanced through which a 6 mm × 28 mm Begraft expanded polytetrafluoroethylene (ePTFE)-covered stent (Bentley InnoMed, Germany) is implanted. The stent proximal region is postdilated with a 10 mm × 30 mm semicompliant Crystal Balloon (Balt, France). The pseudoaneurysm total exclusion is confirmed on the angiographic follow-up (figure 2B-F, arrow; video 2 of the supplementary data). The patient’s clinical progression is good, and she currently remains asymptomatic without clinical or radiographic data of pulmonary infarction at 6-month follow-up.

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AUTHORS’ CONTRIBUTIONS

All the authors contributed equally to the drafting of this manuscript.

CONFLICTS OF INTEREST

None whatsoever.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M2200350.
Early angina after coronary artery bypass grafting

Angina temprana después de cirugía de revascularización coronaria

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This is the case of a surgery performed on a 73-year-old man with severe aortic stenosis and severe coronary artery disease of both left anterior descending (LAD) and right coronary (RCA) arteries. Surgery included the implantation of a no. 21 St. Jude Trifecta aortic bioprosthesis (Saint Jude Inc, United States) and surgical coronary artery revascularization of left internal mammary artery to the LAD (LIMA-LAD) and saphenous vein to right coronary artery (SV-RCA). The patient presented with signs of progressive exertional angina pectoris exactly 1 month after surgery in an external consultation.

The transthoracic echocardiogram revealed the presence of a normally functioning aortic valvular bioprosthesis. The coronary angiography confirmed the already known native coronary artery disease, a patent LIMA-LAD grafting, and a SV grafting that remained unconnected to the distal RCA filling the coronary venous sinus (figure 1 and video 1 of the supplementary data). The cardiac computed tomography (CT) scan confirmed the connection between the SV grafting and the middle cardiac vein that eventually drains into the coronary sinus (figure 2). The RCA was percutaneously revascularized by implanting 1 drug-eluting stent. In a medical-surgical session it was decided to close the SV grafting with the implantation of a 6 mm x 12 mm AVP4 (Abbot, United States) that turned out successful (figure 3 and video 2 of the supplementary data). The patient’s angina pectoris became alleviated after percutaneous revascularization and right chamber dilatation was prevented with the closure of the SV grafting.
We should know the surgical coronary complications and bring alternative solutions to the table. This promotes collaboration between clinical cardiology, interventional cardiology, and cardiovascular surgery

All procedures were performed according to the ethical standards established by the institutional and national research ethics committee and in full compliance with the Declaration of Helsinki from 1964 and further amendments or comparable ethical standards. The study patient’s informed consent was obtained.

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**AUTHORS’ CONTRIBUTIONS**

R. Mori: data and figure curation, drafting of the original manuscript. D. Gemma: data and figure curation, drafting of the original manuscript. A. Casado: drafting of the original manuscript. F. Sliwinsky: drafting of the original manuscript. A. Romero: data and figure curation, drafting of the original manuscript. J. Palazuelos: idea, supervision, review, and edition.

**CONFLICTS OF INTEREST**

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Percutaneous closure of coronary ostial anastomoses pseudoaneurysm after Bentall

Cierre percutáneo de seudoaneurisma en anastomosis coronaria tras Bentall

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Aortic pseudoaneurysm is a rare and serious complications after surgical aortic valve replacement. Its appearance in the reimplantation region of coronary arteries has been documented on very few occasions.

This is the case of a 53-year-old man with a Stanford type A acute aortic dissection. The aortic root and ascending aorta were replaced with coronary artery reimplantation (modified Bentall-Bono technique) with favorable early disease progression.

The thoracoabdominal computed tomography scan performed 25 days after surgery to study an incidental renal mass revealed the presence of a 14 mm x 10 mm hyperdense nodular image in the arterial phase of posterior location with respect to the left main coronary artery ostium consistent with a postoperative pseudoaneurysm (figure 1A,C, circle). A 3D transesophageal echocardiography confirmed the presence of a pseudoaneurysm surrounding the aortic root with flow inside stemming from the suture of the left main coronary artery (figure 2A,D, asterisk and arrow).

Given the high risk of reintervention, the coronary angiography confirmed the presence of a shunt between the suture of left main coronary artery and the saccular space of pseudoaneurysm (figure 3A, arrow). Selective microcatheterization of this sac was performed (PX SLIM, Penumbra Inc., United States; microcatheter with a minimum inner lumen of 0.025 inch) with insertion of 2 0.020 inch mechanical platinum coils for controlled delivery (Penumbra Coil 400, Penumbra Inc., United States) for a total length of 55 mm. The fistula was closed with good immediate results (figure 3B,C, and videos 1-4 of the supplementary data).

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The 3D transesophageal echocardiography performed 30 days after the procedure revealed a minimum residual flow towards the pseudoaneurysm (video 5 of the supplementary data). The computed tomography scans performed at follow-up showed no residual shunt and good disease progression.

The transcatheter approach is a promising alternative to surgery to treat coronary pseudoaneurysms after Bentall procedure, especially in high-surgical risk patients.

The patient’s informed consent was obtained for publication purposes.

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AUTHORS’ CONTRIBUTIONS

All the authors have been involved in the process of drafting this manuscript. They all read and approved its final version for publication purposes.

CONFLICTS OF INTEREST

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