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Safety and efficacy of the BASILICA technique in patients at high risk of coronary obstruction undergoing TAVI



Eficacia y seguridad de la técnica BASILICA en pacientes con alto riesgo de obstrucción coronaria sometidos a TAVI

To the Editor,

Coronary artery obstruction (CAO) is an uncommon complication of transcatheter aortic valve replacement (TAVR), with an incidence of less than 1%. Preemptive action is essential, as CAO is

associated with high in-hospital mortality (30%-50%).¹ CAO occurs when the percutaneously implanted valve displaces the native or prosthetic valve leaflets towards the coronary ostium or the sinotubular junction and “sequesters” the sinuses of Valsalva. The most common technique used to prevent CAO in high-risk patients is coronary protection with an angioplasty guidewire and chimney stenting. The technique, however, is associated with long-term complications,² such as stent thrombosis and future difficulties accessing the coronary circulation for selective catheterization. These limitations have prompted the search for alternative CAO prevention methods. One noteworthy technique

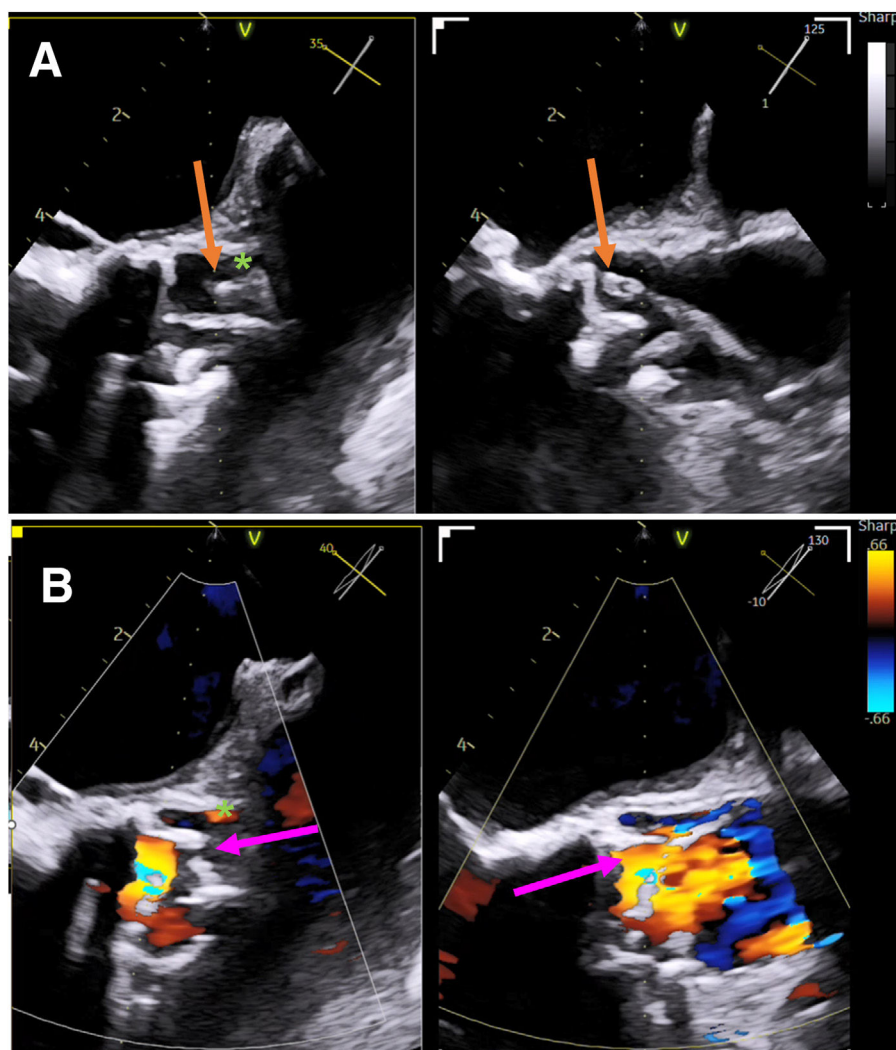


Figure 1. Transesophageal echocardiographic images acquired during the BASILICA procedure (short-axis view of aortic valve with biplanar imaging). A: the arrows show the tip of the catheter over the aortic cusp before laceration; the asterisk shows the left main coronary artery. B: the arrows show the lacerated cusp.

is BASILICA, which stands for bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (figure 1).³ Although the BASILICA technique is promising, little has been published on its effectiveness in Spain. The aim of this study was to describe preliminary outcomes in patients at high risk of CAO who underwent BASILICA during TAVR.

We studied 13 consecutive patients at high risk for CAO who underwent the BASILICA procedure during TAVR at our hospital between December 2021 and March 2023. These patients accounted for 4.1% of all patients who underwent TAVR during this period. The study was approved by the ethics committee of our institution and all patients provided signed informed consent. Baseline characteristics, procedure details, and long-term follow-up events are summarized in table 1. Most of the patients (77%) were women. Computed tomography (CT) was used to identify high-risk features for CAO,³ namely, low origin of coronary artery (< 10 mm), cusp height < coronary artery height, virtual valve-to-coronary artery distance < 4 mm, and, in the case of native valve procedures, calcium volume in the culprit cusp > 600 mm³ based on the threshold established by Khan et al. in 2023.³ Prior to this, calcium volume was assessed qualitatively. In all patients, the procedure was performed under general anesthesia with orotracheal intubation and transesophageal echocardiographic monitoring. BASILICA was performed on a bioprosthetic aortic valve (valve-in-valve procedure) in 4 patients (31%). Overall, the technique was successful in 12 (92%) of the 13 patients. It failed in 1 patient undergoing a valve-in-valve procedure who had a severely calcified prosthetic cusp that could not be lacerated. Self-expanding valves were used in 77% of patients. A protective guidewire was implanted in 54% of procedures, but chimney stenting was not necessary. Two patients developed procedure-related complications: 1 uncomplicated aortic intramural hematoma (without coronary obstruction or aortic dissection), which resolved completely, and 1 transient ST-segment elevation. TAVR was successful in all patients. None of the patients developed CAO or required bailout treatment with chimney stenting. Subsequent coronary catheterization was performed successfully and without complications in all patients. There were no deaths or cardiovascular events (including delayed CAO) over a median follow-up of 7.6 months [4.9–13.1] months. During follow-up, 1 patient was admitted for a pseudoaneurysm requiring surgical intervention at the primary femoral access site.

Careful patient selection using CT scanning is crucial for preventing CAO during TAVR. Several anatomic and procedure-related factors have been linked to an increased risk of CAO.³ Surgical aortic valve replacement is the method of choice for patients with a high risk of CAO, but prohibitive risk precludes surgery in a significant number of patients. The alternative is to perform TAVR and accept the risk of CAO. One method for mitigating risk is prophylactic coronary prevention with a guidewire and placement of a chimney stent to be deployed in the event of obstruction. The stent, however, can be deformed by the TAVR prosthesis, leading to thrombosis, long-term antithrombotic treatment, and the risk of harmful bleeding events and future engagement difficulties as the stent is left “floating” in the aorta. The BASILICA technique was developed to overcome these limitations.⁴ The safety and effectiveness outcomes observed for this technique in our series are similar to previous reports.⁵ Early experience, however, is limited, and randomized trials will be needed to demonstrate the true impact of BASILICA. The main limitations of our study are its small sample size and the absence of a control group. In conclusion, based on our preliminary effectiveness and safety findings, the BASILICA technique may be a promising alternative for patients at high risk of COA during TAVR.

Table 1

Baseline patient characteristics, procedure characteristics, and follow-up events

	Total (n = 13)
<i>Baseline characteristics</i>	
Age, y	80 [75–82]
Female	10 (77)
Previous stroke	1 (8)
Previous ischemic heart disease	7 (54)
Previous GFR, mL/min/m ²	1.12 [1.03–1.5]
NYHA class > II	12 (93)
EuroSCORE II, %	5.9 [2.6–13.7]
STS score	6.08 [3.2–12.8]
<i>Echocardiogram and computed tomography characteristics</i>	
LVEF, %	55 [37–60]
Peak aortic gradient, mmHg	88 [66–110]
Mean aortic gradient, mmHg	48 [40–70]
Aortic valve area, cm ²	0.76 [0.58–0.85]
Coronary artery height, mm	8 [6–8.9]
Cusp height, mm	11.3 [10.5–12.8]
Cusp height > coronary artery height, %	13 (100)
Virtual distance from TAVR prosthesis to coronary artery, mm	3.3 [2.7–5]
Calcium volume in culprit cusp, mm ³	398 [217–511]
Eccentric ostium (> 15°)	0
<i>Procedure characteristics and complications</i>	
Valve-in-valve	4 (31)
Left cusp	13 (100)
Successful BASILICA	12 (92)
Predilation	7 (54)
Cerebral embolic protection	7 (54)
Transcatheter aortic valve implanted	
Self-expanding	10 (77)
Balloon-expandable	3 (23)
Prosthetic valve size, mm	25 [23–25.5]
Use of coronary guidewire protection, %	7 (54)
Chimney stent implantation	0
Successful TAVR	13 (100)
Procedure time, min	208 [168–237]
Fluoroscopy time, min	58 [47–73]
Contrast, mL	187 [140–280]
Intraprocedural complications ^a	2 (15)
Definitive pacemaker implantation	2 (16)
Aortic valve regurgitation ≥ moderate	0
<i>Medium-term events; median follow-up, 7.6 [4.9–13.1] mo</i>	
Mortality	0
Cerebrovascular accident	0
Coronary artery obstruction	0
Acute myocardial infarction	0
Endocarditis	0
Mean gradient, mmHg	10 [7–13]
Aortic valve regurgitation ≥ moderate	0

BASILICA, bioprosthetic scallop intentional laceration to prevent coronary artery obstruction; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; STS, Society of Thoracic Surgery; TAVR, transcatheter aortic valve replacement.

Values are expressed as No. (%) or median [interquartile range].

^a Two patients developed complications associated with the BASILICA technique (one developed uncomplicated aortic intramural hematoma and the other, transient ST-segment elevation).

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AUTHORS' CONTRIBUTIONS

The authors accept full responsibility for the content of this manuscript as defined by International Committee of Medical Journal Editors. A. Regueiro conceived the study and designed the analysis. P. Cepas-Guillén and R. Gabani conducted the analysis. A. Regueiro, M. Giménez-Milà, L. Sanchis, and X. Freixa revised and edited the manuscript.

CONFLICTS OF INTEREST

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Age and sex differences in pulmonary embolism mortality rates in Spain from 1999 to 2021



Diferencias según sexo y edad de la tasa de mortalidad por tromboembolia pulmonar en España desde 1999 a 2021

To the Editor,

The incidence of pulmonary embolism (PE) has been on the rise in Spain and other European countries, potentially influenced by factors such as longer life expectancy and the presence of conditions that increase the risk of venous thromboembolism.^{1,2} Other factors that could have contributed to the observed increase are improved diagnostic methods and increased awareness of PE. However, despite the higher incidence, in-hospital and age-standardized mortality rates have decreased in Spain, suggesting improved identification of low-risk cases and advancements in treatment.^{3,4} Age-standardized mortality rates (ASMRs) have generally decreased in European Union countries, including Spain.⁴ Nevertheless, previous studies on PE mortality in Spain have primarily focused on older age groups, necessitating an examination of all age groups and the differentiation of younger populations.

This study collected data on population and PE-related deaths from the National Institute of Statistics in Spain, covering the period from 1999 to 2021. International classification of diseases (ICD-10) codes, including “acute pulmonary embolism with or without acute cor pulmonale” (I26) and nonfatal venous thromboembolic (VTE) manifestations (eg, deep vein thrombosis [DVT] or phlebitis/thrombophlebitis), were used to identify PE-related deaths, as used in previous studies.⁵ ASMRs were calculated using the European standard population. We used joinpoint regression

models to identify significant changes in mortality trends and calculated annual percentage changes (APC) for each segment. To assess the overall trend from 1999 to 2021, we derived a geometrically weighted average of the different APCs, providing a concise summary of the overall trend.

Figure 1 depicts the ASMRs (all ages) due to PE in Spain from 1999 to 2021 by sex. The ASMRs demonstrated a significant decrease in both sexes, with an APC of –3.8% in men and –3.3% in women. From 1999 to 2021, ASMRs decreased from 11.3 to 4.8 deaths per 100 000 person-years for men and from 9.4 to 4.5 deaths per 100 000 person-years for women. For both men and women, a change in the trend occurred in 2014 for men and in 2017 for women, marking a division between 2 distinct trends. Initially, there was a substantial annual decline in mortality rates for both males (–5.8%) and females (–4.5%). This positive trend was followed by a subsequent period of stabilized rates for both sexes.

Figure 2 illustrates the truncated ASMRs for different age groups (< 35, 35–64, and ≥ 65 years) by sex. Globally, rates remained stable in the population aged < 35 years, but with differences in the pattern between sexes. A detailed joinpoint analysis showed a significant change in trend among males in 2012, with an initial decrease (–6.6%) followed by stabilization. Females in this age group did not show a significant change in trend. Overall, in the group aged 35 to 64 years, rates decreased for men but remained stable for women. The joinpoint analysis identified a turning point in 2011 for men and in 2010 for women, dividing the study period into 2 phases: an initial decline (–5.6% for men and –4.3% for women), followed by a period of increasing rates (3.3% for men and 3.4% for women). In the group aged ≥ 65 years, rates decreased steadily throughout the study period for both men and women (–4.2% and –3.6%, respectively).