Transapical Implantation in the Catheterization Laboratory of the Second Generation Engager Aortic Valve

Implante transapical de la prótesis aórtica de segunda generación Engager™ en la sala de hemodinámica

To the Editor,

Implantation of aortic valve prosthesis is the treatment of choice for patients with severe and symptomatic aortic valve stenosis unamenable to surgery. It is thus an alternative to surgery for high-risk patients.[1–3]

Second generation aortic valve prostheses have been developed to overcome the limitation of the devices currently used, namely, poor affixation and device embolization, perivalvular aortic regurgitation, and atrioventricular conduction disorders. One of these second generation devices is the Engager Aortic Valve (Medtronic Inc, Minneapolis, Minnesota, United States) for transapical implantation. The device can be repositioned and recaptured and it is designed to achieve an anatomical orientation, thereby helping reduce paravalvular regurgitation.

In this article, we describe the first experience reported in Spain of the transapical implantation of this prosthesis in a catheterization laboratory.

Medtronic's biological Engager device has 3 leaflets of bovine pericardium affixed to a nitinol structure. It has a central, self-expanding frame whose proximal part is attached to left ventricular outflow tract. This frame has an external polyester skirt and a support structure and is affixed in 3 places to the aortic part of the central frame (the so-called *commissural posts*) between which 3 control arms are located, anchored to the base of the sinus of Valsalva. It is available in a size of 26 mm (while drafting this article, the 23 mm prosthesis was withdrawn from the market because of elevated residual gradients). The deployment system comprises a 29 Fr introducer and the catheter in which the prosthesis is mounted.

The evaluation of candidates prior to implantation should include a computed tomography angiography to measure the size of the aortic annulus, the sinus of Valsalva, and the sinotubular junction and to identify the best point of access in the chest wall and the optimum working position.[4,5]

The procedures are performed in the catheterization laboratory under general anesthetic with transesophageal echocardiography by a multidisciplinary team of heart surgeons, interventional cardiologists, an imagining expert, and an anesthetist. An extracorporeal circulation device was made ready in the corridor.

The procedure comprises the following phases (Figure): a minithoracotomy is performed (Figure A) and the apex is punctured by inserting a 6 Fr introducer. A standard guidewire is passed through the aortic valve and then exchanged for a 260-cm Amplatz Super Stiff guidewire. The aortic valvuloplasty is then performed (Figure B). The deployment system is advanced until it has passed through the aortic valve in anterograde position (Figure C). The prosthesis is located in the ascending aorta above the aortic valve plane and rotated to find the correct orientation with fluoroscopic guidance. The control arms are then opened and the device pulled until it lies on the sinuses (Figure D). Angiography and transesophageal echocardiography are used to ensure that the device is appropriately positioned; if the positioning is incorrect, the control arms can be recaptured and the device repositioned. Finally, the commissural posts are released and then the proximal part of the prosthesis, which is now fully deployed (Figures E-F). After the appropriate angiographic, hemodynamic, and echocardiographic evaluations, the introducer is withdrawn from the apex and the ventricular access is closed.

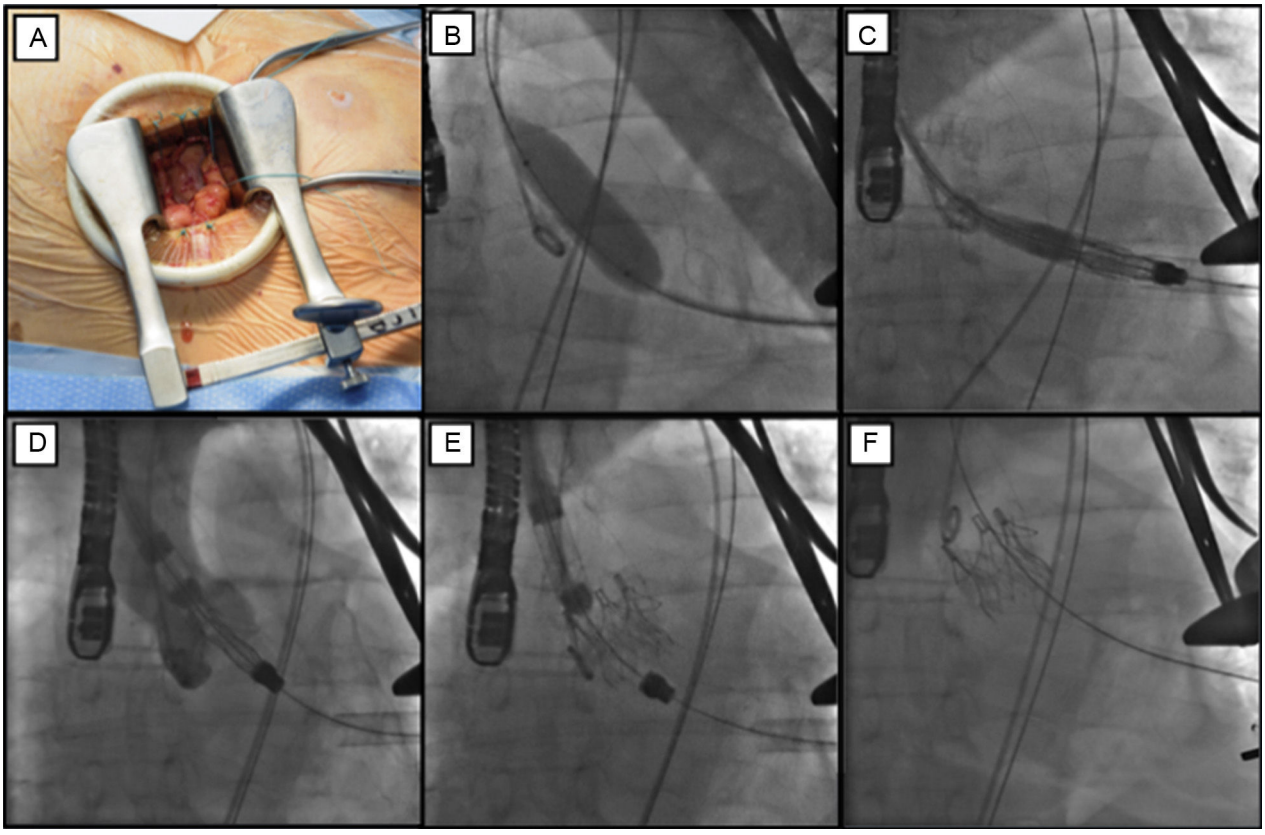

Figure. Description of the procedure.

Table
Patient Baseline Characteristics and Outcomes

	Patients				
	1	2	3	4	5
Sex	Male	Male	Male	Male	Male
Age, y	73	79	77	72	71
Associated disease	CABG, PVD	PVD, fragility	Porcelain aorta, COPD, PVD	Porcelain aorta, PVD, CRD, COPD	Prior radiotherapy, PVD
STS score	4.1	8.9	6.3	6.6	1.34
EuroSCORE	11.3	6.5	9	6.3	3.7
Baseline data					
Maximum gradient, mmHg	99	84	88	73	132
Average gradient, mmHg	45	37	57	38	70
AVA, cm^2	0.63	0.48	0.56	0.8	0.47
Aortic regurgitation	Mild	No	Mild	Moderate	No
LVEF, %	70	60	60	40	63
Annulus diameter, mm	73.7	79.4	74.1	73.8	75.5
Derived diameter, mm	23.5	25.3	23.6	23.5	24
STJ diameter, mm	28.2	28.1	26.2	30.2	27.1
Average SV radius, mm	17.34	17.2	15.8	18.7	16.7
Procedure					
Prosthesis, mm	26	26	26	26	26
Repositioning	No	No	No	No	No
Postimplantation echocardiographic parameters					
Maximum gradient, mmHg	25	28	38	24	35
Regurgitation	No	Mild-moderate	No	No	Mild
Pacemaker placement	No	Yes	No	No	No
Outcome	Good	Good	Death due to multiorgan failure after 4 days	Good	Good

AVA, aortic valve area; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; CRD, chronic renal disease; LVEF, left ventricular ejection fraction; PVD, peripheral vascular disease; STJ, sinotubular junction; STS, Society of Thoracic Surgeons; SV, sinus of Valsalva.

Between February 23 and April 23, 2015, 5 patients were treated. The baseline characteristics and outcomes are shown in the Table. In all cases, the prosthesis was correctly positioned. One patient died on the fourth day after implantation due to refractory multiorgan failure. In this case, no abnormal gradients or significant aortic regurgitation were detected. The remaining patients had a favorable outcome with no further admissions to hospital after a mean follow-up of 221 ± 31 days.

This article reports the first series in Spain to date of the Engager valve. One of the potential advantages observed in our series was the feasibility of performing the implantation procedure in a catheterization laboratory with the possibility of using extracorporeal circulation if necessary. Thus, the logistic bottleneck of the availability of an operating theater (in case it is necessary to switch to an open heart procedure) is avoided.

The type of implantation requires close cooperation between the interventional cardiologist, other specialists, and the heart surgeon and is a clear example of converging areas of expertise in certain aspects of these specialties.

None of the patients selected had conditions amenable to surgery although they all had an intermediate surgical risk. The indication for transapical access was the presence of severe peripheral vascular disease. There is no evidence of superiority of this approach compared to others, although the aortic arch is subject to less manipulation in this case.[5,6] The success rate for the procedure was very high and comparable to that reported in other series. There were no cases of poor affixation or device recapture.[6]

In conclusion, our series is the first experience in Spain and demonstrates the feasibility and effectiveness of use of Medtronic's second generation Engager transcatheter device implanted with transapical access in a catheterization laboratory.

CONFLICTS OF INTEREST

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SAMe-TT_2R_2 Score Does Not Predict Time in Therapeutic Range in Atrial Fibrillation Patients After Hospitalization for Acute Decompensated Heart Failure

La puntuación SAMe-TT_2R_2 no predice el tiempo en rango terapéutico tras un ingreso por insuficiencia cardiaca aguda en pacientes con fibrilación auricular

To the Editor,

The SAMe-TT_2R_2 score has been proposed as a way to predict the acceptability of anticoagulation control in patients with nonvalvular atrial fibrillation.[1] This score has been shown to be useful in different cohorts,[2] but there have been no assessments of its usefulness in patients with recently decompensated heart failure (HF).

Given that atrial fibrillation and HF often occur concurrently and that HF is associated with poor anticoagulation control,[1] we believe that validation of the SAMe-TT_2R_2 score in patients with HF could be a useful exercise for clinical practice. Thus, with the aim of extending the validity of this scale, we assessed its predictive and discriminative capacity in a cohort of patients with nonvalvular atrial fibrillation receiving anticoagulation therapy with vitamin K antagonists and with recently decompensated HF.

The study was conducted according to the tenets of the Declaration of Helsinki. The retrospective analysis used data collected for a prospective registry in the cardiology department of a tertiary hospital between January 2008 and September 2011. The study included all patients with nonvalvular atrial fibrillation who received anticoagulant therapy with vitamin K antagonists after discharge following an episode of acute decompensated heart failure. Patients with a contraindication for the new anticoagulants and those with fewer than 2 international normalized ratio (INR) measurements in the 6 months after hospital discharge were excluded (n = 19). The SAMe-TT_2R_2 score was calculated at the time of inclusion for all patients. The time in therapeutic range (TTR) was estimated according to the Roosendaal method and poor anticoagulation control was defined as TTR $< 65\%$. A binary logistic regression analysis was conducted to assess the association between SAMe-TT_2R_2 score and INR control. Discriminatory capacity was analyzed by calculating the area under the receiver operating characteristic (ROC) curve. The model was calibrated using the Hosmer-Lemeshow goodness of fit test.

In total, 108 patients were included. The median number of INR measurements was 8 (interquartile range [IQR], 6.25-10; range, 3-16). The median SAMe-TT_2R_2 score was 2 (IQR, 1-2). Overall, 70% (n = 76) of the patients had an SAMe-TT_2R_2 score ≥ 2. The mean estimated TTR during follow-up was 48% $\pm$ 24% and 73% (n = 79) had a TTR $< 65\%$. As shown in the Table, of the components of the score, no factor was significantly associated with poor INR control in this population.

The SAMe-TT_2R_2 score was similar in patients with TTR $\geq 65\%$ and in those with TTR $< 65\%$ (1.9 $\pm$ 0.8vs 2.1 $\pm$ 1.0, respectively; $P = .415$). The percentage of patients with SAMe-TT_2R_2 score ≥ 2 did not differ between those with TTR $\geq 65\%$ and those with TTR $< 65\%$ (69% vs 75%, respectively; $P = .504$; Figure). The calibration of the score was good (Hosmer-Lemeshow test, $P = .75$). However, in the discrimination analysis, the area under the ROC curve was 0.54 with a 95% confidence interval of 0.42-0.66 and so it was not possible to establish a cutoff to predict INR control.

In our cohort of patients with nonvalvular atrial fibrillation and recently decompensated HF, INR control was poor and the SAMe-TT_2R_2 score was not useful for identifying patients with good or poor anticoagulation with vitamin K antagonists. These results contrast with those of a study in which prior HF was not significantly associated with worse INR control in patients with nonvalvular atrial fibrillation (TTR $< 65\%$: 47.4% in patients with HF vs 52.6% in other patients; $P = .189$).[3] However, we believe that it is not history of HF that is responsible for poor anticoagulation control but rather the severity of HF. In our study, all patients had recently decompensated HF, placing them in a high risk group. In view of our results, we believe that these patients should be more closely monitored, or they could be treated with direct oral anticoagulants given the poor anticoagulation control with vitamin K antagonists in most cases. In fact, in large randomized phase III trials with currently available direct anticoagulants, patients with HF were well represented (between 32.0% and 62.5%) and, in the subgroup analysis, there was no statistically significant heterogeneity with respect to efficacy or safety in the treatment of these patients.[4–6] Our results show the need for additional validation studies for the SAMe-TT_2R_2 score in these patients. One of the main limitations of the study is the small sample size and its retrospective design. The clinical profile of our patients (as in other series of acute HF), with SAMe-TT_2R_2 scores > 2 in 70%, can be explained by the low discriminatory capacity in this context. Finally, it would be clinically useful to develop new scoring systems that could identify patients who will have poorly controlled anticoagulation with vitamin K antagonists in this scenario.

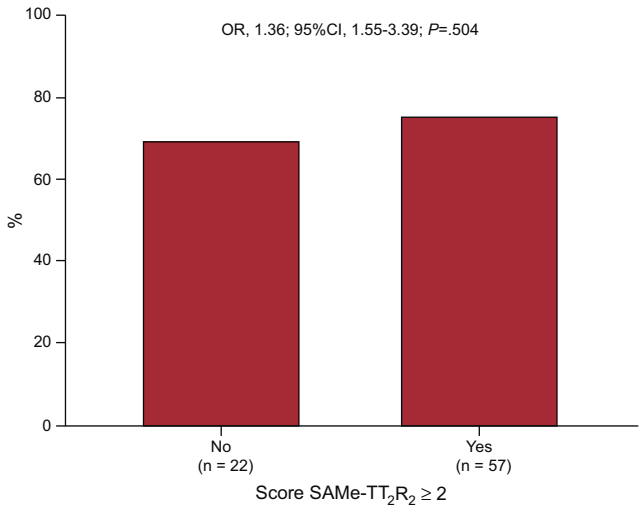

Figure. The percentage of patients with time in therapeutic range $< 65\%$ according to the SAMe-TT_2R_2 score. CI, confidence interval; OR, odds ratio.