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Initial Experience in the Iberian Peninsula With the Transfemoral ACURATE-neo TF Transcatheter Aortic Prosthesis: Procedure and Outcomes

Implante percutáneo transfemoral de la prótesis aórtica ACURATE-neo TF: características del procedimiento y resultados. Experiencia inicial en Iberia

To the Editor,

Percutaneous aortic valve implantation is currently an alternative to surgical valve replacement in patients with severe symptomatic aortic stenosis at high surgical risk or with contraindications for surgery.[1] The ACURATE-Neo TF self-expandable aortic valve (Symetis SA, Lausanne, Switzerland) was approved for implantation in Europe in late 2014. We analyzed the initial experience related to all ACURATE-Neo TF prostheses implanted in the Iberian Peninsula to date.

ACURATE-Neo TF is a porcine pericardial tissue valve mounted on a nitinol stent consisting of several parts (Figure A): 3 stabilizing arches that allow the valve to self-align during implantation to ensure final coaxiality of the valve with the native annulus; the upper crown–that is, the central segment of the scaffold where the leaflets are sutured–which functions as a supra-annular valve (the inverted hook configuration directs the native valve leaflets toward the annulus, decreasing the possibility of occluding the coronary ostia and reducing the degree of paravalvular leak); and the lower crown, the most distal segment, which is implanted with minimal extension into the left ventricular outflow tract to decrease the incidence of conduction disturbances. The inner and outer surfaces of this part of the prosthesis are also covered with pericardial tissue to seal against paravalvular leak. The soldering material located in this segment generates a radiolucent line while the valve is encased within the release system and serves as a guide during implantation. ACURATE-Neo TF comes in 3 sizes–small, medium, and large–which are suitable to treat aortic annuli diameters ranging from 21 to 27 mm.

The prosthesis is compressed within 2 sheaths at the distal end of the delivery catheter, and release is carried out in 2 steps. To advance the catheter, an 18-Fr introducer is required or a 13- to 15-Fr expandable introducer for the 3 sizes. The release handle contains

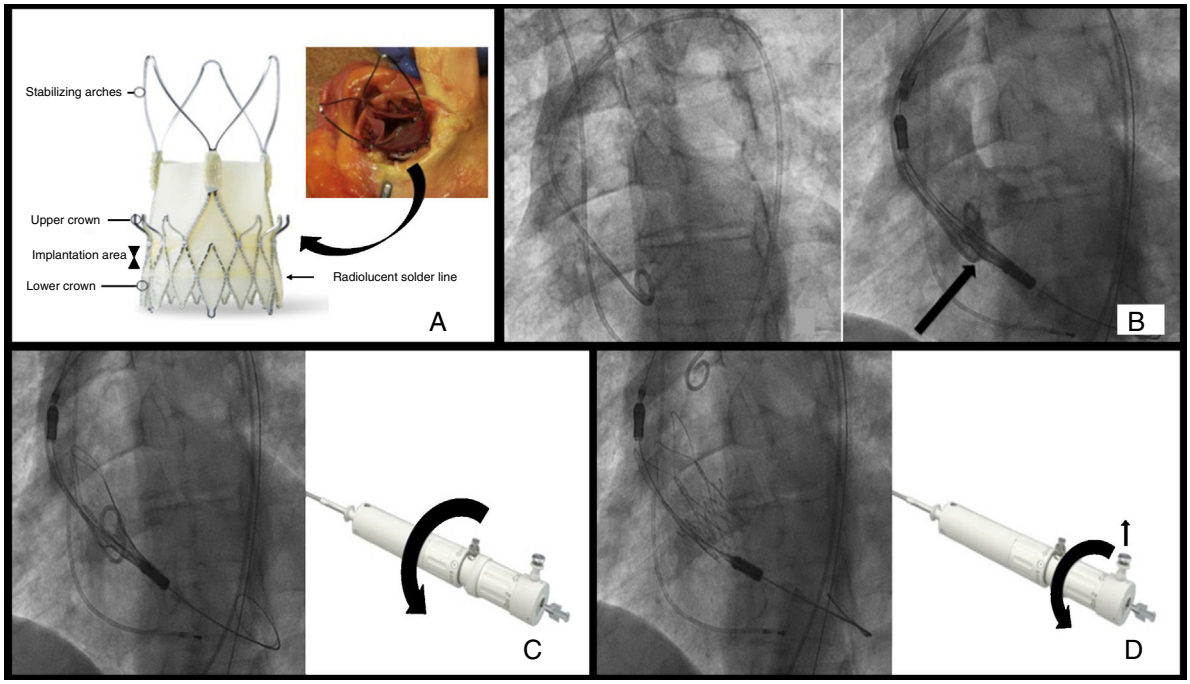

Figure. A: structure of the prosthetic valve; the arrow indicates the position of the upper crown and its relationship with the native valve leaflets in a real case. B: initial position. C: release, first step; the curved arrow indicates the direction of rotation of the distal knob; D: release, second step and deployment; the vertical arrow indicates the safety button that must be removed and the curved arrow the direction of rotation of the proximal knob.

Table
Baseline and Procedure-related Variables

Baseline characteristics	
Age. years	81.3 ± 7.0
Sex, female	16 (55.2)
NYHA	
I-II	4 (13.8)
III-IV	22 (75.9)
Cardiovascular risk factors	
HT	23 (79.3)
DLP	15 (51.7)
DM	8 (27.6)
Ischemic heart disease	10 (34.5)
PCI before implant placement	2 (6.8)
Peripheral arterial disease	3 (10.3)
Previous stroke	4 (13.8)
COPD	9 (31)
Smoker	2 (6.8)
Chronic renal failure	10 (34.5)
Previous pacemaker	2 (6.8)
Surgical risk	
Logistic EuroSCORE, %	14.9 ± 7.2
Logistic EuroSCORE > 20%	6 (20,6)
EuroSCORE II, %	3.9 ± 2.5
STS, %	4.3 ± 2.1
Indication	
Frailty	11 (37.9)
Porcelain aorta	8 (27.6)
High risk	7 (24.1)
Others	3 (10.3)
Echocardiographic parameters	
Mean gradient, mmHg	49.2 ± 12.4
Maximum gradient, mmHg	79.5 ± 17.3
Aortic valve area, cm^2	0.6 ± 0.1
Mitral regurgitation > II	11 (37.9)
LVEF, %	55.7 ± 15.7
Procedure	
Implant success	29 (100)
Sedation/local anesthesia	26 (89.6)
Femoral access	29 (100)
Previous valvuloplasty	28 (96.6)
Prosthesis postdilatation	14 (48.3)
Residual aortic regurgitation ≥ 2	1 (3.4)
Aortic valve area following implantation, cm^2	1.8 ± 0.2
Fluoroscopy time, min	16.9 ± 4.4
Contrast volume, mL	200.3 ± 72.7
Acute complications	
Periprocedure AMI	0
CIN	1 (3.4)
Major stroke	0
Major vascular complication	1 (3.4)
Minor vascular complication	5 (17.2)
De novo LBBB	4 (13.8)
Definitive pacemaker implantation	3 (10.3)
Duration hospitalization, days	6.9 ± 1.8
Follow-up	
Follow-up time, days	230.0 ± 197.2
In-hospital and 30-day mortality	1 (3.4)
NYHA at 30 days	
I-II	27 (93.1)
III-IV	1 (3.4)
Mortality during follow-up	0

AMI, acute myocardial infarction; CIN, contrast-induced nephropathy; COPD, chronic obstructive pulmonary disease; DLP, dyslipidemia; DM, diabetes mellitus; EuroSCORE, European System for Cardiac Operative Risk Stratification; HT, hypertension; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association functional class; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons.
Continuous variables are expressed as the mean ± deviation and categorical values as No. (%).

2 rotational knobs: the distal knob releases the stabilizing arches and upper crown, whereas the proximal knob releases the lower crown, at which time the valve is completely deployed. To prevent inadvertent release of the lower crown, the handle contains a safety button that must be removed to allow rotation of the proximal knob.

Aortic balloon valvuloplasty is recommended prior to implantation. Once the valve is advanced to the native annulus, 2-step deployment occurs from the top down; that is, from the aorta to the left ventricle, unlike other self-expanding valves. It is important to know that the valve is not retrievable.

Initial position: As in other percutaneous prostheses, the 3 coronary sinuses must be aligned to identify the valvular annulus. This is used as a reference to guide positioning of the implant, which should extend between 4 and 6 mm into the left ventricular outflow tract. To achieve this objective, the radiopaque solder marker should be aligned with the annulus (Figure B).

Step 1: Once the initial position is reached, the upper crown and stabilizing arches are consecutively released by rotating the distal knob on the handle in a counterclockwise direction. At this point, the valve position can still be readjusted by gently retracting or pushing the catheter forward. During these maneuvers, it is important not to insert the prosthesis into the left ventricle with the upper crown deployed; given its configuration, it will be very difficult to return it to the aorta. (Figure C).

Step 2: Finally, the lower crown is released and the prosthesis is fully deployed and functioning. Although the prosthesis is already very stable in this last step, overpacing can be useful to avoid undesirable final movements. The lower crown is released by rotating the proximal knob in a counterclockwise direction after removing the safety button (Figure D).

Once the prosthesis has been deployed, the catheter is retrieved from the left ventricle and the device is re-encapsulated in the descending aorta by rotating the 2 knobs in the opposite order and direction to that used for releasing the prosthesis.

We present the outcome of ACURATE-Neo TF use in 29 patients, 28 with severe aortic stenosis and 1 with severe aortic failure due to dysfunction of a surgical prosthesis. The baseline characteristics of the patients, procedure-related data, and follow-up information are provided in Table.

In our initial series of 29 patients and in line with the currently available evidence compiled in registries and in small real-world reports,[2,3] percutaneous implantation of the ACURATE-neo TF aortic valve prosthesis was safe and was associated with a low incidence of complications and mortality at 30 days. The results were particularly good in terms of residual paravalvular leak and requirement for pacemaker implantation in comparison with other self-expandable valves. The larger profile and smaller range of sizes relative to other valves make ACURATE-neo TF accessible to a smaller number of patients, and the incidence of vascular complications (mainly minor ones) was somewhat higher.

The design of the upper crown, explained above, makes this aortic valve prosthesis particularly indicated for patients with low positioning of the coronary ostia or with aortas with narrow sinuses of Valsalva, as the risk of coronary occlusion is higher in these cases.

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Antiplatelet Monotherapy After Percutaneous Coronary Intervention. Contemporary Long-term Outcomes and Matched Comparison With Routine Clinical Practice

Monoterapia antiplaquetaria tras intervención coronaria percutánea. Resultados contemporáneos a largo plazo y comparación con la práctica habitual

To the Editor,

Some patients cannot receive aspirin, and are therefore unable to receive dual antiplatelet therapy (DAPT) following a percutaneous intervention. For these patients, antiplatelet monotherapy (APM) with a $P2Y_{12}$ inhibitor ($iP2Y_{12}$) is a potential option, although there is little published data on this therapy. Our aim was to investigate the incidence of APM use in clinical practice and to determine the outcome in this group compared with that in patients receiving DAPT. From August 2008 to April 2016, we enrolled all patients receiving APM (ticlopidine 150 mg/12 h, clopidogrel 75 mg/24 h, ticagrelor 90 mg/12 h, or prasugrel 10 mg/24 h) following angioplasty. Patients receiving anticoagulant agents at hospital discharge or during follow-up (according to telephone contact or medical visit) were excluded, leaving a total of 37 patients for the study.

Clinical variables and the reasons for APM use were recorded (Table). The incidence of APM use was 0.42% with a median follow-up of 48.8 months; 27% had received one of the newer antiplatelet agents (6, prasugrel; 4, ticagrelor). Patients receiving APM were matched (1:1) with a control group given DAPT according to the standard clinical practice, selected from 1438 consecutive patients undergoing stent placement in our center between 2011 and 2013. The criteria for matching were age, sex, hypertension, dyslipidemia, diabetes, smoking, clinical presentation, type of stent (drug-eluting/metallic), and ejection fraction. Among the controls, 2 received prasugrel. Compared with patients given DAPT, the group receiving APM showed no significant differences in the rate of major cardiovascular events at 3 years (mortality, reinfarction, or revascularization requirement; $P = .810$) (Figure). In both groups, major cardiovascular events occurred mainly within the first year. Four patients in each group died during follow-up. There was 1 major bleeding event in the DAPT group and none in the APM group during follow-up (nonsignificant difference).

Park et al.[1] investigated the development of bleeding with APM–either aspirin or clopidogrel–following DAPT use, and reported that major bleeding rates were similar in the comparison of these 2 agents. Gastrointestinal bleeding is more common with aspirin than clopidogrel, and DAPT with these agents increases the risk of gastrointestinal bleeding by 2- or 3-fold compared with aspirin alone.[2] There were no cases of stent thrombosis during follow-up in our study, likely because of the low incidence of this phenomenon ($< 1\%$ per year) and the small size of the sample. Although previous studies have indicated that stent thrombosis rates after DAPT discontinuation are significant and are related to discontinuing the second antiplatelet agent, the absence of this event in our study raises the hypothesis that $iP2Y_{12}$ agents may be able to maintain an adequate antithrombotic state. Data on $iP2Y_{12}$ monotherapy are scarce and some information is from patients who have undergone early DAPT discontinuation. Ferreira-González et al.[3] have indicated that there is a variable relationship in time between occurrence of events and the day of discontinuation. The PARIS registry has shown that APM (understood as early discontinuation of DAPT, which may be temporary or permanent) carried out under medical supervision can provide acceptable results.[4]

Another finding of our study is related to the type of $iP2Y_{12}$. We observed a trend toward more favorable outcomes in patients receiving the newer $iP2Y_{12}$ agents (Figure B), possibly because of greater individual variability in pharmacodynamics, CYP2C19 polymorphisms in patients requiring antiplatelet therapy with clopidogrel, and a more potent antiplatelet action of the newer agents.[5]

Effective strategies are available in clinical practice for treating patients with aspirin allergy and contraindications for implanting a drug-eluting stent, such as desensitization protocols, likely the preferable option, or substituting aspirin for an analog or another antiplatelet agent (indobufen, trapidil, triflusal).[6] Nonetheless, these measures sometimes fail or are not applied for various reasons. Additionally, in populations with an elevated bleeding risk, attempts are made to reduce DAPT to a minimum. A strategy of $iP2Y_{12}$ monotherapy could be useful in both these scenarios. Results are pending for the TWILIGHT and GLOBAL LEADERS studies, which may establish broader indications for the use of APM.