Scientific letters

Transfemoral transcatheter tricuspid valve replacement with the Cardiovalve system

Reemplazo percutáneo de la válvula tricúspide por vía femoral con el sistema Cardiovalve

To the Editor,

We present the first 2 cases of transfemoral transcatheter tricuspid valve replacement performed in Spain.

The patients, both symptomatic, had torrential tricuspid regurgitation (TR), high surgical risk (TRI-SCORE, 34% and 14%), severe dilation, and moderate right ventricular (RV) dysfunction (figure 1A, video 1 of the supplementary material). Surgery was ruled out by the multidisciplinary team and it was decided to attempt a transcatheter approach. Repair was not considered because of the anatomic characteristics (gap size > 8 mm, marked annular dilatation, significant leaflet restriction, and, in 1 of the patients, rheumatic involvement). The chosen procedure was orthotopic valve replacement with the Cardiovalve system (Cardiovalve, Or-Yehuda, Israel). Both patients consented to the procedure and its publication. Their clinical characteristics are summarized in table 1.

The Cardiovalve system is designed for mitral and tricuspid valve replacement. It consists of a steerable, transfemoral catheter (32-Fr) and a trileaflet bovine pericardial valve sutured using Dacron to a dual (atrial and ventricular) self-expanding, welded nitinol frame for robust radial strength. The structure features 24 grasping legs for atraumatic anchoring of the valve to the native mitral annulus. The valve is available in 3 sizes covering annulus diameters ranging from 36 to 55 mm. Choice of size is based on computed tomography measurements.[1]

The procedures were performed under general anesthesia with fluoroscopic and transesophageal echocardiographic (TEE) guidance and fusion imaging with HeartNavigator (Philips, The Netherlands).

The right femoral vein was surgically exposed and an 18-Fr catheter (Cook Medical, USA) implanted. Using an Agilis Nxt steerable introducer (Abbott, USA), a pigtail catheter was delivered to the right ventricular apex, enabling advancement of an extra-small, high-support Safari guidewire (Boston Scientific, United States). It is essential that this guidewire does not interfere with the chordae tendineae (figure 1B).

The introducer with the Cardiovalve (extra large in both cases) was then advanced. Using the control wheels, the system was directed towards the valve plane (figure 1C) and raised until the leaflet grasping legs could be opened in the atrium (figure 1D). Once the system was centered, the path was corrected. The system was then advanced into the RV and the native leaflets grasped. Adequate capture was checked using 3-dimensional multiplanar reconstruction (figure 1E, video 2 of the supplementary material). The atrial flange, followed by the ventricular flange, was then released to complete deployment (figure 1F). The results were evaluated by TEE. Successful implantation was achieved in both cases, with no evidence of residual TR and a gradient < 3 mmHg (videos 3 and 4 of the supplementary material). Recovery was largely uneventful, with 1 patient developing a small hematoma at the vascular access site and the other showing a transient drop in platelet count. They were discharged on days 7 and 10, respectively. Clinical progress was favorable at 3 months in both cases. Follow-up echocardiograms showed correct alignment of the valves, no significant decline in RV function, and an insignificant gradient. Moderate paravalvular regurgitation was observed in 1 of the patients.

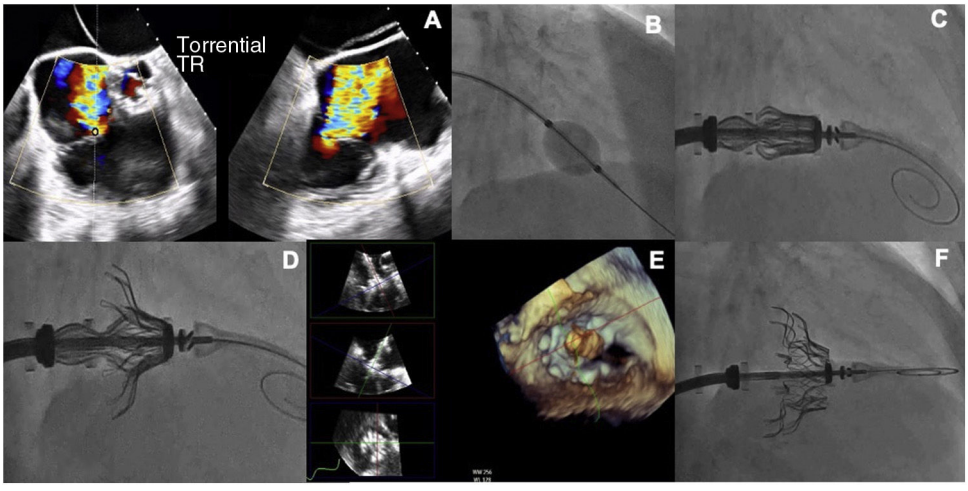

Figure 1. A: in-hospital glycemic control based on neurological outcome at 6 months. B: comparison of the regression model receiving operator curves for neurological outcome. Adding mean glycemia in the model improved the area under the curve from 0.848 (red curve) to 0.879 (blue curve). CPC, cerebral performance category.

Table 1
Comparison of baseline patient characteristics.

Baseline characteristic	Patient 1	Patient 2
Age, y	82	71
Sex	Female	Female
Previous valve surgery	No	Mechanical mitral and aortic valves
Permanent atrial fibrillation	Yes	Yes
Anticoagulation	Apixaban	Acenocoumarol
Furosemide dose, mg	60	40
Previous TR grade	5	5
Type of TR	Functional	Rheumatic
LV systolic function	55	60
RV systolic function	35	39
Tricuspid annulus diameter, mm	54 × 46	52 × 44
Mean PAP, mmHg	28	14
PCP, mmHg	16	10
V wave	35	17
Cardiac output, L/min	4.4	3.0
EuroSCORE II, %	3.19	2.77
TRI-SCORE, %	34	14
NT-proBNP, pg/mL	1297	714
Creatinine, mg/dL	0.98	0.84
ALT, IU/L	24	27
Total bilirubin, mg/dL	1.02	1.06
Hemoglobin, g/dL	11.6	13.8

ALT, alanine transaminase; LV, left ventricle; NT-proBNP, amino-terminal fraction of pro-brain natriuretic peptide; PAP, pulmonary artery pressure; PCP, pulmonary capillary pressure; RV, right ventricle; TR, tricuspid regurgitation.

TR is a common valve disease with significant clinical consequences (impaired quality of life and increased mortality). Treatments to date have been associated with high morbidity and mortality,[2,3] prompting the development of several transcatheter techniques, which have shown promising results. Although repair procedures are currently more common, their limitations impede high success rates.[3] The emergence of tricuspid valve replacement has created opportunities for patients who are not candidates for repair procedures, such as annuloplasty or edge-to-edge repair. The initial results observed with transfemoral tricuspid valve replacement are highly encouraging, with high success rates, few complications, and near-complete elimination of TR.[4] The Cardiovalve system is a new alternative for tricuspid valve replacement. It has a low profile that does not interfere with the RV structures or outflow tract, comes in 3 sizes compatible with a wide range of annulus diameters, and has multiple leaflet grasping legs to ensure firm anchoring and an atrial sealing flange to minimize the risk of perivalvular leaks.

In conclusion, transcatheter tricuspid valve replacement using the Cardiovalve system may afford an opportunity for treating patients with anatomic limitations impeding other treatments.

FUNDING

None.

AUTHORS' CONTRIBUTIONS

All the authors contributed to this work. B. Caneiro-Queija and R. Estévez-Loureiro conceived the paper and collected the data. B. Caneiro-Queija, R. Estévez-Loureiro, and M. Barreiro-Pérez wrote the manuscript and M. Barreiro-Pérez, M. Piñón-Esteban, J. Baz-Alonso, and A. Íñiguez-Romo critically reviewed it. All the authors approved the final version.

CONFLICTS OF INTEREST

None.

APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version, at https://doi.org/10.1016/j.rec.2022.08.011

Berenice Caneiro-Queija,[a] Rodrigo Estévez-Loureiro,[a,*] Miguel Piñón-Esteban,[b] Manuel Barreiro-Pérez,[a] José A. Baz-Alonso,[a] and Andrés Íñiguez-Romo[a]

[a]*Departamento de Cardiología, Hospital Universitario Álvaro Cunqueiro, Vigo, Pontevedra, Spain*
[b]*Departamento de Cirugía Cardiaca, Hospital Universitario Álvaro Cunqueiro, Vigo, Pontevedra, Spain*

* Corresponding author.
E-mail address: roiestevez@hotmail.com (R. Estévez-Loureiro)..
@RodrigoEstvez1 @manuelbarreirop @b_caneiro @miguelpinon_73

Available online 10 October 2022

REFERENCES

1. Aoi S, Wiley J, Ho E, Goldberg Y, Chau M, Latib A. Transcatheter tricuspid valve implantation with the Cardiovalve system. *Future Cardiol.* 2021;17:963–969.
2. Taramasso M, Benfari G, van der Bijl P, et al. Transcatheter Versus Medical Treatment of Patients With Symptomatic Severe Tricuspid Regurgitation. *J Am Coll Cardiol.* 2019;74:2998–3008.
3. Praz F, Muraru D, Kreidel F, et al. Transcatheter treatment for tricuspid valve disease. *EuroIntervention.* 2021;17:791–808.
4. Fam NP, von Bardeleben RS, Hensey M, et al. Transfemoral Transcatheter Tricuspid Valve Replacement with the EVOQUE System: A Multicenter, Observational, First-in-Human Experience. *JACC Cardiovasc Interv.* 2021;14:501–511.

https://doi.org/10.1016/j.rec.2022.08.011
1885-5857/

Age and stabilization of admissions for heart failure in Spain (2006-2019). The beginning of the end of the "epidemic"?

Edad y estabilización de los ingresos por insuficiencia cardiaca en España (2006-2019). ¿El principio del fin de la «epidemia»?

To the Editor,

Heart failure (HF) has been considered to be the great cardiovascular"epidemic"of the 21st century due to its high and increasing incidence and prevalence as well as its high mortality.[1,2] One of the consequences of the enormous magnitude and severity of HF is the large number of hospital admissions, which are frequent despite treatment and lead to worsening prognosis, deterioration in the quality of life of patients and caregivers, and a high economic burden on the health care system.[2,3] Indeed, several studies have shown that the admissions rate for HF in Spain since the 1990s has been steadily increasing[4] and that this trend has continued in the early years of 21st century.[5,6] The RECALCAR study of the Spanish Society of Cardiology[6] has shown that one of the main reasons for the increasing incidence of HF admissions is population aging.

To further investigate this trend in Spain and the influence of advanced age on the number of HF hospitalizations, we studied the prevalence of admissions for HF episodes in Spanish Health Care System (HCS) hospitals. The data source was the minimum data set (MBDS) of the Ministry of Health. We selected all admissions of patients with a main diagnosis of HF between January 1, 2006 and December 31, 2019. These episodes were coded according to the International Classification of Diseases (ICD-9 until 2015; ICD-10 from 2016 onward).

From 2006 to 2009, there were 371 566 admissions for HF in Spanish HCS hospitals. However, from 2016 to 2019, there were 456 461 admissions, representing a significant increase of 22.8% ($P < .001$) despite underreporting in 2016 due to changes in the coding system. Nevertheless, when adjusted for age and sex (direct method), the admission rate (age- and sex-adjusted admissions per 100 000 population) was lower from 2017 to 2019 than from 2006 to 2015 (271 vs 286; $P < .001$). From 2006 to 2019, the percentage of patients aged at least 75 years admitted for HF significantly increased vs all HF admissions (from 69.9% in 2007 to 77.5% in 2019 [$P < .001$]). The number of admissions in this age group also significantly increased from 262 629 (2006-2009) to 351 589 (2016-2019). Indeed, this 33.8% increase was larger than the increase in total HF admissions (22.8%). Table 1 shows the trend (2006-2019) in the number of HF admissions, the age- and sex-adjusted rate of admissions per 100 000 population, the number and percentage of admissions of patients aged at least 75 years, and the number of admissions and age- and sex-adjusted rates of men and women aged at least 75 years. The overall incidence rate ratio is shown and also for the periods 2006 to 2015 and 2017 to 2019. Although there was an increasing trend in the number of admissions for HF, it can be seen that, from 2006 to 2019, the age- and sex-adjusted admission rate tended to decrease (IRR, 0.98; 95% confidence interval [95%CI], 0.98-0.99; $P < .001$) and then flattened from 2017 to 2019 (IRR, 1; 95%CI, 1-1; $P < .001$) (figure 1A). However, in that period, there was a significant increase in the number and percentage of HF admissions of patients aged at least 75 years (table 1). Table 1 also shows a decrease in HF admissions between 2015 and 2016, which was due to changes in the MDS coding system (ICD-9 until 2015; ICD-10 from 2016 onward). However, the slope representing the increase in the number of admissions remained similar before and after the change in coding (see figure 1B, joinpoint model).

These results suggest 2 main points: *a)* in Spain, the age- and sex-adjusted admissions rate per 100 000 population has recently decreased; this is the first time this trend has been observed; and *b)* the percentage of admissions among patients aged at least 75 years

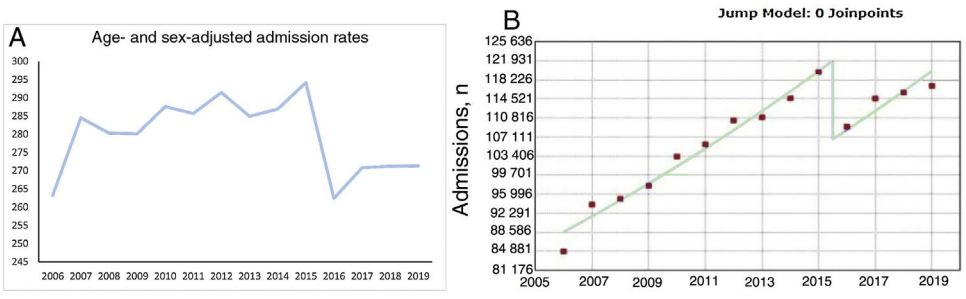

Figure 1. A: trend in the adjusted admission rates of patients aged at least 75 years admitted for heart failure. In 2016, the age- and sex-adjusted admission rate decreased (underreporting); from 2017 onward, it remains at 271/100 000 population. B: joinpoint model of the number of admissions from 2006 to 2019; there was a decrease of 12.78% per year from 2015 to 2016. The annual percentage change and average annual percentage change are significant and equal (3.4), indicating that the trend did not change.