

Scientific letters

**The V-Wave Device for the Treatment of Heart Failure. Initial Experience in Europe**



**Dispositivo V-Wave para el tratamiento de la insuficiencia cardiaca. Experiencia inicial en Europa**

**To the Editor,**

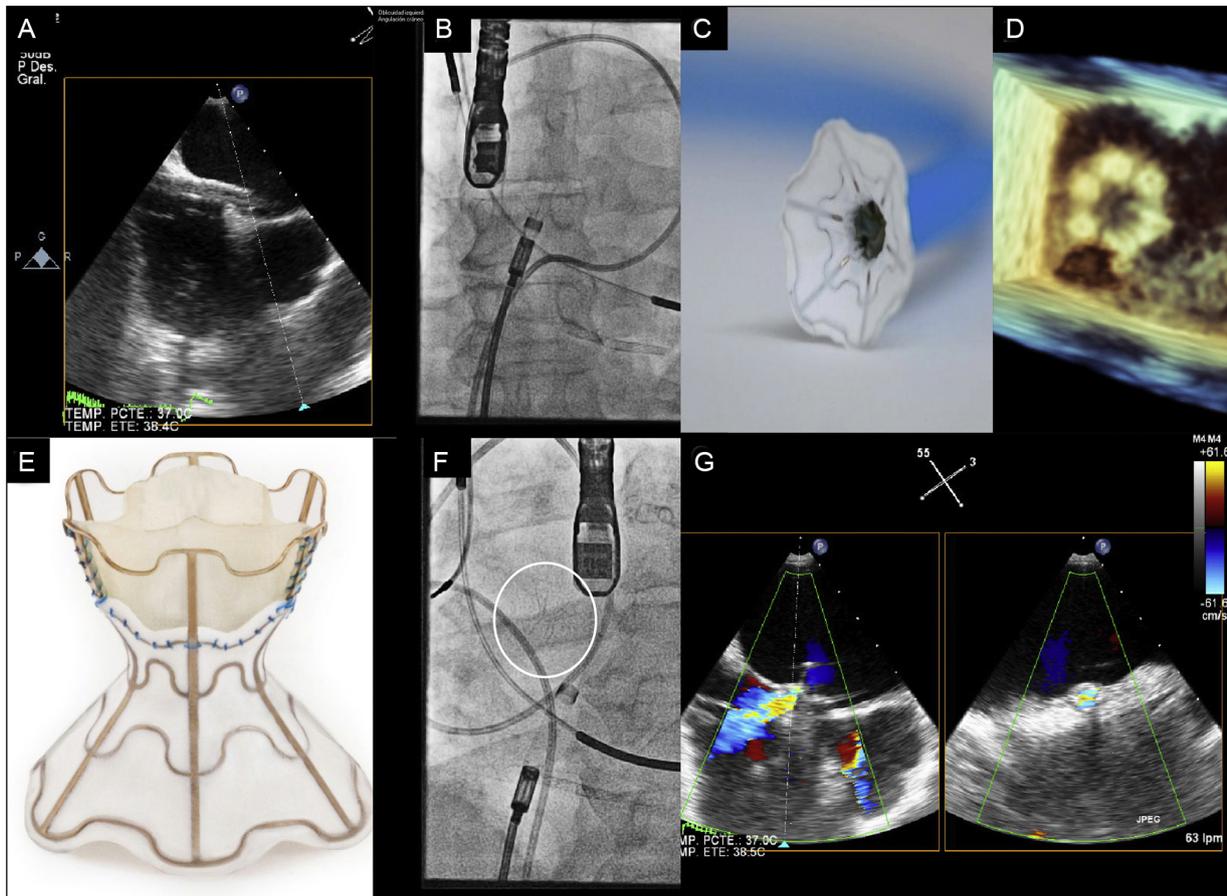
Left heart failure is the final manifestation of various heart diseases involving left ventricular dysfunction, such as ischemic heart disease.<sup>1</sup> Due to treatment advances, the prevalence of left heart failure is growing, but its natural course is associated with a continual decrease in quality of life, rehospitalizations, and early mortality.<sup>2</sup> Previous studies have shown that tight control of left atrial pressure is associated with improved ventricular function and functional class, suggesting that this strategy could improve prognosis.<sup>1</sup>

The V-Wave device (V-Wave Ltd, Or Akiva, Israel) is based on this concept and on past experience of the creation of interatrial shunts to treat patients with congenital heart disease or ventricular assist devices.<sup>3-5</sup> The V-Wave device, which permanently reduces left atrial pressure, is composed of an hourglass-shaped nitinol frame

with a polytetrafluoroethylene polymer coating on its left side and a valve with 3 bovine pericardium leaflets on its right side to prevent paradoxical embolisms and early shunt closure (Figure).

The first patient was described in Canada<sup>6</sup> and the technology has recently been introduced in Europe, where the first 2 implants were successfully performed with the approval of the *Agencia Española de Medicamentos y Productos Sanitarios* (Spanish Agency for Medicines and Medical Devices). The selection criteria for this first-in-man study are summarized in the Table. Detailed clinical (Kansas City Cardiomyopathy Questionnaire [KCCQ]) and functional (6-minute walk test) tests were performed, as well as measurement of the aminoterminal fraction of brain natriuretic peptide (NT-proBNP) and right heart catheterization.

The first patient was a 73-year-old man with partially revascularized chronic ischemic heart disease and a cardiac resynchronization therapy device. He had severe left ventricular dysfunction (24%), moderate mitral regurgitation (II/IV), and acceptable right ventricular function (tricuspid annular plane systolic excursion [TAPSE] of 14 mm). His 6-minute walk test distance was 253 meters and his KCCQ score was 35.42, and the right heart catheter showed cardiac output of 3.5 L/min,



**Figure.** A: advancement of the sheath until the left atrium via the fossa ovalis. B, C, and D: images from angiography (B), bench testing (C), and 3D echocardiography (D) of the opening of the left part of the device in the left atrium. E, F, and G: images from bench testing (E), angiography (F), and color Doppler echocardiography (G) of the unfolded V-Wave.

**Table**

Summary of the Inclusion and Exclusion Criteria for Candidates of the V-Wave Device in this First-in-man Study

Patients with chronic ischemic/nonischemic cardiomyopathy in New York Heart Association class III or class IV in outpatient follow-up, American College of Cardiology / American Heart Association stage C with the following inclusion/exclusion criteria:

## Inclusion criteria:

1. Maximum tolerated doses of guideline-indicated drugs for the treatment of heart failure.
2. Cardiac resynchronization therapy (if indicated) for at least 90 days previously.
3. Implantable cardioverter-defibrillator (if indicated) for at least 30 days previously.
4. Left ventricular ejection fraction  $> 15\%$  and  $\leq 40\%$ .
5. The following right heart catheterization parameters: PCP  $\geq 15$  and  $\leq 28$  mmHg, DBP  $> 4$  and  $\leq 11$  mmHg, mean PCP-DBP gradient  $\leq 16$  mmHg.
6. NT-proBNP  $> 1500$  pg/mL.
7. Signed informed consent specifying risks (of femoral access, transseptal puncture, the device itself, anesthesia, and transesophageal echocardiography).

## Exclusion criteria:

1. Severe right ventricular dysfunction.
2. Severe pulmonary hypertension (systolic PAP  $> 70$  mmHg).
3. Severe valve disease.
4. Heart transplant expected in the following 6 months.
5. Thickness of the septum at the fossa ovalis  $> 3$  mm.
6. Active malignancy.
7. Coronary bypass, PCI, or acute myocardial infarction in the previous 90 days.
8. Coagulation disorder.
9. Stroke in the previous 6 months.
10. Persistent/permanent atrial fibrillation.
11. Intraventricular thrombus.
12. Nonpatent femoral venous access or inferior vena cava.
13. Contraindication to transesophageal echocardiography.
14. Severe ventilatory disease.
15. Life expectancy less than 1 y due to noncardiac causes.

DBP, diastolic blood pressure; NT-proBNP, aminoterminal fraction of brain natriuretic peptide; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; PCP, pulmonary capillary pressure.

pulmonary capillary pressure of 26 mmHg, and right atrial pressure of 10 mmHg. The patient's NT-proBNP level was 3341 pg/mL.

The second patient was a 70-year-old man with surgically and percutaneously revascularized ischemic dilated cardiomyopathy and a cardioverter-defibrillator. He had left ventricular dysfunction (28%), moderate mitral regurgitation (II/IV), and TAPSE of 19 mm. His 6-minute walk test distance was 236 meters and his KCCQ score was 42.45, and the right heart catheter showed cardiac output of 4.8 L/min, pulmonary capillary pressure of 16 mmHg, and right atrial pressure of 5 mmHg. The patient's NT-proBNP level was 1526 pg/mL.

Despite receiving optimal medical therapy and high-dose diuretics (120 mg and 80 mg, respectively), both patients showed New York Heart Association (NYHA) functional class III dyspnea and orthopnea. Approval was obtained from a committee of heart failure experts and, once an informed consent form had been signed, we decided to implant the V-Wave device. The procedure was performed under general anesthesia to improve the tolerability of transesophageal echocardiography. The right atrium was accessed via a femoral vein approach, a transseptal puncture was made at the level of the fossa ovalis, and a 14-Fr sheath was inserted into the left atrium (Figure A-D). The device was attached to a delivery catheter and advanced through the sheath until its first portion opened in the middle part of the left atrium. Once correct apposition of the device to the septum was confirmed, the

device was released from the delivery catheter. After a slight pull of the sheath, the second part of the device opened in the right atrium and the correct fixation of the device in the interatrial septum was confirmed (Figure E-G; see the [video of the supplementary material](#)). Following implantation, the left-right shunt was immediately visualized in both patients via transesophageal echocardiography (Figure G). Both patients were discharged 24 hours after the procedure with no complications and with instructions for 3-month oral anticoagulation therapy, during which time no other therapeutic modifications could be performed according to the protocol.

At a 3-month follow-up, the V-Wave device was patent and both patients were in NYHA functional class II, without orthopnea and with KCCQ scores of 62.5 and 63.54, respectively. Improvements were also evident in objective parameters, such as increases of 27.3% and 19.0% in the 6-minute walk test distance, NT-proBNP values of 2663 pg/mL and 1129 pg/mL, cardiac output of 4.6 L/min, and pulmonary capillary pressure of 23 mmHg for the first patient (Qp:Qs = 1.3) and 5.2 L/min and 12 mmHg for the second (Qp:Qs = 1.2). Nonetheless, the promising results of this new therapeutic approach require long-term validation.

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**CONFLICTS OF INTERESTS**

J. Rodés-Cabau is a consultant for V-Wave Ltd.

**SUPPLEMENTARY MATERIAL**

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## Transapical Valve-in-valve Implantation in Failed Mitral Bioprostheses



### Implante transapical de prótesis valvular mitral sobre bioprótesis degeneradas

#### To the Editor,

Reoperation for mitral bioprosthesis dysfunction is a challenging procedure due to patients' clinical status and the technical difficulties associated with resecting the prosthesis and implanting a new valve in the weakened mitral annulus; in addition, the redo surgery carries the risk of structural damage to the myocardium and perivalvular leakage.

Transcatheter valve-in-valve implantation into a deteriorated mitral bioprosthesis is a little used technique,<sup>1–4</sup> but in complex patients it provides an alternative to conventional surgery that avoids cardiac dissection, extracorporeal circulation, and myocardial ischemia. Most prostheses are implanted via the transapical route because this approach provides direct coaxial access to the valve with shorter delivery catheters; however, another access option is the femoral vein, followed by perforation of the interatrial septum and anterograde valve implantation.

From January 2007 to September 2014, the surgical team at our center performed 70 implantations via the transapical route. In 6 patients, a new valve was implanted in a deteriorated prosthesis: 4 in the aortic position and 2 in the mitral position. The clinical characteristics of the 2 patients selected for the mitral procedure are summarized in the [Table](#).

Both mitral valve implantations were carried out under general anesthesia in the cardiac catheterization laboratory by 2 surgeons and a cardiac catheterization specialist. A left anterior minithoracotomy was performed through the fifth or sixth intercostal space, and transapical access through the pericardial opening was

secured by 2 U sutures with teflon-supported 3/0 monofilament suture thread. The ventricular apex was punctured with a guidewire, which was advanced through the opening of the mitral prosthesis into the left atrium. To prevent traumatic perforation of the atrial wall, this guidewire was then exchanged for a preformed high-support guidewire. Coaxial alignment with the ring of the deteriorated bioprosthesis was guided by radiology and echocardiography. This procedure was more challenging with the Epic bioprosthesis because its annulus is only faintly radiopaque; in contrast, the Perimount bioprosthesis, in addition to having a larger annulus, also has a radiopaque supporting stent. After balloon predilatation, an Edwards SAPIEN XT Transcatheter Heart Valve (Edwards Lifesciences, Irvine, California, United States) was implanted in the opposite orientation to that of a transapical aortic valve implant, following the standard protocol with rapid endocardial pacing ([Figure](#)). The valve sizes used were 23 mm for patient 1 and 26 mm for patient 2. These sizes were chosen according to the manufacturer-specified internal diameters of the original bioprostheses, which were consistent with direct measurements by transesophageal echocardiography (23 mm for the 25-mm Perimount valve and 24.5 mm for the 27-mm Epic valve). In both patients the procedure was completed without technical incident, and correct implantation was confirmed by intraoperative transesophageal echocardiography.

Patient 1 developed cardiogenic shock in the first hours after implantation, with biventricular dysfunction, acute renal failure, and elevated hepatic enzymes; the condition was reversed by amine therapy and the placement of an intra-aortic counterpulsation balloon for 72 hours. The discharge echocardiogram showed normal function of the mitral bioprosthesis, a left ventricular ejection fraction of 35%, and a systolic pulmonary arterial pressure of 70 mmHg.

Patient 2 was extubated 8 hours after device implantation, and did not require amine therapy at any time. During hospitalization,

**Table**  
Baseline Clinical Profile of the 2 Patients

	Patient 1	Patient 2
Age, y	79	82
Sex	Female	Male
Comorbidities	PVD	PVD, spondylodiscitis, prosthesis dysfunction <sup>a</sup>
Previous surgery	MVR+CP×4 (2004)	OMC (1979), MVR+CB×3+TA (2011), MVR (2012) <sup>b</sup>
Prosthesis type	25-mm Perimount	27-mm Epic
Mitral valve disorder	Moderate combined regurgitation and stenosis MVA: 1.1 cm <sup>2</sup> MR: grade III	Severe regurgitation MVA: 2.2 cm <sup>2</sup> MR: grade IV
LVEF, %	45	55
SPAP, mmHg	65	95
NYHA functional class	III	III
Logistic EuroSCORE I	58.12	44.47

CB, coronary bypass; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; MVA, mitral valve area; MVR, mitral valve replacement; NYHA: New York Heart Association; OMC, open mitral commissurotomy; PVD, peripheral vascular disease; SPAP, systolic pulmonary arterial pressure; TA, tricuspid annuloplasty.

<sup>a</sup> 2014: Severe mitral regurgitation due to perforation of a prosthetic leaflet. Imaging results were consistent with endocarditis, but the patient had no fever, and blood cultures were negative.

<sup>b</sup> 2012: Prosthesis replaced due to endocarditis caused by *Abiotrophia defectiva*.