Left atrial decompression through unidirectional left-to-right interatrial shunt for the treatment of left heart failure: first-in-man experience with the V-Wave device

Ignacio J. Amat-Santos¹, MD; Sebastien Bergeron¹, MD; Mathieu Bernier¹, MD; Ricardo Allende¹, MD; Henrique Barbosa Ribeiro¹, MD; Marina Urena¹, MD; Philippe Pibarot¹, PhD; Stefan Verheye², MD, PhD; Gad Keren³, MD; Menashe Yaacoby⁴, PhD; Yaacov Nitzan⁴, PhD; William T. Abraham⁵, MD; Josep Rodés-Cabau¹*, MD

¹. Department of Cardiology, Quebec Heart & Lung Institute, Quebec City, Quebec, Canada; ². Antwerp Cardiovascular Center, Antwerp, Belgium; ³. Department of Cardiology, Tel Aviv Medical Center, Tel Aviv, Israel; ⁴. V-Wave Ltd, Or-Akiva, Israel; ⁵. Division of Cardiovascular Medicine, Ohio State University Hospital, Ohio, USA

The accompanying supplementary data are published online at: http://www.eurointervention.com/ahead_of_print/201405-07

Abstract

Aims: Elevated filling pressures of the left atrium (LA) are associated with poorer outcomes in patients with chronic heart failure. The V-Wave is a new percutaneously implanted device intended to decrease the LA pressure by the shunting of blood from the LA to the right atrium. This report describes the first-in-man experience with the V-Wave device.

Methods and results: A 70-year-old man with a history of heart failure of ischaemic origin, left ventricular dysfunction (LVEF: 35%, pulmonary wedge: 19 mmHg), no right heart dysfunction, NYHA Class III and orthopnoea despite optimal treatment, was accepted for V-Wave device implantation. The device consists of an ePTFE encapsulated nitinol frame that is implanted at the level of the interatrial septum and contains a trileaflet pericardium tissue valve sutured inside which allows a unidirectional LA to right atrium shunt. The procedure was performed through a transfemoral venous approach under fluoroscopic and TEE guidance. The device was successfully implanted and the patient was discharged 24 hours after the procedure with no complications. At three-month follow-up a left-to-right shunt through the device was confirmed by TEE. The patient was in NYHA Class II, without orthopnoea, the Kansas City Cardiomyopathy index was 77.6 (from 39.1 at baseline) and NT-proBNP was 322 ng/mL (from 502 ng/mL at baseline). The QP/QS was 1.17 and the pulmonary wedge was 8 mmHg, with no changes in pulmonary pressure or right ventricular function.

Conclusions: Left atrial decompression through a unidirectional left-to-right interatrial shunt represents a new concept for the treatment of patients with left ventricular failure. The present report shows the feasibility of applying this new therapy with the successful and uneventful implantation of the V-Wave device, which was associated with significant improvement in functional, quality of life and haemodynamic parameters at 90 days.

© Europa Digital & Publishing 2014. All rights reserved.

*Corresponding author: Quebec Heart & Lung Institute, Laval University, 2725 Chemin Ste-Foy, Quebec City, Quebec, G1V 4G5, Canada. E-mail: josep.rodes@criucpq.ulaval.ca
Introduction

Heart failure (HF) is a highly prevalent disease that affects 1-2% of the population. Despite recent advances in its treatment, many patients with HF continue to deteriorate while on optimal therapy leading to a decline in quality of life (QoL), a high rate of re-hospitalisations, and increased costs¹. This highlights the importance of continuous progress and innovation for improving the treatment of HF.

Elevated left atrium (LA) pressure is present in most patients with chronic HF hospitalised due to HF decompensation. Strict control of LA pressure by invasive monitoring and physician-directed self-management have been associated with significant improvement in left ventricular ejection fraction (LVEF) and NYHA class, as well as with a major reduction in re-hospitalisations and mortality at midterm follow-up². Also, the closure of congenital atrial septal defects has been associated with a rise in LA pressures and decompensated HF in some patients³-⁴. It has been suggested that atrial septal balloon septostomy may be useful in the setting of LV dysfunction with acute HF to permit left heart decompression and recovery of LV function⁵-¹². Finally, several small studies in the setting of pulmonary hypertension and right ventricular dysfunction have shown that creating an interatrial shunt to decrease right atrial pressure may be associated with a significant improvement in symptoms and haemodynamics¹³-²⁰. Therefore, the creation of a unidirectional left-to-right shunt in patients with left-sided HF may provide relief from acute episodes of LA pressure increase, decrease LA pressure over time and prevent re-hospitalisations and functional class deterioration.

The V-Wave device (V-Wave Ltd, Or Akiva, Israel) is a new percutaneously implanted device, intended to decrease LA filling pressure by the shunting of blood volume from the LA to the right atrium (Figure 1A, Figure 1B). The device consists of an ePTFE encapsulated nitinol frame that is implanted at the level of the interatrial septum and contains a trileaflet porcine pericardium tissue valve sutured inside which allows a unidirectional flow from the LA to the right atrium if the pressure gradient exceeds 5 mmHg. The device has been evaluated in an ovine model of ischaemic HF that included a total of 21 sheep (14 with an implanted device and seven controls). The V-Wave implantation was associated with a persistent decrease in LA pressure with no increase in right atrial or pulmonary pressure. All devices showed patent interatrial shunting throughout the entire duration of the study (12 weeks), and device implantation was associated with improved LVEF and lower mortality (7% vs. 43% in controls, p=0.049). The present report describes the first-in-human experience with the V-Wave device in a patient diagnosed with HF and in NYHA Class III despite optimal medical therapy. Selection criteria for the implantation of the V-Wave device are summarised in Table 1.

The patient was a 70-year-old man with a history of HF due to prior large anterior myocardial infarction with coronary artery bypass grafting. Other comorbidities included diabetes, dyslipidaemia, mild chronic obstructive pulmonary disease, and atrial fibrillation treated with anticoagulation therapy (rivaroxaban). Echocardiography showed depression of LVEF (35%), mild mitral...
Table 1. Summary of the main patient selection criteria for the implantation of the V-Wave device.

- Patient with chronic (> six months) ischaemic or non-ischaemic cardiomyopathy (primary or secondary), ACC/AHA Stage C, NYHA Class III or ambulatory Class IV heart failure despite optimal medical therapy as defined by ACC/AHA guidelines, where optimal means:
  - Best tolerated drugs/doses
  - AND
  - Cardiac resynchronisation therapy for at least 90 days
  - AND
  - Implanted cardio-defibrillator at least 30 days prior to the V-Wave implantation
  - LVEF >15% and ≤40%
  - Normal right ventricular function.
  - Absence of severe pulmonary hypertension (mean pulmonary artery pressure <55 mmHg and transpulmonary gradient ≤12 mmHg).
  - Absence of severe valvulopathy.
  - Right heart catheterisation with the following parameters: mean PCWP (wedge) ≥15 mmHg and ≤28 mmHg; mean gradient between PCWP and right atrial pressure ≤16 mmHg.
  - Patient is not likely to undergo heart transplantation within the next six months.
  - Absence of severe mitral regurgitation.
  - Femoral venous access is possible and inferior vena cava is patent.
  - No contraindication for TEE.

ACC: American College of Cardiology; AHA: American Heart Association; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; TEE: transoesophageal echocardiography.

Table 2. Haemodynamic and echocardiographic data at baseline and at three months following the V-Wave device implantation.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Baseline</th>
<th>3-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Haemodynamic variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right atrial pressure (mmHg)</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Right ventricular pressure (mmHg)</td>
<td>28/5</td>
<td>28/4</td>
</tr>
<tr>
<td>Pulmonary artery pressure (mmHg)</td>
<td>31/14/20</td>
<td>28/11/18</td>
</tr>
<tr>
<td>Pulmonary wedge pressure (mmHg)</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Cardiac output (L/min)</td>
<td>5.7</td>
<td>5.9</td>
</tr>
<tr>
<td>Cardiac index (L/min/m²)</td>
<td>2.5</td>
<td>2.6</td>
</tr>
<tr>
<td><strong>Echocardiographic variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Telediastolic LV diameter (mm)</td>
<td>66</td>
<td>67</td>
</tr>
<tr>
<td>LA volume (mm³)</td>
<td>43</td>
<td>45</td>
</tr>
<tr>
<td>RV function / TAPSE (mm)</td>
<td>Normal / 19</td>
<td>Normal / 20</td>
</tr>
<tr>
<td>Telediastolic RV diameter (mm)</td>
<td>40</td>
<td>39</td>
</tr>
<tr>
<td>SPPA (mmHg)</td>
<td>37</td>
<td>38</td>
</tr>
<tr>
<td>Mitral regurgitation degree</td>
<td>II/IV</td>
<td>II/IV</td>
</tr>
</tbody>
</table>

LA: left atrium; LVEF: left ventricular ejection fraction; RV: right ventricular; SPPA: systolic pressure of the pulmonary artery; TAPSE: tricuspid annular plane systolic excursion.
Conclusion
In conclusion, LA decompression through unidirectional left-to-right interatrial shunt represents a new concept for the treatment of patients with HF. The present study showed the feasibility of applying this new therapy with the successful and uneventful implantation of the V-Wave device, which was indeed associated with significant improvement in functional class, QoL, and haemodynamic parameters at three-month follow-up. Future studies will have to demonstrate the efficacy of this treatment for patients diagnosed with HF. Also, a longer follow-up will be needed to ensure that the improvement in haemodynamic and functional parameters is maintained over time.

Impact on daily practice
Most patients with left heart failure hospitalised due to decompensation present elevated left atrial pressure. Decompression of the left atrium through self-regulative left-to-right shunt with the V-Wave device is a new concept for the treatment of heart failure in patients who continue to deteriorate despite maximal treatment. This report represents the first-in-man successful and uneventful implantation of a V-Wave device in a patient with symptomatic left ventricular failure despite maximal therapy. The procedure was associated with significant functional, quality of life and haemodynamic improvement at three-month follow-up. The confirmation of these results in a larger number of patients with a longer follow-up may open a new avenue for the treatment of patients with heart failure.

Acknowledgements
We want to thank Dominique Lachance, MSc, from the Quebec Heart and Lung Institute, for her help in all the logistics related to this case.

Funding
I. Amat-Santos is supported by the Instituto de Salud Carlos III, Madrid, Spain, and Hospital Clinico de Valladolid, Spain (contrato Rio Hortega).

Conflict of interest statement
S. Verheyen, G. Keren, W. Abraham, and J. Rodés-Cabau are consultants for V-Wave Ltd. M. Yaacoby and Y. Nitzan are employees of V-Wave Ltd. The other authors have no potential conflicts of interest to declare.

References


**Online data supplement Moving Image 1.** The V-Wave device: bench test and first-in-human implantation.