Although the usefulness of targeting nonculprit lesions anticipated to be responsible for future cardiovascular events is part of an ongoing investigation (PROSPECT II & PROSPECT ABSORB—an Integrated Natural History Study and Randomized Trial; NCT02171065), we agree with Mahajan et al. that the true prevalence of ruptured or eroded plaques according to detailed imaging modalities such as OCT would be of paramount interest in patients with stable coronary artery disease. However, they should note that in the OCTAVIA (Optical Coherence Tomography Assessment of Gender Diversity In Primary Angioplasty) study, OCT images were obtained at baseline presentation for STEMI, post-stent implantation, and at 9-month follow-up in the culprit vessel only, as part of the prespecified study protocol. Therefore, no information can be extrapolated from this study on the prevalence of destabilized plaques in nonculprit vessels. Differently, the OCT technology available at the time of the study enabled a pullback assessment of the culprit vessel starting from approximately 2 cm distal to the target segment for a total length of approximately 5.4 cm upstream. The prevalence and fate of ruptured or eroded plaques in the culprit vessel beyond the treated lesion along the studied segment will be the objects of an upcoming separate OCTAVIA substudy, which is beyond the scope of the present reply.

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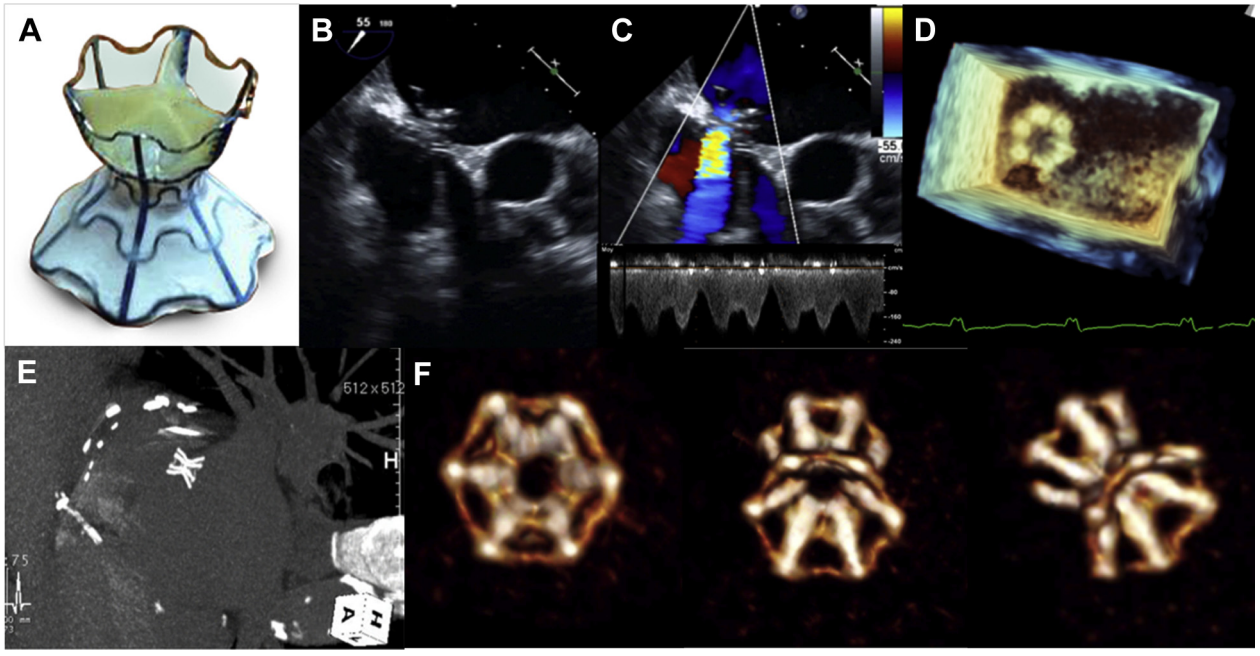
Left Atrial Decompression Using Unidirectional Left-to-Right Interatrial Shunt

Initial Experience in Treating Symptomatic Heart Failure With Preserved Ejection Fraction With the W-Wave Device

Approximately one-half of all heart failure (HF) patients have HF with preserved ejection fraction (HFpEF); the incidence of which is expected to rise in parallel with increasing life expectancy (1). Importantly, and unlike HF with reduced ejection fraction (EF), no specific therapy has thus far proven efficacious in pivotal clinical trials enrolling patients with HFpEF. Most patients with decompensated HF present with elevated left atrial (LA) pressure, and the strict control of LA pressure via invasive monitoring in these patients is associated with significant improvements in New York Heart Association (NYHA) functional class, and quality of life, and significant reductions in re-hospitalizations and mortality (2,3). Reported experience with an open (non-valved) interatrial shunt device (Interatrial Septal Device; DC Devices Inc., Tewksbury, Massachusetts) have demonstrated improvement in NYHA functional class in HFpEF patients (4).

The V-Wave implantable shunt (V-Wave Ltd, Or Akiva, Israel) consists of an ePTFE-encapsulated hourglass shaped nitinol frame which is implanted at the interatrial septum and contains 3 porcine pericardial leaflets sutured within to ensure unidirectional flow from the left to the right atrium (**Figure 1A**). We recently reported the initial successful clinical experience with the V-Wave device in a patient with systolic HF (5). The present case discusses the first experience with the V-Wave device in a patient with HFpEF. A 64-year-old man with a history of coronary artery disease, chronic atrial fibrillation, and ischemic cardiomyopathy with a left ventricular EF of 50% was admitted to our center. Clinically, the patient had HF symptoms of NYHA class III and orthopnea despite high doses of diuretics (furosemide 240 mg/day in divided doses). Right heart catheterization revealed a mean pulmonary wedge pressure of 22 mm Hg, pulmonary artery pressures of 68/21/(39) mm Hg, and a mean right atrial pressure of 12 mm Hg. At baseline, the 6-min hall walk (6MHW) distance was 281 m, the

FIGURE 1 The V-Wave Device



(A) The V-Wave device consists of an hourglass-shaped nitinol frame with ePTFE encapsulation and 3 porcine pericardial leaflets sutured together with a Prolene suture. The lumen size of the device is 5 mm at the level of the fossa. **(B)** Images obtained by transesophageal echocardiography showing the V-Wave device implanted at the level of the fossa ovalis. **(C)** Normal flow through the V-Wave device as evaluated by Doppler and color-Doppler during transesophageal echocardiography. **(D)** Three-dimensional (3D) transesophageal echocardiography images of the V-Wave device immediately post-implantation showing adequate positioning at the fossa ovalis. **(E and F)** 3D reconstruction images of the V-Wave device by computed tomography once implanted.

Kansas City Cardiomyopathy Questionnaire (KCCQ) quality of life score was 38.3, and the NT-proBNP level was 2,983 pg/ml. Following careful evaluation by the heart failure team, the patient was considered a suitable candidate for the V-Wave device implantation. The procedure was approved by Health Canada under the Canadian Special Access program, and the patient provided informed consent for the procedure. The V-Wave shunt was implanted via the femoral venous approach following transseptal puncture at the level of the fossa ovalis (Figures 1B and 1C) using a 14-F sheath which was advanced and positioned in the mid-LA. The left side of the device was opened within the mid-LA; retracted into the interatrial septum, where the device was deployed; and finally, released by further retracting the delivery catheter. The presence of a left-to-right shunt through the device was demonstrated by transesophageal echocardiography (TEE) immediately following device implantation (Figures 1B and 1C). Adequate device positioning was verified by 3-dimensional TEE (Figure 1D) and computed tomography (Figures 1E and 1F). The patient was discharged 24 h post-procedure without complication. TEE at 3-month follow-up demonstrated interatrial shunt patency, and the absence of thrombus. At the 6-month follow-up visit, NYHA class improved to class II (−1 class), the 6MHW distance improved to 617 m (+336 m), the KCCQ score improved to 78.03 points (+39.73 points), and the NT-proBNP level decreased to 1,334 pg/ml (−1,649 pg/ml) when compared with baseline, and orthopnea was no longer present. Echocardiography revealed no changes in left and right ventricular systolic function or elevation in pulmonary arterial pressures.

The present report demonstrates the feasibility and promising preliminary results of creating a unidirectional left-to-right shunt for treating HFpEF symptoms. Extensive evaluation of this novel therapeutic approach in patients with symptomatic HFpEF is warranted.

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