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Letters

TO THE EDITOR

First-in-Man Transseptal Implantation of a "Surgical-Like" Mitral Valve Annuloplasty Device for Functional Mitral Regurgitation

Undersized annuloplasty is an established first-line therapy option for functional mitral regurgitation (MR) (1). Percutaneous direct annuloplasty as a stand-alone therapy, as well as in combination with other transcatheter mitral interventions, aims to reproduce surgical annuloplasty (2).

The "first-in-man" patient was a 69-year-old gentleman with ischemic cardiomyopathy and severe functional MR (effective regurgitant orifice area [EROA] 0.29 cm^2; regurgitant volume [RVol] 39 ml/beat) (**Figure 1**, Online Video 1) admitted in New York Heart Association (NYHA) functional class III after recurrent episodes of decompensated heart failure in the previous 3 months. He had a clinical history of permanent atrial fibrillation, prior coronary artery bypass grafting (patent left internal mammary artery graft to the left anterior descending coronary artery, left radial artery "T" graft to the right posterior descending coronary artery). The EuroSCORE II-estimated risk of operative mortality was 13%. After formal heart team discussion, agreement was reached on attempting transcatheter mitral valve repair with the Cardioband (3) annuloplasty system (Valtech Cardio, Or Yehuda, Israel). The annuloplasty device is delivered through a 25-F steerable transfemoral transseptal delivery system in a supra-annular position, similarly to what is done in surgical mitral valve repair. The device is secured on the mitral annulus using 12 to 16 anchor elements, placed along the implant, in a counterclockwise direction. Once the Cardioband is completely implanted, a size adjustment tool is used to reduce the device length under echocardiography guidance. The intervention was performed under general anesthesia and 2-dimensional (2D) and real-time 3-dimensional (3D) transesophageal echocardiographic (TEE) guidance. Although fluoroscopy is fundamental for device handling, 3D echocardiography efficiently guides the intervention, providing the necessary information to proceed safely and effectively. In particular, 3D echocardiography is used to identify the commissures (**Figure 1**, Online Video 2) and to obtain images of the delivery system angulations related to the annulus, whereas 2D imaging (with X-plane functionality) is mostly used to confirm proper location and to rule out leaflet impingement. The transseptal puncture was performed under TEE guidance aiming for an inferior approach because this enables more accurate deployment of the Cardioband. Afterward, an extra support 0.035-inch guidewire was positioned in the upper left pulmonary vein, and this was used to advance a proprietary transseptal steerable sheath. The implant delivery system was then advanced inside the sheath. Using a multiple imaging modality, the first anchoring location was identified. Before the first anchor delivery, the relative position of the delivery system to the circumflex artery was checked by selective arteriography of the left coronary artery. Thereafter, the first anchor was deployed in the anterior commissure with the proprietary torqueable system. Echocardiography and angiography were used to confirm correct anchor deployment. Following implant, the anchor was released from the anchor drive, and the catheter was advanced to the next anchor location, medial and posterior relative to the first one, along the posterior annulus. Commissure-to-commissure anchor deployment required a total of 45 min (**Figure 2**). The delivery system was then retrieved in exchange for a proprietary size adjustment tool, designed to cinch the implanted device by applying tension on a wire activated by a proprietary adjustment mechanism. Following adjustments under TEE guidance, MR was reduced from severe to mild (**Figure 1**, Online Videos 1 and 2), with a corresponding change in EROA from 0.29 cm^2 to 0.09 cm^2. The septolateral dimension was reduced from 39 mm to 30 mm (**Figure 1**). This amount of annular remodeling is similar to what is usually achieved with undersized surgical annuloplasty. The Cardioband was then disconnected from the size adjustment catheter, and the transseptal steerable sheath was retrieved. Venous access was secured with a "figure of 8" cutaneous suture. The patient was discharged uneventfully 3 days after the intervention. At 1-year follow-up, the patient is in

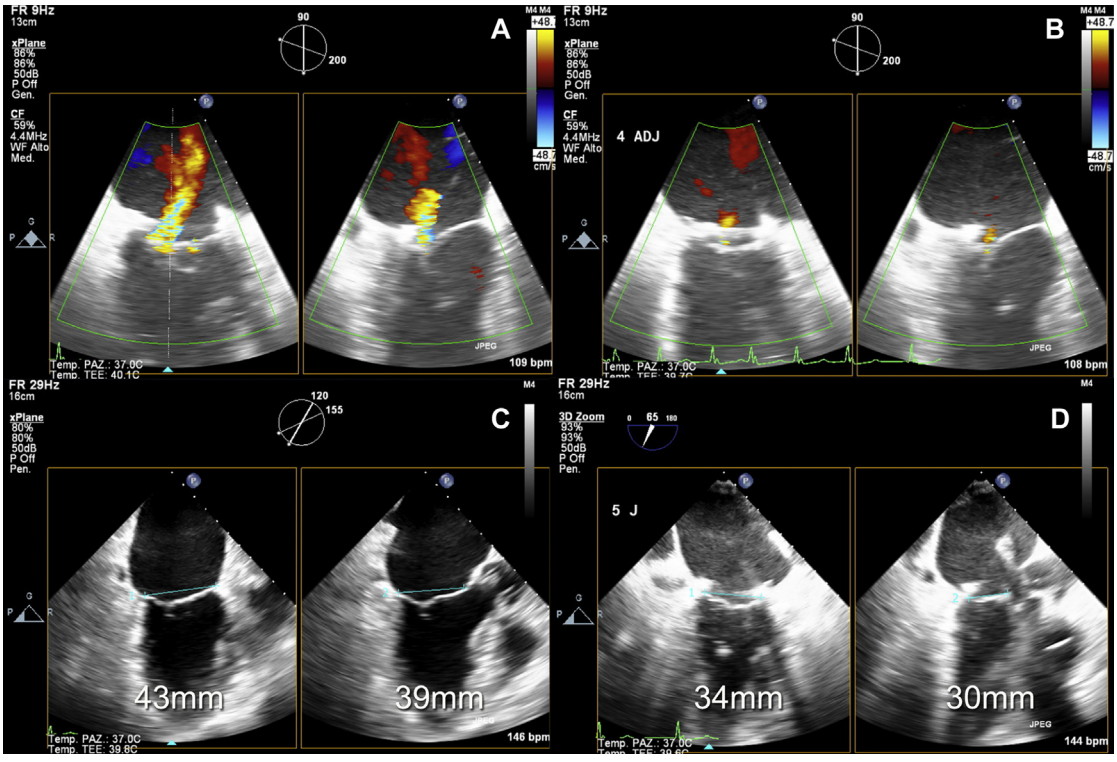

FIGURE 1 **Baseline and Post-Adjustment Echocardiography**

Baseline **(A and C)** and post-adjustment **(B and D)** echocardiography. Following Cardioband implant, but before size adjustment, mitral regurgitation (MR) is still severe **(A)** (Online Video 1); the intercommissural and the septolateral diameters are 43 mm and 39 mm, respectively **(C)**. Following Cardioband size adjustment (Online Video 2), residual MR is minimal **(B)**, and the annulus dimensions are reduced to 34 mm and 30 mm for the intercommissural and the septolateral diameter, respectively **(D)** (Online Video 3).

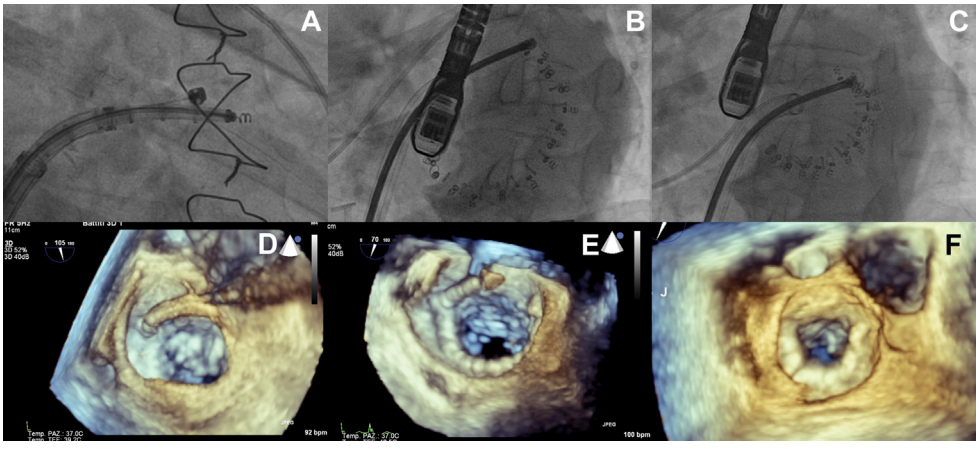

FIGURE 2 **Intraprocedural Multimodality Imaging During Cardioband Implant**

(A to C) Fluoroscopy; **(D to F)** 3-dimensional (3D) echocardiography "surgical" view. **(A and D)** Deployment of the first anchor in the anterolateral commissure; **(B and E)** complete deployment of the implant before size adjustment; **(C and F)** annular reduction after size adjustment, posterior annular cinching is evident on both fluoroscopy and 3D echocardiography.

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NYHA functional class I, and MR severity by TEE (assessed by an independent core-lab) has remained mild (**Figure 1**, Online Video 3) with an EROA = 0.09 cm^2 and RVol = 12 ml/beat.

Transcatheter therapies for treatment of cardiac diseases are increasingly being adopted, particularly for high-risk surgical patients. This case demonstrates the feasibility of percutaneous transseptal delivery of a "surgical-like" adjustable posterior annuloplasty Dacron band. Cardioband implantation was associated with substantial reduction of the septolateral annular dimension, to an extent comparable to that obtained by surgical annuloplasty. Clinical studies are warranted to appraise its risk-benefit balance in absolute terms and in comparison, or in combination, with other transcatheter mitral valve repair strategies.

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APPENDIX For the supplemental videos, please see the online version of this article.

Experience With an Innovative New Food and Drug Administration Pathway for First-in-Human Studies

Carotid Baroreceptor Amplification for Resistant Hypertension

It has now been over 2 years since *JACC: Cardiovascular Interventions* published the Bertog et al. state-of-the-art review (1) "Renal Denervation for Hypertension," detailing the physiological rationale for renal denervation (RDN) in resistant hypertension. Since then, interest in the field of sympathetic modulation soared exponentially but was quickly brought back to earth with the publication of the SYMPLICITY HTN-3 (Renal Denervation in Patients With Uncontrolled Hypertension) study, the only blinded, randomized study of RDN, which failed to meet its pre-specified efficacy endpoint (2). It is currently unclear whether the results of SYMPLICITY-3 were due to technically inadequate ablation, underestimation of additional benefits from study-mediated medical therapy, or inappropriate patient selection, or whether the initial hypothesis was in some way flawed. We believe the former issues are likely in play and that the optimistic conclusions from Bertog et al. (1) for RDN will ultimately hold true. However, given the unmet need of alternative therapeutic options for resistant hypertension, exploration for alternative methods to modulate sympathetic tone is warranted.

It is well known that the carotid baroreflex is an important feedback loop for hemodynamic balance and adrenergic tone. Carotid baroreceptors are known to activate by pulsatile stretch rather than pressure and the receptor response decays when stimulation from stretch is constant, explaining why hemodynamic changes after carotid stenting are generally transient (3). A study of electrical baroreceptor stimulation for treatment of resistant hypertension via a surgical implant adjacent to the carotid sinus was successful in lowering blood pressure (BP), however, it did not meet its pre-specified procedural safety endpoint (4). Although effective, this surgical risk may not be acceptable for most resistant hypertensive patients. Combining knowledge of baroreceptor physiology with known pressure-strain relationships for pressurized tubular structures, we hypothesized that certain geometric changes of the carotid bulb