Evolut R Implantation to Treat Severe Pure Aortic Regurgitation in a Patient With Mitral Bioprosthesis

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Transcatheter aortic valves have been designed to treat high-risk surgical candidates affected by severe aortic stenosis, but little is known about the use of transcatheter valves in patients with severe pure aortic regurgitation. We describe the implantation of Medtronic CoreValve Evolut R (Medtronic, Minneapolis, MN) to treat an 82-year-old patient affected by severe pure aortic regurgitation who underwent prior mitral valve replacement with a biological valve protruding into the left ventricular outflow tract.

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Transcatheter aortic valves have been designed to treat elderly patients considered high-risk surgical candidates. The safety and effectiveness of transcatheter aortic valve implantation (TAVI), in patients affected by severe aortic stenosis, have been demonstrated in numerous observational clinical studies, national registries, and controlled randomized trials [1, 2], but otherwise little is known about the use of TAVI in patients with severe pure aortic regurgitation. Moreover, patients with prior mitral valve surgery have often been excluded from transcatheter-based therapy. We describe the implantation of an Evolut R that maintains the cell geometry of the prior CoreValve prosthesis to optimize frame conformance to the native aortic annulus, the delivery system is designed to have a stable and predictable deployment with the advantage, if necessary, to resheath, reposition, and redeploy the valve [3].

An 82-year-old woman (150 cm, 47 kg) affected by severe pure aortic regurgitation was admitted to our hospital for increasing dyspnea. The patient had undergone in 2013 mitral valve replacement with a Carpentier-Edwards perimount 27 mm (Edwards Lifesciences, Irvine, CA), she was also affected by severe chronic renal failure (creatinine clearance 22 mL/min) and pulmonary hypertension (pulmonary artery pressure 75 mm Hg). After clinical stabilization patient underwent transthoracic and transesophageal echocardiographic (TEE) evaluation that confirmed severe aortic regurgitation with depressed left ventricle (LV) ejection fraction 40%, normal mitral prosthesis function. TEE evidenced that mitral valve struts protrude into LV outflow tract, with a space between the end of the struts and LV septum of 11 mm (Fig 1A), moreover showed short distance between aortic annulus and mitral prosthesis (Fig 1B).

A multislice computed tomography was performed and evidenced a trileaflet noncalcified aortic valve with annulus perimeter of 78 mm (27 mm × 22 mm), the distance between aortic virtual basal ring and mitral prosthesis was 3.1 mm (Fig 1D). A computed tomography scan confirmed that mitral valve struts protrude into the LV outflow tract leaving a free space of 12 mm (Fig 1C).

After Heart Team evaluation a transcatheter aortic valve implantation (TAVI) was preferred. Due to the presence of a mitral prosthesis, pure aortic regurgitation without valve calcifications and annulus area of 450 mm2 the majority of TAVI devices on the market have been excluded. An Evolut R (Medtronic, Minneapolis, MN) implantation was then preferred.

The procedure was performed through right femoral artery, under local anesthesia, in a hybrid operating room. Preprocedure aortography evidenced significant aortic regurgitation (Fig 2A) hemodynamic evaluation revealed an aortic regurgitation index of 15. EnVeo R delivery catheter was than inserted through right femoral and a 29 mm Evolut R was advance. During Evolut R implantation a popout occurred, the valve was then resheathed and redeployed successfully. Normal Evolut R expansion was evident and no interference between the nitinol frame and the Carpentier-Edwards stent was noticed. Final aortography showed trivial paravalvular regurgitation (Fig 2B). Hemodynamics evaluation revealed no transvalvular gradient with a final aortic regurgitation index of 35. The patient had an uneventful hospital course and was discharged home on seventh postoperative day. Predischarged echocardiography showed improved LV function with ejection fraction of 58%, normal aortic valve function with mean gradient of 3 mm Hg, trivial anterior paravalvular regurgitation (Fig 2C), and reduced pulmonary artery pressure (30 mm Hg). A multislice computed tomography without contrast was performed and evidenced full Evolut R expansion (Fig 2D).

Comment

TAVI has now become the standard of care for patients with symptomatic severe aortic stenosis who are considered at extreme risk for surgery and an acceptable

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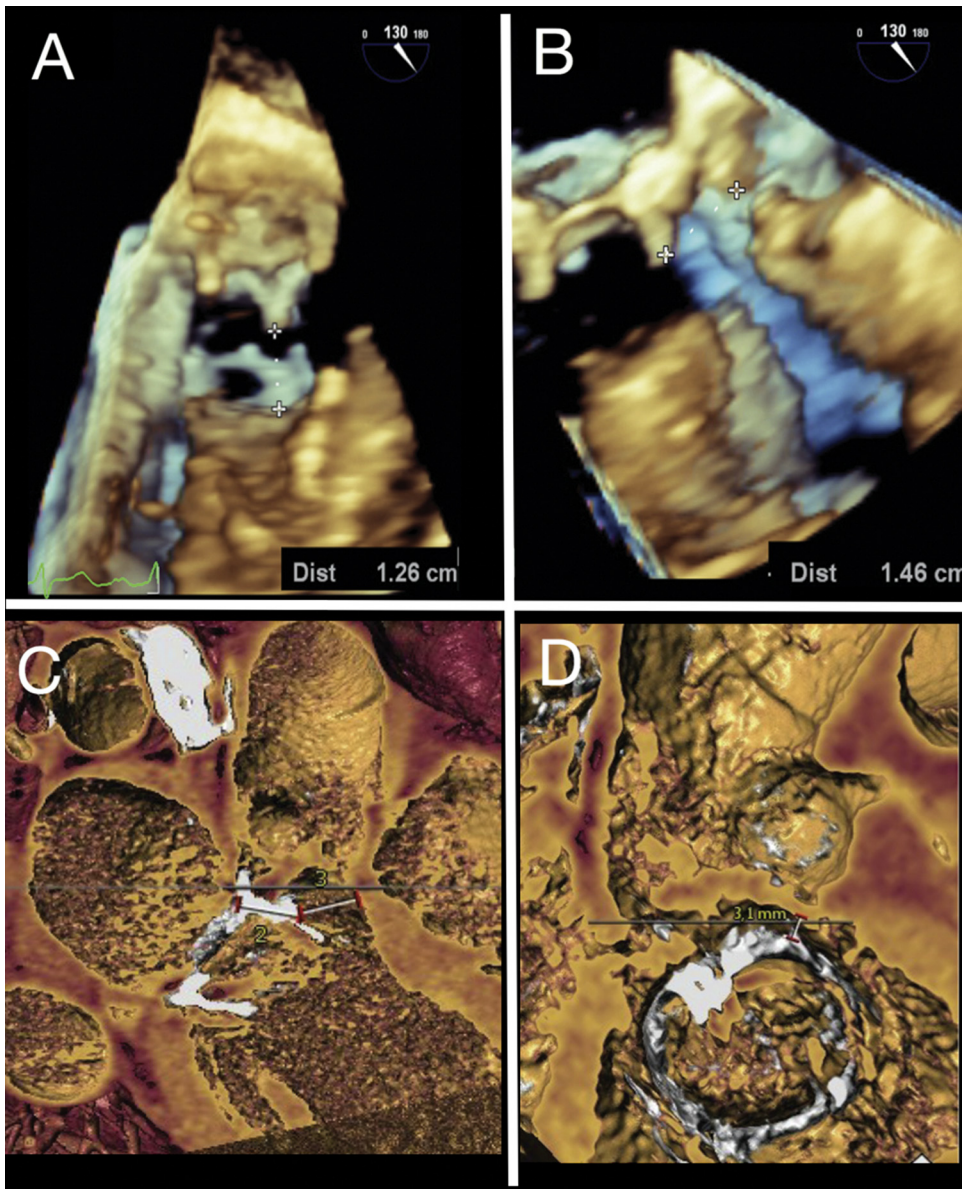

Fig 1. (A) Three-dimensional transesophageal echocardiographic (TEE) reconstruction evidenced mitral valve struts protruding into left ventricular (LV) outflow tract, with a space between the end of the struts and LV septum of 12 mm. (B) Three-dimensional TEE reconstruction evidenced superior mitral bioprosthesis struts at 14 mm from aortic annulus. (C) Electrocardiography (ECG)-gated computed tomography confirmed that mitral valve struts protrude into LV outflow tract leaving a free space of 12 mm between strut and LV septum. (D) ECG-gated computed tomography evidenced a distance between aortic virtual basal ring and mitral prosthesis of 3.1 mm.

alternative to surgery for those at high risk [1, 2]. Many patients with mixed aortic stenosis and at least moderate aortic regurgitation have been successfully treated with TAVI; however, pure severe aortic regurgitation remains a relative contraindication for TAVI [4] Adue to the risk of insufficient anchoring of the transcatheter valve within the non-calcified aortic annulus. Moreover adequate deployment of transcatheter heart valves in an annulus with absent or minimal calcification remains challenging due to the absence of fluoroscopic landmarks, the need for oversizing, and the frequently concomitant dilation of the aortic root or the ascending aorta. [5]

Off-label uses of the self-expanding Medtronic CoreValve, the balloon-expandable Edwards-Sapien XT (Edwards Lifesciences, Irvine, CA), or second-generation devices have been reported for the treatment of pure aortic regurgitation [6]. But limitations have included a high rate of valve-in-valve implantations related to residual aortic regurgitation or the need for significant oversizing with the subsequent risk. The only transcatheter device that received the CE mark to treat patient affected by pure aortic regurgitation is the transapical JenaValve (JenaValve Technology GmbH, Munich, Germany) [7].

Our patient was affected by severe pure aortic regurgitation and had underwent mitral valve replacement with a biological valve that significantly protrude into LV outflow tract; the presence of a mitral prosthesis is considered exclusion criteria for TAVI. This is because concerns exist about possible interference between the mitral prosthetic housing or struts and

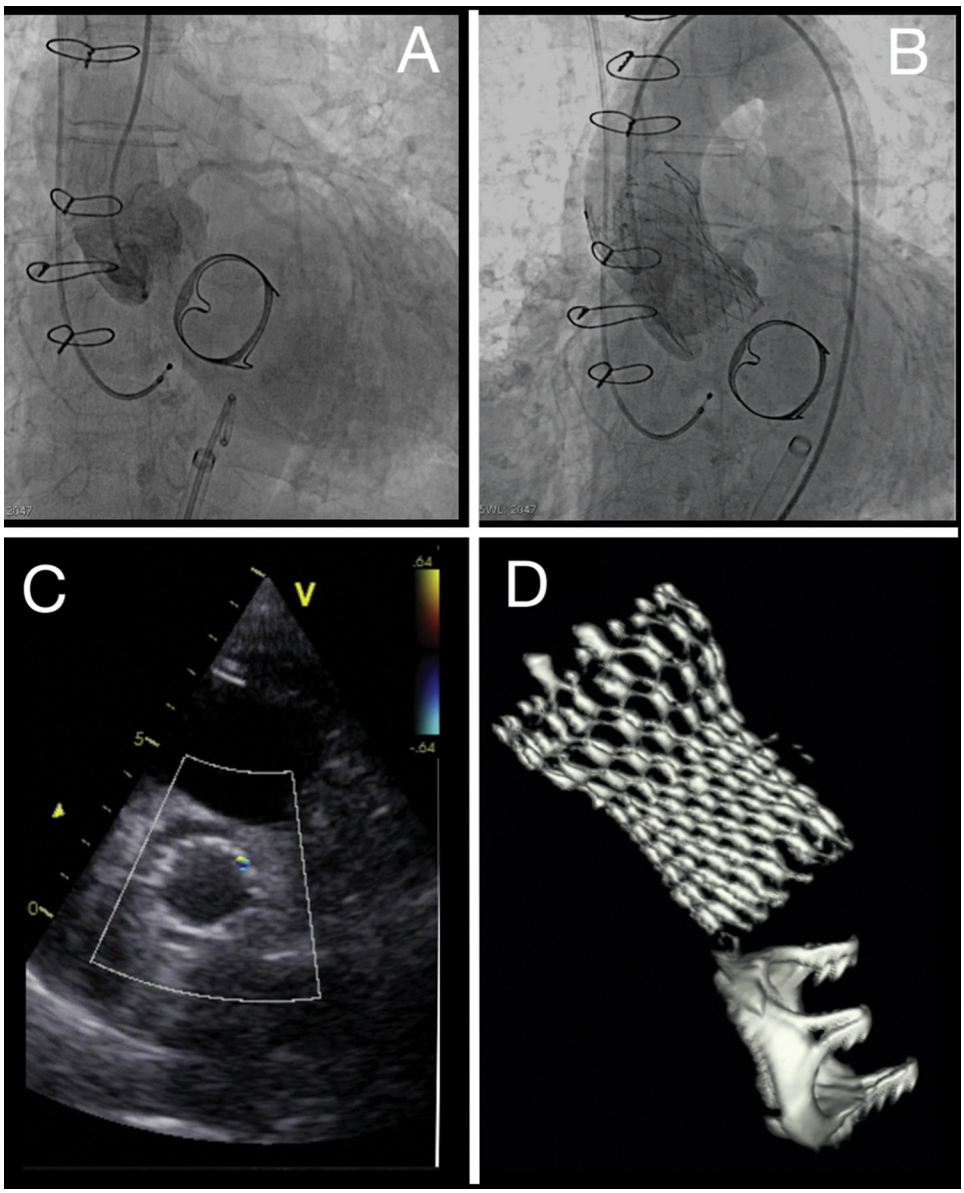

Fig 2. (A) Preprocedure aortography evidenced significant aortic regurgitation. (B) Final aortography shows trivial paravalvular regurgitation with no interference between Evolut R and mitral bioprosthesis. (C) Predischarge echocardiography short-axis view evidence trivial anterolateral paravalvular leak. (D) Predischarge electrocardiography-gated computed tomography evidenced full Evolut R expansion with no interference with mitral bioprosthesis.

transcatheter valve, which might interfere with optimal valve deployment, increasing the risk of prosthesis shift and misplacement; and because the presence of a prosthesis in the mitral position might reduce the mitro-aortic space and limit the expansion of the transcatheter prosthesis. Few single-center experiences have been published in the literature on TAVI in patients with biological or mechanical mitral valve prostheses [8].

The combination of pure aortic regurgitation with an annulus perimeter of 78 mm and the protruding struts of the mitral valve into the LV with a free space of 12 mm between struts and LV septum determined the exclusion of the majority of TAVI devices on the market included the transapical ones. We decided to implant an Evolut R 29 mm considering the self-expanding nitinol frame, the additional anchoring by means of abutment also against the ascending aorta, supraannular valve function, and the possibility to use mitral valve superior struts as foothold to avoid Evolut R migration into LV. Moreover, the possibility of resheath and redeploy successfully the valve was essential in our case.

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