A Novel Technique for Transcatheter Aortic Valve Replacement in Pure Aortic Regurgitation

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Transcatheter aortic valve replacement (TAVR) in pure aortic regurgitation (AR) is challenging, because of the subsequent difficulty in anchoring the transcatheter valve in a noncalcified device landing zone (DLZ). Prestenting can help to prepare a stable DLZ for TAVR in pure AR and prevent valve migration. Here we report the first-in-human implantation of an uncovered stent into a noncalcified aortic valve as a prestenting strategy to prepare an easy DLZ for TAVR in pure AR. We consider this technique a useful novel tool to improve device success, at least as long as specific TAVR devices for pure AR are lacking.

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Transcatheter aortic valve replacement (TAVR) in the presence of pure aortic regurgitation (AR) with otherwise normal native aortic valves is a challenging procedure because of the subsequent difficulty in anchoring the transcatheter valve in a noncalcified device landing zone (DLZ). The lack of calcification predisposes to device migration, which can result in paravalvular leakage or the necessity of implanting a second prosthesis. Compared with early generation devices, off-label use of the latest generation of TAVR prostheses to eliminate pure AR has been associated with improved procedural outcome, but is still associated with reduced device success rates [1]. Specific TAVR devices that have been approved to treat pure AR are currently not available [2, 3]. Prestenting to prepare a stable DLZ for TAVR devices has been described for right heart valve pathologies [4, 5]. Here, we report the first-in-human implantation of an uncovered stent into a noncalcified aortic valve as a prestenting strategy to prepare an easy DLZ for TAVR in pure AR. This innovative approach is a viable alternative in patients with prohibitive surgical risk.

A 77-year old man was admitted with rapidly progressive symptoms of fatigue and shortness of breath 2 years after uneventful left ventricular assist device (LVAD) implantation because of dilative cardiomyopathy. Echocardiography confirmed isolated severe AR with vena contracta of 8 mm. Clinical workup excluded any other cause of the symptoms. Computed tomography showed a mean aortic annular diameter of 25.8 mm and conic enlargement of the left ventricular outflow tract (Fig 1). Because of high surgical risk and contraindications to heart transplantation, elimination of AR by TAVR was performed in accordance with the heart team decision and in consensus with the local ethics committee. To prevent valve migration, an uncovered stent (sinus XL 30 mm, 40 mm length, optimed-Medizinische-Instrumente-GmbH, Ettlingen, Germany) was implanted into the DLZ just before the valve was deployed. A drop in mean arterial blood pressure of 10 mm Hg after stent release was observed but there was no further hemodynamic deterioration even under reduced LVAD flow of 1 L/min. Transfemoral TAVR using a SAPIEN-3 29-mm valve (Edwards Lifesciences, Irvine, CA) was performed (Fig 2). At the end of the uneventful procedure lasting 59 minutes (dose-area product 5,860 $\mu Gy \times m^2$), trace paravalvular AR was observed (Videos 1 and 2). The post-procedural course was uneventful. Computed tomography confirmed stable position of the valve within the stent (Fig 1).

Comment

TAVR has been shown to be effective in eliminating AR after LVAD implantation [6]. However, TAVR in pure AR is generally associated with a necessity of up to 21.2% of implantation of a second valve [1]. Prestenting prepared an easy DLZ for TAVR in pure AR and prevented valve migration.

Potential drawbacks of a prestenting strategy are: (1) hemodynamic deterioration after stent release and prior to TAVR completion; (2) potential ineffectiveness of additional components specifically designed to reduce paravalvular leakage, such as the prosthesis' skirt; (3) interference with anterior mitral leaflet in the case of too

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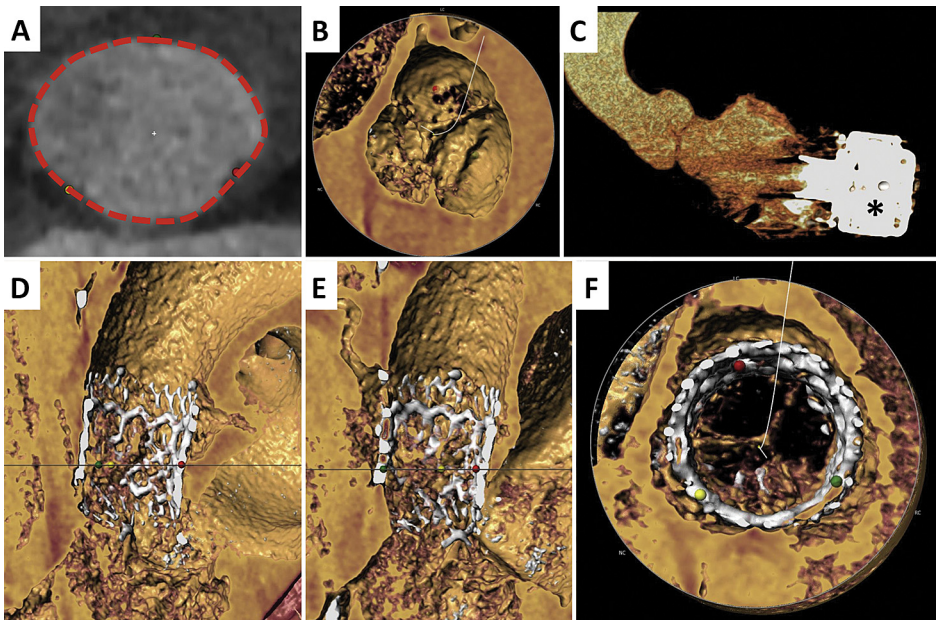

Fig 1. Preprocedural (upper row) and postprocedural (lower row) computed tomography images. (A) Virtual aortic annulus (red dotted line) with an area of 512 mm^2 and a perimeter of 81 mm. (B) View of the noncalcified tricuspid aortic valve. (C) Horizontal view shows conic enlargement of the left ventricular outflow tract and left ventricular assist device in place (asterisk). (D–F) Different views of the transcatheter valve inside the stent embedded in the device landing zone.

deep implantation. We observed only a slight drop in arterial blood pressure after stent deployment until the valve had been implanted. When applying this technique to patients without an LVAD, strategies to keep the time interval between stenting and final valve deployment short are beneficial. Moreover, bailout strategies (such as prophylactic percutaneous placement of cannulas to connect cardiopulmonary bypass immediately if necessary) may be important safety features, at least until initial experience has been gained and safety has been confirmed.

The question arises of which type of TAVR device is most suitable in combination with prestenting techniques. We preferred a balloon-expandable strategy for 3 reasons: the steering capacity of the delivery catheter prevented interference with the upper edge of the stent, valve deployment was fast and straightforward, and the prosthesis instantaneously showed high radial force in a

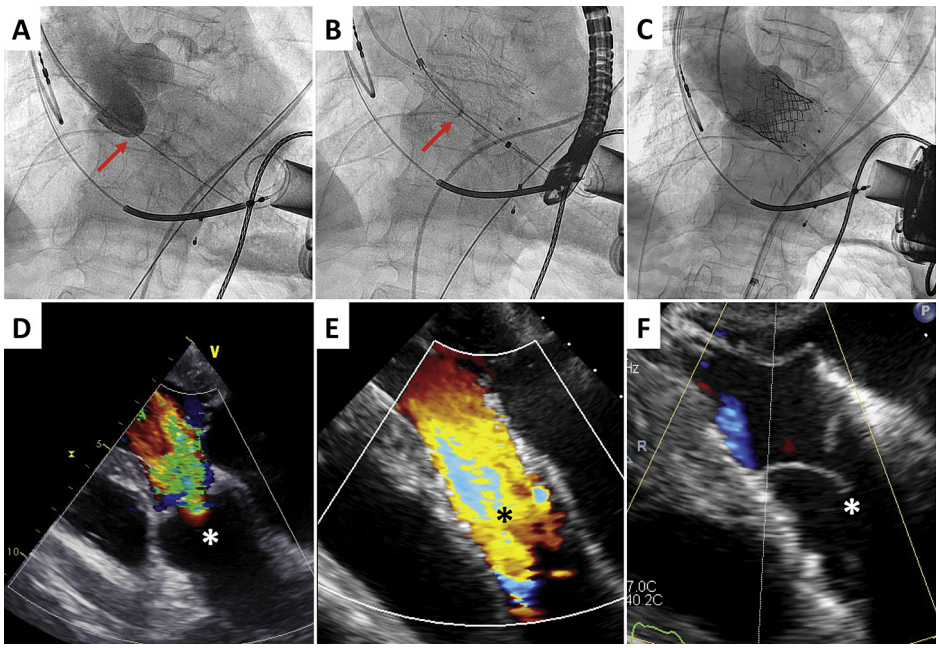

Fig 2. Intraprocedural fluoroscopy (upper row) and transesophageal echocardiography, deep transgastric views (lower row). (A) "3-nadir-view" with a pigtail catheter (red arrow) hosted in the noncoronary sinus. (B) The pigtail catheter (red arrow) was left in place and served as a landmark after stent release (Video 1). (C) Root angiography confirms correct implantation depth (Video 2). (D) Severe aortic regurgitation at beginning of procedure (asterisk = aortic root). (E) Aortic regurgitation after stent release was tolerated well for the short time interval of 3 minutes between stent and valve deployment (asterisk = aortic root). (F) Trace paravalvular regurgitation at end of procedure (asterisk = aortic root).

non-calcified DLZ. Furthermore, the SAPIEN-3 valve (Edwards Lifesciences) demonstrated a high device success rate of 85.4% among all new-generation TAVR prostheses for pure AR treatment [1].

We consider this prestenting technique a useful novel strategy that may also be applicable in patients without mechanical circulatory support, at least as long as specific TAVR devices for pure AR are lacking.

In conclusion, however, it cannot be asserted on the basis of this initial experience (n = 1) that our prestenting technique is equivalent or superior to a classic TAVR strategy. We will aim for a multicenter randomized trial to obtain a scientific answer to that question.

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