




# Allegra Transcatheter Heart Valve inside a Degenerated Sutureless Aortic Bioprosthesis

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## Abstract

### Keywords

- ▶ heart valve
- ▶ transapical
- ▶ percutaneous
- ▶ reoperation
- ▶ aortic valve and root
- ▶ cardiology/ cardiologist

Transcatheter aortic valve-in-valve implantation (VIV) is increasingly being used to successfully treat degenerated surgical aortic valve bioprostheses (SAVs). The new self-expanding transcatheter heart valve Allegra, from New Valve Technology with its special implantation mechanism, has proven its safety and feasibility for patients with degenerated SAVs, but it has never been used in the latest-generation sutureless SAV. To the best of our knowledge, this is the first description of the successful VIV of the Allegra prosthesis into a degenerated sutureless SAV, and the procedure yielded an excellent postinterventional hemodynamic results.

## Introduction

In the therapy of degenerated surgical aortic valve bioprostheses (SAVs), transcatheter aortic valve-in-valve implantation (VIV) is increasingly being used successfully.<sup>1,2</sup> However, the sutureless SAV (Perceval S; LivaNova, London, United Kingdom), as a representative of the latest generation of SAVs, has become established in the standard surgical treatment of severe aortic valve stenosis (AS) and has gained popularity worldwide due to its good hemodynamic outcome and short implantation time.<sup>3</sup> However, these SAVs also degenerate and are, therefore potential candidates for VIV procedures. The new, self-expanding Allegra transcatheter heart valve (THV) (New Valve Technology, Hechingen, Germany) has recently been shown its safety and feasibility for VIV in patients with a small

degenerated SAV, producing excellent hemodynamic results.<sup>4</sup> Here we describe the first successful VIV with the Allegra THV into a degenerated sutureless SAV.

## Case Presentation

An 85-year-old female patient (weight: 84.3 kg, height: 163 cm) presented at our institution with recurrent, worsening dyspnea with light physical activity. Three years previously, she had undergone surgical aortic valve replacement with the Perceval S (size M) due to severe AS via a partial upper mini-sternotomy. On admission, the transesophageal and transthoracic echocardiography showed severe stenosis of the sutureless SAV with a maximum/mean transvalvular gradient of 79/55 mm Hg, an effective orifice area of 0.6 cm<sup>2</sup>, an internal diameter of the SAV of 17 mm, a

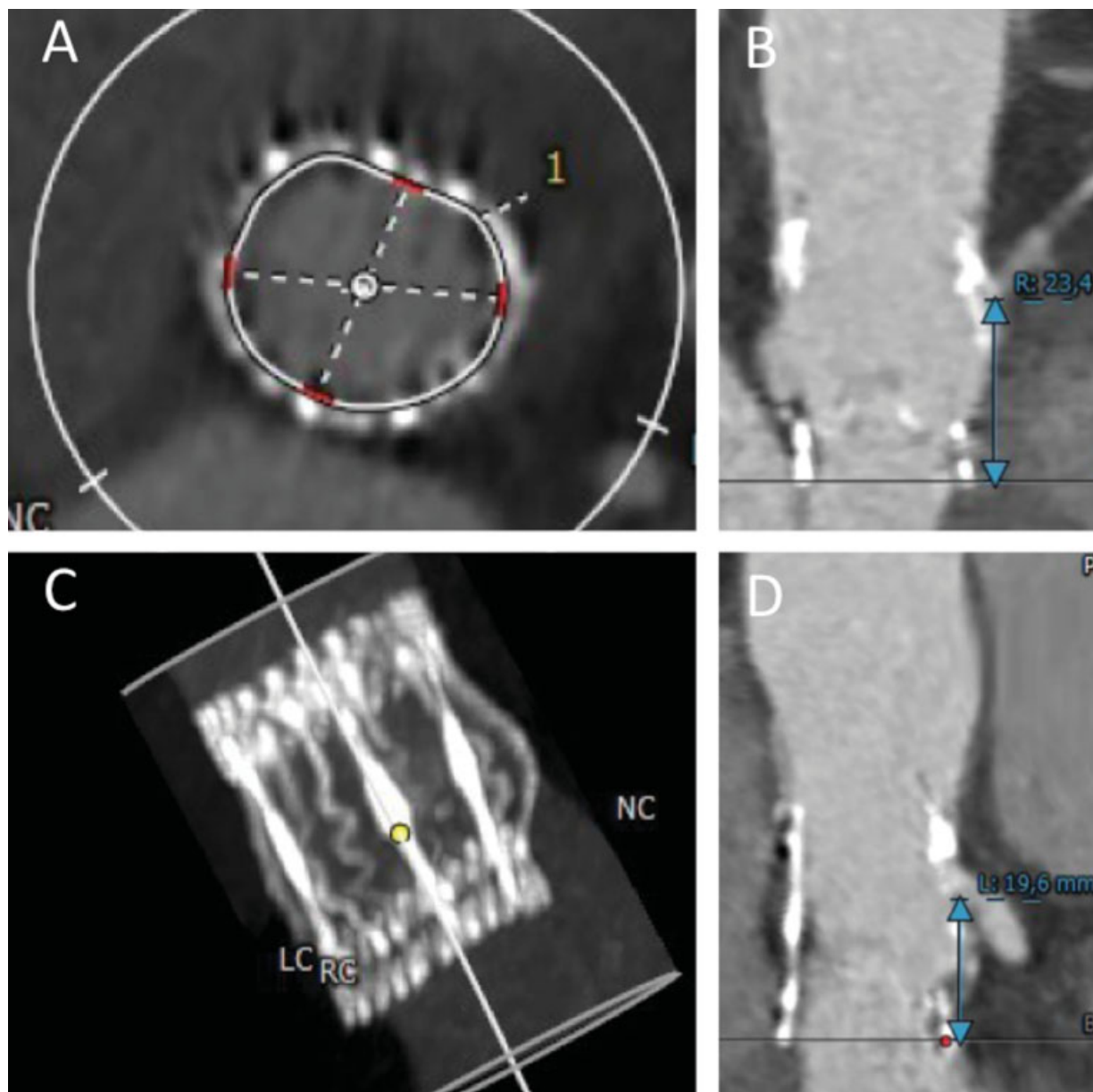
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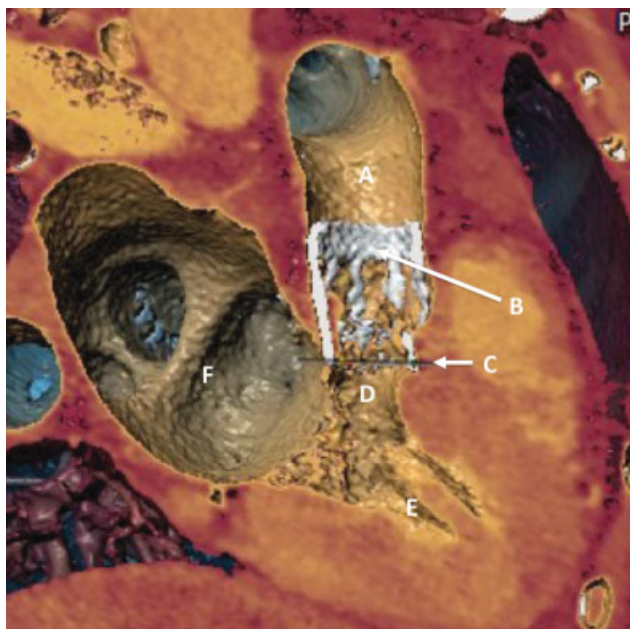
**Fig. 1** Multislice spiral computed tomography. Annulus plane of the sutureless surgical aortic valve bioprosthesis (A), right coronary (RC) ostium height (B), stent frame of the surgical sutureless aortic valve bioprosthesis (NC = non-coronary) (C), left coronary (LC) ostium height (D).

mild aortic regurgitation without any paravalvular leakage (PVL), and severe tricuspid valve regurgitation. The left ventricular ejection fraction was 55%, but the right heart function was impaired (tricuspid annular plane systolic excursion of 15 mm). A multislice spiral computed tomographic (CT) scan showed a typically shaped aortic root and ascending aorta without any calcification of the aortic valvular cusps. The stent frame of the sutureless SAV was not dislocated but was slightly oval shaped (► **Figs. 1** and **2**). Due to the age and increased surgical risk EuroSCORE (European System for Cardiac Operative Risk Evaluation) II: 6.21% and Society of Thoracic Surgeons Score: 11.9%), the patient was considered to be a candidate for a transcatheter VIV by the heart team. According to the manufacturer, the inner diameter of the size-M Perceval S was between 19.5 and 21.0 mm. However, CT scan measurements were made to determine

the true internal diameter of the sutureless SAV (annulus area: 303 mm<sup>2</sup>, annulus perimeter: 62.4 mm, and effective annulus diameter: 19.3 mm; ► **Fig. 1A**).

Due to the implanted sutureless SAV with a very small effective, slightly oval-shaped annulus, and the preprocedural high transvalvular gradient, we needed a THV in this patient that could lead to an excellent hemodynamic result despite the unfavorable preinterventional conditions. Therefore, we decided to implant a self-expandable, supra-annular THV. Based on the promising data on its use in VIV therapy inside SAVs with small true inner diameters,<sup>4</sup> we chose the 23-mm Allegra THV in this patient.

We performed the VIV procedure in a standard manner (► **Video 1**) and used a 20 mm × 40 mm noncompliant balloon for predilatation (► **Fig. 3B**) to modulate the annulus



**Fig. 2** Multilayer spiral computed tomography. Volume rendering of the aortic root with the sutureless SAV inside. Ascending aorta (A), stent frame of the surgical sutureless aortic valve bioprosthesis (B), aortic annulus (C), left ventricular outflow tract (D), left ventricle (E), and left atrium (F).

of the SAV more round. The Allegra THV was first positioned optimally within the annulus of the sutureless SAV and the “permaflow mode” was activated (►Fig. 3C). Subsequently, the lower part of the device was freed by “tip release” (►Fig. 3D). No postdilatation was needed in view of the excellent hemodynamic results with an invasive transvalvular gradient of 5 mmHg. Based on The Valve Academic Research Consortium II criteria, no major adverse event occurred during the hospital stay. Hypostatic pneumonia was treated with systemic antibiotics, and a puncture evacuated pleural effusion on the right side. The patient was discharged 9 days after the procedure to a rehabilitation center with a maximum/mean transvalvular pressure gradient measured by transthoracic echocardiography of 19/9 mm Hg and no apparent PVL.

#### Video 1

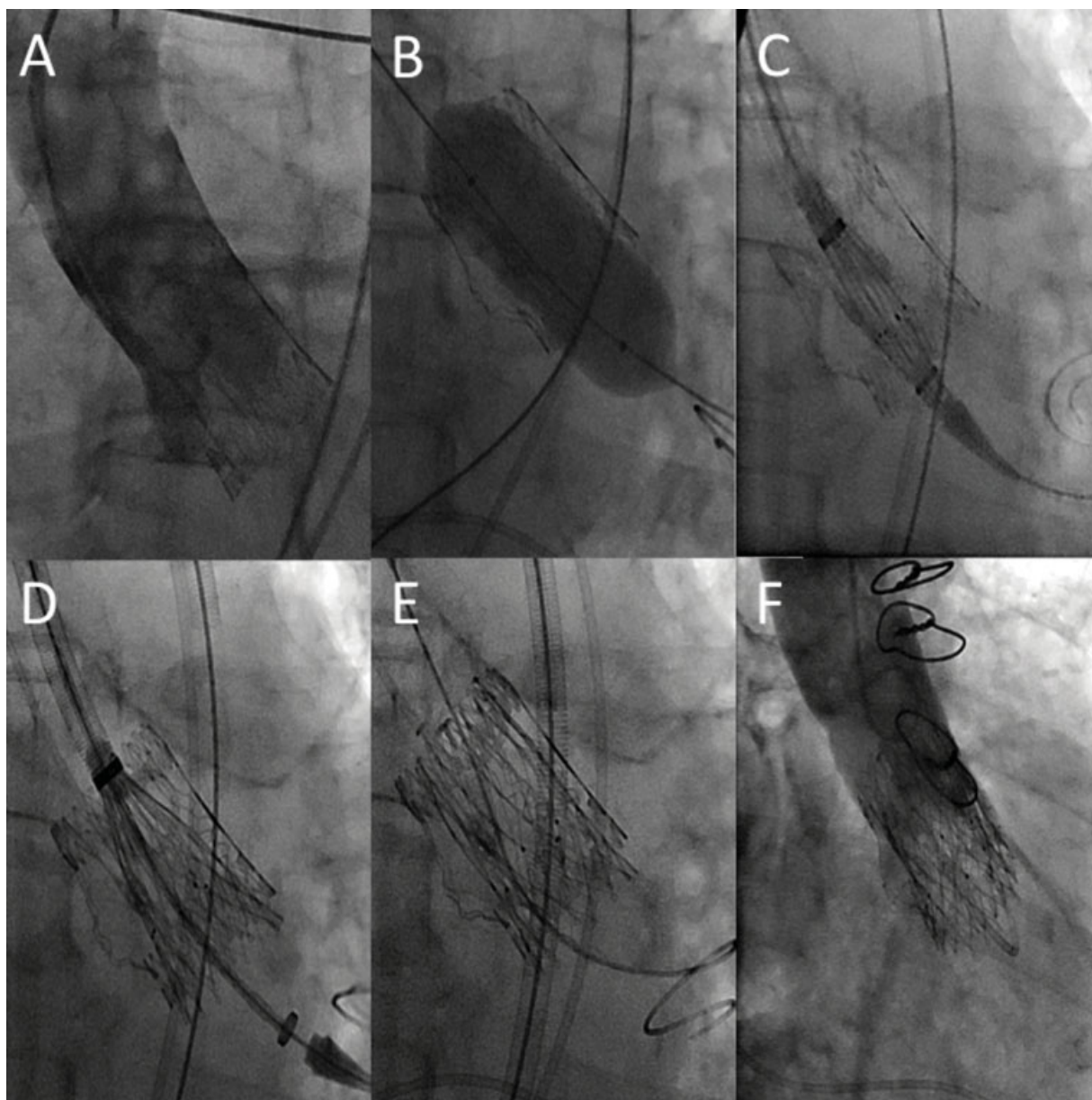
Fluoroscopy of the transcatheter aortic valve-in-valve implantation procedure. Online content including video sequences viewable at: <https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0040-1721483>.

## Discussion

Due to the natural degeneration process of SAVs, the frequency of VIV in sutureless SAV will increase in the coming years. Considering the very promising hemodynamic results of the Allegra THV,<sup>4</sup> it is an excellent candidate for

use in VIV procedures in SAVs with a small true internal diameter. However, it has never been used in degenerated sutureless SAV.

A strong argument for using self-expanding THVs in VIV procedures is less-structural valve deterioration in the long-term compared with balloon-expandable valves in the therapy of native AS.<sup>5</sup> This difference is likely to become more critical as the native aortic valve annulus diameter or the inner diameter of a degenerated SAV decreases over time.<sup>4</sup> Moreover, the self-expanding THV is superior in the short-term hemodynamic outcome after VIV therapy.<sup>6</sup> The benefit of the self-expanding THV is that they have fewer problems with incomplete deflation or distortion within a degenerated SAV. The supra-annular valve design is less vulnerable and usually results in a larger effective orifice area and a lower transvalvular gradient, almost regardless of a small and/or asymmetric annulus. Despite their excellent hemodynamic long-term outcome, above-mentioned positive features, and the recapture ability of some devices, they are used in less than one-third of VIV in latest-generation SAVs.<sup>7</sup> Unfortunately, with some self-expanding THVs, accessing the coronary arteries after VIV can be difficult. However, due to a sophisticated closed-cell, diamond-shaped configuration of the nitinol stent frame with a variable cell size distribution, the Allegra THV allows easy access for potential percutaneous coronary intervention at a later stage. With the implantation of the popular self-expanding Evolut R THV (Medtronic Inc., Minneapolis, Minnesota, United States) in our case, postinterventional access to the coronary arteries would have been nearly impossible. Also, the stent frame configuration of the Allegra THV leads to improved coronary perfusion and very low post-interventional transvalvular gradients, even after VIV.<sup>4</sup> In our case, we were able to reduce the maximum/mean transvalvular pressure gradient from 79/55 mm Hg to 19/9 mm Hg. Furthermore, different levels of radial force enhance a safe anchoring of the Allegra within the aortic annulus. The six radiopaque gold markers placed at the valve plane level to indicate the bottom part of the semilunar valve assist the operator in positioning this THV corrected, especially during VIV. The prosthesis’s ventricular inflow section is covered by a bovine pericardial sealing skirt to mitigate paravalvular prosthetic regurgitation. Unfortunately, no direct comparisons of the performance in VIV of the Allegra and other self-expanding THVs have been made. However, the Evolut R and the Portico (St. Jude Medical, Inc., St. Paul, Minnesota, United States) were compared in a matched analysis based on the VIVID registry; here, the Evolut R ( $n = 108$ ) was superior to the Portico ( $n = 54$ ) in terms of postinterventional effective orifice area and mean gradient (1.67 vs. 1.31 cm<sup>2</sup>;  $p = 0.001$  and  $14 \pm 7.5$  vs.  $17 \pm 7.5$  mm Hg;  $p = 0.02$ , respectively).<sup>8</sup> In the multicentric VIVAL trial ( $n = 30$ ) of the Allegra in VIV procedures, these parameters (effective orifice area:  $1.40 \pm 0.52$  cm<sup>2</sup>, mean gradient:  $14.8 \pm 6.5$  mm Hg)<sup>4</sup> are comparable to those for the Evolut R from the VIVID registry. In our case, the good



**Fig. 3** Fluoroscopy of the transcatheter aortic valve-in-valve implantation procedure. Preimplantation aortography (A), predilatation valvuloplasty (B), permaflow mode (C), tip-release (D); final result (E), and postimplantation aortography (F).

hemodynamic properties of the Allegra were confirmed, even in the small annulus of the degenerated sutureless SAV.

## Conclusion

A VIV procedure using the Allegra THV into the Perceval S sutureless SAV is feasible with an excellent hemodynamic result.

### Funding

None.

### Conflict of Interest

None declared.

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