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CASE REPORT
Valvular heart disease

Acurate Neo2 for valve-in-valve treatment of degenerated 3F Enable sutureless bioprosthetic valve in nonagenarian patient: a case report

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Background Sutureless bioprosthetic valves (SBVs) are engineered to enable a less invasive surgical valve replacement procedure in patients at high surgical risk. Valve degeneration is a relatively common occurrence across all types of surgical valves, including SBVs. Valve-in-valve (ViV) procedures are increasingly becoming the preferred treatment for many cases of valve degeneration due to their minimally invasive nature and favourable long-term outcomes. However, the specific structural characteristics of SBVs present challenges for ViV procedures, and the evidence on this subject remains limited.

Case summary A 91-year-old man was admitted to our hospital presenting with dyspnoea due to severe aortic regurgitation in a degenerated 3F Enable sutureless valve. Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) was successfully performed using a self-expanding Acurate Neo2 valve, yielding good haemodynamic results without overt interaction between the prosthesis. A 6-month follow-up echocardiogram confirmed excellent valve performance.

Discussion ViV-TAVI is a well-established treatment for bioprosthetic valve failure in high-risk patients. However, sutureless valve degeneration presents a challenging scenario for ViV procedures, with only a limited number of cases performed using the Acurate platform. In this case, we demonstrated the technical feasibility of ViV using the Acurate system in a less explored surgical sutureless bioprosthesis.

Keywords 3F Enable • Surgical sutureless valve • Valve-in-valve TAVI • Self-expandable valve • Aortic regurgitation • Structural valve deterioration • Case report

ESC curriculum 2.2 Echocardiography • 2.4 Cardiac computed tomography • 4.10 Prosthetic valves • 4.1 Aortic regurgitation • 7.5 Cardiac surgery

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Learning points

- Transcatheter aortic valve implantation (TAVI) is an effective approach for bioprosthetic heart valve failure treatment. Although many preliminary experiences are available, data on sutureless bioprosthetic valves (SBVs) are scarce.
- Multimodality imaging for degenerated surgical valve evaluation is a key factor in determining valve-in-valve feasibility and the potential intraprocedural pitfalls.
- Acurate Neo platform shows a good balance between acute haemodynamic performance (supra-annular self-expandable valve) and promising long-term results, minimizing the risk of coronary obstruction (open-cell design).

Introduction

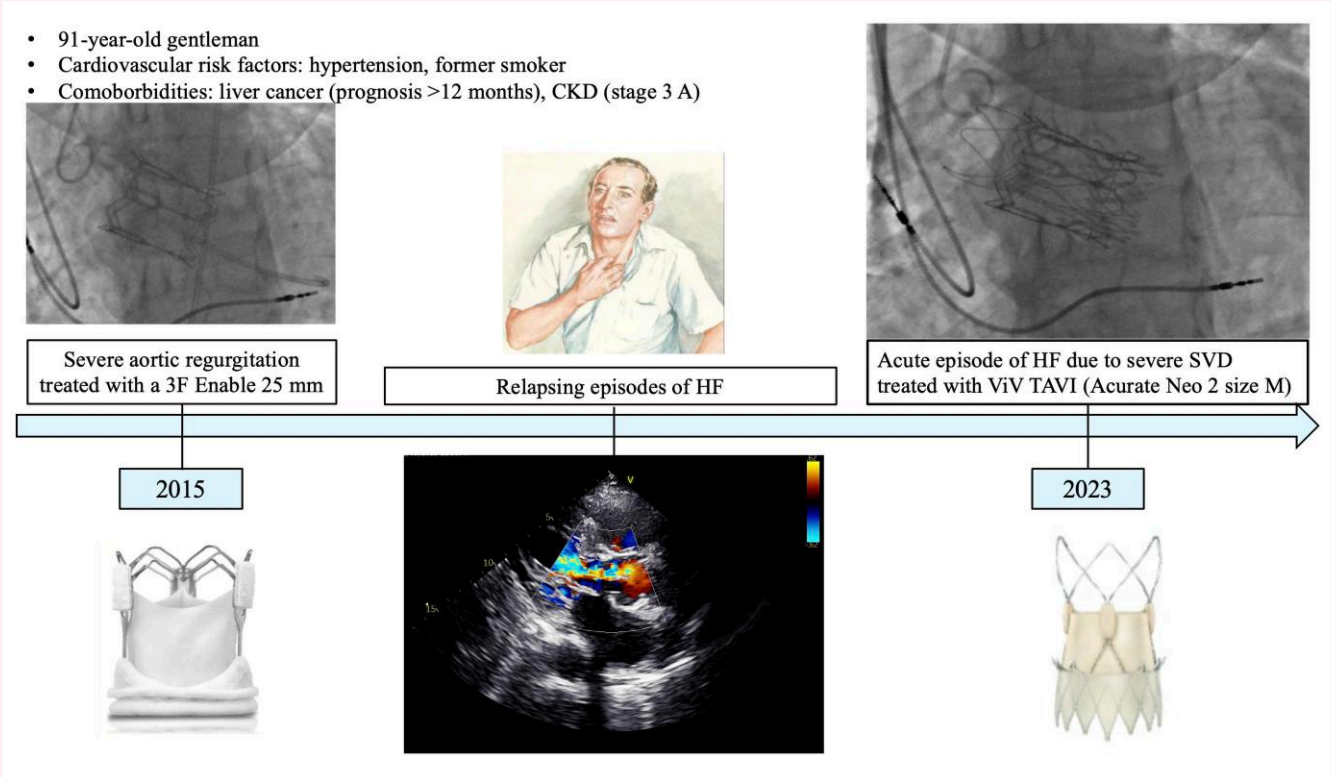
Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is an established but evolving technique for managing bioprosthetic heart valve failure, with favourable outcomes, as reported by large ViV registries.[1] Typically, ViV-TAVI is performed in degenerated stented or stentless bioprosthetic valves and suitable anatomy; however, a lack of evidence exists in sutureless bioprosthetic valve (SBV) failure. Of note, there is also unclear evidence on the feasibility of ViV procedures in degenerated 3F Enable SBVs (Medtronic, Minneapolis, MN, USA) using self-expanding valves (SEVs).[2,3] In this paper, we report a case of a successful ViV-TAVI with Acurate Neo2 in a 3F Enable valve dysfunction.

Summary figure

Clinical history, patient's presentation, and bioprosthesis dysfunction treatment. CKD, chronic kidney disease; HF, heart failure; SVD, structural valve degeneration; ViV, valve-in-valve; TAVI, transcatheter aortic valve implantation.

Case presentation

A 91-year-old man with recurring episodes of heart failure (HF) was admitted to our hospital presenting with dyspnoea and leg swelling accompanied by pitting oedema. A physical exam revealed respiratory distress, crackles, and a 4/6 Levine diastolic murmur upon heart auscultation. His medical history included an aortic valve replacement for severe aortic regurgitation with a 3F Enable 25 mm SBV via an anterior right thoracotomy in 2015, which was complicated by an advanced atrio-ventricular block requiring permanent pacemaker implantation. Other comorbidities included liver cancer (with an estimated survival of over 12 months), chronic kidney disease (CKD), hypertension, and a smoking history. Transthoracic echocardiography (TTE) revealed a mildly reduced ejection fraction (EF) and structural bioprosthetic valve deterioration (SVD) leading to severe intravalvular aortic regurgitation (Doppler aortic PHT of 201 ms with holodiastolic reverse flow in the descending aorta) (*Figure 1*, Supplementary material online, *Video S1*). In preparation for a potential transcatheter heart valve (THV) treatment, a multi-detector computed tomography (MDCT) was performed, confirming severe deterioration of the aortic prosthesis



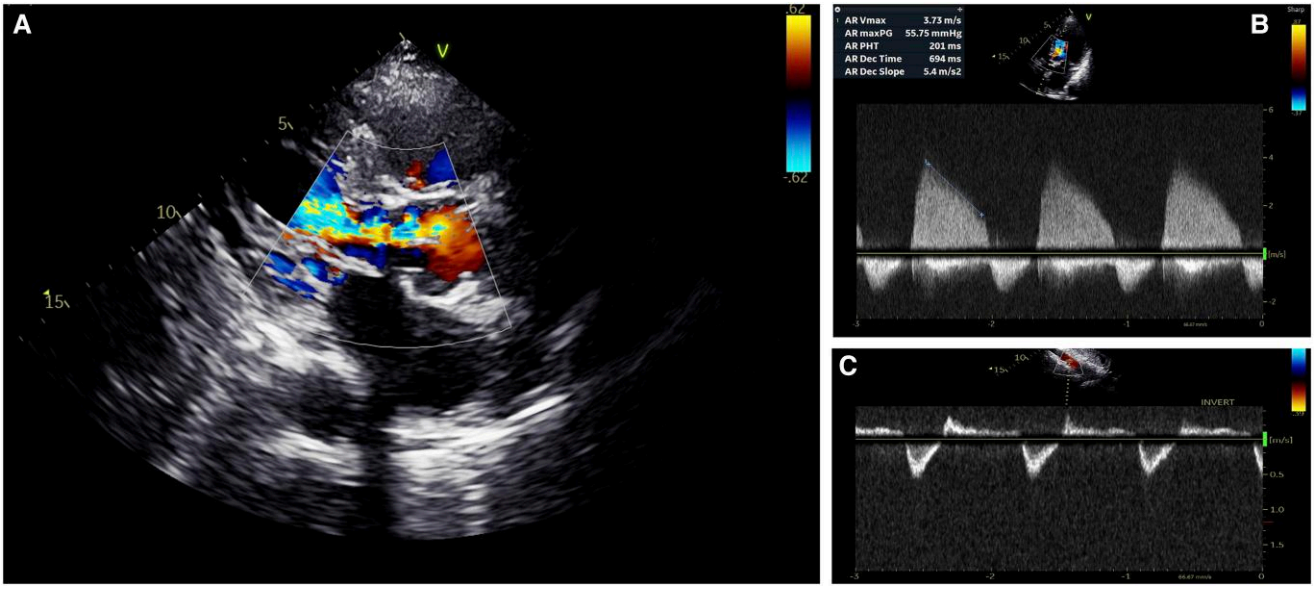


Figure 1 Transthoracic echocardiography showing severe intravalvular aortic regurgitation (*A*) with Doppler aortic pressure half time of 201 ms (*B*) and holodiastolic reverse flow in descending aorta (*C*).

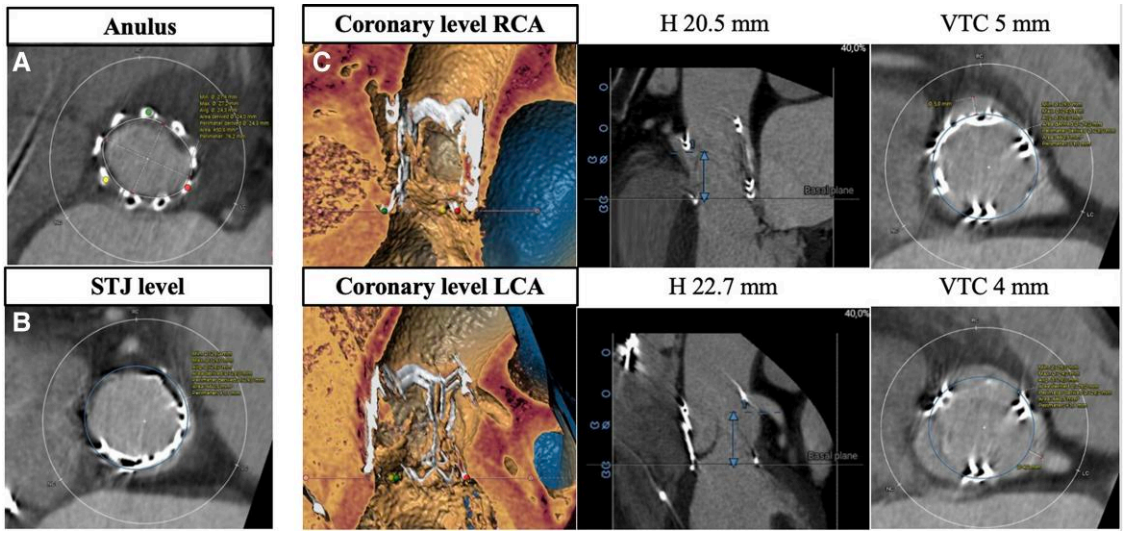


Figure 2 Multi-detector computed tomography study. (*A*) Measurements of the annulus of the surgical aortic valve; (*B*) measurements of sino tubular junction and its relationship with sutureless bioprosthetic valve; (*C–H*) 3D rendering of sutureless bioprosthetic valve and both coronary arteries with an estimation of coronary height (*H*) from the annulus level and virtual transcatheter heart valve-to-coronary ostium distance. RCA, right coronary artery; LCA, left coronary artery; H, coronary height; VTC, virtual transcatheter heart valve-to-coronary ostium distance.

leaflets. The effective inner diameter (ID), measured at the level of the inflow ring of the SBV, was 24 mm with an annular perimeter of 76.2 mm; no relevant left-ventricular outflow tract (LVOT) or annular calcifications were found. The acquired CT-scan images were used to calculate the virtual THV-to-coronary ostium distance (VTC) and the virtual THV-to-sino tubular junction (VTSTJ). The VTC was 4 mm for the right coronary artery and 5 mm for the left coronary artery, with a VTSTJ >2.5 mm (*Figure 2*). The risk of coronary obstruction was low (Type 3A according to the VIVID classification).[4] The peripheral accesses were suitable for TAVI, with no significant calcifications or vessel tortuosity.

Considering the prohibitive surgical risk and suitable anatomy, the Heart Team recommended TAVI as the best treatment strategy. Transcatheter heart valve sizing was determined based on MDCT data and with the ViV digital app. The procedure was performed

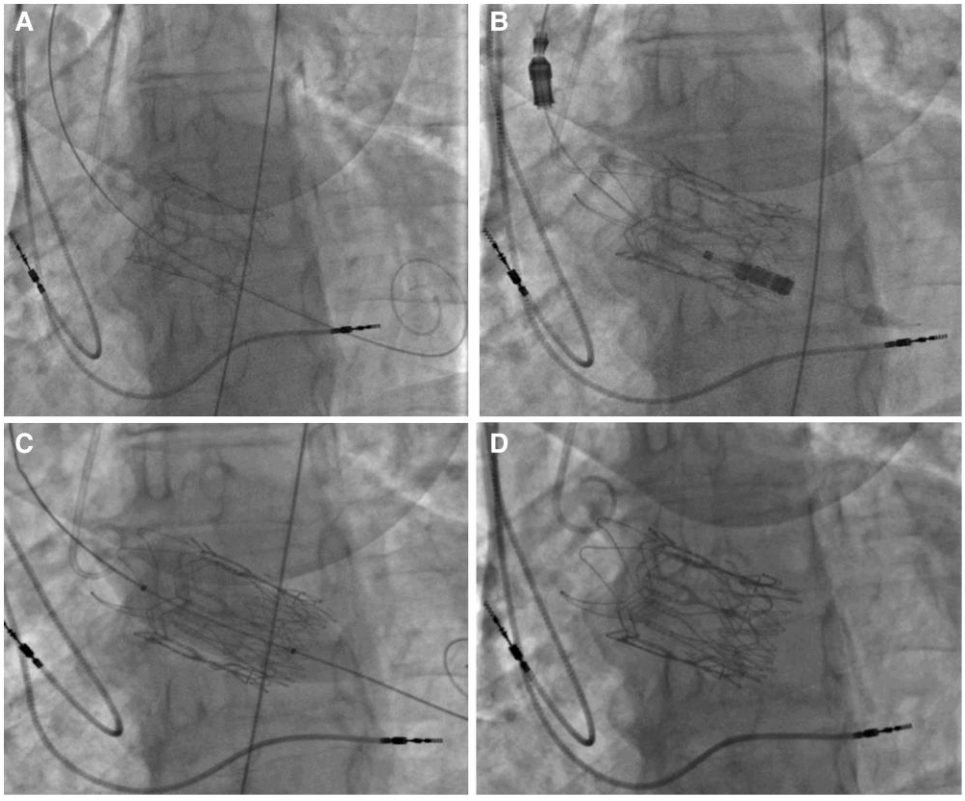


Figure 3 Valve-in-valve transcatheter aortic valve implantation procedure: (*A*) crossing of the surgical valve and positioning of the Safari pre-shaped 0.035″ wire in the left ventricle; (*B*) Acurate Neo2 deployment 3 mm under the lower edge of sutureless bioprosthetic valve hesitating in a slight under-expansion of the transcatheter valve frame; (*C*) post-dilatation with 24 mm valvuloplasty balloon; and (*D*) final angiographic result with optimal surgical valve sealing and good expansion of the transcatheter valve frame.

through right transfemoral access obtained with echo-guided puncture; the right radial artery was used as secondary access for contrast injection. Venous access was unnecessary as rapid pacing was performed using the patient's permanent pacemaker. A supra-annular Acurate Neo2 self-expanding valve (SEV) (Boston Scientific, MA, USA), size M, was advanced on a Safari pre-shaped 0.035″ wire (Boston Scientific, MA, USA) and successfully deployed 3 mm under the lower edge of the Enable valve. Post-dilatation was performed with 24 mm balloon (Simvalve Force, Simeks, EU) obtaining a good final angiographic result (*Figure 3*, Supplementary material online, *Video S2*). Transthoracic echocardiography showed a residual mean gradient of 4 mmHg without evidence of paravalvular leak (PVL) (*Figure 4*, Supplementary material online, *Video S3*). The patient showed significant improvement after the procedure and was discharged after 3 days. In consideration of the patient's high bleeding risk due to advanced age and CKD, and the lack of evidence supporting the use of anticoagulation following ViV procedures, we chose to proceed with single antiplatelet therapy using Aspirin. At 6-month follow-up, the patient was asymptomatic and completely satisfied with the procedural result hesitating in an improved functional capacity (NHYA I). Transthoracic echocardiography confirmed good valve performance (V_{max} 1.65 m/s, mean gradient 6 mmHg, absence of PVL) (*Figure 4*).

Discussion

Structural valve degeneration represents a challenging scenario, mostly in patients treated with SBV who are usually at high surgical risk. Despite current ESC guidelines recommending surgical reintervention for patients with SVD as a Class I-C indication,[5] its use is declining in favour of ViV-TAVI that has shown lower invasiveness and success rate superimposable with surgical replacement.[6] A study by Majmundar *et al.*[7] has compared SAVR and TAVI after first-time THV implantation, reporting non-relevant differences in 30-day and 6-month MACE; therefore, the percutaneous option has shown lower 30-day mortality but higher hospital readmission rate.

Valve-in-valve treatment of a degenerated SBV was first described in 2014.[8] To date, the available experience with ViV-TAVI for degenerated SBV is mainly limited to the treatment of degenerated Perceval (LivaNova, London, UK) valve.[3,9,10] A recent systematic review by Owais *et al.*[11] including 48 patients from 27 case reports and 5 case series, demonstrated acceptable short- and mid-term outcomes for the treatment of degenerated Perceval valves with ViV-TAVI, utilizing both balloon-expanding valve (BEV) and SEV technologies. However, to the best of our knowledge, papers reporting experience in the treatment of degenerated 3F Enable SBV valves are missing. The 3F Enable valve, an equine pericardial valve mounted on a nitinol frame, was the first sutureless valve that obtained CE Mark, facilitating widespread use in patients with aortic valve disease and high preoperative risk. Although the 3F Enable valve was withdrawn from the market in 2015 due to its high migration risk,[12] a not negligible number of patients treated with this valve prompts ongoing consideration regarding the management of valve degeneration.

The potential challenges of a ViV-TAVI for treating degenerated SBVs include the risk of displacement of the surgical valve, coronary

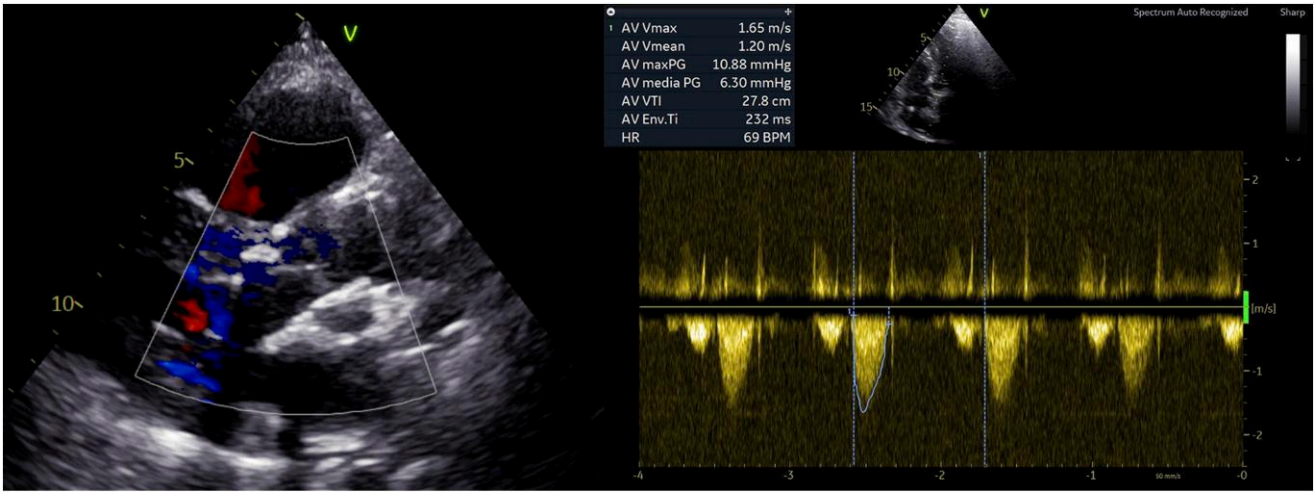


Figure 4 (*A*, *B*) Post-procedural transthoracic echocardiography with residual gradient of 4 mmHg without significant leak. (*C*) Transthoracic echocardiography at 6-month follow-up showing no substantial increase in transvalvular gradient (V_{max} 1.65 m/s, mean gradient 6 mmHg).

obstruction, and poor haemodynamic performance. Indeed, the absence of sutures may increase paravalvular regurgitation, stent-infolding, and valve dislocation. Although the safety of implantation of a THV inside an SBV is debateable, Owais *et al.*[11] have reported no valve displacement and two deaths (one patient suffered by annular rupture, the other one had a complication derived from mechanical support). In the same study,[11] no coronary obstruction cases were reported, suggesting that the configuration of supra-annular frames of some SBV, as for Perceval valve, has an important role in preventing iatrogenic coronary obstruction. To prevent the abovementioned procedural pitfalls, pre-procedural MDCT is always advised to evaluate VTC and VTSTJ measures. In our case, dealing with a Perceval valve, the VTC is ensured by the valve structure itself (considering the distance between the columns and sinusoidal struts); nevertheless, anatomical evaluation is every time warranted for aortic root and sino tubular junction dimensions. As reported in a study by Tang *et al.*,[4] a narrow VTSTJ may lead to sinus sequestration and coronary ostia interference. In this case, we assessed the risk of coronary obstruction as relatively low, which gave us confidence in using the Acurate platform, a device with which we have significant experience. Moreover, we recognized the potential benefit of achieving optimal cusp alignment in this scenario and based on our past success with Acurate in achieving such alignment, we were confident in its effectiveness for this procedure. Regarding the haemodynamic performance, it is a shared opinion that the ViV-TAVI prosthesis implanted in a surgical valve has a poorer haemodynamic profile with elevated mean gradients than surgical reintervention. Landes *et al.*[2] described a comparison between ViV-TAVI in degenerated SBVs and conventional surgical valves in a study involving 56 patients extracted from the VIVID international registry,[13] which includes data from over 2300 patients treated with surgical aortic valves. Patients treated by rapid deployment surgical valve underwent ViV-TAVI showed a numerically more favourable residual valve area and lower residual gradient than patients with conventional surgical valve treated with the same technique. The explanation must be searched in both the failure mechanism of the surgical valve (in the rapid deployment group pure stenosis is less involved) and in the elastic and expandable ring of the SBV that allows the ViV procedure to restore a more favourable frame geometry without surgical valve fracture. It is important to ensure an adequate delivery and implantation depth to obtain the best balance between THV haemodynamic performance and safety. In the present case, the chosen implantation depth was 3 mm below the lower edge of SBV, achieving effective sealing with minor under-expansion addressed by post-dilation with a balloon sized based on the residual ID of the surgical valve. Conversely, Aurigemma *et al.*[14] propose THV implantation 2–3 mm above the lower edge of the SBV to prevent incomplete prosthesis expansion due to leaflet constriction by the nitinol ring of the sutureless valve. In a multicenter registry by Holzamer *et al.*[15] high implantation (with the upper crown positioned above the stent post and leaflets of the surgical valve) compared with low depth (with the upper crown positioned inside the stent post and leaflets of the surgical valve) resulted in lower transvalvular post-procedural gradients at the expense of higher rates of valve embolization and potential earlier valve degeneration. To summarize, the optimal choice for prosthesis implantation depth remains debated; both approaches have shown effectiveness at 6–12 months of follow-up. In this case, selecting the Acurate Neo2 and implanting it 2–3 mm below the SBV appeared to strike a favourable balance between procedural safety—regarding coronary obstruction and embolization risk—and achieving excellent long-term results in terms of mean gradient and PVL. However, the optimal selection of THV for ViV-TAVI remains uncertain. Self-expanding valve with supra-annular design has proven to have a more favourable haemodynamic performance with lower post-procedural gradient than intra-annular BEV.[16] The emerging role of the Acurate Neo platform in ViV-TAVI has been highlighted in an international multicenter registry involving 85 patients treated for SBV degeneration.[15] These findings were recently corroborated by the multicenter international AVENGER registry, which compared two different self-expandable platforms for ViV-TAVI in a large population (Acurate: 251 patients, Evolut: 584 patients), demonstrating similar post-procedural and 1-year outcomes.[17]

Conclusion

Sutureless bioprosthetic valves represent an innovative approach for surgical aortic valve replacement in patients at high surgical risk, showing a less invasive profile with reduced cross-clamp time and cardiopulmonary bypass duration. As any biological valve, the incidence of SVD has a not negligible incidence and its treatment presents significant concerns due to the high-risk profile of patients and the challenges associated with reintervention. Although further evidence is required to determine the optimal treatment approach, this case highlights the

feasibility of a ViV-TAVI using the Acurate Neo2 system in a degenerated 3F Enable SBV, for which wide evidence is currently unavailable. The procedure yielded excellent immediate results and showed good valve performance at 6-month follow-up.

Lead author biography

Andres Agustin Vecchia working as an interventional cardiologist at cardiac cathlab of Città di Alessandria Institute. His interests focus on transcatheter therapies for valvular heart disease.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports* online.

Consent: The authors confirm that a written consent for the submission and publication for this case report, including the images and associated text, has been obtained from the patient in line with COPE guidelines.

Conflict of interest. None declared.

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Data availability

All data are incorporated into the article and its online Supplementary material.

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