ESC European Society of Cardiology

European Heart Journal - Case Reports (2022) **6**, 1–6
https://doi.org/10.1093/ehjcr/ytac279

CASE REPORT
Other

Early Acurate Neo transcatheter heart valve degeneration in a haemodialysis patient successfully managed with Sapien 3 Ultra: a case report

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Received 24 December 2021; first decision 17 February 2022; accepted 29 June 2022; online publish-ahead-of-print 1 July 2022

Background Aortic valve disease is the most prevalent valvular abnormality in the developed world and carries a high risk of morbidity and mortality. Transcatheter aortic valve replacement (TAVR) is favoured over open-heart surgery in high-risk patient categories and is increasingly used in lower-risk groups. End stage kidney disease (ESKD) is associated with premature calcific degeneration of bioprosthetic heart valves. Redo-TAVR requires meticulous pre-procedural planning to avoid the important risks of sinus sequestration and impaired coronary access. Transcatheter aortic valve replacement with the Acurate Neo transcatheter heart valve (THV) has been clinically available for a short time only and there are limited reports describing redo-TAVR in the Acurate Neo.

Case summary We present a case of early, rapid onset, structural valve degeneration in a Acurate Neo, supra-annular, self-expanding THV in a dialysis patient. The patient presented with chest pain and breathlessness 4 years after TAVR with a Acurate Neo for severe stenosis of a bicuspid aortic valve. Echocardiogram now showed severe stenosis of the THV and computed tomography revealed severe THV leaflet calcification but no pannus or leaflet thrombus. After careful pre-procedural planning a S3 Ultra balloon-expandable valve was selected and positioned relatively high to pin the first THV leaflets in a fully open position without compromising coronary artery flow or coronary access.

Discussion End stage kidney disease may cause rapid, calcific degeneration of TAVR valves leading to presentation with severe aortic stenosis. Redo-TAVR in the Acurate Neo THV with a Sapien 3 Ultra is feasible with careful pre-procedural planning to mitigate the risks of sinus sequestration and impaired coronary access.

Keywords Case report • Transcatheter aortic valve implantation • Transcatheter aortic valve replacement • Structural valve degeneration • Redo-TAVR • Acurate Neo • Sapien 3 • Aortic stenosis • End stage kidney disease

ESC Curriculum 9.1 Aortic disease • 4.2 Aortic stenosis

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Handling Editor: Milenko Zoran Cankovic
Peer-reviewers: Radoslaw Parma
Compliance Editor: Nikolaos Spinthakis
Supplementary Material Editor: Michael Waight

Learning points

- To understand the critical role of pre-procedural planning with computed tomography when considering transcatheter aortic valve replacement (TAVR)-in-TAVR to determine the risks of impaired coronary access and coronary ischaemia due to sinus sequestration.
- To understand the optimal positioning of a second transcatheter heart valve (THV) for structural valve degeneration causing stenosis in a Acurate Neo THV.

Introduction

Since the first-in-man TAVR in 2002, there has been continuous development and refinement of the technology.[1] Although the medium-term durability of TAVR valves has been shown to be good in observational studies and randomized studies, the patients studied to date have been higher risk populations with limited life expectancy.[2] With the expansion of indications for TAVR to include populations with lower surgical risk and longer life expectancy, the lifetime probability of SVD has become a real risk and there are subsets of patients who have been shown to have early or even accelerated degeneration of bioprosthetic heart valves.[3] One such population is patients with ESKD requiring renal replacement therapy.[4] Although redo-TAVR is an attractive option for a failing THV a recently identified problem is sinus sequestration and impaired coronary access for selective coronary angiography following redo-TAVR.[5] The Acurate Neo is a nitinol, self-expanding, supra-annular THV, and is a relatively recent addition to the market. As such, there have been very few reports of SVD complicating this valve and its management.

We report a case of early SVD complicating an Acurate Neo THV and describe the careful pre-procedural planning, valve selection, and positioning required to mitigate the risks of coronary obstruction and myocardial ischaemia.

Timeline

Date	Event
May 2017	Started on haemodialysis [end stage kidney disease (ESKD) secondary to reflux nephropathy]
August 2017	Percutaneous coronary intervention (PCI) to right coronary artery (RCA)
October 2017	Transcatheter aortic valve replacement (TAVR) with 25 mm Acurate Neo transcatheter heart valve (THV) for severe (bicuspid) aortic valve stenosis
September 2020	PCI to left main stem (LMS) for ACS ECHO showed normal THV parameters, ejection fraction (EF) 45%
May 2021	Admission with ischaemic colitis; underwent right hemicolectomy with ileostomy Patient in NYHA III–IV ECHO revealed severe transvalvular stenosis [peak pressure gradient 74 mmHg, aortic valve area (AVA) 0.61 cm^2, mild paravalvular regurgitation (PVL), and moderate left ventricle (LV) systolic dysfunction EF 38%].
June 2021	After Heart Team discussion, patient had successful redo-TAVR with 23 mm S3 Ultra THV; course uneventful
November 2021	FU; significant improvement in functional status (NYHA I) ECHO confirmed normal THV function (peak pressure gradient 11 mmHg, mean pressure gradient 6 mmHg, AVA 1.8 cm^2, mild PVL, and EF of 45%)

Case presentation

A 62-year-old female was admitted in May 2021 with an acute abdomen. She was diagnosed with ischaemic colitis and required emergency right hemicolectomy with ileostomy. Following surgery, she complained of breathlessness and recurrent chest pain and examination revealed a loud ejection systolic murmur.

In October 2017, she underwent TAVR with a 25 mm Acurate Neo™ THV (Boston Scientific, Marlborough, MA, USA) for severe symptomatic stenosis of a bicuspid aortic valve. The Heart Team considered TAVR to be the optimal treatment due to high predicted risk for open-heart surgery (EuroSCORE II 10.65%). A self-expandable THV was selected due to the presence of severe annular and LVOT calcification, to mitigate the risk of root injury. The ascending aorta was within normal dimensions (40 mm). Other relevant history included ESKD requiring haemodialysis since 2017, PCI to the RCA in 2017, LMS in 2020, and left anterior descending artery (LAD) in 2021, chronic obstructive pulmonary disease, bronchiectasis, hypertension, and epilepsy. The patient had been under regular follow-up and a transthoracic echocardiogram (TTE) in September 2020 had shown normal aortic valve parameters with peak gradient (peak-PG) 5.7 mmHg, mean gradient (mean-PG) 3.4 mmHg, AVA 1.6 cm^2, mild PVL, and mild left ventricular systolic dysfunction (LVSD) with EF 45% (Timeline).

Transthoracic echocardiogram now (May 2021) revealed severe aortic stenosis (peak-PG 74 mmHg, AVA 0.61 cm^2) mild PVL and EF 38%. Transcatheter heart valve leaflets were not well visualized and transesophageal echocardiogram confirmed severe aortic stenosis (peak-PG 67 mmHg, AVA 0.61 cm^2, DVI 0.22, acceleration time 100 ms), mild PVL, moderate LVSD (EF 38%) with thickened leaflets. Valve thrombosis or pannus was now suspected with early

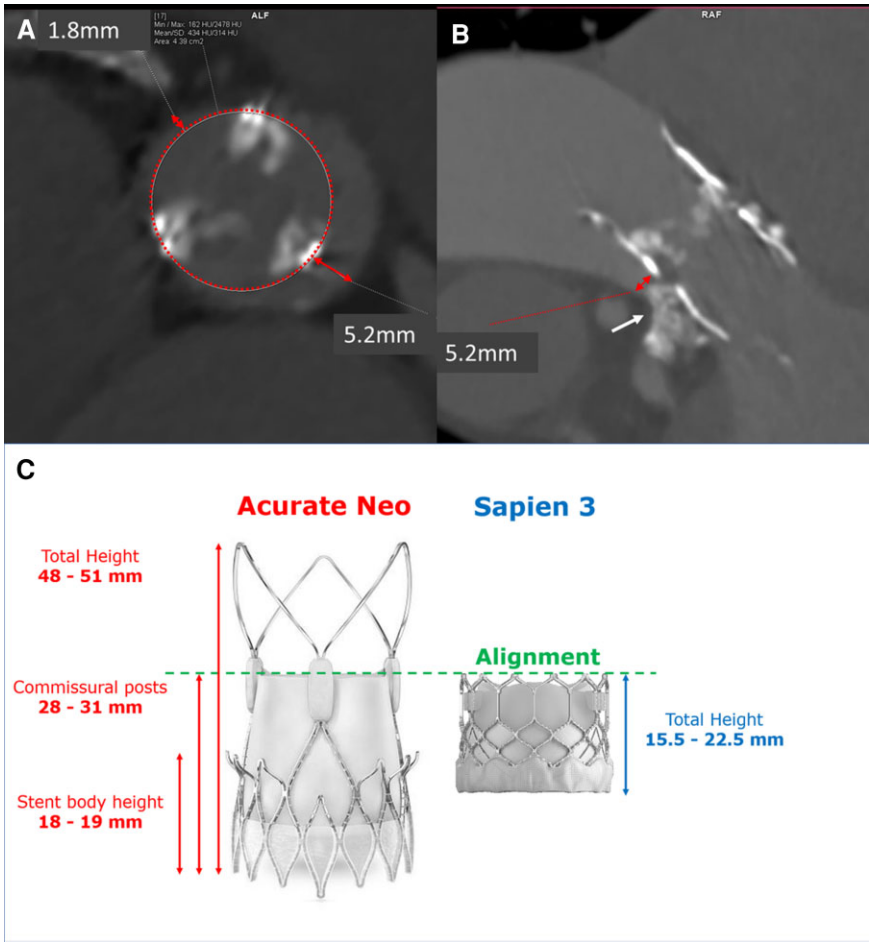

Figure 1 (*A*) Cardiac computed tomography (transverse) through the aorta showing leaflet calcification in the Acurate Neo. Valve-to-aorta above the right coronary artery and left main stem, indicated feasibility of future coronary access and a low risk of sinus sequestration. (*B*) Cardiac computed tomography (long axis.) White arrow shows the stent in the LMCA ostium. (*C*) Alignment of S3 transcatheter heart valve in relation to Acurate Neo transcatheter heart valve to ensure complete leaflet coverage.

degeneration of the THV a more remote possibility. A cardiac CT scan, however, showed no evidence of prosthetic valve thrombosis or pannus but surprisingly diffuse, prosthetic leaflet calcification (*Figure 1A and B*; Supplementary material online, *Video S1*). Cardiac catheterization revealed patent stents (*Figure 2A and B*). Blood tests showed an estimated glomerular filtration rate of 10 mL/min/1.73 m^2, raised serum phosphate (1.93 mmoL/L—ref 0.8–1.5 mmoL/L), normal adjusted calcium (2.52 mmoL/L—ref 2.2–2.6 mmoL/L), raised PTH (43.5 pmoL/L—ref 1.6–7.2 pmoL/L), and grossly elevated troponin levels (Abbott HsTropI 8553 ng/L—ref <16 ng/L). Troponin levels were mildly and chronically elevated (28 ng/L—3 months earlier in March 2021). Electrocardiogram showed sinus rhythm with ST-segment depression and T-wave inversion on the left precordial leads consistent with LV strain pattern.

A diagnosis of rapid, early SVD causing severe aortic stenosis due to ESKD was made. The patient was discussed by the Heart Team but deemed at prohibitive risk for cardiac surgery (EuroSCORE II 17.76%). Transcatheter aortic valve replacement-in-TAVR was considered the optimal therapy. A Sapien S3 Ultra (Edwards Lifesciences, Irvine, CA, USA) was felt to be the optimal device in view of its wide, open, upper row of cells, which increase access to the coronary arteries, along with a short frame height (18 mm for the 23 mm S3 THV). The intention was to position the Sapien 3 Ultra high within the Acurate Neo to ensure full coverage of the degenerate leaflets (*Figure 1C*) and eliminate the risk of residual degenerate leaflet mobility, which could impair the outflow and normal function of the new THV leaflets. The size of the aorta on CT was found to be sufficiently large to allow for placement of a 23 mm Sapien Ultra (*Figure 1A and B*) within the Acurate Neo, which, it was anticipated, would expand in light of its nitinol frame and reduced radial strength at the commissure posts. The valve-to-aorta distance (VTA) above the right coronary sinus was 1.8 mm and the VTA above the left 5.2 mm, indicating a low risk of sinus sequestration and sufficiently large to allow future coronary access with selective catheters (*Figure 1B*).

In June 2021, following recovery from emergency hemicolectomy, the patient underwent urgent in-patient, percutaneous, transfemoral TAVR-in-TAVR. A 3.5 × 12 mm coronary angioplasty balloon was positioned in the LAD (*Figure 2C*). The invasive mean gradient was 55 mmHg, confirming very severe aortic stenosis (*Figure 3A*). A 23 mm Sapien S3 Ultra valve (nominal volume) was positioned to

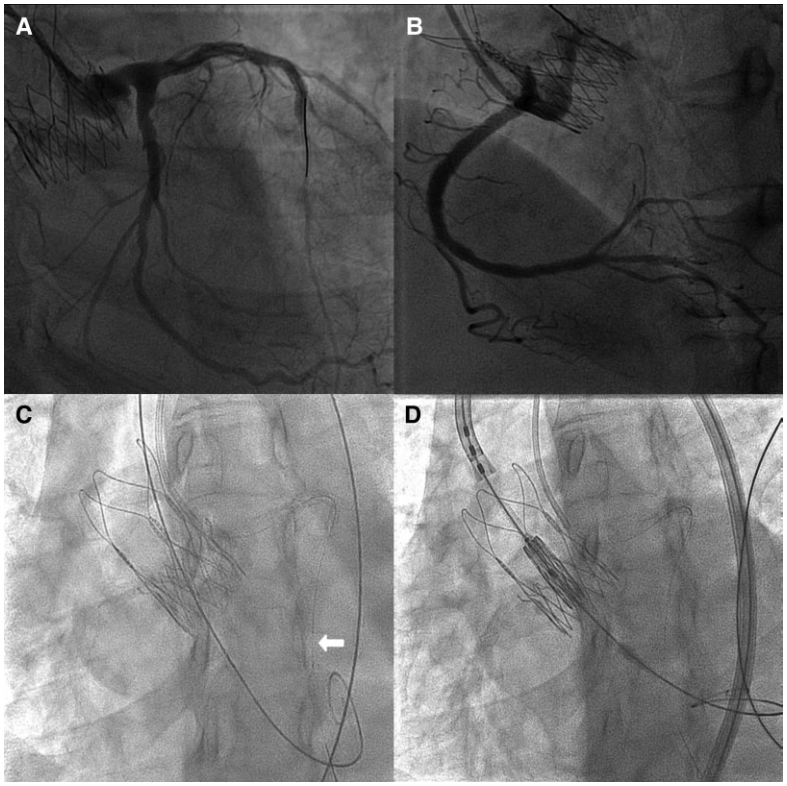

Figure 2 (*A*) Left coronary angiogram. (*B*) Right coronary angiogram. (*C*) Fluoroscopy (left coronary angiogram) image. A 3.5 mm balloon (white arrow) was positioned in the left anterior descending artery. (*D*) Fluoroscopy (left coronary angiogram) showing positioning of the Sapien 3.

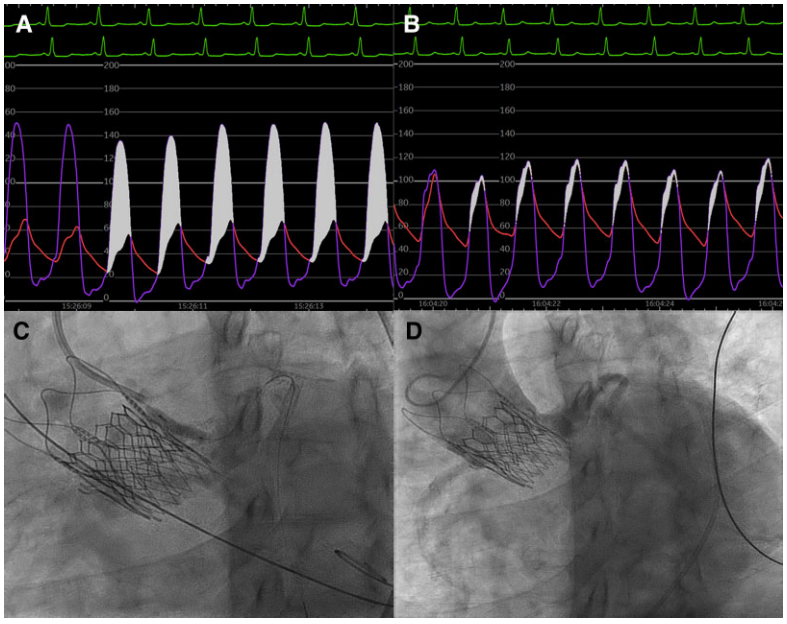

Figure 3 (*A*) Invasive assessment pre-procedure showed a 55 mmHg mean gradient across the Acurate Neo transcatheter heart valve. (*B*) Following transcatheter aortic valve replacement-in-transcatheter aortic valve replacement, mean invasive gradient fell to 9 mmHg. (*C*) Following redo-transcatheter aortic valve replacement, the 3.5 mm balloon was inflated to correct any distortion of the stent in the left main stem. (*D*) Final aortogram showed mild paravalvular regurgitation and good coronary flow.

overlap the top of the Sapien 3 frame with the commissures of the Acurate Neo, to ensure full leaflet coverage (*Figures 1C* and *2D*; Supplementary material online, *Video S2A*). Post-deployment, the invasive mean-PG across the aortic valve was reduced to 9 mmHg (*Figure 3B*). Transthoracic echocardiogram showed no transvalvular regurgitation. There was no compromise of coronary flow but the 3.5 mm balloon was dilated to ensure no distortion of the LMCA stent (*Figure 3C*). The final aortogram showed mild PVL and good coronary flow (*Figure 3D*; Supplementary material online, *Video S2B*). Pre- and post-redo-TAVR echocardiograms are presented in Supplementary material online, *Videos S3 and S4*. At 6 months follow-up, the patient felt well with no exertional chest pain or breathlessness. Transthoracic echocardiogram showed good function of the S3 prosthesis (max gradient 11 mmHg, mean 6 mmHg, valve area 1.8 cm^2), mild PVL, and a LVEF of 45%.

Discussion

To our knowledge, this is the first reported case of early, rapidly progressive SVD due to calcification affecting an Acurate Neo THV. End stage kidney disease is associated with accelerated calcification of the aortic valve and vasculature. However, there are few reports of very rapid, early SVD in THVs in haemodialysis patients due to calcific stenosis.[4] Transcatheter aortic valve replacement-in-TAVR is attractive for SVD affecting THVs and the largest observational study (212 patients) has demonstrated good safety.[6]

A recently recognized problem with redo-TAVR is impaired access to the coronary arteries due to displaced leaflets of the first THV forming a physical barrier.[7,8] This can cause potentially catastrophic sinus sequestration, whereby redo-TAVR may cause the displaced leaflets to meet the sino-tubular junction (STJ), preventing perfusion of the sinuses, potentially causing acute myocardial ischaemia. The risk is generally accepted to be high when the VTA is <2 mm. The VTA is measured as the shortest distance between the THV frame at the commissures and aortic wall, at the STJ or above the LMCA. A 2 mm cut-off is based on the diameter of a 6F catheter. In our case, the VTA above the right sinus was 1.8 mm. Access with a 6F catheter may not be possible but cannulation with 5F catheters should be feasible.

The risk of impaired coronary access following redo-TAVR is greatest in patients with supra-annular THVs.[7,8] There are few reports on redo-TAVR in the Acurate Neo THV. In a recent case of leaflet tear, causing severe aortic regurgitation in an Acurate Neo THV at 36 months, redo-TAVR was performed with a balloon-expandable MyVal THV (Meril, Vapi, India) placed in the native annulus, below the commissures of the Acurate Neo.[9] It was reasoned that such positioning reduced the risk of sinus sequestration and non-coverage of the Acurate commissures was justifiable as the lesion was regurgitation, not stenosis.

Conclusion

In our case, the leaflets of the Acurate were heavily calcified and it was considered that coverage of the degenerate leaflets by the second THV was necessary to ensure good function of the new THV. Importantly, CT imaging showed the diameter of the aorta at the level of the Acurate commissures to be large enough to accommodate the 23 mm Sapien 3 with low risk of sinus sequestration and continued feasibility of coronary access.

Lead author biography

Panagiotis Savvoulidis is a specialized cardiologist in Interventional Cardiology in Canada currently specializing in percutaneous structural heart procedures in UK. He is part of the Cardiology Department at Queen Elizabeth University Hospital in Birmingham, UK. He has an active research interest in aortic valve stenosis pathobiology and percutaneous treatment.

Supplementary material

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

Slide sets: A fully edited slide set detailing these cases and suitable for local presentation is available online as Supplementary data.

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

Conflict of interest: S.N.D. is a proctor for Edwards LifeSciences and Boston Scientific and has received speaker fees from Boston Scientific, Medtronic, and Abiomed. The remaining authors have no conflicts to disclose.

Funding: None declared.

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