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Case Report

Transcatheter Balloon-Expandable Valve-in-Valve to Treat Severe Paravalvular Leak Secondary to ACURATE-*neo* Self-expanding Prosthesis–Annulus Mismatch

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ABSTRACT

A 75-year-old male with severe symptomatic aortic stenosis underwent transcatheter aortic valve implantation with a Large (27-mm) ACURATE-*neo* transcatheter aortic valve, complicated by severe paravalvular leak. He developed rapid and progressive worsening heart failure. Reanalysis of the computed tomography images suggested evidence of prosthesis–annulus mismatch. Therefore, a redo transcatheter aortic valve implantation utilizing a 29-mm SAPIEN 3 transcatheter aortic valve was performed. This case illustrates the importance of proper valve sizing to avoid paravalvular leak, and how to safely cross an ACURATE-*neo* valve to avoid catheter entangling.

RÉSUMÉ

Un homme de 75 ans présentant une sténose aortique symptomatique sévère a subi l'implantation d'une valve aortique par cathéter, dont une ACURATE *neo* de 27-mm compliquée par une fuite paravalvulaire sévère. Par la suite, le patient a présenté une insuffisance cardiaque sévère . Une nouvelle analyse de ses examens tomodensitométriques a indiqué des signes d'incompatibilité entre la prothèse et l'anneau mitral. Il a donc fallu réaliser une nouvelle implantation valvulaire aortique par cathéter avec une valve SAPIEN 3 de 29 mm. Ce cas illustre l'importance d'une bonne évaluation de l'anneau valvulaire pour éviter les fuites paravalvulaires, et décrit comment traverser une valve ACURATE *neo* pour éviter l'enchevêtrement du cathéter.

Redo transcatheter aortic valve implantation (TAVI) will become increasingly common as the overall volume of TAVI procedures increases. Moderate paravalvular leak (PVL) rates with the ACURATE-*neo* (Boston Scientific, Marlborough, MA) were seen to occur in 3.6% of cases, with an increasing incidence in more-calcified valves of up to 5.8%.[1,2] A recent randomized controlled trial comparing the ACURATE-*neo* with the SAPIEN 3 (Edwards Lifesciences, Irvine, CA) found significantly higher rates of PVL with the former transcatheter aortic valve (TAV).[3]

Case

A 75-year-old man presented with severe symptomatic aortic stenosis. He had multiple comorbidities, including hypertension, dyslipidemia, Parkinson's disease, and significant chronic pulmonary disease secondary to tuberculosis with subsequent bronchiectasis. Doppler echocardiography demonstrated a heavily calcified and severely stenotic aortic valve, with a mean gradient of 73 mm Hg, and a left ventricular ejection fraction that dropped from 55% to 35% over the last 6 months. Coronary angiography showed no obstructive coronary disease. Based on his preoperative risk assessment (Society of Thoracic Surgeons score: 5.75%), the heart team considered the patient suitable for a transfemoral TAVI approach. Pre-procedural computed tomography (CT) suggested an aortic perimeter of 81.2 mm, a mean diameter of 25 mm, and an area of 510.8 mm^2, with satisfactory coronary heights; therefore, a Large (27-mm) ACURATE-*neo* TAV was recommended. The procedure was performed using a percutaneous right femoral approach. Balloon valvuloplasty was performed with a 25 × 40 mm NuCLEUS-X balloon (NuMED Canada Inc, Cornwall, ON) and the ACURATE-*neo* valve was implanted. Immediately after deployment, transesophageal echocardiography revealed moderate-to-severe PVL. The TAV was then postdilated with the same 25-mm balloon, which fluoroscopically expanded well; however, recoil was noted immediately upon balloon deflation. Subsequent transesophageal echocardiography revealed moderate PVL and a mean gradient of 3 mm Hg. The patient was extubated that evening and transferred to the ward. However, he became progressively more dyspneic over the next 5 days, with progressive left ventricular dilatation seen on his echocardiogram, which showed severe PVL (Fig. 1A).

We measured the CT scan at our institution and obtained an aortic annulus perimeter of 85 mm, with a mean diameter of 27 mm, an area of 555 mm^2, and a severely calcified valve

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Ethics Statement: This case report adheres with ethical guidelines.

See page 1322 for disclosure information.

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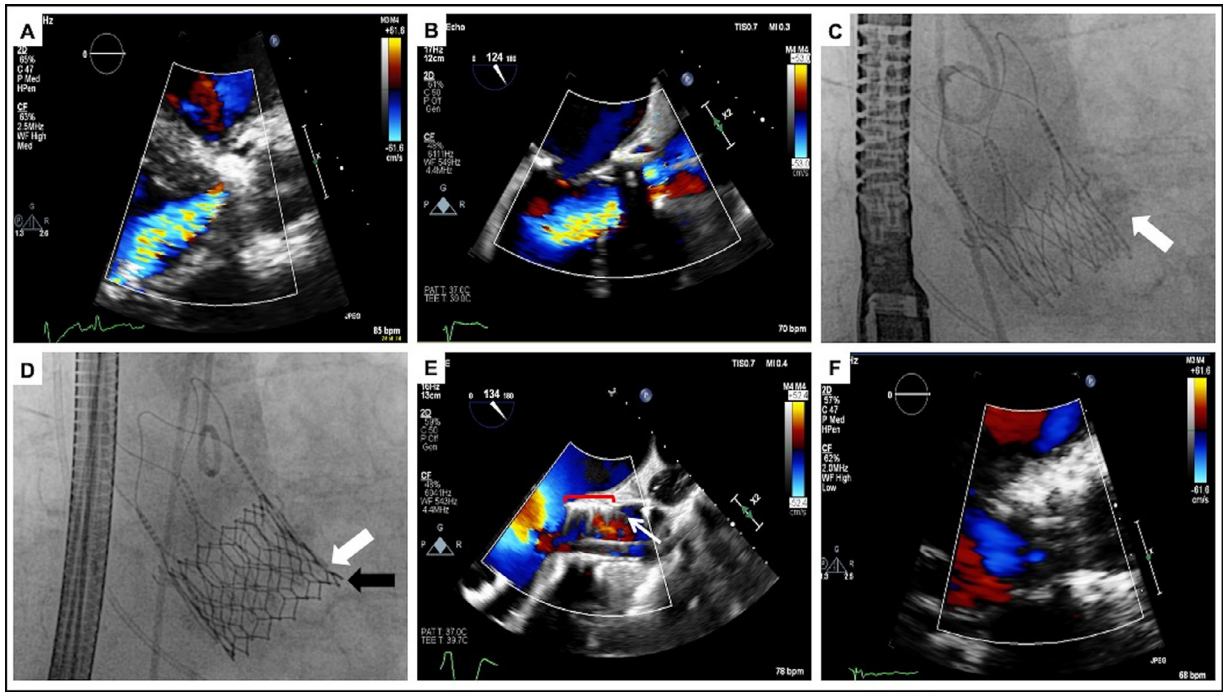

Figure 1. (**A**) Transthoracic and (**B**) transesophageal images showing severe paravalvular leakage of the ACURATE-*neo* transcatheter aortic valve (TAV). (**C**) Fluoroscopic image showing a gap between the ACURATE-*neo* TAV and the aortic annulus (**white arrow**). (**D**) Fluoroscopic image post TAV-in-TAV showing the SAPIEN 3 TAV deployed slightly ventricular to the edge of the ACURATE-*neo* (**white arrow** and **black arrow** indicate the edge of the ACURATE-*neo* and SAPIEN 3, respectively) to seal the paravalvular leak. (**E**) Transesophageal and (**F**) transthoracic images after TAV-in-TAV with a 29-mm SAPIEN 3 balloon-expandable TAV within the ACURATE-*neo* self-expanding TAV showing a trace of paravalvular leakage. In panel **E red bracket** indicates the SAPIEN 3 stent framein relationship to the supra-annular remaining tissue leaflet of the ACURATE-*neo* (indicated by the **white arrow**).

with an Agatston score of 6283. Therefore, the underlying mechanism was presumed to be due to an undersized prosthesis. The heart team felt redo TAVI with a 29-mm SAPIEN 3 was appropriate, and this procedure was performed 7 days after the initial TAVI. Intraprocedural transesophageal images confirmed a severe PVL (Fig. 1B). Percutaneous left femoral access was obtained, and a 16-French eSheath was then inserted. An aortogram showed severe PVL, and we could see a gap between the ACURATE-*neo* TAV and the aortic annulus, toward the left coronary cusp (Fig. 1C). The 5-French pigtail catheter was then carefully advanced over a 145-cm 0.035-inch J-type wire and placed above the supra-annular portion of the ACURATE-*neo* with special care, to avoid crossing through the stabilization arches, and carefully manipulated until it slipped through the supra-annular leaflets into the left ventricle (Video 1, view video online). Multiple fluoroscopic angles were then used to confirm that the pigtail was going through the centre of the TAV, before the J-type guidewire was replaced with a Safari 2 (Boston Scientific, Boston, MA) pre-shaped wire and the pigtail catheter was withdrawn. The SAPIEN 3 TAV was prepared at its nominal inflation size, then advanced over the wire and positioned across the ACURATE-*neo* valve using fluoroscopic guidance; then, it was fully deployed under rapid ventricular pacing and using slow-balloon inflation targeting the ventricular edge of the ACURATE-*neo* to seal the PVL with the skirt of the SAPIEN 3 TAV (Fig. 1D; Videos 2 and 3, view videos online). Immediately after this procedure, transesophageal echocardiography showed a trace of a PVL (Fig. 1E; Video 4, view video online), and aortography revealed normal coronary filling and a trace-to-mild PVL. A transthoracic echocardiogram showed a mean gradient of 4 mm Hg and a trace PVL (Fig. 1F). The patient was discharged to home 5 days after the redo-TAVI. At the 6-month follow-up visit, he was in New York Heart Association class I-II.

Discussion

We report a case of using a SAPIEN 3 TAV to treat severe PVL in an ACURATE-*neo* TAV. The rationale behind this strategy is based on several key factors. First, the initial TAV selection led to significant prosthesis–annulus mismatch as the underlying mechanism of severe PVL. Indeed, because initial CT measurements placed the annulus at the upper limit of appropriateness for the ACURATE-*neo* (although discrepant measurements such as this are not uncommon in clinical practice),[4] a larger TAV would be a more appropriate choice. Second, the radial force of the ACURATE-*neo* may not be the same as that of the SAPIEN 3 or Evolut R/Pro (Medtronic, Minneapolis, MN).[5,6] Furthermore, increased calcification in the device landing zone has been associated with more-than-mild PVL with the ACURATE-*neo*, with reported rates of moderate and severe PVL of up to 5% and 13%, respectively. In addition, the degree of peri-annular calcification,

oversizing, and the presence of annular plaque protrusions, among other issues, have been found to be factors associated with significant PVL.[7]

Third, the outer skirt of the SAPIEN 3, which in the case of incomplete apposition—that is, owing to significant calcification—may help it conform to the native anatomy and reduce PVL.[8] Fourth, another learning point of this case is the technique for crossing the ACURATE-*neo,* and perhaps any TAV, in order to ensure that the guidewire is not entangled within the stabilization arches or within the TAV struts, and is not piercing a leaflet, while using a straight guidewire for crossing. Utilizing a pigtail catheter with the J-type guidewire inside of it rather than a straight guidewire decreases the likelihood of the wire becoming entangled. Importantly, like a valve-in-valve procedure for a failed surgical bioprosthesis, balancing the risk of coronary occlusion is of paramount importance while making decisions during the TAVI-in-TAVI process. Finally, as 2 prostheses are essentially working in series, the potential implications of residual supra-valvular leaflet tissue (Fig. 1E and Video 4, view video online) for TAV thrombosis or thromboembolic events, as well as those of long-term valve durability, are unknown.

In summary, this case illustrates the treatment of prosthesis −annulus mismatch with TAVI-in-TAVI. Careful analysis of the pre-procedural CT measurements is of paramount importance when sizing a TAV. In cases of borderline annular measurements, a larger TAV would be a more appropriate choice, and paying attention to the morphology and dimension of the left ventricular outflow tract is important. Finally, crossing over a supra-annular TAV must be performed patiently, to avoid guidewire and catheter entanglement.

Novel Teaching Points

- When discrepant measurements of the aortic annulus are encountered, a larger transcatheter aortic valve is a more appropriate choice.

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at doi:10.1016/j.cjco.2021.06.004.