JACC: CASE REPORTS VOL. 29, 2024

VALVULAR HEART DISEASE

CASE REPORT: CLINICAL CASE SERIES

Mind the Gap in TAVR

Recognizing and Managing Misloaded Self-Expanding TAVR Devices

Aninda Omar, MD,[a] Anna Damlin, MD, PhD,[a,b,c,d] Andreas Rück, MD, PhD,[a,b] Magnus Settergren, MD, PhD,[a,b] Dinos Verouhis, MD, PhD,[a,b] Rickard Linder, MD, PhD,[a,b] Christopher U. Meduri, MD, PhD,[a] Nawzad Saleh, MD, PhD[a,b]

ABSTRACT

Misloading during transcatheter aortic valve replacement (TAVR) is rare but can cause unpredictable valve release if unrecognized. We describe how to identify a misloaded ACURATE neo2 device, and 3 methods to solve this by using a modified technique of valve deployment, ipsilateral extraction, and contralateral valve externalization with extracorporeal valve release. (J Am Coll Cardiol Case Rep 2024;29:102192) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

The ACURATE neo2 (Boston Scientific) is a self-expanding transcatheter aortic valve (TAV) with supra-annular leaflet position. It is one of several self-expanding valves (SEVs) used in transcatheter aortic valve replacement (TAVR) and has shown favorable outcomes.[1] In rare cases, a phenomenon described as "misloading" is seen with this valve, causing abnormal valve deployment during TAVR. Typically, deployment is controlled by 2 knobs that release the valve from the aortic (knob 1) to the ventricular (knob 2) end.

LEARNING OBJECTIVES

- To appreciate fluoroscopic signs suggesting misloading of a self-expanding ACURATE neo2 during TAVR.
- To recognize possible complications after misloading of this particular TAV.
- To manage misloading of this particular TAV.

Misloading results in detachment of the lower stent crown of the valve from the stent holder of the delivery system, resulting in a nonfunctional knob 2. Accordingly, the valve will be fully released prematurely when turning knob 1 in a bottom-to-top fashion. Simply retracting the valve through the sheath retrogradely is difficult due to the free cells catching the distal end of the sheath (**Figure 1**, Video 1). Instructions for use include ectopic implantation or retraction through the sheath, with vascular surgeons on standby in case surgical cutdown to the femoral artery is warranted, which carries the risk of additional complications. Herein we describe 3 cases in which this particular TAV was misloaded, along with novel ways to manage this rare complication.

PATIENT PRESENTATION

Patient 1 was a 90-year-old man with stage 3 chronic kidney disease and severe aortic stenosis.

From the [a]Department of Cardiology, Karolinska University Hospital, Stockholm, Sweden; [b]Unit of Cardiology, Department of Medicine, Karolinska Institutet, Stockholm, Sweden; [c]Department of Clinical Physiology, Karolinska University Hospital, Stockholm, Sweden; and the [d]Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received August 25, 2023; revised manuscript received October 17, 2023, accepted October 30, 2023.

ISSN 2666-0849 https://doi.org/10.1016/j.jaccas.2023.102192

Patient 2 was an 83-year-old man with type 2 diabetes mellitus and severe aortic stenosis. Patient 3 was an 89-year-old woman with previous coronary artery bypass graft, type 2 diabetes mellitus, stage 3 chronic kidney disease, and severe paradoxical low-flow, low-gradient aortic stenosis. Preoperative vascular evaluations are summarized in Figure 2.

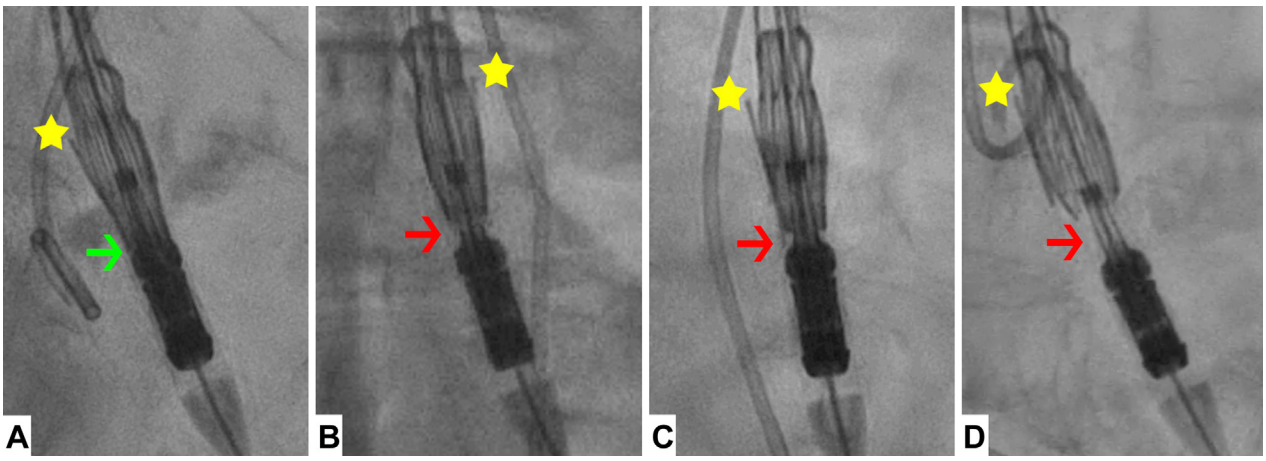
DIAGNOSIS AND MANAGEMENT

All 3 patients were scheduled for transfemoral TAVR through the right common femoral artery (CFA) with a 25-mm ACURATE neo2. Predilatation was performed with a 22-mm non-compliant balloon according to standard practice. The prostheses were introduced through a 14-F expandable iSLEEVE sheath (Boston Scientific). Misloading was suspected from fluoroscopy at the level of the descending aorta because of the telltale small gap between the lower stent crown and the stent holder and further confirmed at the level of the ascending aorta after correction of parallax (Figure 1).

PATIENT 1 (IPSILATERAL RETRACTION). The decision was made to not proceed with the implantation. As a precaution, a 14-F introducer was inserted through the left CFA, and a 22-mm Reliant balloon (Medtronic) for abdominal aortic occlusion was kept available. The misloaded TAV was retracted to the 14-F expandable sheath, and the delivery system, together with the 14-F expandable sheath, were successfully removed en bloc with the Safari preshaped left ventricular (LV) guidewire (Boston Scientific) still in place. A new 14-F expandable sheath was instantly introduced through the right CFA over the preshaped LV guidewire without significant bleeding. A new 25-mm, self-expanding TAV was successfully implanted. The second delivery system and the 14-F expandable sheath were removed, and an 18-F MANTA (Teleflex Inc) vascular closure device was deployed. Because of moderate bleeding, a peripheral balloon was advanced from the left femoral access site to the puncture site at the right femoral access site. After 2 minutes of inflation, hemostasis was achieved.

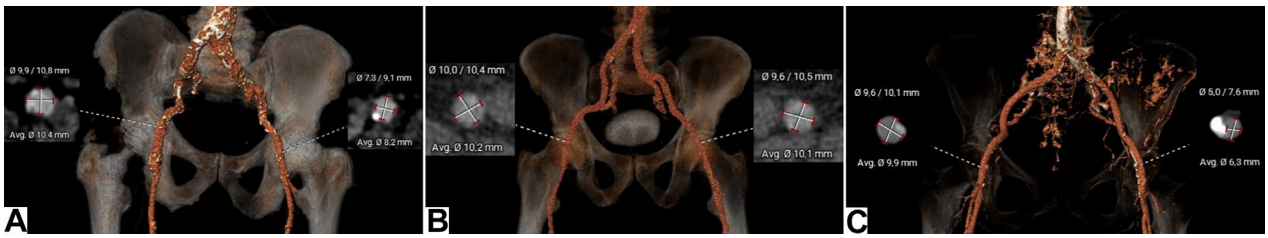
PATIENT 2 (CONTRALATERAL EXTERNALIZATION). The decision was made to not proceed with the implantation. As the delivery system was retracted partly into the 14-F expandable sheath toward the right CFA, it was not easily removed en bloc due to significant resistance because the free cells of the 25-mm, self-expanding TAV interfered with the 14-F expandable sheath (Figure 1, Video 1). After a multidisciplinary consultation that included vascular surgeons, a 24-F Sentrant introducer sheath (Medtronic) was inserted through the left CFA. The preshaped LV guidewire in the left ventricle was retracted to the abdominal aorta, snared to the contralateral left femoral artery, and externalized. The TAV and delivery system could

FIGURE 1 Fluoroscopic Signs of a Misloaded ACURATE neo2 Before Deployment



(A) Correct loading. (B to D) Fluoroscopic signs in patients 1 (B), 2 (C), and 3 (D), respectively. Green arrow indicates no gap and the red arrows indicate gaps between lower stent crown and stent holder. Yellow stars indicate free cells of the transcatheter aortic valve.

FIGURE 2 **Preoperative MSCT Analysis**



Preoperative multislice computed tomography (MSCT) analysis (3mensio, Pie Medical Imaging) of patients 1 (A), 2 (B), and 3 (C), respectively. Access site diameter, degree of calcification, and tortuosity were measured and carefully evaluated.

then be advanced over the preshaped LV guidewire through the 24-F introducer sheath in the left CFA (Video 2). The misloaded TAV was then released extracorporeally. The delivery system was subsequently retracted and removed without resistance through the right CFA together with the 14-F expandable sheath without removing the previously snared preshaped LV guidewire.

In the right CFA, the sheath was changed to a 20-F introducer (Cook Medical) over the preshaped LV guidewire under manual compression of the right CFA. A new 25-mm, self-expanding TAV was implanted through the left CFA without difficulties. The right CFA was closed with the 18-F vascular closure device, but due to moderate bleeding, a covered stent (10 × 60 mm, Covera Vascular Covered Stent, BD, Becton, Dickinson, & Company) from the left CFA was used to achieve access site closure. Use of contrast agent injection showed no signs of vascular injuries in the femoral or iliac arteries bilaterally or in the abdominal aorta. The 24-F introducer sheath was removed from the left CFA and closed with the 18-F vascular closure device.

PATIENT 3 (IN SITU DEPLOYMENT). Because the patient was hemodynamically unstable after predilation, the decision was made to rapidly deliver the misloaded TAV. Diverging from the normal step-by-step implantation procedure, the 25-mm, self-expanding TAV was deployed without prior commissural alignment by turning only knob 1 under rapid pacing on the LV wire (182 beats/min) to minimize risk of misplacement (Video 3). Importantly, the radiopaque marker on the delivery system is not a reliable indicator of implantation depth in a misloaded valve as it travels down during deployment. Instead, the first intersection of cells on the stent was used for positioning, and the implantation depth was adequate.

FOLLOW-UP

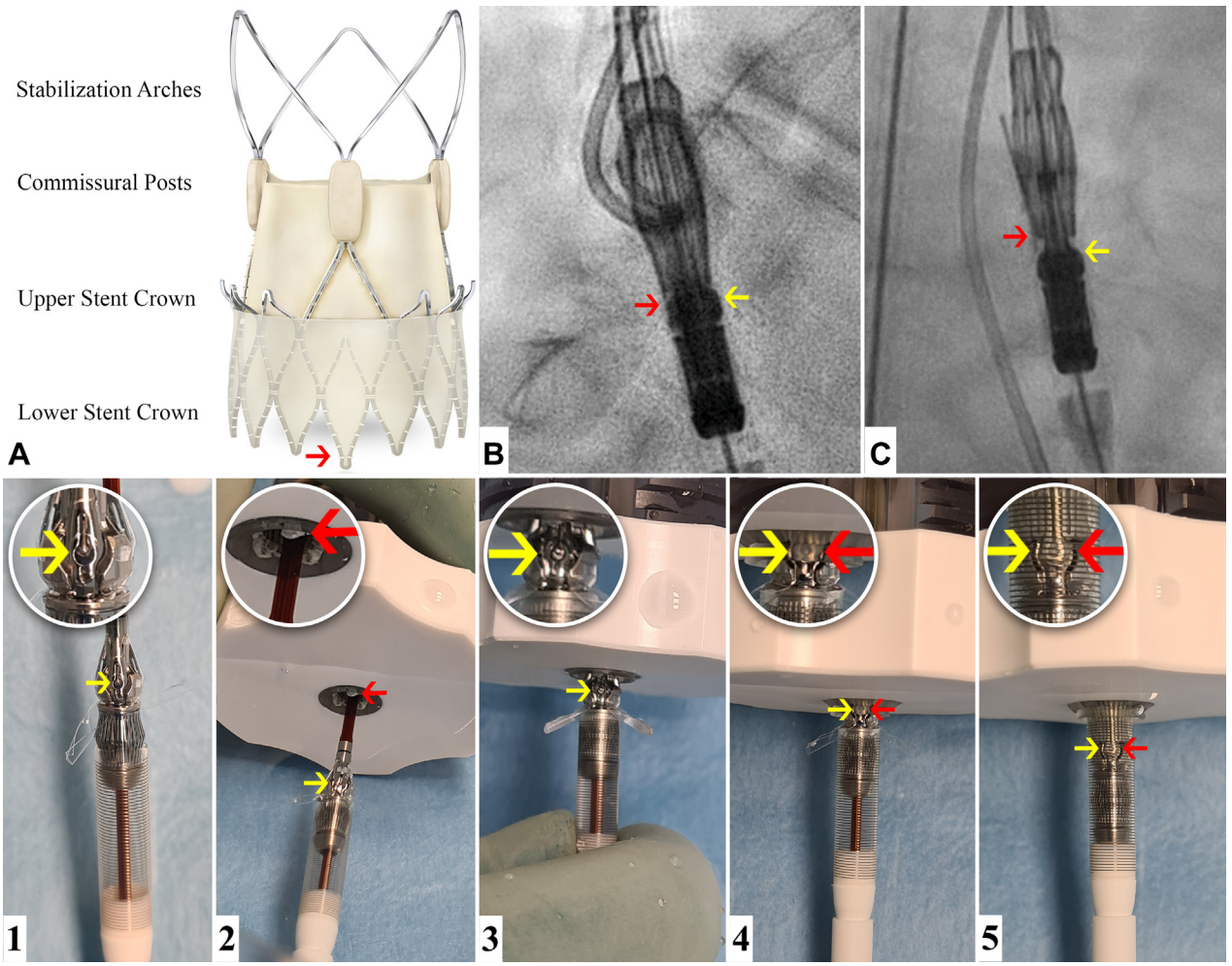
All 3 patients had uneventful postoperative care without any adverse outcomes except for patient 2 who, as per the Valve Academic Research Consortium 2 definition,[2] developed major bleeding (Bleeding Academic Research Consortium type 3a) and minor vascular complications due to the unplanned stenting of the CFA.

DISCUSSION

Periprocedural malfunctions of SEVs are very rare. To our knowledge, this is the first report of misloading of the self-expanding ACURATE neo2 in which the lower stent crown of the device and the stent holder of the delivery system were disconnected. In our experience with >1,700 implanted SEVs of this particular TAV, these are the only 3 cases (0.2%) in which this malfunction occurred. Although rare, it is important to recognize, as misloading of this TAV will deploy in an unexpected way.

The fluoroscopic signature of misloading is a small gap between the lower stent crown and the stent holder of this TAV (**Figure 1**). It is subtle and can be missed if not meticulously looked for. However, misloading of the valve will become obvious once deployment starts with the turning of knob 1 because this causes premature release of the valve. As the valve is loaded onto the delivery system, 3 “pins” on the stent holder are anchored to 3 corresponding “hooks” on the lower stent crown to connect the 2 parts (**Figure 3**). The 3 connection points may be detached individually, making the fluoroscopic signature petite (patients 1 and 2), or they may be disconnected altogether, with a more obvious gap (patient 3). Hence, acquiring additional projections and correcting for parallax is important if misloading is suspected.

FIGURE 3 **"Hooks" and "Pins" of the ACURATE neo2**



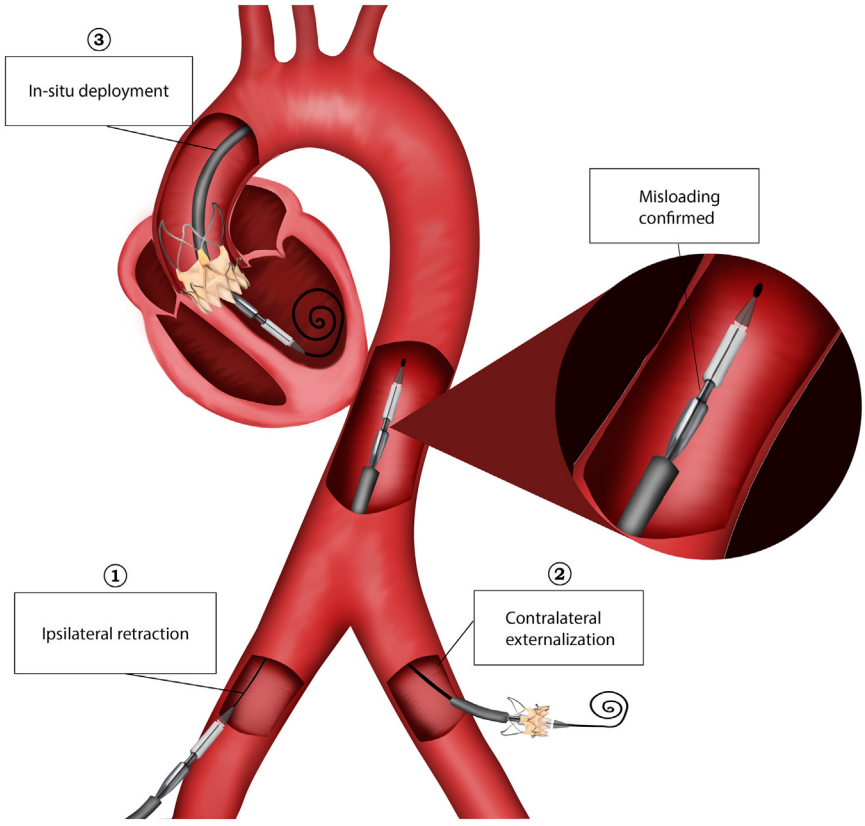
(A) Schematic illustration of ACURATE neo2 and core structures. (A to C) Showing the relationship between "hooks" and "pins" on a correctly loaded (B) and misloaded (C) ACURATE neo2. 1 to 5: Process of anchoring "hooks" to "pins" during valve loading. Red arrows: "hooks" on the lower stent crown of the valve. Yellow arrows: "pins" on the stent holder of the delivery system.

The instructions for use of the misloaded TAV recommend taking the valve out, with vascular surgeons on standby, or ectopically deploying it in the suprarenal descending aorta. Herein, we describe 2 additional methods to safely manage this situation (Figure 4). The first method involves removing the valve from the contralateral CFA by snaring and externalizing the preshaped LV guidewire. The second method, in the case of a hemodynamically unstable patient or poor contralateral vascular access, is in situ deployment. In the case of in situ deployment of a misloaded ACURATE neo2, only knob 1 should be used, and rapid pacing should be considered to stabilize the deployment. It is important to note that the radiopaque marker on the delivery system will not be reliable during deployment of the misloaded TAV; instead, the stent frame should be used for positioning.

CONCLUSIONS

In rare cases, the self-expanding ACURATE neo2 can be misloaded, which carries the risk of unpredictable release of the valve. Herein, we describe: 1) the means to diagnose misloading by fluoroscopic signs; 2) possible complications of misloading; and 3) 2 novel approaches for managing misloading of this particular TAV.

FIGURE 4 Schematic Illustration of the Management of a Misloaded ACURATE neo2 in Patients 1, 2, and 3



FUNDING SUPPORT AND AUTHOR DISCLOSURES

Dr Rück has received grants and personal fees from Boston Scientific Corporation; and personal fees from Edwards Lifesciences, Abbott, and Anteris Technologies, outside of the submitted work. Dr Settergren has received grants and personal fees from W.L. Gore, Abbott, Boston Scientific Corporation, Edwards Lifesciences, and Anteris Technologies, outside the submitted work. Dr Meduri is the chief medical officer for Anteris Technologies; and a consultant for Boston Scientific Corporation, Abbott, Alleviant, VDyne, Cardiovalve, XDot, and V2V, outside of the submitted work. Dr Linder has received grants and personal fees from Boston Scientific Corporation, outside of the submitted work. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr Aninda Omar, Karolinska University Hospital, Department of Cardiology, SE-17176 Stockholm, Sweden. E-mail: Aninda.omar@regionstockholm.se.

REFERENCES

1. Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: transcatheter aortic valve implantation with ACURATE neo2 in a European population. *J Am Heart Assoc*. 2023;12:e029464.

2. Kappetein AP, Head SJ, Généreux P, et al. Valve Academic Research Consortium-2. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Thorac Cardiovasc Surg*. 2013;145:6-23.

KEY WORDS ACURATE, misloading, self-expanding valve, TAVI

APPENDIX For supplemental videos, please see the online version of this paper.