

## First transaortic transcatheter aortic valve implantation with Acurate Neo: case report and technical recommendations

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Background	In more than 90%, transcatheter aortic valve implantation (TAVI) is performed via transfemoral access. Alternative access routes are necessary for patients with unfavourable femoral arteries.
Case summary	We report of a 68-year-old female with symptomatic severe aortic stenosis in whom surgical aortic valve replacement was prohibited due to her severe co-morbidities. Both femoral arteries and both subclavian arteries were unsuitable for TAVI access. Surgical aortic valve replacement and transapical TAVI were deferred due to extremely high operative risk and very low originating left coronary artery of 7 mm from the annulus. Hence, we decided to implant a self-expanding TAVI device with a low risk of coronary obstruction (Acurate Neo 2 prosthesis) via transaortic approach, which to our knowledge is the first case worldwide.
Conclusion	The present case demonstrates the feasibility of implanting the Acurate Neo 2 system via transaortic approach when certain key points are respected. Transaortic TAVI with the Acurate Neo 2 offers a minimally invasive treatment of high operative risk patients with low originating coronary arteries.
Keywords	TAVI • Aortic stenosis • Transaortic access • Case report
ESC curriculum	4.2 Aortic stenosis • 4.10 Prosthetic valves

#### Learning points

- When standard transfemoral approach is not possible, several alternative approaches are available. Transaortic transcatheter aortic valve implantation is a feasible treatment option for patients even with newer valve systems.
- Implantation of the Acurate Neo 2 via transaortic access is safe when certain key points are minded: length of the ascending aorta should be above 60 mm, partial sternotomy is preferable over right intercostal access, 21–22 Fr sheaths should be preferred over expandable sheaths to minimize the risk of aortic injury, and rapid pacing throughout the whole valve prosthesis-releasing process is recommended to stabilize the valve position.

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Transcatheter aortic valve implantation (TAVI) is a common treatment option for patients with symptomatic severe aortic stenosis (AS). After more than 20 years of worldwide experience, transfemoral access is the preferred route to implant the TAVI prosthesis with excellent clinical outcome data and with a class la recommendation for patients  $\geq 75$ years old or who are at high risk for surgery or inoperable.<sup>1–3</sup> However, in a minority of patients, transfemoral access is not possible due to several reasons such as peripheral artery disease, too small diameter for the TAVI delivery system, or extremely tortuous and calcified femoral/iliac vessels. Subclavian access is often the next choice of access. but cases of subclavian arteriosclerosis, transapical, transcarotid, transcaval, or transaortic approach present alternative options, depending on the centre experience. Transapical access has shown higher 30-day mortality rates and bears some drawbacks such as potential myocardial damage leading to left ventricular dysfunction, apical bleeding, or even rupture. Furthermore, it is limited to the implantation of only one TAVI system, Edwards Sapien (Edwards Lifesciences Corp., Irvine, CA, USA), which might be unsuitable for certain anatomies. The Acurate TA system is no longer available. By using a transaortic approach, left ventricular injury is avoided and cardiac surgeons are very familiar with ascending aorta cannulation. Transaortic TAVI with both Edwards Sapien and Medtronic Evolut® devices (Medtronic, Minnesota, USA) has been described previously.<sup>4–7</sup> In this case report, we present the first transaortic implantation of an Acurate Neo 2 system (Boston Scientific Corp., Natick, MA, USA) to treat a patient with severe AS and unfavourable transfemoral and trans-subclavian access.

## Summary figure

Time	Events
Admission	A 68-year-old woman with several co-morbidities presented with symptoms of heart failure NYHA class III. Auscultation revealed a loud ejection murmur over the aortic area, radiating to the carotid arteries.
Investigations	Transthoracic echocardiogram: severe AS with a valve area of 0.7 cm <sup>2</sup> and mean transvalvular gradient of 50 mmHg.
	CT scan: annulus diameter was 21.5 mm, annulus to left coronary height was only 7.4 mm, and distance to right coronary artery was 14.5 mm. Both femoral arteries and both subclavian arteries were unsuitable for TAVI access.
Intervention	TAVI was performed via transaortic approach with the Acurate Neo 2 to minimize the risk of coronary obstruction. The valve prosthesis was implanted via upper partial sternotomy from the ascending aorta at the height of the right brachiocephalic artery through a 21 Fr Certitude Sheath under rapid pacing. The final angiogram displayed good valve position with patent coronary arteries.
Day 5 after intervention	Echocardiography: correct TAVI position with a mean gradient of 9 mmHg and no paravalvular leakage. Patient's symptoms were much improved with NYHA class II.

## **Case summary**

A 68-year-old woman presented to the cardiology clinic with symptoms of heart failure. Her baseline functional status was classified with dyspnoea New York Heart Association (NYHA) class III with mild peripheral oedema, and she reported no angina. Her baseline medication consisted of acetylsalicylic acid, bisoprolol 10 mg/day, allopurinol 100 mg/day, simvastatin 20 mg/day, levothyroxine 125 µg/day, and high doses of diuretics, torasemide 300 mg/day. Her vital signs showed a blood pressure of 118/ 65 mmHg, a heart rate of 71 b.p.m., a respiratory rate of 22/min, and an oxygen saturation of 99%. Auscultation of the heart revealed a loud ejection murmur over the aortic area, radiating to the carotid arteries. The electrocardiogram demonstrated sinus rhythm without specific changes. Laboratory test showed elevated creatinine of 5.7 mg/dL at a glomerular filtration rate of 7 mL/min and N-terminal pro b-type natriuretic peptide of 10 200 pg/mL. Haemoglobin level (12.7 g/dL) was normal at admission. Transthoracic echocardiogram revealed a severe AS with a valve area of 0.7 cm<sup>2</sup> and mean transvalvular gradient of 50 mmHg (Figure 1). Left ventricular ejection fraction was 52% and the mitral valve had a mild insufficiency.

Co-morbidities consisted of coronary artery disease with intermediate stenosis of the left descending and right coronary arteries. Furthermore, she had cerebral artery disease with 60–70% stenosis of the right carotid artery and 80% stenosis of the left carotid artery, peripheral artery disease, and non-insulin-dependent diabetes and had been receiving haemodialysis treatment in the last 4 years due to autosomal dominant polycystic kidney disease with endstage renal failure. During the last 3 months, the patient had been hospitalized twice because of bleeding from gastrointestinal angiodysplasia requiring blood transfusions. Pre-operative risk assessment revealed a Euro SCORE II of 3.33% and Society of Thoracic Surgeons Score of 4.21%. Due to the several co-morbidities, she was screened for TAVI procedure at an external hospital.

Aortic annulus size was measured with 21.5 mm by computed tomography (CT) scan with moderate calcifications of the native leaflets, annulus to left coronary height was only 7.4 mm, and distance to right coronary artery was 14.5 mm. Both femoral arteries and both subclavian arteries were unsuitable for TAVI access (*Figure 2*). She was deferred for transapical access and open-heart surgery due to extremely high risk.

Our institutional heart team decided to perform TAVI with the Acurate Neo 2 to minimize the risk of coronary obstruction with the left coronary artery (LCA) originating at only 7.4 mm above the annulus. Transcarotid access was not possible due to calcifications of the right brachiocephalic and left carotid artery; hence, transaortic was chosen as the access route. The Acurate Neo 2 valve size S was successfully implanted via upper partial sternotomy and transaortic approach under general anaesthesia. A minimized median sternotomy approach dividing only the manubrium was chosen for the opportunity to move and turn the sheath towards the left shoulder for valve positioning in the outer curve of the aorta. A temporary pacemaker lead was placed in the right ventricle via the right femoral vein. The skin incision was 5 cm long. After partial sternotomy, the pericardium was opened, and two pledged U-sutures were placed on the anterior wall of the ascending aorta at the height of the right brachiocephalic artery. Through direct needle puncture, a J-shaped soft guidewire and a 10 Fr short sheath were advanced in the ascending aorta. Via multipurpose catheter, the aortic valve was crossed with a straight-tipped hydrophilic Terumo wire and then exchanged to pigtail catheter in the left ventricle with subsequent introduction of the pre-shaped Safari wire. A second 6F marker pigtail catheter was placed in the non-coronary sinus via the left femoral artery with difficulties, which were overcome by using a J-tipped hydrophilic Terumo wire. Angiogram in anterior-posterior projection demonstrated the three-cusp view and sufficient length of the ascending



Figure 1 Transthoracic echocardiography with calcified aortic valve and severe normal flow/high gradient stenosis, mean gradient of 50 mmHg, and calculated valve orifice area of 0.8 cm<sup>2</sup>.



**Figure 2** Pre-procedural computed tomography (CT) scan: (A) aortic annulus of 21.5 mm, area of 357 mm<sup>2</sup>, and perimeter of 67.8 mm; (B) aortic valve calcification, (C) distance from annulus to left coronary artery, (D) femoral vessel; (E) right subclavian artery; (F) left subclavian artery; and (G) ascending aorta with sufficient length from annulus to brachiocephalic arteries.



**Figure 3** (A) Angiogram of the aortic root prior to valve implantation; (B) 21 Fr Certitude Sheath placed in the aortic and balloon pre-dilation under rapid pacing; (*C*–*E*) angiographic positioning of the Acurate Neo 2 valve system; and (*F*) final angiography with optimal position of the valve and patent coronary arteries.

aorta. The 10 Fr sheath was exchanged for a 21 Fr Certitude Sheath (Edwards Lifesciences), which is usually used for transapical TAVI access. Pre-dilation of the native aortic valve was performed under rapid pacing with a 20 mm Mammoth balloon. Hereafter, the Acurate Neo 2 S was advanced and positioned in the annulus. Implantation with the release of the upper crown and aortic arches and the complete valve release were performed under rapid pacing to allow more stability of the system. The final angiogram displayed good valve position with patent coronary arteries (*Figure 3*). The patient was monitored in the intensive care unit for 12 h after the procedure before being transferred to the cardiology ward. The hospital stay was prolonged due to interventional therapy of her severe peripheral artery disease with chronic ulcer at her right heel and necessity of intravenous antibiotic therapy.

Final echocardiography on Day 5 after transaortic TAVI showed correct TAVI position with a mean gradient of 9 mmHg and no paravalvular leakage. Patient's symptoms were almost completely relieved at discharge on Day 17 with NYHA functional class II.

### Discussion

According to the current European Society of Cardiology guidelines, non-transfemoral TAVI has only a class IIb recommendation for patients who are inoperable or unsuitable for transfemoral TAVI.<sup>1</sup> However, several cases and observational studies have demonstrated transaortic TAVI to be a feasible option for patients with unfavourable femoral, subclavian, or transcarotid access. While supra-aortic approach was associated with lower 30-day mortality rates, these access routes are not feasible in the presence of calcification in the supra-aortic branches. Transaortic TAVI remains a valuable option compared with transapical, especially in patients with reduced left ventricular function.<sup>8</sup> Up to date, only implantation of Edwards Sapien or Medtronic Evolut® TAVI systems has been performed via transaortic route. To our knowledge, this is the first implantation of the Acurate Neo 2 valve system via transaortic access, which we chose to minimize the risk of coronary obstruction due to low originating LCA. The valve design of this TAVI prosthesis with a stent body height of 18 mm and extra-large open cells of the stabilization arches provides coronary access. Implantation of this TAVI system via transaortic approach raised a lot of concern, since it appeared to be difficult to align the crimped valve system along the outer curve of the ascending aorta. Herein, we demonstrate that it is possible and safe to implant the Acurate Neo 2 system via transaortic approach when certain key points are respected.

 Length of the ascending aorta (annulus to potential access site in the ascending aorta) should be above 60 mm measured on CT scan.

- (2) Partial sternotomy is preferable over right intercostal access, because it allows to manoeuvre the sheath more freely and almost aligns the valve system to the outer curve.
- (3) 21–22 Fr sheaths should be preferred over expandable sheaths to minimize the risk of aortic injury. One operating assistant should be entrusted solely to keep the sheath at the correct position (1 to max. 2 cm inside the aorta) and correct angle.
- (4) Rapid pacing throughout the whole valve prosthesis-releasing process (Steps 1 and 2) is recommended to stabilize the valve position in the aortic annulus.

In conclusion, transaortic approach is a valuable access route for AS patients with unfavourable femoral or subclavian arteries because it avoids left ventricular damage compared to transapical access. This case demonstrates the feasibility of implanting an Acurate Neo 2 TAVI system via transaortic access when certain key points are minded and might expand the possibilities of treating patients who were declined due to anatomic risks. Certainly, more cases and studies are necessary to gain expertise in this access route with this certain TAVI system.

### Lead author biography



Dr Smita Scholtz is a senior consultant and interventional cardiologist at the Clinic for General and Interventional Cardiology/Angiology at the Heart and Diabetes Center NRW in Bad Oeynhausen, Germany. She graduated from MHH Hannover, Germany in 2005, and completed her residency in Bad Oeynhausen in 2011. Academic degree 'Privatdozent' (habilitation) was awarded in 2022 by the University of Bochum. Her interests include the treatment of aortic valve diseases.

coronary interventions, and hypertrophic cardiomyopathy.

**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 accordance with COPE guidelines.

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#### Data availability

Data will be made available from the authors on reasonable request.

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