First implantation of the Acurate neo2 prosthesis in a patient with aortic stenosis in Poland

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A 78-year-old woman with a history of myocardial infarction, arterial hypertension, atrial fibrillation, pulmonary embolism, and osteoarthritis, who underwent previous percutaneous coronary interventions, was admitted to our hospital with severe heart failure. Echocardiography revealed severe aortic stenosis (mean and maximum gradient, 45 and 75 mm Hg, respectively), mild aortic regurgitation, and normal ejection fraction. After careful evaluation of the patient's medical history, imaging results, and perioperative risk (logistic EuroSCORE, 14.9; EuroSCORE II, 3%), the Heart Team decided to refer her for transcatheter aortic valve implantation (TAVI). The procedure was performed on October 10, 2020 in the hybrid room, under local anaesthesia with puncture of femoral arteries and Proglide preclosure technique. After valve predilatation with the Osypka VACS III 24 mm × 400 mm balloon (Osypka, Rheinfelden, Germany), the Acurate neo2 size L aortic valve (Boston Scientific, Marlborough, Massachusetts, United States) was successfully implanted (FIGURE 1A–1D). No postdilatation was required. After the procedure, no paravalvular leak (PVL) was present and the peak transvalvular gradient decreased to 12 mm Hg.

Acurate neo2 (FIGURE 1E) is a new generation TAVI system designed to treat patients with aortic stenosis. Compared with the previous version,[1] both the prosthesis and the delivery system have several innovative features which simplify the procedure and should optimize clinical outcome. The prosthesis is currently available in 3 sizes: S (23 mm), M (25 mm), and L (27 mm). Three porcine pericardial leaflets with the BioFix anticalcification process are fixed in the nitinol stent covered with a sealing skirt. The delivery system is designed for flexible and intuitive positioning (FIGURE 1F). The position sheath is extended and the insertion aid is shortened. The 14F iSLEEVE Expandable Introducer has low profile which simplifies access and provides a smooth insertion even for small and complex arteries (≥5.5 mm). A radiopaque positioning marker determines clear visual positioning reference, crucial for a successful implantation. Enhanced tip design improves guidewire transition and tracking.

The major advantage of this valve is a new Active PVseal Technology designed to minimize PVL, especially in irregular and calcified valves. The prosthesis has inner and outer pericardial skirts and the extended sealing skirt covers the full waist of the stent. The rate of PVL was evaluated in 120 patients in the Acurate neo2 CE-Mark Study which was presented during the PCR London Valves in 2018[2] (30-day outcome) and at the Transcatheter Valve Therapies (TVT) Conference in 2019[3] (1-year outcome). The PVL rates were lower than reported for the previous Acurate neo prosthesis, with 97% of patients with none, trivial, or mild and only 3% with moderate PVL at 30 days, and 97.5% and 2.5% with none to mild and moderate PVL, respectively, in 1-year follow-up.

Since coronary angiography may be necessary in some patients after TAVI,[4,5] large open cells facilitate coronary access even in low coronary ostia. Several features of the prosthesis diminish the risk of pacemaker implantation (minimal protrusion into the left ventricular outflow tract and top-down deployment). Top-down deployment differs from the deployment of other prostheses. The prosthesis is released starting with the upper

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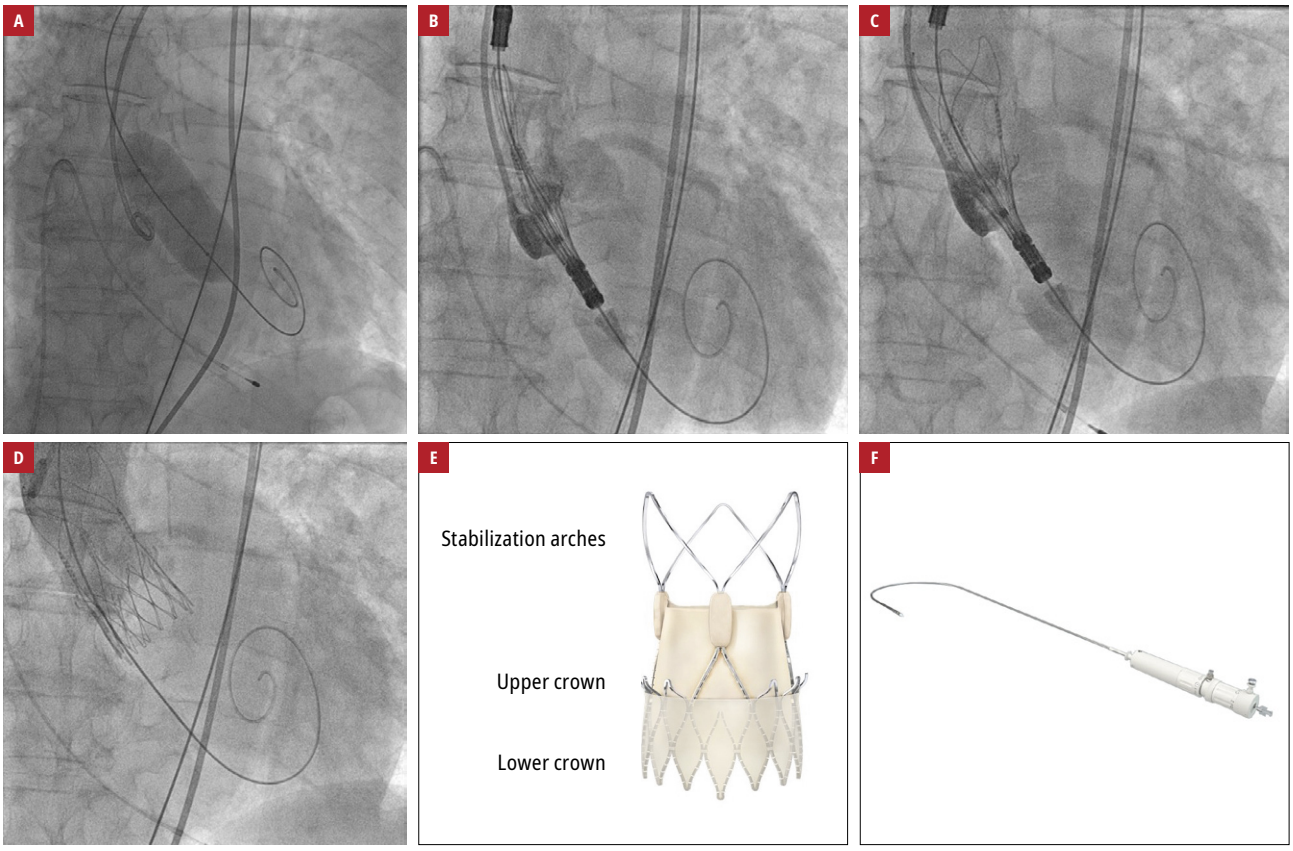

FIGURE 1 – The Acurate neo2 prosthesis and implantation stages; **A** – valve predilatation with the Osypka 24 mm × 400 mm balloon; **B** – Acurate neo2 after opening of the upper crown: confirmation of the proper position of the prosthesis; **C** – Acurate neo2 with fully opened stabilisation arches; **D** – Acurate neo2 after implantation: final angiogram; **E** – Acurate neo2 prosthesis; **F** – delivery system. Images **E**, **F** provided by courtesy of Boston Scientific. Copyright 2020 Boston Scientific Corporation or its affiliates. All rights reserved.

crown anchoring to the native valve leaflets, then the stabilization arches are deployed, which provide axial self-alignment within the native annulus, and finally, the lower crown is opened in the left ventricular outflow tract. Rapid pacing during deployment is not required. The prosthesis may be postdilated if necessary. Main limitation of the current version of the prosthesis is the lack of possibility to use it in bicuspid valves and in valves with parameters larger than 27 mm for the aortic annulus diameter and 85 mm for the perimeter.

ARTICLE INFORMATION

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