Navitor valve — a new TAVI solution for patients with aortic stenosis

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A 71-year-old man with a history of severely symptomatic aortic stenosis, peripheral artery disease, chronic coronary syndrome, after previous percutaneous coronary interventions and with end-stage kidney disease receiving dialysis, was admitted to our hospital. Echocardiography revealed a calcified aortic valve with mean and maximum gradients of 60 and 104 mm Hg, respectively, mild aortic regurgitation, moderate tricuspid regurgitation, severe secondary pulmonary hypertension, and mild contractility impairment with preserved left ventricular ejection fraction. Severe aortic valve calcification and narrowing atherosclerotic lesions in femoral arteries were shown on computed tomography (Supplementary material, *Figure S1*). The perioperative risk was high (logistic EuroSCORE 21.32; EuroSCORE II 4.1%) thus the heart team decided to qualify the patient for transcatheter aortic valve implantation (TAVI).

The procedure (the first one in Poland) was performed on June 9, 2021, in the hybrid room under local anesthesia. The left femoral artery access was achieved by the surgical cutdown and a 14 F sheath was inserted. After valve predilatation with Nucleus Z-Med II 23 mm × 4.0 cm balloon (NuMED, Hopkinton, NJ, USA) over Safari wire, the 29 mm Navitor valve (Abbott, Abbott Park, IL, USA) was successfully implanted with one reposition needed to obtain proper valve position (Figure 1). Since moderate paravalvular leak (PVL) was observed, postdilatation with Nucleus Z-Med II 26 mm × 4.0 cm balloon (NuMED, Hopkinton, NJ, USA) was performed with complete PVL elimination and mean transvalvular gradient decrease to 8 mm Hg (Supplementary material, *Figure S2*). The post-operative period was uneventful, without conduction disturbances, and the patient was discharged home on day 3.

TAVI is an established and safe therapeutic option for patients with severe aortic stenosis [1–3]. The self-expanding Navitor valve (successor of Portico valve) (Figure 1) is the newest TAVI solution for patients with severe aortic stenosis, which is available in Poland and some other European countries. The prosthesis has intra-annular leaflets and large frame cells, which enhances coronary access in case of future interventions and is currently available in four sizes: 23 mm, 25 mm, 27 mm, and 29 mm. The key innovation is an active outer fabric cuff designed to reduce the PVL risk by close integration to the native valve. The cuff actively synchronizes to the cardiac cycle and expands to fill calcification-related gaps between the aortic annulus and prosthesis. The Navitor is implanted using Abbott's FlexNav delivery system (Abbott, Plymouth, MN, USA) designed to improve flexibility and stability of the delivery even in patients with minimal femoral artery diameters (>5 mm). The low 14 F profile of the delivery system reduces vascular complication risks.

In our patient, the access was obtained through a surgical cut-down due to significant atherosclerotic changes in the femoral arteries, which is a standard of care in our center [4, 5]. One repositioning maneuver was easily obtained and, according to the manufacturer's recommendation, up to 3 attempts may be undertaken during the procedure.

The safety and efficacy of the new valve were evaluated in the Portico NG prospec-

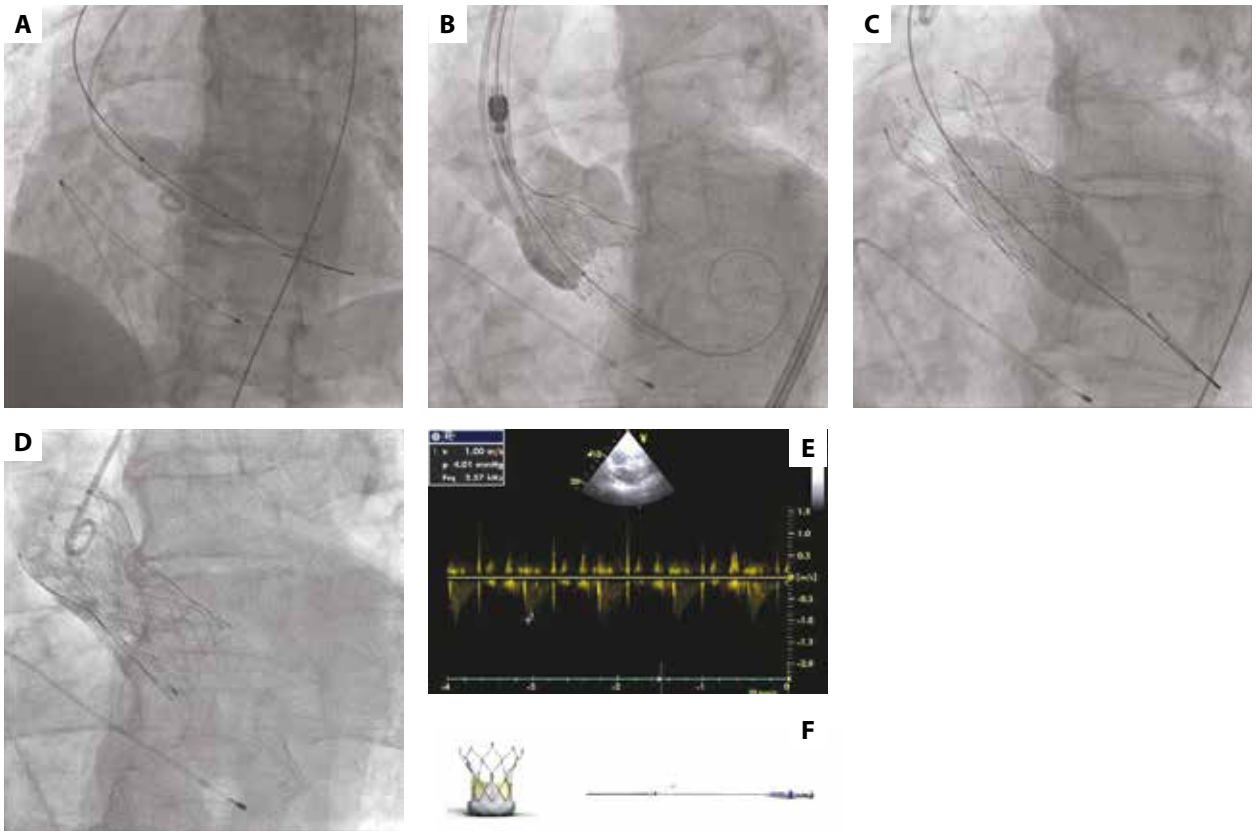

Figure 1. A. Native aortic valve predilatation with Nucleus balloon over Safari wire. **B.** Partially implanted Navitor valve — contrast injection showing proper implantation height and preserved flow to coronary arteries. **C.** Postdilatation of implanted Navitor valve in order to decrease the rate of paravalvular leak (PVL). **D.** Final aortogram showing the proper position of implanted valve with no PVL. **E.** ECHO examination after the procedure — low maximum transprosthesis gradient. **F.** Navitor transcatheter aortic valve implantation (TAVI) with FlexNav delivery system

tive, multi-center study conducted in 120 patients with high or extreme surgical risks. The first results of the trial were presented during EuroPCR 2021, showing 0% 30-day mortality with none or trace PVL in 80% of patients, with the remaining 20% showing only mild PVL — none had a moderate or severe leak. Moreover, effective orifice areas were comparable to supra-annular valves, and low single-digit gradients were noted. Fifteen percent of patients required pacemaker implantation after TAVI with Navitor, however, it should be pointed out that the majority of them had presented with pre-existing conduction disturbances. A 5-year long follow-up is ongoing. Moreover, the VANTAGE — an international, pre-market clinical trial in patients at low-to-intermediate risk has just started.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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