CLINICAL VIGNETTE

First implantation of the new Lotus Edge transcatheter aortic valve in Poland

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We present data on the first implantation of the Lotus Edge transcatheter aortic valve (FIGURE 1A and 1B) in Poland and other Central and Eastern European countries performed in our hospital on June 26, 2019.

A 78-year-old woman with a history of severe aortic stenosis after previous cardiac surgery in 2014 (biological mitral prosthesis and tricuspid valve ring implantation) complicated by third-degree atrioventricular block requiring implantation of VVI type pacemaker, with arterial hypertension, mild renal insufficiency, permanent atrial fibrillation (CHA_2DS_2-VASc score, 4 points; HAS-BLED score, 2 points) presented with dyspnea (New York Heart Association class III; N-terminal fragment of the prohormone brain natriuretic peptide, 2632 pg/ml) and chest pain. Coronary angiography was normal. Echocardiography revealed good ejection fraction with severe aortic stenosis and moderate aortic insufficiency (maximal aortic gradient, 82 mm Hg; mean aortic gradient, 53 mm Hg; aortic valve area, 0.6 cm^2), left ventricular hypertrophy, proper function of mitral valve prosthesis, and mild tricuspid insufficiency. Multislice computed tomography showed a moderately calcified tricuspid aortic valve with calcium extending into left ventricular outflow tract, aortic annulus perimeter of 65.1 mm and area of 329.1 mm^2, distance to coronary arteries was low, 8.9 mm on the left side, and quite good femoral access, although some calcifications were present at the puncture site. After considering the patient's past medical history and risk scores (EUROSCORE II [European System for Cardiac Operative Risk Evaluation II], 5.17%; STS [the Society of Thoracic Surgeons score], 5.324%), the Heart Team decided to refer the patient for transcatheter aortic valve implantation.

The procedure was done under general anesthesia with puncture of femoral arteries and preclosure technique. The 23-mm Lotus Edge valve (Boston Scientific, Marlborough, Massachusetts, United States) was successfully implanted over Safari guidewire (Boston Scientific) under transesophageal echocardiography and angio control to avoid interaction between an implanted transcatheter aortic valve and a mitral valve prosthesis. After implantation, the peak pressure gradient decreased to 5 mm Hg, and diastolic aortic pressure was 65 mm Hg. No paravalvular leak was detected (FIGURE 1C–1F).

The Lotus valve has been examined in several studies (REPRISE I, II-IIE, RESPOND) with remarkably low rate of paravalvular leaks (PVLs) (about 0.6% of patients displaying moderate to severe PVL); however, there was a relatively high need for permanent pacemaker implantation (24%–38% of pacemaker-naive patients).[1] More recently, the REPRISE III study has shown that Lotus valve was noninferior to self-expanding CoreValve / Evolut R (Medtronic, Minneapolis, Minnesota, United States).[2] The previous Lotus valve system was recalled from the market due to problems with the device's locking system.

The new Lotus Edge valve system consists, similarly to the previous version, of a braided single-wire nitinol frame with 3 bovine pericardial leaflets and features an adaptive polymer membrane seal at the lower half to reduce PVL. It is available in 3 sizes (23, 25, and 27 mm) and will also be obtainable in 21 and 29 mm in the near future.[3] The Lotus Edge delivery catheter

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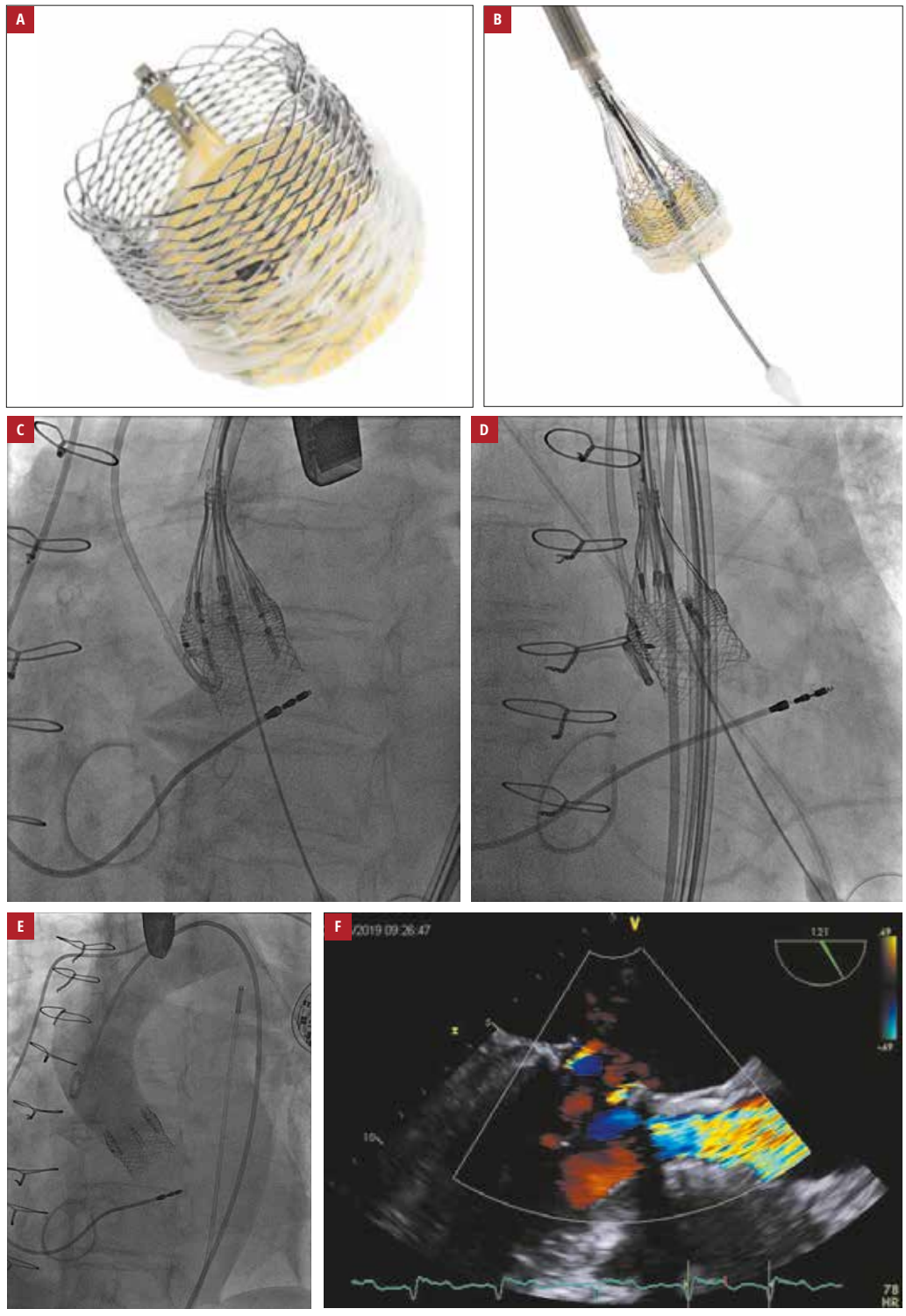

FIGURE 1 **A** – Lotus Edge valve; **B** – Lotus Edge valve attached to the delivery system; **C** – angiogram from the procedure showing the valve just before the final locking; **D** – angiogram from the procedure showing the valve after release; **E** – angiogram at the end of the procedure—no leak around the device; **F** – final transesophageal echocardiography showing good function of the transcatheter aortic valve and mitral valve bioprosthesis; **A** and **B** – reproduced with permission from Boston Scientific (Marlborough, United States)

has increased flexibility with an optimized pre-shape curve and reduced (by 3 French) proximal catheter profile. Guided by a marker, the device is mechanically expanded in the desired position and allows for full recapture and reposition after evaluation of the initial result and is locked after reaching the final position. Another new feature is the Depth Guard—modification to the delivery system with the aim to reduce the need for new pacemaker implantation (in RESPOND Extension, a significant reduction to 17.8% was observed).[3]

ARTICLE INFORMATION

CONFLICT OF INTEREST MG and Boston Scientific concluded a proctoring agreement. MG is a Boston Scientific Advisory Board Member and receives honoraria for lectures. Other authors do not report any conflict of interest.

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