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The new generation is coming. Percutaneous implantation of the fully repositionable Lotus® aortic valve prosthesis: the first Polish experience

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Abstract

Transcatheter aortic valve implantation (TAVI) is nowadays an accepted method of treatment for patients with symptomatic severe aortic stenosis who are inoperable or at very high risk of classic surgical aortic valve replacement. The Lotus valve system is a new generation TAVI device composed of a self-expanding stent prosthesis with implemented bovine pericardial leaflets, which is designed to facilitate repositioning, resheathing, and retrieval, even in the fully expanded and functioning position before the final release. In addition, the Lotus valve is surrounded by a flexible membrane to seal paravalvular gaps between the prosthesis and native valve. We present the first Polish experiences with the Lotus valve system. Due to its unique features, the Lotus valve may improve the prognosis in patients with inoperable or high risk critical aortic stenosis.

Key words: transcatheter aortic valve implantation, Lotus valve system

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is nowadays an accepted method of treatment for patients with symptomatic severe aortic stenosis who are deemed to be inoperable or at very high risk of classic surgical aortic valve replacement (AVR). Recent studies and registries confirmed the efficacy and relative safety of TAVI [1–3]. Some complications, such as paravalvular leakage (PVL), conduction abnormalities and device migration, are at least partially related to valve construction and positioning. Accurate placement of the current generation devices may be challenging and the ability of repositioning the prosthesis during implantation is limited. Moreover, the severe calcification of the valve may lead to the presence of paravalvular aortic regurgitation (PVL) in up to 47% of cases because of incomplete paravalvular sealing [1, 2, 4]. PVL, as has been shown, significantly deteriorates short and long term prognosis after TAVI procedure [2]. Therefore, new developments in transcatheter valve techniques are trying to address these technical issues.

The Lotus valve system (Boston Scientific, MA, USA) is a new generation device composed of a self-expanding stent prosthesis with implemented bovine pericardial leaflets, which is designed to facilitate repositioning, resheathing and retrieval, even in the fully expanded and functioning position before the final release. In addition, the Lotus valve is surrounded by a flexible membrane to seal paravalvular gaps between the prosthesis and native valve [5].

In this report we describe the first two cases of Lotus valve implantation in Poland.

DEVICE DESCRIPTION

The Lotus valve system consists of two components: the Lotus valve prosthesis, and the Lotus delivery catheter. The catheter is preshaped with a bend in the distal portion of the catheter to facilitate the passage through the aortic arch and positioning of the prosthesis within the native aortic valve. The prosthesis is squeezed and pre-loaded in the distal tip of the catheter. The Lotus valve prosthesis consists of bovine pericardial tissue valve leaflets with proven biocompatibility sutured to the braided, self-expanding nitinol frame (Fig. 1). The prosthesis has a triple configuration design: (1) longitudinal configuration — during device delivery when stretched in the delivery catheter which enables a small profile; (2) inter-

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Figure 1. The Lotus valve prosthesis. The bovine pericardial leaflets are sutured to the self-expanding nitinol frame. The lower part of the nitinol stent is surrounded by a flexible sealing membrane (adaptive seal) made by polyurethane

mediate configuration — pulling back the outer (sheath) catheter after passage of the native valve, the self-expanding structure shortens and expands radially, reducing its height and gaining radial force, and finally (3) the locked configuration — the prosthesis is opened and fully deployed. A wire mechanism allows for additional active stent compression to support the expansion forces. To secure this compressed state, the prosthesis is locked in this position using the three posts and buckles locking mechanism attached to the inner surface of the nitinol frame. At this point, the entire procedure is still reversible, with the ability to completely unlock and resheath the device with subsequent repositioning or removal. The central radiopaque marker localised in the middle of the frame facilitates the positioning of the valve. If the valve position is correct, the final release mechanism is activated which frees the prosthesis from the attached cables. The prosthesis is designed not to block the passage of blood through the aortic outflow during implantation. Therefore, there is no need for rapid ventricular pacing to establish a functional standstill, and valve implantation is haemodynamically well tolerated throughout the entire procedure (no blood pressure drop-out). At the outer surface the lower part of the nitinol frame is surrounded by a flexible sealing membrane (adaptive seal) made by polyurethane, which fills potential gaps between the prosthesis and native valve to minimise the PVL.

The Lotus valve system is, up till now available in two sizes. The 23 mm prosthesis allows insertion in annuli between 20 to 23 mm if other aortic root measurements are congruent. It is delivered via a 18 F femoral sheath over a 260 cm wire. The 27 mm prosthesis is suitable for annuli between 23 to 27 mm. It is delivered via a 20 F equivalent femoral sheath over a 300 cm wire. In the so-called locked position, the devices are 19 mm high and 23 mm or 27 mm wide.

CASE 1

An 83-year-old woman with severe aortic stenosis was referred to our institution for consideration of TAVI. She had a history of chest pain, dizziness and dyspnoea (New York Heart Association [NYHA] class IV), arterial hypertension and chronic kidney disease. She had undergone pulmonary oedema two months earlier and non-ST segment elevation myocardial infarction one month earlier, treated with percutaneous intervention of left anterior descending artery with drug eluting stent implantation. Moreover, critical stenosis of left internal carotid artery was found and percutaneous transluminal angioplasty of the artery with stent implantation was performed ten days before. Physical examination revealed in auscultation of the heart a loud systolic murmur. In transthoracic echocardiography, severe calcifications of aortic valve with severe stenosis (aortic valve area 0.6 cm^2, peak gradient 89 mm Hg, mean gradient 54 mm Hg) with mild regurgitation were shown. In multi-detector computed tomography (MDCT), the annulus diameter was 25 mm × 26.5 mm. She was deemed to be at high surgical risk by the Heart Team with high surgical risk scores (Society of Thoracic Surgeons' [STS] score of 4.99% and logistic EuroScore 53.4%, EuroScore II 9.79%).

The procedure was performed under general anaesthesia with transoesophageal echocardiographic assistance. The left femoral artery was cannulated under fluoroscopic guidance and the right femoral artery cannulated during contralateral contrast injection. The Prostar system (Abbott, IL, USA) was introduced and the sheath upsized to the small Lotus introducer. A balloon valvuloplasty was performed using a 20 mm × 40 mm Z-Med (Numed) balloon. The Lotus valve prosthesis was then deployed under fluoroscopic guidance by rotating the delivery knob counter clockwise. After careful evaluation of valve position and relations of posts and buckles, the prosthesis was released from the delivery catheter (Fig. 2). The final assessment by angiogram and echocardiography confirmed the stable position of the prosthesis without aortic regurgitation. The patient was discharged on day 6. After a one month follow-up, the patient's clinical status had improved significantly — she was NYHA class I/II, without chest pain.

CASE 2

An 88-year-old female patient with severe aortic stenosis (aortic valve area 0.9 cm^2, peak gradient 86 mm Hg, mean gradient 45 mm Hg) and a history of heart failure NYHA III, triple pulmonary oedema, previous myocardial infarction (ejection fraction 50%), percutaneous coronary intervention of the left anterior descending artery, diabetes type 2 on insulin and chronic kidney disease, was selected for TAVI after a Heart Team meeting due to the high risk of AVR (STS score 11%, logistic EuroScore 18.26%, EuroScore II 11%).

The procedure was conducted under general anaesthesia. The right and left femoral arteries were cannulated and then the Prostar system (Abbott, IL, USA) was introduced to the right femoral artery. The small Lotus introducer (18 F) and 270 mm delivery wire were used. Subsequently, balloon valvuloplasty was performed using a 20 × 18 mm Z-Med (Numed) balloon. The 23 mm Lotus delivery catheter was then advanced retrograde through the aorta without encountering difficulties while passing through the aortic arch. The catheter tip housing the Lotus valve was then introduced toward the left ventricle over the diseased native aortic valve. By pulling back the outer catheter (sheath), the Lotus valve was exposed. It expanded from the longitudinal configuration to the compressed state with radial expansion. After confirmation of the adequate prosthesis position, active compression followed by activation of the locking mechanism was applied. At this point, the device reached its final dimension with maximal radial force. The prosthesis was in optimal position within the native valve without compromising the coronary ostia and no evidence of paravalvular leaks, and then the device was released completely (Fig. 3).

Only mild PVL aortic regurgitation was shown in control aortography.

The patient was discharged on day 8. After a one month follow-up, she was in good general condition, NYHA class I.

DISCUSSION

We here describe the first Lotus valve implantations in Poland. The Lotus valve was designed to eliminate some disadvantages of the previous generation prostheses. First-in-man the valve was implanted in 2007 [6]. Subsequently its safety and efficacy were confirmed in the REPRISE I and II trials [5, 7]. It received CE marking in 2013.

The Lotus valve is deployed by manual unsheathing, where rotation of the delivery handle allows the device to shorten along its locking mechanism while radially expanding. This facilitates accurate device placement and allows the process to be performed without rapid ventricular pacing. If optimal positioning is not achieved initially, the ability to partially or fully re-sheath the prosthesis allows it to be repositioned and exact placement accomplished. This mechanism also affords the ability to examine the device in its final functioning position before the final release. Gooley et al. [8] described recently a case of full re-sheathing and retrieval of the Lotus valve to facilitate change in the prosthesis size. The authors stated that the unique design features of the valve are particularly useful in cases where appropriate size cannot be accurately determined on pre-procedural imaging.

The next advantage of the Lotus valve is an adaptive membrane surrounding the nitinol frame which fills the gaps between the prosthesis and the native valve. This reduces significantly PVL. In the REPRISE II trial (60 patients), the rates of mild and moderate aortic regurgitation were only 18.9%

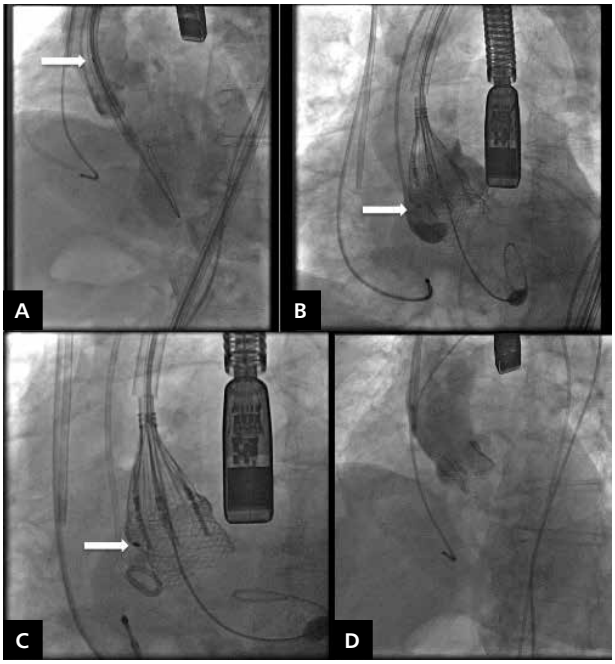

Figure 2. Angiographic images of the procedure in Case 1. Advancement of the Lotus delivery system over a guiding wire placed across the native aortic valve (**A**). White arrows — radiopaque marker localised in the middle of the frame facilitates the positioning of the valve. By pulling back the sheath, the self-expanding nitinol frame shortens and expands radially reducing its height and gaining radial force (**B**). After careful evaluation of the prosthesis position and relations of posts and buckles (**C**), the prosthesis was released from the delivery catheter (**D**)

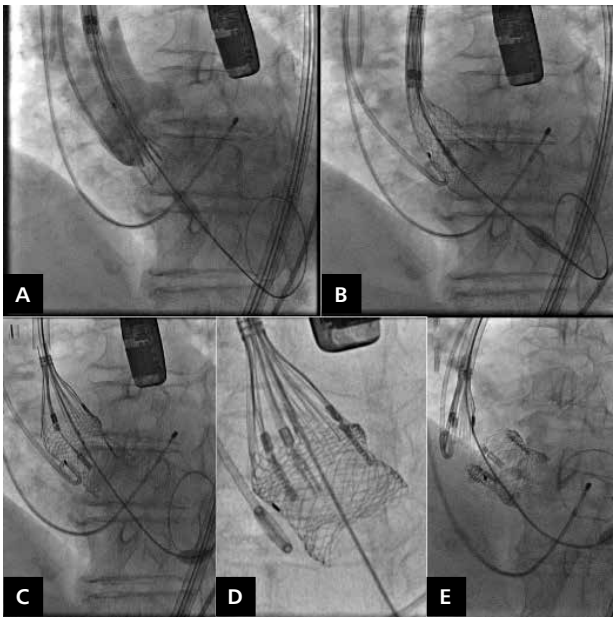

Figure 3. Images from Case 2. Opening the valve by pulling back the outer catheter (sheath) (**A**, **B**). The valve in an open position (**C**). Careful evaluation of the position of the posts and buckles is necessary (**D**). The prosthesis was then released completely (**E**)

and 1.9%, respectively [5]. No severe regurgitation was noted. This fact is of crucial importance and may significantly influence the prognosis in TAVI patients.

CONCLUSIONS

We have presented the first Polish experiences with the Lotus valve system. Due to its unique features, the Lotus valve may improve the prognosis in patients with inoperable or high risk critical aortic stenosis. Further studies are mandatory to confirm the device's clinical efficacy and safety in a real-life population.

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Nadchodzi nowa generacja. Przezskórna implantacja nowej, repozycjonowalnej protezy zastawki aortalnej Lotus®: pierwsze polskie doświadczenia

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Streszczenie

Przezskórne wszczepienie zastawki aortalnej (TAVI) jest obecnie uznaną metodą leczenia chorych z objawową ciężką stenozą aortalną z bardzo wysokim ryzykiem klasycznej chirurgicznej wymiany zastawki aortalnej. Proteza zastawki aortalnej Lotus Valve System jest urządzeniem TAVI nowej generacji. Składa się ona z samorozprężalnej protezy (stentu) z przytwierdzonymi płatkami wykonanymi z osierdzia wołowego. Konstrukcja protezy ułatwia wszczepienie, uwalnianie i ewentualnie przemieszczanie zastawki podczas implantacji i umożliwie prawidłową pracę płatków zastawki nawet przed końcowym uwolnieniem protezy. Ponadto zastawka Lotus jest otoczona elastyczną membraną do uszczelniania przecieków między protezą i pierścieniem zastawki aortalnej. W niniejszej pracy zaprezentowano pierwsze polskie doświadczenia z systemem Lotus. Ze względu na swoje unikalne cechy zastawka Lotus może poprawić rokowanie u pacjentów z nieoperacyjnym, krytycznym zwężeniem zastawki aortalnej.

Słowa kluczowe: przezskórne wszczepienie protezy zastawki aortalnej, zastawka Lotus

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