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Efficacy and safety of the Lotus Valve System for treatment of patients with severe aortic valve stenosis and intermediate surgical risk: Results from the Nordic Lotus-TAVR registry

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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) has become an established therapeutic option for patients with symptomatic, severe aortic valve stenosis (AS) who are ineligible or at high risk for conventional valvular surgery. In Northwestern Europe, the TAVR technology is also increasingly used to treat patients with an intermediate risk profile.

Methods and results: The study was designed as an independent Nordic multicenter registry of intermediate risk patients treated with the Lotus Valve System (Boston Scientific, MA, USA; N = 154). Valve Academic Research Consortium (VARC)-defined device success was obtained in 97.4%. A Lotus Valve was successfully implanted in all patients. There was no valve migration, embolization, ectopic valve deployment, or TAV-in-TAV deployment. The VARC-defined combined safety rate at 30 days was 92.2%, with a mortality rate of 1.9% and stroke rate of 3.2%. The clinical efficacy rate after 30 days was 91.6% — only one patient had moderate aortic regurgitation. When considering only those patients in the late experience group (N = 79), the combined safety and clinical efficacy rates were 93.7% and 92.4%, respectively. The pacemaker implantation rate was 27.9% — this rate was 12.8% in case of a combined implantation depth <4 mm and a device/annulus ratio < 1.05.

Conclusions: The present study demonstrates the efficacy and safety of the repositionable, retrievable Lotus Valve System in intermediate risk patients with AS. The VARC-defined device success rate was 97.4% with a 30-day patient safety and clinical efficacy rate of more than 90%. Less than moderate aortic regurgitation was obtained in 99.4% of patients.

1. Introduction

Transcatheter aortic valve replacement (TAVR) has become an established therapeutic option for patients with symptomatic, severe aortic valve stenosis (AS), who are ineligible or at high risk for conventional surgical aortic valve replacement (SAVR) [1–4]. In Northwestern Europe, the TAVR technology is also increasingly used to treat patients with an intermediate risk profile — this practice was recently supported by results from the NOTION trial indicating that TAVR is also a viable option for patients with a lower risk profile [5].

In the REPRISE I feasibility study [6] and prospective, single-arm REPRISE II CE-Mark trial [7], the safety and effectiveness of the new Lotus Valve System was studied in patients with severe AS who are at high surgical risk. In the current study, we aimed to study the real-world performance of the Lotus Valve System in patients with an intermediate risk profile.

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2. Methods

2.1. Data collection

The study was designed as an independent, Nordic multicenter voluntary registry of patients with severe AS and an intermediate surgical risk profile treated with the Lotus Valve System. Intermediate risk was defined as a Society of Thoracic Surgeons (STS) risk score ≥3 and <8, or EuroSCORE II ≥2 and <10. The local Heart Team reviewed all patients, and TAVR was offered in case of intermediate-to-high surgical risk based on STS score and/or EuroSCORE in combination with frailty score (Katz ADL score, 5 meter walk time, grip strength, albumin). In total, 232 patients were treated with the Lotus TAVR system in eight Nordic TAVR centers — of these, 154 patients had an intermediate surgical risk profile. Data on baseline patient characteristics, procedural variables and outcomes, echocardiographic parameters, and Valve Academic Research Consortium (VARC)-defined 30-day clinical outcomes [8] were collected up to August 2015. Follow-up data on adverse events were censored in September 2015. An informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.2. Device description

The Lotus Valve System (Boston Scientific, MA, USA, Fig. 1) has been described previously [9]. Briefly, the system includes a bioprosthetic aortic valve consisting of three bovine pericardial leaflets attached to a braided nitinol frame with a radiopaque marker and a catheter-based system for introduction and retrograde delivery via the femoral artery. Three valve sizes are available: 23 mm, 25 mm, and 27 mm. The valve is pre-attached to the delivery system. The valve is designed to expand radially as the valve shortens during deployment. An adaptive seal surrounds the inflow portion of the device and is designed to minimize paravalvular leak (PVL). The device is introduced through a dedicated 20 to 22 Fr introducer sheath using conventional percutaneous catheterization techniques or via a surgical cut-down.

2.3. Procedural steps

The majority of procedures were performed by transfemoral approach. After crossing the stenotic aortic valve and, in some cases, balloon valvuloplasty, the Lotus Valve System catheter is advanced across the annulus over a stiff guidewire (0.035-in.) and positioned so that the tip of the catheter is just on the ventricular side of the annulus. Unsheathing is initiated by rotating the control knob of the handle counter-clockwise. During unsheathing, the once-elongated valve frame shortens and radially expands, and the radiopaque marker advances from its initial position and moves towards the aortic annulus. Once in the optimal position, the operator manipulates the catheter to maintain marker position in the sinus of Valsalva — approximately 5 mm distal to the aortic annulus. While maintaining marker alignment, the operator continues to unsheath the valve, resulting in radial expansion and anchoring within the aortic annulus. At this stage, aortography and/or echocardiography are typically performed to evaluate valve position. Based on these assessments, the decision is taken to resheath and reposition the valve in case of suboptimal positioning or to lock the valve when optimal positioning is achieved. Once the valve is locked in the desired position, the release process can begin by sliding the release window and rotating the release collar clockwise, resulting in the release of the valve from the delivery catheter. The delivery catheter is then resheathed and the device is retracted through the introducer sheath.

Post-procedural antithrombotic regime was dual antiplatelet therapy for three to six months followed by aspirin life-long. In case of atrial fibrillation or other indications for anticoagulation, warfarin and clopidogrel was given for three to six months followed by life-long warfarin.

2.4. Statistics

Categorical variables are reported as absolute values and percentages (%). Continuous variables are presented as means ± standard deviation (SD) or median and range for perimeter-derived aortic annulus diameter. For the early safety and clinical efficacy endpoint at 30 days, a separate analysis was performed in which the first fifteen Lotus TAVR procedures performed in every centre were categorized as early experience. This additional analysis resulted in early experience (N = 75) and late experience (N = 79) outcome data. All statistical analyses were performed with SPSS version 20 (IBM Corp., USA).

3. Results

3.1. Patient population

The study population consisted of 154 intermediate risk patients treated with the Lotus Valve System in eight different Nordic centres. Four centres contributed more than 20 cases, whereas the other four centres had a volume of 10 or less Lotus TAVR cases at the moment of data collection (see Supplementary File 1). Baseline characteristics of the study population are shown in Table 1. Mean age was 82.2 ±

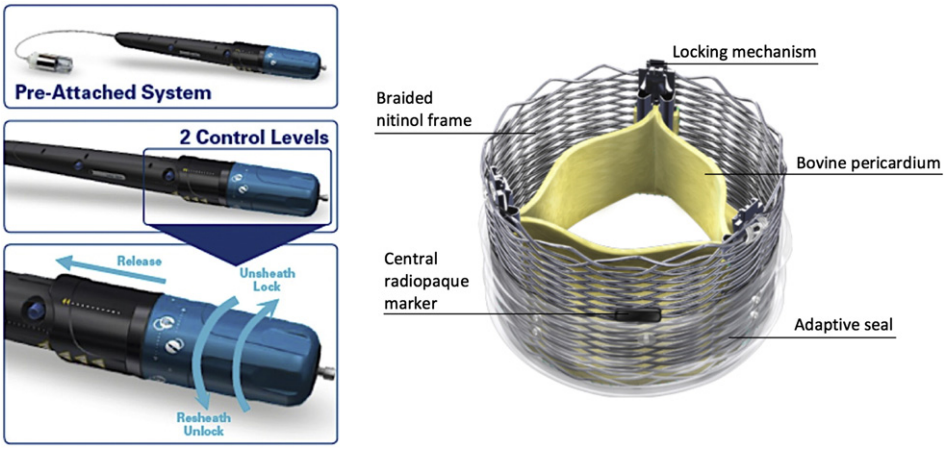

Fig. 1. The Lotus Valve System has three bovine pericardial tissue leaflets, a braided nitinol frame, a central radiopaque marker to aid positioning, and a polyurethane/polycarbonate outer seal designed to conform to irregular anatomic surfaces and minimize paravalvular leak. The braided structure shortens axially and expands radially during implantation and is locked in position using a post-and-buckle locking mechanism. This figure is used with permission from Boston Scientific, MA, USA.