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STRUCTURAL

Comparison of Self-Expanding and Mechanically Expanded Transcatheter Aortic Valve Prostheses

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ABSTRACT

OBJECTIVES The aim of this study was to determine whether transcatheter aortic valve replacement (TAVR) with the mechanically expanded Lotus valve (Boston Scientific, Natick Massachusetts) offers potential benefits over treatment with the self-expanding CoreValve (Medtronic, Minneapolis, Minnesota).

BACKGROUND New-generation transcatheter aortic valve systems are emerging in clinical trials and practice with design features aimed at improving safety and efficacy. To date, these devices have not been compared systematically with current-generation devices.

METHODS A total of 100 patients (83.4 ± 4.8 years of age, 44% male, Society of Thoracic Surgeons Predicted Risk of Mortality score of 5.5 ± 2.4) were assessed. Fifty consecutive patients undergoing a Lotus transcatheter aortic valve replacement were enrolled and compared with 50 matched patients treated with a CoreValve. An independent core laboratory reviewed all echocardiographic data, and an independent clinical events committee adjudicated all events.

RESULTS Valve Academic Research Consortium 2–defined device success was 84% and 64% in the Lotus and CoreValve cohorts, respectively ($p = 0.02$). This difference was driven by lower rates of moderate or greater aortic regurgitation (4% vs. 16.7%, respectively; $p = 0.04$) and higher rates of successfully implanting a single device in the correct anatomic position (100% vs. 86%, respectively; $p = 0.06$). Cardiovascular mortality rate (0% vs. 4%, respectively; $p = 0.32$), major stroke rate (4% vs. 2%, respectively; $p = 0.56$), and permanent pacemaker insertion rate (28% vs. 18%, respectively; $p = 0.23$) were not different at 30 days in the Lotus and CoreValve cohorts.

CONCLUSIONS In this matched comparison of high surgical risk patients undergoing transcatheter aortic valve replacement, the use of the Lotus device was associated with higher rates of Valve Academic Research Consortium 2–defined device success compared with the CoreValve. This was driven by higher rates of correct anatomic positioning and lower incidences of moderate paraprosthetic regurgitation. The clinical significance of these differences needs to be tested in a large randomized, controlled trial. (J Am Coll Cardiol Intv 2015;8:962–71) © 2015 by the American College of Cardiology Foundation.

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Transcatheter aortic valve replacement (TAVR) has proved to be a safe and effective treatment for severe aortic stenosis in appropriately selected high and extremely high surgical risk patients (1,2). Since its inception in 2002 (3), TAVR has gained wide acceptance and clinical approval in many countries on the basis of a rapidly growing body of evidence. As a result, adoption of the technology and implant rates have grown nearly exponentially (4,5).

Most global TAVR experience has been obtained with either the Edwards SAPIEN or SAPIEN XT (Edwards Lifesciences, Irvine, California) or the Medtronic CoreValve device, (Minneapolis, Minnesota); however, a growing number of next-generation prostheses are now entering clinical trials and routine practice (6–9). Most of these devices incorporate novel features designed to reduce the modest yet important complications identified with current-generation devices. Data supporting enhanced safety and efficacy of new-generation devices, however, are modest and derived from single-arm studies.

The CoreValve Revalving System (Medtronic) is a self-expanding device fashioned from nitinol wire. The distinctive frame has a flared inflow portion to anchor in the native annulus, a constrained midsegment to avoid coronary obstruction, and a flared outflow portion to improve coaxial alignment to the aortic flow plane. In a U.S. pivotal trial, the CoreValve was found to have a significantly higher survival rate at 1 year than surgical valve replacement in a high-risk cohort (10). These results mirror favorable safety and efficacy data from large single-center (11,12), national (13–15), and multinational (16) registries.

The Lotus device (Boston Scientific, Natick, Massachusetts) is a new TAVR device that uses a unique mechanical expansion mechanism. It is made of a single braided nitinol wire and 3 bovine pericardial leaflets. The outer surface of the lower half of the frame is covered with an adaptive seal, essentially a polymer membrane that concertinas as the device is expanded and, in doing so, occupies any small residual interstices, sealing the frame against the native aortoventricular interface (8,17). This has been reported to reduce the rate of paraprosthetic aortic regurgitation (PAR). The device is fully repositionable and resheathable, even in the completely expanded position, allowing for fine control and the potential for removal should the device position or size be deemed suboptimal. The Lotus device was studied in the REPRISE I (Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus™ Valve System) (18), the REPRISE II (Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus™ Valve System—Evaluation of Safety and Performance) (19), and REPRISE II Extension single-arm trials.

Although there has been an adoption of new devices such as the Lotus at some centers, to date, there have been no systematic head-to-head comparisons, with independent core laboratory assessments, of devices to accurately determine their relative safety and efficacy.

ABBREVIATIONS AND ACRONYMS

EOA = effective orifice area

MDCT = multidetector computed tomography

PAR = paraprosthetic aortic regurgitation

TAVR = transcatheter aortic valve replacement

TTE = transthoracic echocardiography

VARC2 = Valve Academic Research Consortium 2

METHODS

STUDY POPULATION. A total of 100 patients (mean age, 83.4 ± 4.8 years, 44% male) with symptomatic severe aortic stenosis were included in this study. Fifty consecutive and prospectively enrolled patients receiving a Lotus transcatheter device were compared with 50 matched patients who had undergone TAVR with the CoreValve device during the same period.

All patients were treated at a single Australian center. All patients were deemed to be at high or extremely high surgical risk because of an increased Society of Thoracic Surgeons Predicted Risk of Mortality score (higher than 8) and/or the collective opinion of the institution's Heart Team after a comprehensive history, examination, and frailty assessment (dominant hand-grip strength, 5-m gait speed, and serum albumin). Patients were eligible for inclusion if they had severe aortic stenosis based on echocardiographic criteria (mean transaortic gradient ≥40 mm Hg or aortic velocity ≥4 m/s and an aortic valve area ≤1 cm^2 or indexed aortic valve area ≤0.7 cm^2/m^2) and reported symptoms attributable to severe aortic stenosis (**Table 1**).

All patients were assessed in a systematic and standardized manner beginning with their attendance and clinical evaluation at our Structural Heart Disease Clinic. All patients underwent multidetector computed tomography (MDCT), transthoracic echocardiography (TTE), invasive angiography, and right heart catheterization before inclusion. Only patients who had MDCT annular sizing that allowed for treatment with either device (according to the respective instructions for use) and were treated via the femoral access route were considered suitable for the study. Patients were matched on age, sex, Society of Thoracic Surgeons score, and frailty indexes.

PRE-PROCEDURAL MDCT ASSESSMENT. All patients underwent prospectively electrocardiography-gated,