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1-Year Outcomes With the Fully Repositionable and Retrievable Lotus Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis

Results of the REPRISE II Study

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ABSTRACT

OBJECTIVES This analysis presents the first report of 1-year outcomes of the 120 patients enrolled in the REPRISE II (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System-Evaluation of Safety and Performance) study.

BACKGROUND The fully repositionable and retrievable Lotus Valve (Boston Scientific, Marlborough, Massachusetts) was designed to facilitate accurate positioning, early valve function, and hemodynamic stability during deployment and to minimize paravalvular regurgitation in patients undergoing transcatheter aortic valve replacement.

METHODS The study enrolled 120 symptomatic patients 70 years of age or older at 14 centers in Australia and Europe. Patients had severe calcific aortic stenosis and were deemed to be at high or extreme risk of surgery based on assessment by the heart team.

RESULTS The mean age was 84.4 ± 5.3 years, 57% (68 of 120) of patients were women, and the mean Society of Thoracic Surgeons score was 7.1 ± 4.6. The mean baseline aortic valve area was 0.7 ± 0.2 cm^2, and the mean transvalvular pressure gradient was 46.4 ± 15.0 mm Hg. All patients were successfully implanted with a Lotus Valve, and 1-year clinical follow-up was available for 99.2% (119 of 120 of patients). The mean 1-year transvalvular aortic pressure gradient was 12.6 ± 5.7 mm Hg, and the mean valve area was 1.7 ± 0.5 cm^2. A total of 88.6% patients had no or trivial paravalvular aortic regurgitation at 1 year by independent core lab adjudication, and 97.1% of patients were New York Heart Association functional class I or II. At 1 year, the all-cause mortality rate was 10.9% (13 of 119 patients), disabling stroke rate was 3.4% (4 of 119 patients), disabling bleeding rate was 5.9% (7 of 119 patients), with no repeat procedures for valve-related dysfunction. A total of 31.9% (38 of 119 patients) underwent new permanent pacemaker implantation at 1 year.

CONCLUSIONS At 1 year of follow-up, the Lotus Valve demonstrated excellent valve hemodynamics, no moderate or severe paravalvular regurgitation, and significant and sustained improvement in New York Heart Association functional class status, with good clinical outcomes. (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System-Evaluation of Safety and Performance [REPRISE II]; NCT01627691) (J Am Coll Cardiol Intv 2016;9:376-84) © 2016 by the American College of Cardiology Foundation. Published by Elsevier. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

The repositionable and fully retrievable Lotus Valve (Boston Scientific, Marlborough, Massachusetts) was designed to facilitate accurate primary positioning, early valve function, and hemodynamic stability during deployment and to minimize paravalvular regurgitation in patients with severe aortic stenosis who are deemed at high or extreme surgical risk (1). The Lotus Valve has received CE mark in Europe based in part on the initial results of the REPRISE II (Repositionable Percutaneous Placement of Stenotic Aortic Valve Through Implantation of Lotus Valve System-Evaluation of Safety and Performance) study (2). At 30 days, the mean aortic valve pressure gradient was 11.5 ± 5.2 mm Hg, with a 1-sided 98.7% upper confidence limit of 12.6, which was significantly less than the predetermined performance goal of 18 mm Hg (1-sample *t* test, $p < 0.0001$), and, thus, the primary device performance endpoint was met. The primary safety endpoint, defined as all-cause mortality at 30 days, was 4.2% (5 of 119 patients). The observed rate of moderate or severe paravalvular regurgitation was low at 30 days, with only 1 patient (1.0%) having moderate paravalvular regurgitation and no patients having severe paravalvular regurgitation (2). This analysis of the 120-patient REPRISE II study presents the first publication of 1-year outcomes with the Lotus Valve in a substantial number of patients.

SEE PAGE 385

METHODS

The REPRISE II study design and methods were previously described in detail and are briefly summarized here (2).

DEVICE DESCRIPTION. The Boston Scientific Lotus Valve System consists of a woven nitinol-framed bioprosthesis with bovine pericardium leaflets, which is pre-mounted on a transfemoral catheter delivery system. The valve is expanded via a controlled mechanical expansion that facilitates repositioning or full retrieval even after the valve is fully expanded and locked in its final position; rapid pacing is not required during implantation, and the valve functions early in deployment, providing hemodynamic stability. The design also incorporates a polymeric outer Adaptive Seal designed to minimize paravalvular regurgitation. The Lotus Introducer Set is composed of a dilator and an introducer sheath and is used as an accessory in the procedure. Two valve sizes were available in the REPRISE II study: 23 mm (for patients with a native aortic annulus of 19 to 23 mm) and 27 mm (for patients with a native aortic annulus of 23 to 27 mm).

ABBREVIATIONS AND ACRONYMS

NYHA = New York Heart Association

SF-12 = 12-Item Short-Form Health Survey

TAVR = transcatheter aortic valve replacement

TTE = transthoracic echocardiography

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