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Surgical Sutureless and Transcatheter Aortic Valves

Hemodynamic Performance and Clinical Outcomes in Propensity Score-Matched High-Risk Populations With Severe Aortic Stenosis

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ABSTRACT

OBJECTIVES In propensity score–matched patients with severe aortic stenosis treated with surgical aortic valve replacement (AVR) with the 3f Enable sutureless prosthesis (Medtronic, Minneapolis, Minnesota) or transcatheter aortic valve replacement (TAVR), the hemodynamic performance of both valves and mid-term survival of patients were evaluated.

BACKGROUND Data on hemodynamic performance of surgical sutureless bioprostheses in high operative risk patients with aortic stenosis are scarce.

METHODS Of 258 patients undergoing TAVR or surgical aortic valve replacement with the 3f Enable valve, 80 (79 ± 5 years of age, 100% men) were included in the current analysis on the basis of propensity score 1:1 matching for baseline clinical and hemodynamic characteristics. All patients had hemodynamic echocardiographic evaluation at baseline and discharge. Mid-term survival was analyzed.

RESULTS Compared with the 3f Enable valve, TAVR prostheses (Edwards SAPIEN XT [Edwards Lifesciences, Irvine, California] and CoreValve [Medtronic]) had larger effective orifice area index (1.00 ± 0.30 cm^2/m^2 vs. 0.76 ± 0.22 cm^2/m^2; $p < 0.001$), lower pressure gradient (8.14 ± 4.21 mm Hg vs. 10.72 ± 4.01 mm Hg; $p = 0.006$), less frequent prosthesis-patient mismatch (30.0% vs. 67.5%; $p = 0.001$), and low flow (46.2% vs. 72.5%; $p = 0.02$), but more frequent aortic regurgitation (87.5% vs. 20.0%; $p < 0.001$). The presence of prosthesis-patient mismatch was independently associated with a low-flow state at discharge (odds ratio: 4.70; $p = 0.004$) and independently associated with the use of the sutureless prosthesis (odds ratio: 3.90; $p = 0.02$). However, the survival of the 2 groups was comparable after 1.5-year (interquartile range: 0.79 to 2.01 years) follow-up (log-rank test, $p = 0.95$).

CONCLUSIONS TAVR prostheses demonstrated better hemodynamics than the 3f Enable valve but a higher incidence of aortic regurgitation. However, these differences did not influence mid-term survival of patients. (J Am Coll Cardiol Intv 2015;8:670–7) © 2015 by the American College of Cardiology Foundation.

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In patients with severe aortic stenosis and high operative risk, transcatheter aortic valve replacement (TAVR) has been shown to be noninferior to conventional surgical aortic valve replacement (AVR) when using the balloon-expandable Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California) and superior to surgical AVR when using the self-expandable CoreValve (Medtronic, Minneapolis, Minnesota) (1-3). Recently, surgical AVR with sutureless prostheses offers minimal surgical access, reduced aortic cross-clamping, and cardiopulmonary bypass times compared with classic surgical replacement, and, in contrast to TAVR, the native calcified valve is removed (4-6). In patients with severe aortic stenosis and high operative risk, perioperative complications and in-hospital mortality associated with surgical AVR using sutureless valves are comparable to those with TAVR (4,6,7). Compared with stentless aortic bioprostheses, TAVR prostheses have demonstrated superior hemodynamics (8). However, little

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is known about the hemodynamics of sutureless valves in comparison with TAVR prostheses. In propensity score-matched populations, the present evaluation compared the hemodynamic performance of the sutureless 3f Enable valve (Medtronic, Minneapolis, Minnesota) (**Figure 1**) and transcatheter valves (SAPIEN XT and CoreValve). In addition, the midterm survival of patients undergoing surgical sutureless AVR and patients treated with TAVR was evaluated.

METHODS

IDENTIFICATION OF PATIENTS. Patients with symptomatic severe aortic stenosis (aortic valve area index <0.6 cm^2/m^2) (9) who were treated according to the Heart Team (10) with surgical AVR using the 3f Enable valve or with TAVR at the Leiden University Medical Centre between November 2007 and February 2013 were evaluated. Only patients with a successful procedure, defined as no immediate procedural mortality within 72 h post-procedure (11), were considered eligible for the current analysis. The immediate procedural mortality rate was 2% for surgical AVR using the 3f Enable and 4.5% for TAVR. The Institutional Review Board of the Leiden University Medical Center approved this retrospective analysis of clinically acquired data and waived the need for written patient informed consent.

PROSTHESIS SELECTION AND REPLACEMENT. TAVR was performed according to current recommendations (12). The type of valve, Edwards SAPIEN XT or CoreValve, the size of valve and implantation access (transfemoral or transapical) were selected before the procedure on the basis of the multidetector row computed tomography measurements (13).

Surgical sutureless AVR was performed as recently described (4). The 3f Enable sutureless bioprosthesis was implanted and deployed after a medial sternotomy via a transverse aortotomy and after excision of the native valve and decalcification of the aortic annulus (5,14,15). The size of the valve (19, 21, 23, 25, or 27 mm) was selected during the procedure, on the basis of aortic annulus direct observation and measurement with surgical calipers of standard diameter (5).

HEMODYNAMIC ASSESSMENT WITH ECHOCARDIOGRAPHY. Transthoracic echocardiography was performed at baseline (pre-AVR) and at hospital discharge. Using continuous wave Doppler, the peak velocity through the valve (native and bioprosthesis) and the mean transvalvular pressure gradient were obtained, and the aortic valve area of the native valve and the

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation

AVR = aortic valve replacement

CI = confidence interval

OR = odds ratio

PPM = patient-prosthesis mismatch

SVi = stroke volume index

TAVR = transcatheter aortic valve replacement

FIGURE 1 3f Enable Aortic Root Bioprosthesis

The valve consists of a self-expanding nitinol frame and 3 equine pericardial leaflets that form a tube, preserving the aortic sinuses and restoring native stress distribution. Reprinted with permission from Medtronic Inc.