North American single-center experience with a sutureless aortic bioprosthesis

Benoit de Varennes, MD,[a] Kevin Lachapelle, MD,[a] Renzo Cecere, MD,[a] Isabel Szczepkowski, RN,[a] and Jean Buithieu, MD[b]

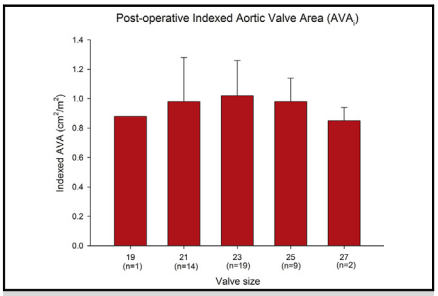
ABSTRACT

Objective: Surgical sutureless aortic valves have the potential for shorter procedural times and could benefit patients with increased risk. The Enable (Medtronic Inc, Minneapolis, Minn) valve is a bioprosthesis housed in a Nitinol cage allowing folding and deployment once implanted. We aimed to evaluate the early clinical and echocardiographic results with the Enable valve.

Methods: Patients with aortic stenosis, Society of Thoracic Surgeons score greater than 5.0%, the need for combined procedures, and frailty were considered for Enable implantation.

Results: Between August 2012 and October 2014, 63 patients underwent implantation of the Enable valve (Medtronic Inc, Minneapolis, Minn). Thirty patients underwent isolated aortic valve replacement. Combined procedures were aortic valve replacement/coronary artery bypass grafting (26), aortic valve replacement/mitral valve repair (2), aortic valve replacement/mitral valve repair/coronary artery bypass grafting (2), and aortic valve replacement/ascending aortic graft (3). Predicted Society of Thoracic Surgeons score was 8.06 ± 7.73 (0.94-41.30). Implant success was 100%. Mean crossclamp time for isolated aortic valve replacement was 44 ± 14 minutes (30-91). Thirty-day mortality was 1.6% (1/63), and late mortality was 3.2% (2/62). No mortality was valve related. Intraoperative need for revision was 6.3% (4/63). Early migration requiring reoperation occurred in 1.6% of patients (1/63). Postoperative indexed aortic valve area was 1.08 ± 0.22 cm^2/m^2, and peak and mean gradients were 17 ± 7 mm Hg and 9 ± 4 mm Hg, respectively. The rate of complications was as follows: pacemaker 3.1% (2/63), transient ischemic attack 1.6% (1/63), other thromboembolic events 0%, bleeding 0%, and endocarditis 0%. Mean follow-up was 10 ± 8 months. At latest follow-up, 61 patients were in New York Heart Association class I. Moderate or severe aortic regurgitation did not develop in any patients in the follow-up period.

Conclusions: The Enable bioprosthesis is an acceptable alternative to conventional aortic valve replacement in higher-risk patients. The early hemodynamic performance seems favorable. (J Thorac Cardiovasc Surg 2015;■:1-8)



The AVA$_i$ (cm^2/m^2) of the Enable (Medtronic Inc, Minneapolis, Minn) aortic bioprosthesis according to size.

Central Message

The Enable (Medtronic Inc, Minneapolis, Minn) bioprosthesis can be inserted safely and reproducibly in high-risk patients and offers excellent hemodynamic performance.

Perspective

With increasing risks of patients requiring AVR, a need for shorter clamp time and ease of less-invasive procedures have arisen. Sutureless aortic bioprostheses have the potential for faster implantation via minimally invasive approaches with the hemodynamic features of stentless valves. As these valves are gaining popularity in Europe, there has been little experience in the United States.

ACD

Aortic valve replacement (AVR) remains the gold standard for the treatment of severe or symptomatic aortic stenosis. Despite significant improvements in the design of surgical valve prostheses and cardiac surgical technique, patients with comorbidities such as advanced age, frailty, poor ventricular function, pulmonary disease, and associated cardiac pathologies continue to have high mortality and morbidity when subjected to open surgical treatment.[1,2] Transcatheter aortic valve implantation (TAVI) is a recent addition to our armamentarium and is an acceptable alternative to surgical AVR in patients deemed inoperable or at high surgical risk.

Despite encouraging early clinical results and excellent hemodynamic performance, long-term durability (>5 years) data for TAVI have yet to be demonstrated, and the issue of the long-term consequences of retaining calcified native aortic valve tissue requires further study. Newer stentless surgical aortic bioprostheses have the potential for superior

From the Divisions of [a]Cardiac Surgery and [b]Cardiology, McGill University Health Centre, Montreal, Québec, Canada.

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Address for reprints: Benoit de Varennes, MD, McGill University Health Centre, 687 Pine Ave West Suite S8-86, Montreal, Québec, Canada H3A 1A1 (E-mail: benoit.devarennes@muhc.mcgill.ca).

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Abbreviations and Acronyms

AVA_i = indexed aortic valve area
AVR = aortic valve replacement
NYHA = New York Heart Association
STS = Society of Thoracic Surgeons
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography

hemodynamics because of the absence of the obstructive elements of stented valves, but they remain surgically more challenging. The ATS 3*f* Enable Aortic Bioprosthesis Model 6000 (Medtronic Inc, Minneapolis, Minn) is a stentless, equine pericardial valve supported by a self-expanding Nitinol frame covered with a thin polyester fabric at the level of contact with the native annulus. Outward radial expansion forces against the annulus keep the prosthesis in place, similar to a TAVI prosthesis. Single or double guiding sutures are used to position and maintain the valve in place during deployment. Long-term stabilization of the valve is achieved by tissue ingrowth at the annular level. Because the only contact area necessary for stabilization is at the annulus, the valve performance is not affected by aortic root dilatation. As opposed to TAVI, complete surgical debridement of the diseased native valve is routinely performed because the presence of residual calcium is not necessary for valve stabilization.

The first human Enable implant was performed in Poland in 2005.[3] Since the initial report, European studies have reported good early and intermediate results and note a reduction in both crossclamp and bypass times after implantation of the Enable valve.[4-7] The valve is especially well suited for minimally invasive approaches. Because the Enable valve is not yet commercially available in the United States or Canada, no North American data have been available for comparison. Through applications to the Special Access Program of Health Canada, we received authorization to use the Enable valve in patients who were deemed to present a high procedural risk with standard, sutured AVR or who were not TAVI candidates. We report the results of the first North American, single-center experience with the Enable valve implanted in a high-risk cohort of patients.

MATERIALS AND METHODS

Patients

A total of 63 patients were enrolled in this retrospective, single-center, nonrandomized study. Participants underwent operation at the McGill University Health Centre between August 2012 and October 2014. The study was approved by the McGill University Health Centre Ethics committee.

Individual requests for authorization to implant the Enable valve were reviewed by members of the Special Access Program of Health Canada for each patient considered a candidate. Each patient was informed of the status of the device in Canada and had to agree to receive the valve. Patients requiring AVR with or without concomitant procedures were considered candidates for the Enable prosthesis if the preoperative Society of Thoracic Surgeons (STS) predicted mortality risk was 5.0% or greater. Other inclusion criteria involved patient comorbid conditions (physical disabilities, morbid obesity, chronic pulmonary disease, immunosuppression, frailty) for which a shorter cardiopulmonary bypass time or a minimally invasive approach would potentially reduce perioperative complications. Patients who were turned down for TAVI by the Heart Team were also considered for Enable implantation.

Exclusion criteria were the presence of active endocarditis, sinotubular junction diameter smaller than annular diameter, presence of previous proximal coronary graft anastomoses at an aortic level precluding a high aortotomy, severe annular dilatation (left ventricular outflow tract >27 mm, aortic root diameter >4.5 cm), and connective tissue disorders (Marfan, Ehlers–Danlos, Loeys–Dietz syndromes).

Procedure

The surgical approach was through a full sternotomy or a partial upper sternotomy into the fourth intercostal space. Perioperative transesophageal echocardiography (TEE) was used in all patients. After central aortic and atrial cannulation, cardiopulmonary bypass was instituted and cold blood cardioplegic arrest was achieved. A high transverse aortotomy (2-4 cm above the sinotubular junction, depending on the valve size estimated by TEE or visual inspection of the aorta) was performed, and the native valve was completely excised. The annulus was carefully debrided, and small defects, if any, were closed by 4-0 monofilament sutures. Careful sizing of the native annulus was performed keeping in mind that a 2- to 3-mm gap between the sizer and the native annulus is necessary to allow for the 6.0 mm expansion of the prosthesis that will occur after full deployment. During preparation of the prosthesis, 1 or 2 guiding sutures (4-0 Prolene, Ethicon Inc, Somerville, NJ) were passed through the nadir of the noncoronary cusp annulus (1 guiding suture) and the nadir of the left coronary cusp annulus (second guiding suture). Once the folded valve was brought into the surgical field, the guiding suture was passed through the inflow cuff of the prosthesis that was then delivered into position. Warm saline flushing and manual expansion were used to promote full deployment of the prosthesis against all portions of the native annulus. If the prosthesis was improperly positioned, cold saline flush allowed for in situ refolding and the valve was pulled out and repositioned as described earlier. After visual confirmation of the proper position of the valve, the aortotomy was closed.

TEE assessment was performed after weaning from cardiopulmonary bypass to assess proper positioning and presence and severity of aortic regurgitation and transvalvular gradients. Patients received low-dose aspirin only if they had associated coronary artery disease or underwent concomitant coronary artery bypass grafting. Warfarin was administered only to patients who had atrial fibrillation or a mechanical mitral prosthesis.

Follow-up

Transthoracic echocardiography was performed at the time of hospital discharge, at 3 to 6 months, at 11 to 15 months, and annually thereafter. Hemodynamic parameters were assessed via transthoracic echocardiography by 2-dimensional M-mode, pulsed-wave, and color-flow imaging. Echocardiograms were obtained at McGill University Health Centre or the referring center. Clinic visits with the treating surgeon were done at the same intervals. Data were collected by a research nurse.

Statistical Analysis

For general demographic, clinical, and operative data, descriptive statistical methods were used and expressed as mean ± standard deviation. Categoric variables are presented as numbers with percentages.

RESULTS

Between August 2012 and October 2014, 63 patients (54% were male, 46% were female) underwent AVR