Two Hundred Consecutive Implantations of the Sutureless 3f Enable Aortic Valve: What We Have Learned

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Background. In this article we present a consecutive single-center experience of implantation of the Medtronic 3f Enable aortic valve (Medtronic Inc, Minneapolis, MN).

Methods. Between March 2011 and October 2014, 200 consecutive patients (mean age, 76.4 ± 5.9 years; logistic EuroScore, 7.8% ± 7.0%) in our unit received the 3f Enable valve. This is a retrospective analysis of this prospective monocentric cohort.

Results. The 3f Enable valve could be implanted in all the scheduled 141 isolated aortic valve replacement (AVR) procedures (14 full sternotomies, 73 ministernotomies, 44 minithoracotomies, and 10 thoracoscopic approaches) and 59 combined procedures (all using full sternotomy). Reclamping was necessary in 7 (3.5%) patients (paravalvular leakage [PVL] was ≥ grade 1 because of undersizing or prosthetic misalignment); mean cross-clamp and cardiopulmonary bypass (CPB) times were 65 ± 31 and 91 ± 39 minutes, respectively. Sixteen (8%) patients required early implantation of a pacemaker (PM). At a mean follow-up of 12.6 ± 8.1 months, mean transvalvular gradient and effective orifice area (EOA) were 9.8 ± 4.4 mm Hg and 1.87 ± 0.6 cm^2, respectively. Mild PVL was present in 7 (3.5%) patients and moderate PVL was present in 5 (2.5%) patients. No device migration was registered, and no moderate PVL was detected in the last 100 patients of the cohort. Overall, 3-year survival was 78%.

Conclusions. The 3f Enable valve shows excellent results regarding PVL but in our experience required a learning curve and a refinement of the technique of implantation. Use of the prosthesis was possible in various less invasive approaches.

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Aortic valve replacement (AVR) is widely accepted as the treatment of choice for aortic valve disease, with excellent long-term results. Because of increasing patient age and comorbidities, alternative techniques have been developed such as transcatheter aortic valve implantation (TAVI) [1] and surgical sutureless (SU) valves [2–4]. The transcatheter option is now becoming the first-line treatment in high-risk surgical patients [5], and very encouraging results are being seen with the use of third-generation devices [6–8]. However, beyond a significant reduction of moderate paravalvular leakage (PVL), TAVI still presents a significant incidence of mild regurgitation and of atrioventricular blocks. Also, a silent and apparent neurologic injury after TAVI is under evaluation before its extension to lower-risk patients [9].

In contrast, new therapeutic tools have been introduced into the surgical armamentarium of AVR: SU bioprostheses. Their advantages are the rapidity of implantation in surgical settings in which stitch passage and knots are technically demanding (eg, minimally invasive operations [10–12], a hypercalcified aortic root [13, 14], and redo operations [15]) and the excellent hemodynamics enhanced by the expansion of the frame of the prosthesis in the decalcified native aortic annulus [16]. The current report describes our experience with implantation of the SU 3f Enable aortic bioprosthesis and is the largest report concerning this model of SU valve.

Patients and Methods

Patient Population

Between March 2011 and October 2014, 200 consecutive patients underwent AVR with an SU 3f Enable bioprosthesis. Exclusion criteria were recent endocarditis, aneurysmal dilatation of the ascending aorta needing surgical correction, allergy to nickel alloys, and age younger

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Abbreviations and Acronyms

AVR = aortic valve replacement
BAV = bicuspid aortic valve
BMI = body mass index
EOA = effective orifice area
MS = ministernotomy
PM = pacemaker
PVL = paravalvular leakage
RAMT = right anterior minithoracotomy
SU = sutureless
TAVI = transcatheter valve implantation
TEAVR = total endoscopic aortic valve replacement

than 65 years. The internal review board authorized progressive extension of indications of this bioprosthesis to some off-label indications (pure aortic insufficiency, bicuspid aortic valves [BAVs], redo operations for degenerative aortic bioprostheses, and concomitant mitral valve operations), and data publication. Patient demographics and characteristics are summarized in Table 1.

Device Description

The 3f Enable bioprosthesis (Medtronic, Inc, Minneapolis, MN) is composed of 3 equal leaflets of equine pericardial tissue treated with glutaraldehyde included in a self-expanding nitinol frame. The properties of nitinol allow the device to be folded, and its radial force stabilizes the valve.

Operative Procedure

All the 3f Enable implantations were performed by 2 senior surgeons. Isolated AVR was performed in 141 patients. Full sternotomy was performed in isolated AVR in only 14 patients in the first implantations (n = 6), in redo operations (n = 7), and in a patient with a hypercalcified ascending aorta (n = 1). A less invasive approach was chosen in 115 patients (57.5%) (Table 2). The most frequent concomitant procedure was coronary artery bypass grafting (CABG), with a mean of 2.2 bypasses (range, 1–3). Proximal anastomoses in CABG were performed with a total aortic cross-clamp. In concomitant mitral operations (n = 17), the mitral procedure was performed before AVR but after removal of the aortic native valve. Sizing of the SU prosthesis was performed after the mitral procedure. If the aortomitral distance (continuity between the mitral prosthesis and the aortic native annulus) was less than 5 mm, use of the SU valve was contraindicated and a sutured aortic prostheses was implanted. Thirty-one patients were excluded for an intraoperatively measured aortomitral curtain height less than 5 mm and received conventional aortic bioprostheses, whereas 20 patients received the SU valve.

Implantation Procedure

Aortic transverse aortotomy was performed approximately 3 cm above the origin of the right coronary artery because of the height of the nitinol stent. The native valve was excised with careful decalcification without injuring the annulus.

SIZING. Sizing of the valve is a crucial step of implantation. The size of the prosthesis is selected by a sizer that enters through the annulus without forcing the passage, according to the manufacturer's recommendations.

IMPLANTATION TECHNIQUE. The following steps of the implantation technique of the valve evolved through our experience.

In the first half of our experience (patients 1–100), the noncoronary leaflet and the corresponding portion of the stent were folded manually. After rinsing in ice-cold water, the prosthesis was partially folded manually. One stitch was passed at the nadir of the aortic annulus of the noncoronary sinus and then into the superior part of the polyester flange and into the nadir of the native noncoronary aortic annulus. The valve was rapidly descended into the aortic root and the guiding stitch was knotted to fix the prosthesis at that point and avoid any migration. The left coronary side of the flange was kept in front of the native annulus using a grasper. The third part (still collapsed) of the prosthesis was expanded toward the native aortic annulus of the right coronary sinus exerting a gentile traction over the flange. After weaning from CPB, systematic transesophageal echocardiography was performed to detect PVL. If PVL was equal to or greater than grade 1, a new aortic cross-clamp was required to reposition or replace the implanted bioprosthesis.

In the second part of our experience (patients 101–200), 2 main technical improvements were systematically added to the initial technique of implantation: first, the prosthesis, once folded, was kept compressed with a 4-0 polypropylene suture passed into the flange of the prosthesis. The reason for this trick is to precisely control the timing of the expansion of the prosthesis by cutting the polypropylene stich, preventing any premature expansion before perfect alignment of the flange with the native annulus. Second, a systematic perioperative surgical control was performed before closing the aorta: a nerve hook was positioned all around the prosthesis, between the polyester flange and native aortic annulus, to exclude any passage toward the ejection tract of the left ventricle. Third, most of the minithoracotomy procedures after patient 100 and all the total endoscopic aortic valve replacement (TEAVR) procedures were performed with video assistance to check the delivery process of the valve.

If the delivery of the bioprosthesis was not satisfactory, each side of the flange was again collapsed toward the central line of the prosthesis and the 3f Enable valve was repositioned. When the sitting of the valve was satisfactory, delivery of the full radial force of the nitinol stent was induced by irrigation with warm saline injection.

Follow-Up

Adverse events were death, stroke, embolism, nonstructural valve dysfunction, hemorrhage, endocarditis, conductive blocks requiring pacemaker (PM) implantation, cardiac decompensation, and PVL, which was