Sutureless Prostheses and Less Invasive Aortic Valve Replacement: Just an Issue of Clamping Time?

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Background. **Recently, sutureless aortic bioprostheses have been increasingly adopted to facilitate minimally invasive aortic valve replacement. We aimed at evaluating the impact of the transition from conventional bioprostheses to the routine use of the 3f Enable prosthesis (Medtronic ATS Medical, Minneapolis, MN) for aortic valve replacement through ministernotomy.**

Methods. **Between November 2009 and November 2012, 83 consecutive minimally invasive aortic valve replacement procedures were performed in our institution by the same surgeon through an upper T-shaped ministernotomy. The earliest 42 patients (group A) received a conventional bioprosthesis, and the later 41 patients (group B) received the sutureless 3f Enable valve. Aortic clamping and cardiopulmonary bypass times, early outcomes, and valve hemodynamics were compared.**

Results. **There was no statistical intergroup difference in baseline characteristics. In-hospital mortality was 1% (a single nonvalve-related death). Average aortic clamping times in group A and group B were, respectively, 85 ± 17 and 47 ± 11 minutes ($p < 0.0001$); the cardiopulmonary bypass time was 108 ± 21 and 69 ± 15 minutes, respectively ($p < 0.0001$). There were three paravalvular leakages in group A (grade I) and four in group B (two grade I, and two grade II); three pacemaker implantations occurred in group B ($p = 0.07$); mean transvalvular gradient at discharge was 16.9 ± 9.1 mm Hg in group A and 11.4 ± 4.3 mm Hg in group B ($p = 0.0007$). During follow-up (average 25.5 ± 12.9 months), one structural valve deterioration was registered in group A, and was treated with a valve-in-valve procedure.**

Conclusions. **In our initial experience, the sutureless 3f Enable technology significantly reduced the clamping and cardiopulmonary bypass times, as well as the mean transvalvular gradient in aortic valve replacement through ministernotomy.**

(Ann Thorac Surg 2015;99:1518–23)

Minimally invasive aortic valve replacement (MIAVR) is being increasingly used in an effort to reduce the postoperative discomfort, morbidity, and mortality among patients who are eligible for surgery. The elderly and the intermediate-risk populations are an important field of applications for such a strategy [1–3]. Upper partial sternotomy was suggested in the 1990s by Cohn and coworkers [4], and it is the most frequent surgical approach for MIAVR. Some groups propose a right minithoracotomy (MT) through the second intercostal space. This strategy is more challenging, and it requires a considerable learning curve and selection of patients depending on the position of the ascending aorta [5].

Minimally invasive techniques improve pulmonary function [6], reduce blood loss [3], and are associated with shorter intensive care unit (ICU) stay compared with standard sternotomy. Nonetheless, operative times (duration of aortic cross-clamp and cardiopulmonary bypass [CPB]) are significantly longer [2, 7, 8] That has limited the diffusion of MIAVR during the last decade. The recent introduction in clinical practice of the aortic sutureless bioprostheses may simplify and shorten operative times in MIAVR, thus influencing the risk-benefit balance between standard sternotomy and ministernotomy (MS) or MT.

The 3f Enable prosthesis (Medtronic ATS Medical, Minneapolis, MN) is a sutureless bioprosthesis whose safety has been demonstrated for implantation by full sternotomy [9, 10]. Implantation has also been reported to

Accepted for publication Dec 30, 2014.

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Dr Vola discloses a financial relationship with Medtronic.

Published by Elsevier

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2014.12.072

Abbreviations and Acronyms

AVR = aortic valve replacement
CPB = cardiopulmonary bypass
ICU = intensive care unit
LVEF = left ventricular ejection fraction
MIAVR = minimally invasive aortic valve replacement
MS = ministernotomy
MT = minithoracotomy
PVL = paravalvular leakage
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography

be feasible through MS [11], as well as right MT [5]. We present herein the impact of the transition from conventional aortic bioprostheses to the routine use of a sutureless valve in the MS aortic valve replacement (AVR) experience of a mid-sized French cardiac surgical center.

Material and Methods

In a retrospective, single-center study design, we revised the perioperative data of a consecutive cohort of bioprosthetic AVR through MS. Included patients provided informed consent for the use of personal data, and the Institutional Review Board approved the study.

The same surgeon operated on all patients. From November 2009 to November 2012, 83 patients affected by aortic valve disease were consecutively selected to receive MIAVR surgery through upper MS. Exclusion criteria for this approach were severe ascending aortic calcifications, presence of venal caval filter or other contraindications to femoral venous cannulation, left ventricular ejection fraction (LVEF) lower than 25%, indication for concomitant ascending aortic replacement or any other associated cardiac procedure, and active endocarditis. Between November 2009 and March 2011, 42 MIAVR operations were performed using conventional aortic bioprostheses (group A). The Enable sutureless valve was introduced into our routine practice in March 2011, and all patients referred for MS AVR with a bioprosthesis were considered for implantation of such a sutureless device. Additional exclusion criteria for sutureless MS AVR were age less than 65 years and aortic annular dilation (larger than 25 mm) in concomitance with a type 0 bicuspid aortic valve. Discordance between the sinotubular junction and aortic annulus diameter was not considered an exclusion criterion, because the sealing of this sutureless device occurs only at the level of the aortic annulus [10]. Therefore, between March 2011 and November 2012, 41 patients received a sutureless Enable I bioprosthesis through MS (group B).

Operative Technique

An upper T-reversed MS was performed at the third intercostal space without sacrifice of the internal thoracic pedicle (Fig 1A). Cardiopulmonary bypass was instituted through direct ascending aortic cannulation and percutaneous cannulation of the right atrium; cardioplegia was delivered antegradely. In the conventional bioprosthesis group, myocardial protection was accomplished with a single dose of intracellular histidine-tryptophan-ketoglutarate cardioplegic solution (Bretschneider; Kohler Chemie, Alsbach-Hahnlein, Germany). Conversely, in the sutureless group, because shorter cross-clamp times were expected, myocardial protection was obtained with one or two doses of warm blood cardioplegia (by cannulation of the coronary ostia for repeat application).

In group A, conventional bioprostheses were implanted. Among those available in our institution, namely, St Jude Epic and Trifecta (St Jude Medical, St Paul, MN), and Sorin Mitroflow (Sorin, Milan, Italy), the Sorin Mitroflow and the St Jude Trifecta were preferably used in case of small aortic annuli (19 mm). A supraannular position with nonpledgetted U stitches was adopted. In group B, the 3f Enable sutureless valve was used. This device consists of an equine pericardial sheet mounted into a self-expandable nitinol stent frame (Fig 1B). A polyester flange covers the inflow aspect, to achieve rapid expansion and facilitate anchorage to the aortic annulus. The nitinol stent confers a rigid structure and symmetric suspension of the valve leaflets for optimal coaptation.

A transverse aortotomy was performed about 3 cm above the origin of the right coronary artery. A nonaggressive decalcification of the aortic annulus was performed, and a regular orifice with a minimal contour of native valve tissue was left in place, to enhance the grip of the polyester flange. The sizer had to pass easily through the annulus. During the 2-minute valve rinsing, a repeat dose of warm cardioplegia may have been delivered, and one guiding stitch was passed at the nadir of the aortic annulus of the noncoronary sinus. The valve was then flooded in cold saline, and the guiding suture passed through the upper part of the polyester flange (Fig 1C). The valve was place into the aortic root, and the guiding suture tied. The left coronary side of the flange was subsequently adapted to the native annulus using a Kelly grasper. The collapsed part of the prosthesis was then deployed at the level of the right coronary sinus; that is performed by a gentle traction over the flange with a grasper. Adhesion between the polyester flange and the native aortic annulus could be verified using a nerve hook (Fig 1D). If the level of deployment was not satisfactory, the device could be recollapsed and repositioned. Full radial force of the nitinol stent was induced by irrigation with warm saline. After weaning from CPB, transesophageal echocardiography (TEE) control imaging was performed to exclude significant paravalvular leakage (PVL), grade I or greater.

Perioperative clinical and echocardiographic data were obtained for all patients of both groups. Before discharge, all patients received transthoracic echocardiography (TTE) control imaging using a Vivid-7 ultrasound platform (General Electric, Milwaukee, WI). Early mortality was defined as death occurring within 30 days after the operation, or later if during the same hospitalization. Paravalvular leakages were classified as