Right anterior minithoracotomy aortic valve replacement with a sutureless bioprosthesis: Early outcomes and 1-year follow-up from 2 European centers

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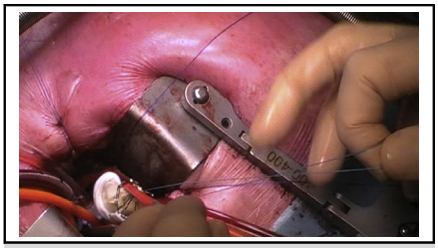
ABSTRACT

Background: A sutureless aortic valve can be inserted through a right anterior minithoracotomy (RAMT) with consistent decreased cross-clamping time and ease of insertion. We report the experience of RAMT implantation of the 3f Enable (Medtronic, Inc, Minneapolis, Minn) self-expanding sutureless bioprosthesis, performed in 2 European cardiac surgery centers.

Method: From September 2012 to April 2014, a total of 71 patients with severe aortic stenosis were selected to receive an aortic valve replacement via RAMT using the sutureless valve. Hemodynamic parameters and clinical outcome were assessed at discharge and up to 16 months postoperatively.

Results: All the patients received the prosthesis with success. One conversion to median sternotomy was necessary, owing to severe pleural adhesions. Overall in-hospital mortality was 2.8%. Mean cardiopulmonary bypass and cross-clamping time were, respectively, 91 ± 29 minutes and 66 ± 19 minutes. Reclamping was necessary in 4 cases (5.6%). Early incidences of grade I or lower paravalvular leakages and pacemaker implantation were, respectively, 4.2% and 5.6%. No paravalvular leakage greater than grade I was registered. The mean follow-up time was 8.1 months; the mean transvalvular gradient was, at discharge and at 6-12 months, respectively, 10.7 ± 4.3 mm Hg and 9.6 ± 3.1 mm Hg. The degree of regurgitation remained stable in all cases. Freedom from all-cause and valve-related mortality was 97% and 99%, respectively, at 1 year.

Conclusions: Aortic valve replacement via RAMT with the 3f Enable valve is a reproducible procedure, as it provides satisfactory hemodynamics, and a low valve-related complication rate. Greater experience is needed to compare the performance of the 3f Enable valve with that of other sutureless valves implanted via the same RAMT procedure. (J Thorac Cardiovasc Surg 2015;149:1052-7)



Folded 3F Enable prosthesis descended into the right anterior minithoracotomy.

Central Message

Sutureless 3f Enable aortic valve replacement is reproducible and safe, combining reasonable cross-clamping times and a low rate of paravalvular leakages. A learning curve in management of the step-by-step delivery of the sutureless prosthesis has to be acquired before proceeding to minithoracotomy.

Perspective

Reduction of cross-clamping time and enhancement of reproducibility of challenging minimally invasive approaches are pivotal indications in use of sutureless valves. This is the first multicentric cohort of right anterior minithoracotomy aortic valve replacements with use of the unique sutureless prosthesis, the 3f Enable valve, that is not balloon expandable and that needs a precise surgical positioning. Incidence of paravalvular leakages seems interestingly low, confirming that this setting may merit a larger diffusion as a first-line option for isolated minimally invasive aortic valve replacement.

See Editorial Commentary page 1058.

Results in favor of transcatheter valve implantation rather than surgical aortic valve replacement in high-risk patients have been published recently.[1] Early results in new-generation transcatheter valve implantation[2] will potentially stimulate the debate concerning surgical versus transcatheter options in intermediate-risk patients. On

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Abbreviations and Acronyms
CPB = cardiopulmonary bypass
NYHA = New York Heart Association
PVL = paravalvular leakage
RAMT = right anterior minithoracotomy

the other hand, persistence of the native valve after transcatheter valve implantation has raised concern regarding persistence of tissues that have potential to act as a nidus for calcified emboli, and altered rheology that promotes thrombosis. This issue is under investigation by Fanning and colleagues[3] as one of the possible causes of neurologic injury that should be assessed before extension of transcatheter valve implantation into populations that are younger and have lower surgical risk. Surgery is the only solution that can remove the underlying pathology, and technical refinement of this procedure is still possible and necessary.

Considerable effort has been made to reduce the iatrogenic effects of surgical aortic valve replacement chest wall trauma. The challenge began with the assessment of ministernotomies,[4,5] and these efforts could evolve into the exclusive thoracoscopic approach.[6] In this stepwise evolution, right anterior minithoracotomy (RAMT) seems to be an adequate compromise, intended as a routine safe and reproducible approach that avoids partial fractures of the sternum[7] and has already shown clinical advantages in term of transfusions, ventilation time, and reduction of postoperative atrial fibrillation onset.[8,9]

The introduction of sutureless technology, which avoids the use of stitches and knots, has the potential to increase the speed of insertion, regardless of the location of incision. Evaluation has been made[10] of large cohorts of patients who have undergone implantation of the Perceval S sutureless bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy) via RAMT, but to the best of our knowledge, no study has been published on a multicenter cohort for which the 3f Enable model 6000 valve (Medtronic, Inc, Minneapolis, Minn) was utilized. The aim of the current study is to analyze our clinical experience with RAMT using the 3f Enable.

METHODS

Patient Population

This study is retrospective and examined a consecutive cohort of patients recruited in 2 centers (St-Etienne University Hospital, St-Etienne, France, and Salus Hospital GVM Care & Research, Reggio Emilia, Italy) between September 2012 and May 2014 who were being evaluated for an implantation with the 3f Enable sutureless valve via RAMT. Inclusion criteria for RAMT implantation of the valve were presence of a severe aortic valve stenosis, age >60 years, and New York Heart Association (NYHA) class III or higher. All candidates for RAMT were explored preoperatively with a thoracic and abdominal computed tomography scan, to detect: presence of heavy calcifications of the ascending aorta, which would contraindicate the RAMT approach; presence of a very short ascending aorta necessitating a retrograde femoral arterial cannulation; and permeability of the iliac arteries and veins.

Exclusion criteria were: an ejection fraction <30%; recent endocarditis; reoperation; an intraoperative aortic annulus measurement >25 mm associated with a bicuspid anatomy; aneurysmal dilatation of the ascending aorta needing surgical correction; any other indication for associated surgical procedures (coronary artery bypass graft, mitral valve surgery); known hypersensitivity to nickel alloys; and nonelective surgery. We selected 71 patients to undergo an aortic valve replacement via RAMT. The internal review board of the 2 institutions allowed treatment of personal data, and patients provided specific written consent.

Data collection from both centers was uniformly performed; included items were preoperative clinical and hemodynamic characteristics, intraoperative and postoperative items, and clinical follow-up and echography data. All recordings were collected in an integrated database. Adverse events were death, stroke, embolism, nonstructural valve dysfunction, hemorrhage, endocarditis, conductive blocks requiring pacemaker implantation, and cardiac decompensation; these were divided into early (within 30 days postoperatively) and late (after 30 days) categories. Clinical neurologic assessment was performed by our cardio-anesthesiologists. Paravalvular leakages (PVLs) were classified as absent (0), trace (<grade I), mild (grade I), moderate (grade II), or severe (grade III or IV). Before discharge, patients underwent transthoracic echocardiography. Echocardiographic examinations were performed with Vivid-7 Dimension ultrasound platforms (GE Healthcare, Milwaukee, Wis).

Follow-up

Clinical and echocardiographic postimplantation evaluation during follow-up was performed at the cardiologic unit in both centers. Control evaluations were performed between 6 months and 1 year after the operation. Data for NYHA classification were presented as the number and percentage of patients in each functional class. During follow-up, transthoracic echocardiography mean and peak transvalvular gradient, valvular orifice area, and presence of leakages were registered. Event-free survival was defined as the absence of: death, stroke, embolism, nonstructural valve dysfunction, hemorrhage, endocarditis, conductive blocks necessitating pacemaker implantation, cardiac decompensation, and reoperation.

Device Description

The 3f Enable valve Figure 1, *A*) is composed of 3 equal leaflets of equine pericardial tissue that are sutured to one another, and have been treated with glutaraldehyde to preserve the structure of the collagen matrix. This part of the device derives from the ATS 3F stentless valve (ATS Medical, Lake Forest, CA). That tubular biologic conduit was reinforced with polyester material and included into a self-expanding nitinol frame, covered on the inflow with a polyester flange; as such, it could be rapidly expanded and fixed into the aortic annulus of the receiver without sutures. The inclusion into the nitinol stent confers a symmetric suspension of the commissures, eliminating technical pitfalls linked to surgical resuspension.

Surgical Technique

Minithoracotomy and exposure. The RAMT management approach adopted is, in brief, the same as that previously proposed by Cerillo and colleagues.[11] After selective endotracheal ventilation, and under transesophageal echography, a second right minithoracotomy of 5 to 7 cm right anterior minithoracotomy is performed in the second intercostal space, followed by femoral venous percutaneous cannulation with the Seldinger technique (using a DLP venous cannula, Medtronic, Inc, Minneapolis, Minn). The pericardium is incised and suspended directly from the skin. That maneuver moves the ascending aorta aside, making evaluation easier of whether a direct aortic antegrade cannulation is