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Clinical Research

Sutureless Aortic Valve Replacement: A Canadian Multicentre Study

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ABSTRACT

Background: Sutureless aortic valve replacement (AVR) has recently been introduced as an alternative to standard AVR in elderly high-risk surgical patients. The purpose of this study was to report the early Canadian experience with sutureless AVR.

Methods: A Canadian multicenter study included 215 consecutive patients from 6 centres who underwent sutureless AVR using the Perceval S bioprosthesis (Sorin Group, Saluggia, Italy) between June 2011 and May 2013. Perioperative clinical and echocardiographic outcomes were assessed in all patients.

Results: Mean age was 79 ± 6 years, and 116 patients (54%) were women. Concomitant procedures included coronary artery bypass grafting in 86 patients (40%), multiple valve procedures in 24 (11%) patients, and septal myectomy in 9 (4%) patients. A full sternotomy was used in 173 cases (80%), a minithoracotomy in 23 (11%) cases,

RÉSUMÉ

Introduction : Le remplacement valvulaire aortique (RVA) sans suture a récemment été introduit comme alternative au RVA standard chez les patients âgés qui sont exposés à un risque chirurgical élevé. Le but de cette étude était de rapporter les toutes premières expériences canadiennes sur le RVA sans suture.

Méthodes : Une étude canadienne multicentrique regroupait 215 patients consécutifs de 6 centres qui ont subi un RVA sans suture par la bioprothèse Perceval S (Sorin Group, Saluggia, Italie) entre juin 2011 et mai 2013. Les résultats cliniques et échocardiographiques périopératoires ont été évalués chez tous les patients.

Résultats : L'étude qui regroupait des patients dont l'âge moyen était de 79 ± 6 ans comptait 116 femmes (54 %). Les interventions concomitantes comprenaient le pontage aortocoronarien chez 86 patients (40 %), de multiples interventions valvulaires chez 24 patients (11 %)

Aortic stenosis (AS) is the most prevalent valvular heart disease in adults.[1] Severe AS is a fatal disease in the absence of mechanical relief, with three quarters of patients dying within 3 years of symptom onset.[2] Surgical aortic valve replacement (AVR) is the gold standard for the treatment of severe symptomatic AS in elderly operable patients.[3] However, the operative risk of AVR increases with age and multiple comorbidities so that a significant proportion of patients > 75 years with severe AS are denied surgery.[1,4] As a result, in recent years, transcatheter aortic valve implantation (TAVI) techniques have garnered much interest and enthusiasm.[5,6] However, these techniques are not without drawbacks and have been associated with increased rates of major vascular complications,[6] stroke,[7] and paravalvular leak (PVL).[8] In addition, the inability to remove the stenosed native aortic valve raises concern about the durability of this procedure.

Sutureless AVR using self-expanding bioprostheses is an emerging and promising alternative to standard AVR in elderly and high-risk surgical patients. The proposed benefits of this technology include enhanced implantability, shorter aortic cross-clamp and cardiopulmonary bypass (CPB) times, favourable hemodynamic performance, and easier access for minimally invasive surgery.[9-12] In addition, this approach allows complete removal of the diseased native valve. Several European case series have shown good early clinical and hemodynamic outcomes.[12-16]

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and a partial sternotomy in 19 (9%) cases. Nineteen cases (9%) were redo procedures. For isolated AVR, mean aortic cross-clamp time was 41±12 minutes. In-hospital mortality occurred in 9 patients (4%). No postoperative valve migration was reported. A total of 37 patients (17%) underwent postoperative implantation of a permanent pacemaker, including 20 patients (9%) who had complete atrioventricular block. Postoperative stroke occurred in 7 patients (3%). Echocardiographic evaluation demonstrated well-seated valves with no significant (2+) valvular or paravalvular aortic insufficiency and a mean aortic gradient of 13 ± 6 mm Hg.

Conclusions: Sutureless AVR using the Perceval S prosthesis is safe and reproducible and results in short operative times. Echocardiographic results are encouraging, with low gradients and no paravalvular aortic insufficiency. However, in this series, sutureless AVR was associated with a high risk of permanent pacemaker implantation.

et la myectomie septale chez 9 patients (4 %). Une sternotomie complète a été pratiquée dans 173 cas (80 %), une mini-thoracotomie, dans 23 cas (11 %) et une sternotomie partielle, dans 19 cas (9 %). Dix-neuf (19) cas (9 %) ont été concernés par des réinterventions. Pour le RVA isolé, le temps moyen de clampage de l'aorte a été de 41 ± 12 minutes. La mortalité intrahospitalière est survenue chez 9 patients (4 %). Aucune migration postopératoire de la valve n'a été rapportée. Un total de 37 patients (17 %) ont subi l'implantation postopératoire d'un stimulateur cardiaque permanent, dont 20 patients (9 %) qui ont eu un bloc auriculoventriculaire complet. Un accident vasculaire cérébral postopératoire est survenu chez 7 patients (3 %). L'évaluation échocardiographique a démontré des valves bien situées sans insuffisance valvulaire ou paravalvulaire aortique significative (2+), et un gradient aortique moyen de 13 ± 6 mm Hg.

Conclusions : Le RVA sans suture par la prothèse Perceval S est sécuritaire et reproductible, et raccourcit le temps opératoire. Les résultats échocardiographiques sont encourageants et démontrent de faibles gradients sans insuffisance aortique paravalvulaire. Cependant, dans cette série, le RVA sans suture a été associé à un risque élevé d'implantation de stimulateur cardiaque permanent.

The purpose of this study was to report the early Canadian experience with sutureless AVR using the Perceval S bioprosthesis (Sorin Group, Saluggia, Italy). This is the first North American cohort of sutureless AVR and one of the largest series to be reported thus far in the literature.

Methods

Between June 2011 and May 2013, 215 consecutive patients from 6 Canadian centres underwent sutureless AVR with the Perceval S prosthesis (Sorin, Saluggia, Italy). Participating centres were located across 3 Canadian provinces (Table 1).

The Perceval S prosthesis is a new-generation sutureless aortic bioprosthesis composed of bovine pericardium mounted within a superelastic Nitinol (nickel-titanium) frame. The valve is collapsed through a dedicated device and deployed using a specific delivery system. A detailed description of the implantation technique for the Perceval S prosthesis is available elsewhere.[16] The valve is available in 4 sizes: small (21 mm), medium (23 mm), large (25 mm), and extra large (27 mm). The latter was introduced in Canada in March 2013 and was not available for most of the study period.

For each case, implantation of the prosthesis required approval by the Canadian Department of Health and Welfare (Ottawa, Ontario, Canada). Informed written consent was obtained for all patients, and the study was approved by the local ethics committee at each institution.

All procedures were carried out using CPB. Three different surgical approaches were used in this series, namely, a full median sternotomy, a ministernotomy, and a right anterior minithoracotomy. The choice of incision was left to the discretion of the surgeon. Hemodynamic parameters were assessed preoperatively and postoperatively before discharge using transthoracic echocardiography.

Data collection was performed using a standardized case report form, which was sent to the principal investigator from each participating hospital. Each centre was responsible for local data collection, and a retrospective analysis of the combined data was performed. The study focused on perioperative clinical and echocardiographic outcomes.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics, version 20 (SPSS, Chicago, IL). Continuous variables are presented as mean ± standard deviation and nominal variables are presented as frequency (%). Improvements in transaortic gradients and aortic effective orifice area were assessed with the Wilcoxon signed-rank test. Changes in left ventricular ejection fraction were assessed using McNemar's test. Statistical significance was set at $\alpha = 0.05$.

Table 1. Number of sutureless valve implants per participating centre

Centre	Total implants (n = 215) (%)	Isolated AVR (n = 102) (%)	Combined procedure (n = 113) (%)	Minimally invasive AVR[a] (n = 42) (%)
Montreal Heart Institute	121 (56)	63 (62)	58 (51)	37 (88)
Southlake Regional Health Center	30 (14)	8 (8)	22 (19)	1 (2)
Hamilton Health Sciences	5 (2)	4 (4)	1 (1)	1 (2)
Trillium Health Center	32 (15)	15 (15)	17 (15)	1 (2)
New Brunswick Heart Center	14 (7)	6 (6)	8 (7)	2 (5)
Laval Hospital	13 (6)	6 (6)	7 (6)	0 (0)

AVR, aortic valve replacement.

[a] Patients who underwent surgery through a ministernotomy or minithoracotomy.