Management of small aortic annulus in the era of sutureless valves: A comparative study among different biological options

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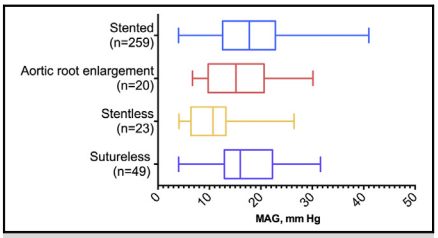
ABSTRACT

Objective: Aortic valve replacement (AVR) in patients with a small aortic annulus is a challenging problem. The objective of this study was to compare 4 surgical approaches in terms of hemodynamics and perioperative outcomes.

Methods: A retrospective single-center study included 351 consecutive patients with a small aortic annulus (≤21 mm) who underwent aortic valve surgery between January 2007 and December 2014. Surgical techniques included standard AVR in 259 (74%) patients, aortic root enlargement in 20 (6%), implantation of a stentless bioprosthesis in 23 (6%), and sutureless AVR in 49 (13%).

Results: Three hundred and eleven (89%) patients were female. The mean Logistic EuroSCORE II varied significantly among the groups and ranged from 6.5% ± 5.4% in the standard AVR group to 9.2% ± 4.7% in the stentless group. Early mortality occurred in 26 (7%) patients. Patients in the stentless group had the lowest aortic valve mean gradients on predischarge transthoracic echocardiography (10.9 ± 6.2 mm Hg; $P < .001$). In the stented group, the Trifecta prosthesis displayed the lowest postoperative mean transaortic gradient (10.3 ± 3.6; $P < .001$) with no severe prosthesis-patient mismatch. Postoperative gradients of the sutureless group were comparable with stented prostheses.

Conclusions: In our study, stentless AVR and Trifecta bioprostheses had the best hemodynamic outcomes. The Perceval sutureless prosthesis provides reasonable hemodynamic performance and is a safe alternative. (J Thorac Cardiovasc Surg 2016;152:1019-28)



Postoperative TTE gradient distribution.

Central Message

Stentless and Trifecta prostheses give the best hemodynamics in cases of small aortic annulus. Sutureless valves are comparable with stented prostheses.

Perspective

Aortic valve replacement in patients with a small aortic annulus is a challenging problem. The present study draws attention to the hemodynamic performance of 4 management strategies (stented AVR, stentless AVR, sutureless AVR, and aortic root enlargement) that could be used in the context of a small aortic annulus (≤21 mm).

See Editorial Commentary page 1028.

Severe aortic stenosis is a lethal disease that requires mechanical relief of left ventricular outflow obstruction.[1] Aortic valve replacement (AVR) is the gold standard treatment for severe symptomatic aortic stenosis.[2] The aim of AVR is to decrease pressure and volume overload on the left ventricle, allowing for left ventricular mass regression. To achieve this goal, residual transvalvular gradients should be minimal. However, implantation of a small aortic valve sometimes leads to high residual gradients, despite a normally functioning prosthesis. In addition, patients with a small aortic annulus, especially those with a large body surface area, are at higher risk of prosthesis-patient mismatch, which is associated with worse clinical outcomes and decreased survival.[3]

Conventional stented valves have a sewing ring that is partially positioned within the blood flow causing relative flow obstruction,[4] especially in patients with a small aortic annulus. To decrease residual gradients and left ventricular

Scanning this QR code will take you to a procedural video.

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Abbreviations and Acronyms

AVR = aortic valve replacement
CABG = coronary artery bypass graft
CPB = cardiopulmonary bypass
EOA = effective orifice area
iEOA = indexed effective orifice area
PPM = permanent pace maker
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography

outflow tract obstruction, several alternatives have been proposed, including aortic root enlargement and root replacement using a stentless bioprosthesis. However, the hemodynamic benefits of these approaches must be weighed against an increased surgical risk because of technical difficulty, prolonged periods of cardiopulmonary bypass (CPB), and myocardial ischemia.[5] Recently, sutureless aortic bioprostheses have been proposed as a new solution to the problem of the small aortic annulus in elderly high-risk surgical patients.[6]

The purpose of this study was to compare the hemodynamic performance among the 4 management strategies (stented AVR, stentless AVR, sutureless AVR, and aortic root enlargement) in the context of a small aortic annulus ($\leq$21 mm).

METHODS

Study Population

Between January 2007 and December 2014, 1703 patients with aortic stenosis who underwent AVR with a biological substitute in our institution were identified. Patients who received a mechanical prosthesis or who underwent a Ross procedure were excluded. In our institution, these operations are performed mainly in younger patients (<60 years). These patients represent a distinct population from the cohort studied herein, as they tend to have a lower surgical risk, with a lower incidence of mortality and morbidity. A total of 351 consecutive patients with an aortic annulus of 21 mm or less were included. Among these, 259 (74%) underwent standard AVR with stented aortic prosthesis, 20 (6%) underwent aortic root enlargement, 23 (6%) underwent implantation of a stentless bioprosthesis, and 49 (13%) underwent sutureless AVR. The population flowchart is shown in Figure 1.

This observational, single-center, cohort study was approved by the local ethics committee and a waiver of consent was obtained.

Data Collection and Follow-up

Clinical data were prospectively collected in our center's Valve Clinic database. When necessary, individual chart review was performed to complete the dataset. Early postoperative outcomes were defined in accordance with the Society of Thoracic Surgeons' Guidelines for Reporting Mortality and Morbidity After Cardiac Valve Interventions.[7] Operative mortality was defined as death occurring within 30 days of surgery or during the index hospitalization. Echocardiographic parameters including mean aortic gradient, peak aortic gradient, effective orifice area (EOA), and indexed EOA (iEOA) were assessed intraoperatively and before discharge. Eligibility for the study was determined on the basis of the preoperative aortic annulus diameter as assessed on intraoperative transesophageal echocardiography (TEE). All measurements were carried out by a single blinded observer. All patients underwent a predischarge transthoracic echocardiography (TTE) at an average of 4 $\pm$ 2 days postoperatively. Moderate and severe prosthesis-patient mismatch was defined as an iEOA between 0.60 to 0.85 cm^2/m^2 and <0.60 cm^2/m^2, respectively.[3] Body surface area was calculated using DuBois's formula. Creatinine clearance was calculated using the Cockcroft-Gault formula.

Outcome Definition

The primary study endpoint was the hemodynamic performance of each approach (mean transaortic pressure gradients, peak transaortic pressure gradients, EOA, iEOA, and incidence of moderate or severe prosthesis-patient mismatch) in postoperative TEE and in TTE at discharge.

Secondary outcomes were early postoperative adverse events. A further analysis was done to compare hemodynamic performance of various stented bioprostheses and patients with aortic annulus <20 mm versus $\geq$20 mm.

Surgical Technique

All surgical procedures were performed by 8 attending surgeons at our institution. The choice of procedure was based on individual patient characteristics and surgeon/patient preference. Aortic root replacement or enlargement was preferred in young patients, especially those who had previously undergone AVR or aortic root surgery. Sutureless prostheses have been implanted in our center since 2011. Sutureless AVR was preferred in older patients (>70 years), patients with calcified aortic root or coronary ostia, and in patients undergoing minimally invasive AVR.

In the standard AVR group, the prosthesis was implanted using interrupted pledgetted mattress sutures. Both supra- and intraannular techniques were used according to the surgeon's preference. Sutureless AVR using the Perceval S prosthesis (Sorin Group, Saluggia, Italy) (Video 1) was performed using a specific delivery system. A catheter balloon was inserted and inflated to complete the prosthesis deployment. All patients undergoing stentless AVR received a complete root replacement. The same aortic root enlargement technique was performed in the 20 patients in this group as follows: the aortotomy incision is extended toward the posterior commissure between the noncoronary and the left coronary aortic cusps, passing through the aortic annulus, and carried 5 to 10 mm downwards where it stops at the anterior mitral leaflet annulus to avoid any postoperative impairment of mitral valve function. A patch of Dacron is then sutured to the V-shaped defect and the aortic prosthesis is implanted.

Statistical Analysis

Continuous variables are presented as means $\pm$ standard deviations and were compared using the Student t test or the Mann-Whitney U test, as appropriate. The Kruskal-Wallis test was used when more than 2 measurements were compared. Only available values were included in the analysis. Categorical variables are presented as frequency (%) and were compared using Pearson's χ^2 test when the expected frequency count for each contingency table's cell was at least 5. Otherwise, a Fisher exact test was used. Statistical significance was set at $\alpha \leq 0.05$. Postoperative aortic gradients and aortic valvular area data were missing in less than 1% of patients. Whenever a value for a given variable was unavailable, the patient was not included in the analysis to avoid any nonresponse bias. Statistical analyses were performed using Statistical Package for Social Sciences v20 (IBM, Armonk, NY).

RESULTS

Patients' Baseline Characteristics

The patient's baseline characteristics are presented in Table 1. The mean age differed significantly among the