# Hemodynamic performance and outcome of percutaneous versus surgical stentless bioprostheses for aortic stenosis with anticipated patient–prosthesis mismatch

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**Objectives:** We aimed to compare the performance and midterm survival of transcutaneous aortic valve replacement (TAVR) and surgically implanted stentless aortic valve replacement (SAVR) for severe aortic stenosis in patients anticipated to have patient–prosthesis mismatch (PPM).

**Methods:** A retrospective analysis was performed of 86 and 49 consecutive TAVR and SAVR patients with severe aortic stenosis and calculated minimal effective orifice area larger than the best projected effective orifice area. Cox hazard analyses were used to assess the effect of TAVR versus SAVR on outcome.

**Results:** The peak and mean transprosthetic gradient at discharge were lower ($P < .001$ for both) in the TAVR group. Mild or greater aortic regurgitation was more frequent in the TAVR group (61% vs 7%; $P < .0001$). At 3 months of follow-up, the mean gradient in the TAVR group was similar to that of the SAVR group but the prevalence of aortic regurgitation was still higher. The unadjusted 3-year survival rate was superior in the SAVR versus TAVR group (91.6% ± 4% vs 67.0% ± 7%; $P = .01$). Adjustments for both age and comorbidity resulted in loss of the difference in mortality between the 2 groups.

**Conclusions:** In patients with anticipated PPM, TAVR offers an immediate lower incidence of PPM than SAVR but a greater prevalence of aortic regurgitation. The differences in transaortic gradients became nonsignificant 3 months postoperatively. The question of whether TAVR is a suitable substitute for SAVR in patients with anticipated PPM, in particular, those who are older and sicker, warrants additional investigation. (J Thorac Cardiovasc Surg 2014;147:1892-9)

ACD

Patient–prosthesis mismatch (PPM) occurs when the effective orifice area (EOA) of a normally functioning prosthesis is too small in relation to the patient's body size, resulting in an abnormally high postoperative gradient.[1] Aortic valve replacement (AVR) in patients with a small aortic annulus for the body surface area (BSA) has been associated with a high incidence of PPM,[2-4] which has been associated with increased mortality, more congestive heart failure, and worse functional capacity.[5] The most widely validated parameter for identifying PPM is the calculated EOA, indexed by the patient's BSA[6] (iEOA). When the aortic iEOA is less than 0.85 $cm^2/m^2$, the patient is considered to have moderate PPM, and when the aortic iEOA is less than 0.65 $cm^2/m^2$, the patient has severe PPM. To avoid PPM, the minimal EOA of the prosthesis to be inserted[1] is calculated by multiplying the patient's BSA by 0.85 and compared with the projected EOA, defined by the size of the patient's annulus diameter and the manufacturer's reference value. Whenever the minimal EOA is more than the projected EOA, PPM is anticipated. For anticipated PPM, several solutions have been proposed, from which AVR with stentless valves (SAVR) has gained popularity owing to the excellent iEOA, low transprosthetic gradients, and greater left ventricular (LV) mass regression.[7] Recently, transcatheter aortic valve replacement (TAVR) has emerged as an alternative to AVR for high-risk patients with aortic stenosis,[8] with respect to relief of stenosis and postprocedural valve hemodynamics.[9]

We sought to compare the hemodynamics and early and midterm outcomes in patients with anticipated PPM, who were treated with either SAVR or TAVR, at our institution.

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## METHODS

### Eligibility and Projected iEOA

Patients were eligible for analysis if they had severe aortic stenosis and were anticipated to have at least moderate PPM according to their BSA and annulus size, assuming a stented bioprosthesis were implanted. To define eligibility, we used the following strategy before aortic valve intervention.[3] We calculated the patient's BSA; calculated the minimal required EOA by multiplying the BSA by 0.85 $cm^2/m^2$; and compared the result obtained in the second step with that of the projected EOA.[10] Patients were eligible for

**Abbreviations and Acronyms**

AR = aortic regurgitation
AVR = aortic valve replacement
BSA = body surface area
CI = confidence interval
EOA = effective orifice area
iEOA = calculated EOA, indexed by the patient's body surface area
HR = hazard ratio
LV = left ventricular
NYHA = New York Heart Association
PPM = patient–prosthesis mismatch
SAVR = stentless aortic valve replacement
TAVR = transcatheter aortic valve replacement

the present study if their minimal required EOA was larger than the highest projected EOA for any type of available stented bioprosthesis.

## SAVR Procedure

All SAVR patients underwent AVR with a Freestyle stentless bioprosthesis (Medtronic Inc, Minneapolis, Minn). The operative technique has been previously described.[11] In brief, all operations were performed through a standard midline sternotomy. Excision of the native aortic valve and annular debridement were followed by sizing with the sizer provided for the Freestyle stentless bioprosthesis valve, with consideration given to the size at both the annulus and the sinotubular ridge. The Freestyle valve was then inserted in the subcoronary position or as a full root replacement. When subcoronary insertion was applied, a 2-layer suture technique was used.

## TAVR Procedure

All TAVR procedures were performed in patients with severe symptomatic aortic stenosis with a balloon-expandable valve (Edwards SAPIEN, Edwards LifeSciences, Inc, Irvine, Calif) or a self-expandable valve (CoreValve, Medtronic, Inc) through the transfemoral approach with the patient under local anesthesia. The valve prosthesis size was selected on the basis of the aortic annulus measurements obtained by transesophageal echocardiography performed before the procedure. For the balloon-expandable valve, a 23-mm valve was selected if the aortic annulus was 17 to 21 mm, with a 26-mm valve selected, if the aortic annulus was 22 to 25 mm. For the self-expandable valve, a 26-mm valve was selected if the aortic annulus was 20 to 23 mm, with a 29-mm valve selected if the aortic annulus was 23 to 27 mm. Balloon aortic valvuloplasty was performed in all patients before valve implantation. Immediately after valve deployment, evaluation of the presence and severity of aortic regurgitation (AR) was assessed visually by determination of the relative amount of radiographic contrast medium in the ventricle after injection into the proximal aorta and classified using a scale of 0 to 4. Balloon dilation was performed in cases of significant paravalvular AR, defined as AR of grade 2 or greater. After balloon dilation, the presence and degree of AR was again evaluated, and a second dilation was performed at the discretion of the physician.

## Study Design

The present study was a nonrandomized, retrospective, single-center study. Because it was judged to be a low-risk, retrospective analysis, the institutional review board approved wavering of informed consent. The study was designed with 2 aims. First, to assess the hemodynamic performance of TAVR compared with SAVR in terms of the transprosthetic gradient and prevention of severe PPM in patients identified to have a high risk of PPM. Second, the TAVR and SAVR patients were compared for midterm survival.

The first step was to identify the TAVR cohort. From January 2009 to December 2011, 200 TAVR procedures were performed in patients with severe aortic stenosis at our institution. In 86 patients, the calculated minimal EOA was larger than the best projected EOA[10] for any type of available stented bioprosthesis, and these patients were considered eligible for analysis (TAVR cohort). Second, we compared the TAVR patients with 49 consecutive patients (SAVR cohort) with severe aortic stenosis, identified from a prospective registry database of all 192 patients who had undergone SAVR with a stentless Freestyle bioprosthesis (Medtronic, Inc) during the same period, who were similar to the TAVR group for the predefined inclusion characteristics. The patients in both cohorts (TAVR and SAVR) had undergone AVR contemporaneously. The presence of a bicuspid aortic valve was a contraindication for TAVR, and we, therefore, also excluded patients with a bicuspid valve from the SAVR cohort. All echocardiographic data were collected at baseline, before hospital discharge, and at the 3-month follow-up examination. Survival was calculated from AVR (either TAVR or SAVR) until the date of the last clinical encounter for all patients.

## Baseline, Follow-up, and Clinical Outcomes

The baseline clinical data were collected by interviewing the patients and reviewing their medical files. Coexisting conditions were evaluated using the Charlson comorbidity index,[12] which contains different categories of comorbidities. Clinical follow-up data were obtained by a review of the medical records, surveys, and telephone interviews. The cause of death was determined by a review of all medical records, telephone interviews, and death certificates. The event used as the endpoint was all-cause mortality.

## Echocardiography

Two-dimensional transthoracic echocardiography was performed in a standard manner using the same equipment (iE33, Philips Medical Systems, Bothell, Wash).

The ejection fraction was calculated using the Simpson method,[13] and the LV diameters, interventricular septal and posterior wall width, LV mass, relative wall thickness, LV stroke, and cardiac output were calculated as recommended.[13]

The severity of aortic stenosis was defined by the maximal velocity across the aortic valve, the mean pressure gradient, and the aortic valve area, calculated by the standard continuity equation (maximal velocity, >4 m/s; mean gradient, >40 mm Hg; and aortic valve area, <1.0 $cm^2$). Grading of AR after TAVR or SAVR was performed in a semiquantitative fashion, using color Doppler imaging, according to the number of jets, the jet width in the central jets, and the circumferential extent of the jet in paravalvular AR using the parasternal long-axis, parasternal short-axis, and apical long-axis views. AR was classified as follows: 0, absent; 1, trivial or mild; 2, mild-to-moderate; 3, moderate; and 4, severe. To estimate the effective regurgitant orifice (EOA) after TAVR, we used the methods described by Clavel et al.[14]

## Statistical Analysis

Continuous normally distributed parameters are presented as the mean ± standard deviation and were compared using the Student *t* test or paired *t* test, as appropriate. Ordinal and/or non-normally distributed data are presented as the median and first and third quartiles and were compared using the Wilcoxon rank sum or Wilcoxon signed rank test. Categorical data were compared between groups using the chi-square test or Fisher's exact test, whenever the expected values in any of the cells of a contingency table were less than 5. Unadjusted and adjusted Cox proportional hazards