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Incidence, Timing, and Predictors of Valve Hemodynamic Deterioration After Transcatheter Aortic Valve Replacement

Multicenter Registry

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ABSTRACT

BACKGROUND Scarce data exist on the incidence of and factors associated with valve hemodynamic deterioration (VHD) after transcatheter aortic valve replacement (TAVR).

OBJECTIVES This study sought to determine the incidence, timing, and predictors of VHD in a large cohort of patients undergoing TAVR.

METHODS This multicenter registry included 1,521 patients (48% male; 80 ± 7 years of age) who underwent TAVR. Mean echocardiographic follow-up was 20 ± 13 months (minimum: 6 months). Echocardiographic examinations were performed at discharge, at 6 to 12 months, and yearly thereafter. Annualized changes in mean gradient (mm Hg/year) were calculated by dividing the difference between the mean gradient at last follow-up and the gradient at discharge by the time between examinations. VHD was defined as a ≥10 mm Hg increase in transprosthetic mean gradient during follow-up compared with discharge assessment.

RESULTS The overall mean annualized rate of transprosthetic gradient progression during follow-up was 0.30 ± 4.99 mm Hg/year. A total of 68 patients met criteria of VHD (incidence: 4.5% during follow-up). The absence of anticoagulation therapy at hospital discharge ($p = 0.002$), a valve-in-valve (TAVR in a surgical valve) procedure ($p = 0.032$), the use of a 23-mm valve ($p = 0.016$), and a greater body mass index ($p = 0.001$) were independent predictors of VHD.

CONCLUSIONS There was a mild but significant increase in transvalvular gradients over time after TAVR. The lack of anticoagulation therapy, a valve-in-valve procedure, a greater body mass index, and the use of a 23-mm transcatheter valve were associated with higher rates of VHD post-TAVR. Further prospective studies are required to determine whether a specific antithrombotic therapy post-TAVR may reduce the risk of VHD. (J Am Coll Cardiol 2016;67:644–55)
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Structural valve degeneration (SVD) is the main cause of bioprosthetic valve failure after surgical aortic valve replacement (SAVR). The reported incidence of SVD after SAVR at 1, 10, and 15 years has been <1%, 10% to 30%, and 20% to 50%, respectively (1–3). These data traditionally have been determined on the basis of the incidence of reoperation after surgical bioprosthetic valve failure. However, this approach may underestimate the true incidence of SVD (4,5), and several studies have proposed to define SVD occurrence according to the development of valve hemodynamic dysfunction documented by Doppler echocardiography (6–8). With this approach, Mahjoub et al. (8) found a 20% SVD incidence during a mean follow-up of 8 years post-SAVR. Valve hemodynamic deterioration (VHD) as documented by Doppler echocardiography may be related to calcific degeneration of bioprosthetic valve leaflets (i.e., SVD), but it may also result from thrombosis or pannus ingrowth.

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Transcatheter aortic valve replacement (TAVR) is well established for treating patients with symptomatic severe aortic stenosis who are at high or prohibitive surgical risk (9). Although SVD requiring valve replacement is a rare entity within the first years after TAVR (10,11), scarce data exist on subclinical bioprosthetic hemodynamic dysfunction after TAVR. Investigators have suggested that rapid changes in transvalvular gradients may be the hallmark of valve thrombosis despite the absence of clinical symptoms (12–14). Given that antithrombotic or anticoagulation therapies post-TAVR are not currently well established, it is of the utmost importance to determine whether subclinical valve thrombosis could be an underlying pathophysiological mechanism contributing to transcatheter valve failure. We aimed to establish the incidence and risk factors of VHD within a large population of patients who had undergone TAVR.

METHODS

Between May 2007 and October 2014, 2,418 consecutive patients underwent TAVR in 10 participating centers. Patients were considered eligible for this multicenter study if they had undergone at least 2 echocardiograms post-TAVR (at discharge and at a minimum of 6- to 12-month follow-up). A total of 1,521 patients satisfied these criteria and were included in our study. Eligibility for TAVR, valve type, and access route were determined at each center by a local heart team composed of interventional cardiologists and cardiac surgeons. Clinical, procedural, and echocardiographic data were prospectively gathered within a TAVR database at each participating center. This study was not a prespecified analysis at the time of the creation of the database; therefore, data were analyzed retrospectively. Clinical follow-up was undertaken during clinical visits or through telephone contact, or both, at 1 month post-TAVR, at 6 to 12 months post-TAVR, and yearly thereafter in all participating centers. Clinical events were prospectively recorded and defined according to VARC-2 (Valve Academic Research Consortium-2) criteria (15).

ECHOCARDIOGRAPHIC ASSESSMENT. Transthoracic echocardiography (TTE) examinations were performed at baseline, at hospital discharge, at 6 to 12 months post-TAVR, and yearly thereafter.

All TTE examinations were conducted according to American Society of Echocardiography guidelines (16,17). Peak transprosthetic flow velocity was determined by continuous-wave Doppler imaging. The mean transprosthetic gradient was calculated using the modified Bernoulli formula. Absolute change in mean gradient was calculated as the gradient at last follow-up minus the gradient at discharge. Annualized change in mean gradient (mm Hg/year) was calculated by dividing the absolute change in gradient by the time between examinations. VHD was defined as an absolute change in gradient of ≥10 mm Hg during follow-up (8,18). Early VHD was defined as a ≥10 mm Hg increase in mean gradient within the first year after TAVR compared with discharge assessment. Moderate and severe postoperative prosthesis-patient mismatches (PPMs) were defined as an indexed effective orifice area (EOA) of ≥0.65 to ≤0.85 cm^2/m^2 and <0.65 cm^2/m^2, respectively (19).

STATISTICAL ANALYSIS. Categorical variables are reported as number (percent) and continuous variables as mean ± SD or median (25th to 75th interquartile range [IQR]), depending on variable distribution. Group comparisons were analyzed with the Student *t* test or Wilcoxon rank sum test for continuous variables and the chi-square test or Fisher exact test for categorical variables. Changes in mean transaortic gradient measurements over time (discharge, 6 months to 1, 2, 3, and 4 years) were evaluated with repeated-measures analyses of variance. The normality assumption was verified with the Shapiro-Wilk tests on the error distribution from the Cholesky factorization of the statistical model. Mean

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation
BMI = body mass index
CT = computed tomography
EOA = effective orifice area
PPM = prosthesis-patient mismatch
SAVR = surgical aortic valve replacement
SVD = structural valve degeneration
TAVR = transcatheter aortic valve replacement
TE = transthoracic echocardiography
TEE = transesophageal echocardiography
THV = transcatheter heart valve
VHD = valve hemodynamic deterioration

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