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Incidence, Predictors, and Clinical Impact of Prosthesis–Patient Mismatch Following Transcatheter Aortic Valve Replacement in Asian Patients

The OCEAN-TAVI Registry

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ABSTRACT

OBJECTIVES The authors sought to investigate the prevalence, risk factors, and mid-term mortality in Asian patients with prosthesis-patient mismatch (PPM) after transcatheter aortic valve replacement (TAVR).

BACKGROUND Little information is available on PPM after TAVR in Asian patients.

METHODS The authors included 1,558 patients enrolled in the OCEAN-TAVI (Optimized transCathEter vAlvular iNtervention) Japanese multicenter registry from October 2013 to July 2016 after excluding patients who died following TAVR before discharge. PPM was defined as moderate if $\geqq 0.65$ but $\leqq 0.85$ cm^2/m^2, or severe if <0.65 cm^2/m^2 at the indexed effective orifice area by post-procedural echocardiography.

RESULTS Of the 1,546 patients, moderate and severe PPM were observed in 138 (8.9%) and 11 (0.7%) patients, respectively. These 149 patients were included in the PPM group. The median age and body surface area were 85 years (interquartile range [IQR]: 81 to 88 years) and 1.41 m^2 (IQR: 1.30 to 1.53 m^2), respectively. In our multivariate analysis, younger age, larger body surface area, smaller aortic valve area, smaller annulus area, no balloon post-dilatation, and use of Edwards Sapien 3 (Edwards Lifesciences, Irvine, California) were identified as independent predictors of PPM. The estimated cumulative all-cause mortality at 1 year using the Kaplan-Meier method was similar between the PPM and non-PPM groups (10.2% vs. 8.3%; log-rank; $p = 0.41$).

CONCLUSIONS The low prevalence of PPM and mortality at 1 year in patients with PPM after TAVR in this Japanese cohort implies that PPM is not a risk factor for mid-term mortality in Asian patients who have undergone TAVR.
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ABBREVIATIONS AND ACRONYMS

AR = aortic valve regurgitation

AVA = aortic valve area

BMI = body mass index

BSA = body surface area

CO = cardiac output

IQR = interquartile range

PPM = prosthesis-patient mismatch

SAVR = surgical aortic valve replacement

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

VARC = Valve Academic Research Consortium

Prosthesis-patient mismatch (PPM) occurs when the effective orifice area of a normally functioning implanted valve prosthesis is small in relation to the patient's body size. It has been reported that the incidence of PPM after surgical aortic valve replacement (SAVR) ranges from 20% to 70% (1-6). Previous studies have demonstrated that severe PPM impairs long-term survival, and that moderate PPM may be associated with worse long-term survival (1-6).

Transcatheter aortic valve replacement (TAVR) is an alternative treatment to SAVR in patients with severe symptomatic aortic stenosis deemed to be intermediate or high risk for surgery (7-12). PPM has also been observed in a considerable number of patients after TAVR despite a lower incidence of PPM in patients after TAVR and better survival in patients with PPM after TAVR than in those with PPM after SAVR (5,6,13-17). A report from the PARTNER trial (Placement of AoRTic TraNscathetER Valve Trial) demonstrated that the incidence of PPM was 46.4%, and that PPM had a negative impact on LV mass regression and mortality at 1 year in the patient subset with no post-procedural aortic valve regurgitation (AR) (6). PPM after TAVR remains an important concern.

SEE PAGE 781

The major determinants of PPM after SAVR are smaller prosthetic device and larger body surface area (BSA) (13,18-20). Similarly, it has been reported that BSA is one of the most powerful predictors of PPM after TAVR (5). Although body size is correlated with aortic annulus size, the ratio of annulus size to BSA differs between Asian and Western cohorts (6,21,22); these facts raise the possibility of disparate incidence and prognosis of PPM after TAVR between Asian and Caucasian cohorts. Nevertheless, the incidence, risk factors, and clinical impact of PPM after TAVR remain unknown in Asian populations.

Thus, the aim of this study was to investigate the incidence, predictors, and mid-term mortality in patients with PPM after TAVR in an Asian cohort using data from a Japanese multicenter prospective registry.

METHODS

STUDY POPULATION AND DESIGN. The OCEAN-TAVI (Optimized transCathEter vAlvular iNtervention) registry is a multicenter prospective registry affiliated with 14 high-volume centers in Japan. This registry was established to monitor and record the procedural results and post-procedural clinical outcomes of TAVR. This trial is registered with the University Hospital Medical Information Network (UMIN000020423). Between October 2013 and July 2016, a total of 1,613 consecutive high-risk Japanese patients with symptomatic, severe AS undergoing TAVR with the Edwards Sapien XT, Edwards Sapien 3 (Edwards Lifesciences, Irvine, California), or Medtronic CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) were prospectively included in the OCEAN-TAVI registry. The inclusion criteria of this registry were previously reported (23-25). We excluded 67 patients because of the following reasons: death after TAVR before discharge (n = 49), conversion to SAVR (n = 5), absence of transcatheter heart valve (THV) as a result of delivery failure or migration of THV (n = 1), and unreliable echocardiographic data as a result of left ventricle obstruction or poor image (n = 12). The remaining 1,546 patients were included in this study.

PROCEDURES. Detailed TAVR procedures have been previously described (23-25). The prosthesis size was determined based on the findings from pre-procedural echocardiography and multidetector computed tomography. The devices were delivered via the transfemoral, trans-subclavian, transaortic, or transapical approaches.

DEFINITIONS OF PPM, VALVE STENOSIS, AND DEVICE-ANNULUS RATIO. Echocardiographic evaluation was performed at baseline before the TAVR procedure and at discharge. PPM was assessed with a post-procedure echocardiogram. Patients with moderate and severe PPM were included in the PPM group in this study. According to the Valve Academic

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