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Predictors for Paravalvular Regurgitation After TAVR With the Self-Expanding Prosthesis: Quantitative Measurement of MDCT Analysis

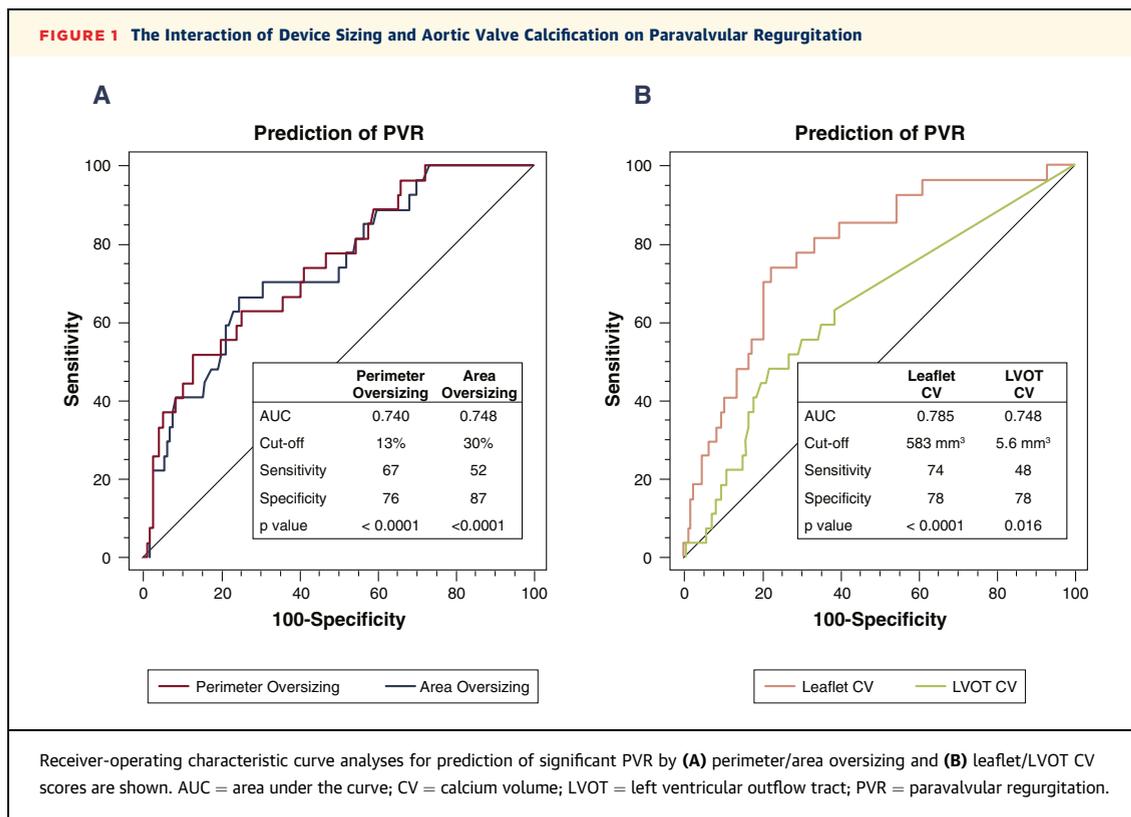


Paravalvular regurgitation (PVR) remains a major concern of transcatheter aortic valve replacement (TAVR) as it is associated with poorer outcomes. PVR after TAVR results from several factors, including, device undersizing, aortic valve calcification, and prosthesis malposition (1). We sought to evaluate the impact of device sizing and aortic valve calcium distribution on PVR after TAVR with self-expanding

prosthesis (CoreValve, Medtronic Inc., Minneapolis, Minnesota).

We examined 183 consecutive patients treated with TAVR using self-expanding prosthesis undergoing pre-procedural multidetector computed tomography after exclusion of patients with low prosthesis implantation (distance between basal skirt of prosthesis and lower edge of noncoronary cusp ≥ 10 mm) and valve-in-valve. All computed tomographic Digital Imaging and Communication in Medicine data were centrally collected and annulus dimensions and calcium volume were retrospectively analyzed at core laboratory in Asan Medical Center as described previously (2). PVR was assessed by transthoracic echocardiography at discharge according to VARC-2 definitions and PVR \geq moderate was categorized as significant PVR (3).

The mean age was 80.2 ± 6.2 years and 48% of patients were female. All patients had severe aortic stenosis with mean pressure gradient of 55.6 ± 18.3 mm Hg and mean aortic valve area of 0.64 ± 0.18 mm². PVR \geq moderate was found in 27 patients (14.8%). The PVR \geq moderate group showed larger annulus size (area 482.9 ± 74.4 mm² vs. 421.3 ± 85.4 mm²; $p = 0.001$; perimeter 79.4 ± 5.8 mm vs. 74.3 ± 7.4 ; $p = 0.001$) and significant smaller



device relative to annulus dimensions (area oversizing $33.2 \pm 13.1\%$ vs. $48.6 \pm 18.6\%$; $p < 0.001$; perimeter oversizing $12.7 \pm 5.5\%$ vs. $18.5 \pm 7.0\%$; $p < 0.001$). In terms of aortic valve calcification, calcium volume in leaflet was higher in the PVR \geq moderate group ($837 \pm 498 \text{ mm}^3$ vs. $420 \pm 347 \text{ mm}^3$; $p < 0.001$), but there were no differences in left ventricle outflow tract ($16 \pm 34 \text{ mm}^3$ vs. $9 \pm 25 \text{ mm}^3$; $p = 0.23$).

Receiver operating characteristics curves for device oversizing variables and aortic valve calcium volume scores in predicting significant PVR identified cut-off values of perimeter oversizing and leaflet calcium volume as 13% and 583 mm^3 , respectively (Figures 1A and 1B). In the multivariable analysis, perimeter oversizing was associated with a reduction in the incidence of significant PVR (odds ratio: 0.90; 95% confidence interval: 0.83 to 0.98; $p = 0.01$), whereas leaflet calcium volume was associated with increased PVR (per increase of 100 mm^3 , odds ratio: 1.18; 95% confidence interval: 1.06 to 1.31; $p = 0.002$). Note that patients with perimeter oversizing $>13\%$ had lower incidence of significant PVR compared to those with a lower degree of oversizing even satisfying the sizing criteria of manufacturer's recommendation (7.1% vs. 33.3%; $p < 0.001$), as well as those with undersized prosthesis by the sizing criteria of manufacturer's recommendation (7.1% vs. 30.8%; $p < 0.05$).

The present study demonstrates that device undersizing and leaflet calcium volume are independently associated with significant PVR following self-expanding prosthesis implantation. In the present study, incidence of significant PVR for patients with severe calcification was much higher than those without severely calcified leaflet even received prosthesis with perimeter oversizing $>13\%$ (26.1% vs. 2.9%; $p < 0.05$). This appears to be the limitation of current prosthesis and further analysis for new generation prosthesis should be assessed. In addition, our study tends to suggest that a higher degree of oversizing than reported in the manufacturer's recommendation is warranted to reduce the incidence of significant PVR. We should acknowledge that the present study is retrospective study and the PVR grading was adjudicated by each local center rather than by a core laboratory. However, board-certified echocardiographers experienced in PVR imaging

assessed PVR grading according to the established guidelines.

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<http://dx.doi.org/10.1016/j.jcmg.2015.10.011>

Please note: This study was supported by a grant from the CardioVascular Research Foundation, Seoul, Republic of Korea. Dr. Corrado Tamburino is associated with Abbott and Medtronic; and has received honoraria for speaking. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Yoon and Ahn contributed equally to this article.

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