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

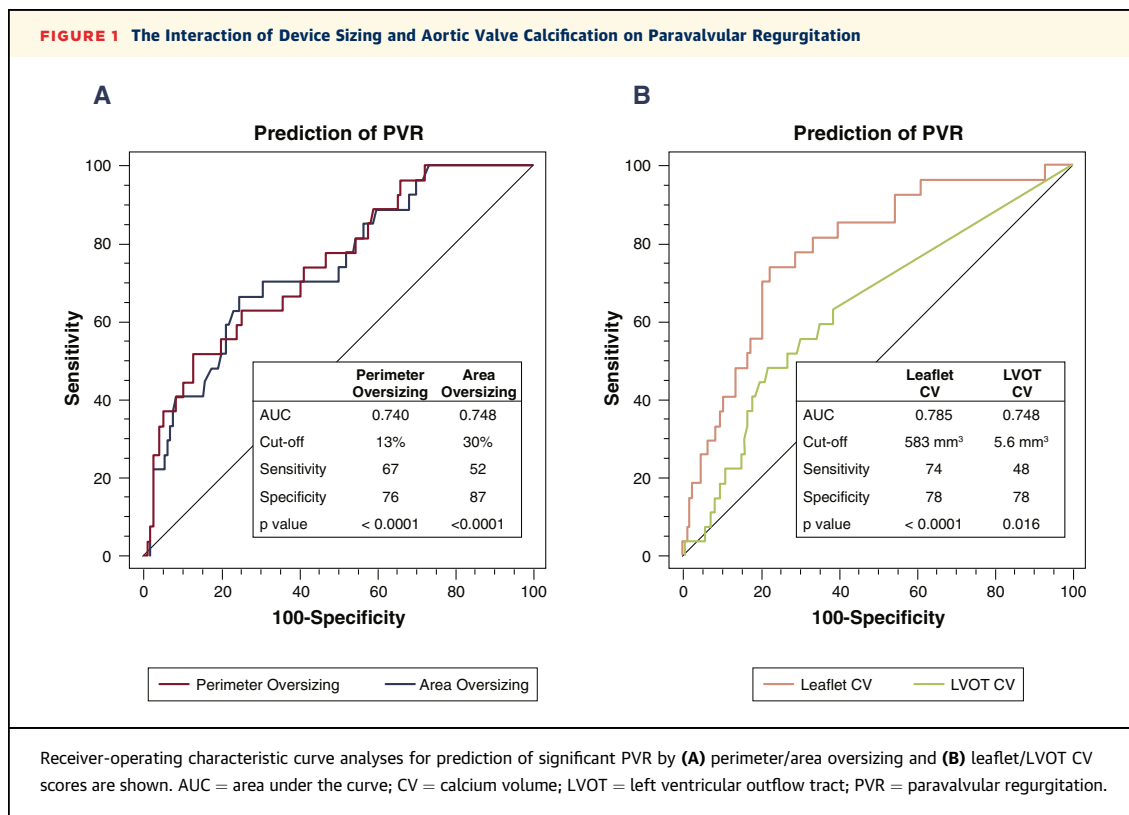


Paravalvular regurgitation (PVR) remains a major concern of transcatheter aortic valve replacement (TAVR) as it is associated with poorer outcomes. PVR after TAVR results from several factors, including, device undersizing, aortic valve calcification, and prosthesis malposition (1). We sought to evaluate 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  $\geq 10$  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  $80.2 \pm 6.2$  years and 48% of patients were female. All patients had severe aortic stenosis with mean pressure gradient of  $55.6 \pm 18.3$  mm Hg and mean aortic valve area of  $0.64 \pm 0.18$  mm<sup>2</sup>. PVR  $\geq$  moderate was found in 27 patients (14.8%). The PVR  $\geq$  moderate group showed larger annulus size (area  $482.9 \pm 74.4$  mm<sup>2</sup> vs.  $421.3 \pm 85.4$  mm<sup>2</sup>;  $p = 0.001$ ; perimeter  $79.4 \pm 5.8$  mm vs.  $74.3 \pm 7.4$ ;  $p = 0.001$ ) 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  $583 \text{ mm}^3$ , 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  $100 \text{ mm}^3$ , 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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