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RESEARCH LETTER

Standardized Invasive Hemodynamics for Management of Patients With Elevated Echocardiographic Gradients Post-Transcatheter Aortic Valve Replacement at Midterm Follow-Up

Madeleine Barker¹, MD; Amr E. Abbas², MD; John G. Webb, MD; Philippe Pibarot³, MD; Janarthanan Sathananthan, MBChB, MPH; Nathan Brunner, MD; Dee Dee Wang, MD; Jia Wang, MSc; Martin B. Leon, MD; David A. Wood⁴, MD

The Valve Academic Research Consortium-3 (VARC-3) proposes a multiparameter echocardiographic-derived approach for structural valve degeneration of transcatheter heart valves (THVs).¹ In clinical practice, physicians may be guided by mean gradient (MG) alone to suspect structural valve degeneration.^{1,2} Several reports have demonstrated discordance between echocardiography-derived and direct invasive measurement of MG immediately post-TAVR, with lower gradients observed with invasive measures, attributed to limitations of the Bernoulli equation and impact of pressure recovery.³ The role of invasive hemodynamics for the assessment of elevated echocardiography-derived MGs at midterm follow-up post-TAVR is unknown and may have important implications.

This prospective pilot study compared echocardiographic and invasive transaortic MGs in patients who met the VARC-3 criteria for \geq stage 2 (moderate) hemodynamic valve deterioration (HVD) or a MG \geq 20 mmHg on any follow-up transthoracic echocardiogram (TTE) $>$ 1 month post-TAVR. All eligible patients underwent standardized invasive hemodynamic (SIH) testing with a simultaneous on-table TTE. Before SIH, all patients had computed tomography to exclude hypoattenuated leaflet thickening or thrombosis. This study was approved by the institutional review board, and procedures followed were in accordance with institutional guidelines. The data to support the findings of this study are available from the corresponding author upon reasonable request.

SIH is performed as follows: two 6F pigtail catheters were positioned in the ascending aorta to assess for pressure tracings quality and difference. One pigtail catheter was then advanced across the THV and positioned as deep in the left ventricular cavity. The proximal pigtail catheter was positioned at the origin of the transverse arch to obtain a gradient across the aortic valve and eliminate the impact of pressure recovery (average of 3 measurements). An on-table TTE was done concurrently. All hemodynamic tracings were reviewed by 2 independent readers at the CCI-CIC Hemodynamic Core Lab using the Mac-Lab software (GE Healthcare).

Between July 2020 and January 2021, 13 patients with an echocardiographic MG \geq 20 mmHg on follow-up post-TAVR (2–39 months; median, 19.2 months) and 5 of whom with \geq stage-2 VARC-3 HVD underwent SIH and simultaneous on-table TTE. All 13 patients had Sapien 3 THVs, and 4 patients had undergone valve-in-valve TAVR in failed surgical bioprostheses. Mean (SD) difference between on-table echocardiographic and invasive MG was 6.1 ± 5.6 mmHg ($P=0.002$; paired t test). When compared with invasive MG, the follow-up TTE MG was also significantly higher with mean (SD) difference of 11.5 ± 8.4 mmHg ($P<0.001$, paired t test). The Bland-Altman plot demonstrates a wide limit of agreement, indicating that echocardiography and direct invasive MG measurements are not interchangeable with no detectable trend between the difference and magnitude of the measured

Key Words: echocardiography ■ follow-up studies ■ heart valves ■ physicians ■ transcatheter aortic valve replacement

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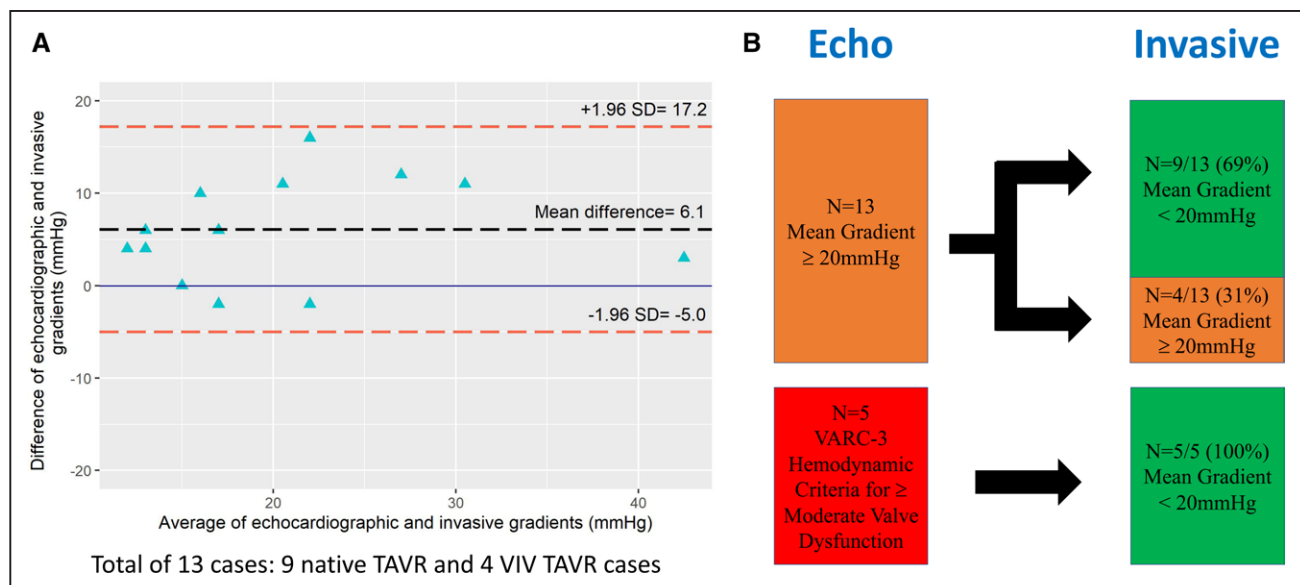


Figure. Discordance between echocardiography (echo) and standardized invasive hemodynamics (SIH).

A, Bland-Altman plot between echo-derived and direct invasive measures of transaortic valve gradients post-transcatheter aortic valve replacement (TAVR). A positive value indicates a higher gradient using on-table transthoracic echocardiogram compared with SIH. **B**, Using SIH instead of echo-derived gradients, 9 (69.2%) patients now had a mean transaortic gradient <20 mmHg. All 5 patients who met Valve Academic Research Consortium-3 (VARC-3) hemodynamic criteria for \geq moderate valve dysfunction were not found to have hemodynamic valve deterioration (HVD) by invasive measurement. VIV indicates valve-in-valve.



value (Figure [A]). SIH is an additive tool in the setting of elevated echocardiography-derived MG on follow-up after TAVR, 9 (69.2%) patients had an MG <20 mmHg, and all 5 patients who met the VARC-3 criteria for \geq stage 2 HVD had an invasive MG <20 mmHg (Figure [B]).

This is the first hemodynamic core laboratory adjudicated prospective study using a standardized, reproducible protocol to measure invasive MG, which demonstrated a significant discordance between echocardiographic and invasive MGs at follow-up after TAVR. Importantly, all patients who met the VARC-3 criteria for \geq stage 2 HVD by echocardiography were not found to have HVD by invasive measurement, thus possibly avoiding unnecessary valvular reintervention. This study demonstrates the additive role of SIH in patients with echocardiographic structural valve degeneration post-TAVR and may help guide the assessment of THV function. The role of invasive hemodynamics and a comparison of echocardiography-calculated and invasively measured pressure recovery, defined by the difference between MG 1 cm above the THV frame and at the origin of the transverse arch, will be further investigated in the larger prospective multicenter DISCORDANCE TAVR study (Standardized Invasive Hemodynamics for Monitoring Acute and Long-Term Valve Performance in Patients With Elevated Gradients Post-Transcatheter Aortic Valve Replacement: The DISCORDANCE TAVR Study; <https://www.clinicaltrials.gov>; unique identifier: NCT04827238) in patients who meet the VARC-3 criteria for \geq stage 2 HVD.

ARTICLE INFORMATION

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