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ORIGINAL RESEARCH

CORONARY, PERIPHERAL, AND STRUCTURAL INTERVENTIONS

Construct Validity of a Novel Fiberoptic TAVR Guidewire for Invasive Pressure Measurements

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ABSTRACT

BACKGROUND A novel fiberoptic transcatheter aortic valve replacement (TAVR) guidewire was developed that enables continuous hemodynamic monitoring, easy pacing over the wire, and guiding of the valve prosthesis.

OBJECTIVES This study aimed to evaluate construct validity of hemodynamic measurements obtained with the fiberoptic TAVR guidewire compared to conventional fluid-filled pigtail catheters.

METHODS This prospective registry study included patients undergoing TAVR. Complete hemodynamic assessment was performed in-duplo with the fiberoptic TAVR guidewire and conventional pigtail catheters. Primary endpoint was the agreement between modalities for post-TAVR mean pressure gradient (PG). Secondary endpoints included agreement in assessing paravalvular regurgitation and in-depth signal analysis using a validated automated algorithm.

RESULTS This study included 150 patients (mean age 79.7 ± 5.8 years; 46.7% female). Comparison of invasive pressure measurements yielded moderate to excellent agreement (intraclass correlation coefficient [ICC]-range: 0.65 to 0.95). Bias was observed in left ventricular end-diastolic pressure (LVEDP), with the fiberoptic guidewire measuring higher LVEDPs (+3.5 mm Hg). Post-TAVR mean PG showed a mean absolute difference of 2.7 ± 2.1 mm Hg (ICC: 0.67), minimal bias (−0.45 mm Hg), and 87% concordance with a discrete cutoff (10 mm Hg). Good overall agreement was observed for most indices of paravalvular regurgitation (ICC-range: 0.81-0.87). Automated algorithm assessment revealed fewer artefacts and calibration errors for the fiberoptic guidewire ($P = 0.048$), repeat analysis improved mean PG agreement (ICC-range: 0.80-0.85).

CONCLUSIONS The fiberoptic guidewire effectively classified clinically relevant transvalvular gradients with limited bias post-TAVR, although it produced higher LVEDPs, possibly reflecting wire-induced leaflet interaction. Algorithm-derived assessment revealed the fiberoptic guidewire producing measurements with fewer artefacts and calibration errors, supporting its proof-of-concept potential to complement current invasive assessment standards.
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ABBREVIATIONS AND ACRONYMS

AoDBP = aortic diastolic blood pressure

AoSBP = aortic systolic blood pressure

ARI = aortic regurgitation index

DD = diastolic delta

ICC = intraclass correlation coefficient

LV = left ventricle

LVEDP = left ventricular end-diastolic pressure

LVSP = left ventricular systolic pressure

PCI = percutaneous coronary intervention

PG = pressure gradient

PVR = paravalvular regurgitation

TAVR = transcatheter aortic valve replacement

TTE = transthoracic echocardiography

Transcatheter aortic valve replacement (TAVR) has become a widely adopted percutaneous alternative to surgical valve replacement in an increasingly younger and lower-risk population, demanding a high degree of procedural success and prolonged prosthesis durability. Hemodynamic optimization of the valve prosthesis may play a central role in improving patient outcomes. Recently, a novel TAVR guidewire equipped with an integrated fiberoptic pressure sensor was developed to guide valve delivery, provide easy pacing-over-the-wire, and enable real-time invasive hemodynamic monitoring. The guidewire has been shown to enhance procedural efficiency[1] while providing effective and safe pacing.[2,3] Despite these advantages, robust data on the construct validity of its hemodynamic measurements remain scarce.[4]

Both residual transvalvular gradients and paravalvular regurgitation (PVR) post-TAVR pose significant risks to valve durability and patient outcomes. Invasively measured residual transvalvular gradients are associated with a significantly increased risk of all-cause mortality.[5] Similarly, PVR graded as more than a trace is associated with increased mortality and early valve deterioration.[6-10] Post-TAVR hemodynamic valve performance, that is residual gradient and the presence of PVR, is commonly assessed using fluoroscopy, angiography, and/or transthoracic echocardiography (TTE). However, these modalities lack diagnostic accuracy for transvalvular pressure gradients and/or PVR. This is reflected by TTE-derived residual pressure gradients correlating poorly with post-TAVR outcomes,[11,12] as well as TTE and angiography underestimating PVR severity compared to the gold standard cardiac magnetic resonance imaging.[13,14]

Alternatively, invasive hemodynamic measurements have shown great promise in providing high accuracy for both assessing residual transvalvular gradients[5] and PVR.[15-19] Traditionally, invasive measurements are obtained using 2 fluid-filled pigtail catheters placed above and below the aortic valve. However, pigtail catheter measurements can be cumbersome, and the fluid-filled nature of these catheters makes them susceptible to oscillations that cause artefacts.[20] In contrast, the recently introduced fiberoptic TAVR guidewire features an integrated solid-state sensor that enables continuous hemodynamic monitoring without the need to exchange for a second pigtail catheter. Furthermore, its solid-state design theoretically makes it less susceptible to oscillation-induced pressure artefacts. This fiberoptic TAVR guidewire thereby simplifies and potentially enhances invasive hemodynamic guidance during TAVR. Accordingly, the aim of this study was to evaluate the construct validity of the fiberoptic pressure sensor guidewire compared to conventional double fluid-filled pigtail catheter measurements in a real-world setting for the assessment of valve performance following TAVR. As both modalities rely on different software packages with different calculation algorithms, hampering direct comparison, we also aimed to compare the 2 modalities using our previously validated automated algorithm.[21]

METHODS

STUDY DESIGN. The current study was a single-center, investigator-initiated, prospective registry study including patients undergoing TAVR for severe aortic stenosis between February 2025 and January 2026 at the Radboud University Medical Center, Nijmegen, the Netherlands. Patients at high pre-procedural risk for conduction disturbances (ie, pre-operative right bundle branch block), and patients undergoing valve-in-valve procedures were excluded. All patients enrolled in this study were accepted for TAVR after discussion within a multidisciplinary heart team. The study was approved by the Medical Research Ethics Committee of the Radboud University Medical Center (2025-18557), and all

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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participants provided written informed consent regarding the use of their data. This study was conducted in accordance with the Declaration of Helsinki.

TAVR PROCEDURE. All TAVR procedures were performed in accordance with the hospital's standard of care and consistent with international guidelines. To assess the construct validity of the novel guidewire's hemodynamic measurements in a real-world setting, the fiberoptic TAVR guidewire was concomitantly used for both valve deployment and rapid ventricular pacing. For all TAVR procedures, a minimally invasive strategy was pursued, with radial secondary access whenever feasible.[22,23] The decision to perform postdilation was based on angiography (≥ moderate PVR or prosthesis underexpansion) performed without the fiberoptic guidewire in place, and on pigtail catheter derived invasive pressure measurements (elevated residual gradient). The expected risk-benefit ratio of postdilation, incorporating factors such as calcification distribution, annular and sinotubular junction anatomy, and the likely mechanism underlying the residual gradient or PVR, was considered on a case-by-case basis.

INVASIVE HEMODYNAMIC MEASUREMENTS. Fiberoptic guidewire (SavvyWire; Haemonetics) measurements were performed using the fiberoptic sensor positioned in the left ventricle (LV). Transvalvular gradients were subsequently calculated from the fiberoptic guidewire signal and the aortic pressure signal obtained from a pigtail catheter placed in the noncoronary cusp. Double pigtail catheter measurements were performed using 2 fluid-filled pigtail catheters (Impulse; Boston Scientific), each connected to a separate fluid management system with integrated pressure transducers (Navilyst Medical). Measurements were performed using both modalities at the following procedural steps: 1) before valve replacement; 2) following valve replacement; and if applicable 3) following postdilation. To prevent the need for an additional arterial access, minimize leaflet interaction, and better simulate real-world practice, fiberoptic and double pigtail catheter measurements were performed consecutively.

Pressure transducers in the fluid management systems were zeroed at the start of every procedure, and pigtail catheters were flushed before each measurement. Equalization and time delay of the fiberoptic derived pressures were performed according to the instructions for use. Equalization was performed by matching the pressures of the fiberoptic sensor with the transducer connected to the aortic pigtail catheter when both the sensor and aortic pigtail catheter were situated in the ascending aorta just above the aortic annulus. Equalization was performed both preprosthesis and postprosthesis deployment. Time delay was performed automatically, using the dedicated function integrated in the OptoMonitor (Haemonetics). Hemodynamic assessments were averaged across at least 4 consecutive cardiac cycles in patients with stable sinus rhythm at the time of measurement, and across at least 6 cycles in patients who were paced due to conduction disturbances, who had atrial fibrillation, and/or who had frequent premature ventricular contractions.

Hemodynamic measurements included aortic systolic and diastolic blood pressure, LV systolic (LVSP) and end-diastolic pressure (LVEDP), mean transvalvular pressure gradient (mean PG), and hemodynamic indices of PVR (ie, diastolic delta [DD],[16] heart rate-adjusted DD,[17] aortic regurgitation index [ARI],[18] and the ARI-ratio[19]). Pigtail catheter-derived hemodynamic data were captured in Sensis Vibe (Siemens Healthcare), and fiberoptic pressure measurements were captured using the OptoMonitor. Collected data were prospectively entered in a Castor Electronic Data Capture database (Castor EDC).

Comparison of fiberoptic guidewire and double pigtail catheter measurements were performed in the following order. First, isolated hemodynamic measurements (aortic systolic blood pressure, aortic diastolic blood pressure, LVSP, and LVEDP) were compared individually. Second, the mean transvalvular pressure gradients were compared. Third, the aforementioned hemodynamic indices of PVR were compared between the 2 pressure measurement modalities. Finally, raw pressure signals from both modalities were extracted, and transvalvular gradients were recalculated using our validated automated algorithm.

ENDPOINTS. The primary study endpoint was the construct validity of fiberoptic guidewire derived mean PG measurements post-TAVR, compared to double pigtail catheter measurements of the mean PG. Post-TAVR was defined as the final set of measurements after the procedure, either directly after valve deployment or after subsequent postdilation, if applicable.

Secondary endpoints included the construct validity of fiberoptic guidewire-derived isolated pressure measurements and indices of PVR. In addition, pressure gradients were compared again after automated analysis of fiberoptic guidewire- and pigtail catheter–derived continuous raw pressure signals. Furthermore, the use of the fiberoptic guidewire was evaluated for efficacy and safety endpoints, defined as successful pacing capture, technical success (according to the Valve Academic Research Consortium-3 criteria), and 30-day valve performance as objectified by TTE-derived mean PG and degree of PVR. Finally, TTE-derived gradients were compared with invasive measurements to assess correlation between modalities.

STATISTICAL ANALYSES. No formal sample size calculation was performed, as this is the first study assessing construct validity of fiberoptic invasive pressure measurements in a real-world TAVR cohort. Cohort size reflected the expected number of patients during the study period. Continuous data are presented as means and SDs (±SD), or as medians with IQRs whenever appropriate. Categorical data are presented as frequencies and percentages (%).

To evaluate the construct validity of post-TAVR mean PG measurements obtained with the fiberoptic guidewire, several comparisons were made with those obtained using double pigtail catheters. First, the mean absolute difference between fiberoptic guidewire and pigtail catheter-derived measurements was calculated. Agreement between both modalities was subsequently assessed using intraclass correlation coefficients (ICCs), which were based on a two-way mixed-effects model with absolute agreement and single measures. In addition, Bland-Altman analyses were performed to assess potential bias between measurements, while the SE of measurement (SEM) was calculated to quantify random error, providing added context for the observed agreement. To account for potential hemodynamic variation resulting from the consecutive acquisition of measurements, a sensitivity analysis was performed using linear regression to assess the association between the time interval separating measurements and the observed difference in mean PG. To evaluate the clinical implications of potential differences between measurements, concordance across gradient measurements was calculated using a previously defined clinically relevant cutoff of 10 mm Hg.[5]

Secondary evaluations included the construct validity of fiberoptic sensor-derived isolated pressure measurements and indices of PVR, which were compared to double pigtail catheter measurements using ICC and SEM calculations, stratified by pre- and post-TAVR phases. The correlation of the mean PG measured by both fiberoptic guidewire and pigtail catheters with the 30-day TTE-derived mean PG was assessed using the Pearson correlation coefficient.

As the fiberoptic guidewire and pigtail catheter measurements use different methods for calculating mean PG, potential differences in observed gradients could be caused purely by calculation differences. To eliminate this, a sensitivity analysis was performed using our own previously validated automated algorithm[21] on the raw pressure signals from both the fiberoptic sensor and the pigtail catheters, followed by repeating the analysis using the algorithm-derived parameters. In addition to eliminating calculation bias, this approach enabled in-depth analysis of signal quality, with exclusion of cardiac cycles affected by rhythm or pressure artefacts and signals with calibration errors.[21] In addition, algorithm-based analyses were repeated to evaluate agreement across varying signal quality thresholds. All analyses were performed in SPSS (version 29.0; IBM) and R (version 4.4.1; Posit PBC) using the "irr" package. Two-tailed P values of <0.05 were considered statistically significant for all analyses.

RESULTS

BASELINE AND PROCEDURAL CHARACTERISTICS. In total, 150 patients were enrolled. The mean age was 79.7 ± 5.8 years, with 46.7% being women (Table 1). European System for Cardiac Operative Risk Evaluation II score (EuroSCORE) was 2.6% ± 1.7%. The mean LV ejection fraction was 52.2% ± 8.9%, with 16.7% (25/150) of patients having a reduced LV ejection fraction. Fifteen patients (11.1%) had moderate aortic regurgitation. Procedural characteristics are presented in Table 2. Patients were predominantly treated using the femoral artery as primary access (n = 147, 98.0%). A pacing-over-the-wire strategy was used in all patients. Most patients were treated using a self-expanding TAVR device (n = 144, 96.0%), and local anesthesia was used in 132 patients (88.0%). Predilation and postdilation were performed in 128 (85.3%) and 32 patients (21.3%), respectively.

ISOLATED PRESSURE MEASUREMENTS. Post-TAVR, consecutive measurements were obtained with both modalities at a mean interval of 328 ± 128 seconds. Invasive pressure measurements obtained with the

TABLE 1 Baseline Characteristics (N = 150)

Demographics	
Age, y	79.7 ± 5.8
Women, n (%)	70 (46.7)
Body mass index, kg/m^2	26.9 ± 5.0
Comorbidities	
Obesity, n (%)	34 (22.7)
Diabetes requiring insulin, n (%)	7 (4.7)
Coronary artery disease, n (%)	50 (33.3)
Peripheral artery disease, n (%)	14 (9.3)
Chronic obstructive pulmonary disease, n (%)	16 (10.7)
Atrial fibrillation n (%)	22 (14.7)
Prior pacemaker implantation, n (%)	16 (10.7)
NYHA functional class III/IV, n (%)	35 (23.3)
CKD-EPI-GFR, mL/min	65.6 ± 15.9
EuroSCORE II, %	2.6 ± 1.7
Pre-TAVR echocardiography	
AVA, cm^2	0.76 ± 0.19
Mean PG, mm Hg	43.9 ± 12.8
Vmax, m/s	4.3 ± 0.6
LVEF, %	52.5 ± 8.7
Normal LV function (LVEF >50%)	125 (83.3)
Moderate LV function (LVEF 30%-50%)	20 (13.3)
Poor LV function (LVEF <30%)	3 (2.0)
Very poor LV function (LVEF <21%)	2 (1.3)
≥Moderate aortic regurgitation, n (%)	18 (12.0)
≥Moderate mitral regurgitation, n (%)	17 (11.3)

Values are mean ± SD, or ns (%).

AVA = aortic valve area; CKD-EPI-GFR = chronic kidney disease epidemiology collaboration equation for glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; PG = pressure gradient; LV = left ventricle; LVEF = left ventricular ejection fraction; TAVR = transcatheter aortic valve replacement; Vmax = peak aortic valve velocity.

TABLE 2 Procedural Characteristics (N = 150)

Primary access (percutaneous), n (%)	
Femoral	147 (98.0)
Subclavian	3 (2.0)
Anesthesia, n (%)	
Local	132 (88.0)
Conscious sedation	8 (5.3)
General	10 (6.7)
Primary pacing-over-the-wire strategy, *n* (%)	150 (100)
Predilation, n (%)	128 (85.3)
Postdilation, n (%)	32 (21.3)
Direct valve-in-valve replacement, n (%)	0 (0.0)
Valve, n (%)	
Medtronic Evolut FX+	
26 mm	25 (16.7)
29 mm	63 (42.0)
34 mm	54 (36.0)
Meril Myval Octapro	
21.5 mm	1 (0.7)
23 mm	2 (1.3)
26 mm	1 (0.7)
27.5 mm	1 (0.7)
30.5 mm	1 (0.7)
Abbott	
29 mm (Portico)	1 (0.7)
25 mm (Navitor)	1 (0.7)
Angiographic degree of PVR postimplantation	
No/trace	110 (73.3)
Mild	37 (24.7)
Moderate	3 (2.0)
Severe	0 (0.0)

Values are are n (%).

PVR = paravalvular regurgitation.

fiberoptic guidewire, compared with those obtained using double pigtail catheters, yielded ICC values ranging from 0.65 to 0.95, indicating moderate to excellent agreement (Table 3, Figure 1). Very high agreement was observed for LVSP measurements (ICC: 0.93 [95% CI: 0.90-0.95]). Moderate agreement was observed for LVEDP measurements (ICC: 0.65 [0.47-0.77]), with the fiberoptic guidewire measuring higher end-diastolic pressures (bias 3.5 mm Hg) (Figure 2). Comparable inferences were made when evaluating pre-TAVR measurements (Table 3, Figure 3).

TRANSVALVULAR PRESSURE GRADIENTS. When comparing transvalvular gradient measurements obtained with the fiberoptic guidewire and double pigtail catheters, the mean absolute difference for mean PG post-TAVR was 2.7 ± 2.1 mm Hg. This corresponded to an ICC of 0.67 (95% CI: 0.54-0.76), indicating moderate agreement between the fiberoptic guidewire and double pigtail catheter measurements of mean PG. Bland-Altman analysis revealed that, on a group level, the fiberoptic guidewire measured slightly lower mean gradients compared to double pigtail catheters (bias −0.45 mm Hg) (Figure 4), with a calculated SEM of 1.9 mm Hg for the fiberoptic guidewire measurements. A sensitivity analysis including only hemodynamically stable patients (mean arterial pressure ≥65 mm Hg, n = 144) yielded identical results (ICC: 0.67; 95% CI: 0.54-0.76). Similarly, no differences were observed for patients with permanent atrial fibrillation (n = 14; ICC: 0.69; 95% CI: 0.073-0.90). No correlation was observed between the time interval separating measurements and the difference in mean pressure gradient across modalities (R^2 = 0.003)

TABLE 3 Comparison of Fiberoptic Guidewire and Double Fluid-Filled Pigtail–Derived Invasive Hemodynamic Measurements

Pre-TAVR (n = 150)	Fiberoptic Guidewire	Double Pigtail	ICC (95% CI)	Standard Error of Measurement (SEM)
Isolated pressure measurements				
AoSBP, mm Hg	141.2 ± 27.9	138.2 ± 28.6	0.94 (0.91-0.95)	6.9
AoDBP, mm Hg	66.0 ± 14.5	63.9 ± 13.6	0.91 (0.88-0.94)	4.2
LVSP, mm Hg	191.5 ± 34.8	194.7 ± 34.9	0.95 (0.92-0.96)	7.8
LVEDP, mm Hg	19.3 ± 8.0	19.6 ± 7.7	0.67 (0.55-0.77)	4.5
Transvalvular systolic pressure gradients				
Mean PG, mm Hg	45.5 ± 16.8	48.5 ± 17.0	0.93 (0.89-0.96)	4.5
Indices of PVR				
DD, mm Hg	46.7 ± 15.4	44.3 ± 12.7	0.84 (0.78-0.89)	5.7
HR-DD, mm Hg/bpm	53.3 ± 16.8	48.9 ± 13.7	0.80 (0.68-0.87)	6.9
ARI	33.2 ± 9.8	32.6 ± 9.4	0.80 (0.73-0.86)	4.3
ARI-ratio	N/A	N/A	N/A	N/A
Post-TAVR (n = 150)	**Fiberoptic guidewire**	**Double pigtail**	**ICC (95%CI)**	**Standard Error of Measurement (SEM)**
Isolated pressure measurements				
AoSBP, mm Hg	150.6 ± 31.3	150.0 ± 29.6	0.94 (0.92-0.96)	7.5
AoDBP, mm Hg	65.0 ± 14.6	65.6 ± 13.2	0.94 (0.91-0.96)	3.4
LVSP, mm Hg	153.5 ± 31.3	153.9 ± 28.8	0.93 (0.90-0.95)	8.0
LVEDP, mm Hg	22.3 ± 9.2	18.9 ± 6.6	0.65 (0.47-0.77)	4.8
Transvalvular systolic pressure gradients				
Mean PG, mm Hg	4.8 ± 3.2	5.2 ± 3.5	0.67 (0.54-0.76)	1.9
Indices of PVR				
DD, mm Hg	42.7 ± 15.6	46.7 ± 12.3	0.87 (0.77-0.92)	5.1
HR-DD, mm Hg/beats/min	48.0 ± 15.7	52.2 ± 12.7	0.82 (0.72-0.88)	6.1
ARI	28.4 ± 9.1	31.6 ± 7.7	0.81 (0.66-0.89)	3.7
ARI-ratio	0.87 ± 0.31	1.00 ± 0.33	0.63 (0.45-0.75)	0.19

Values are mean ± SD.

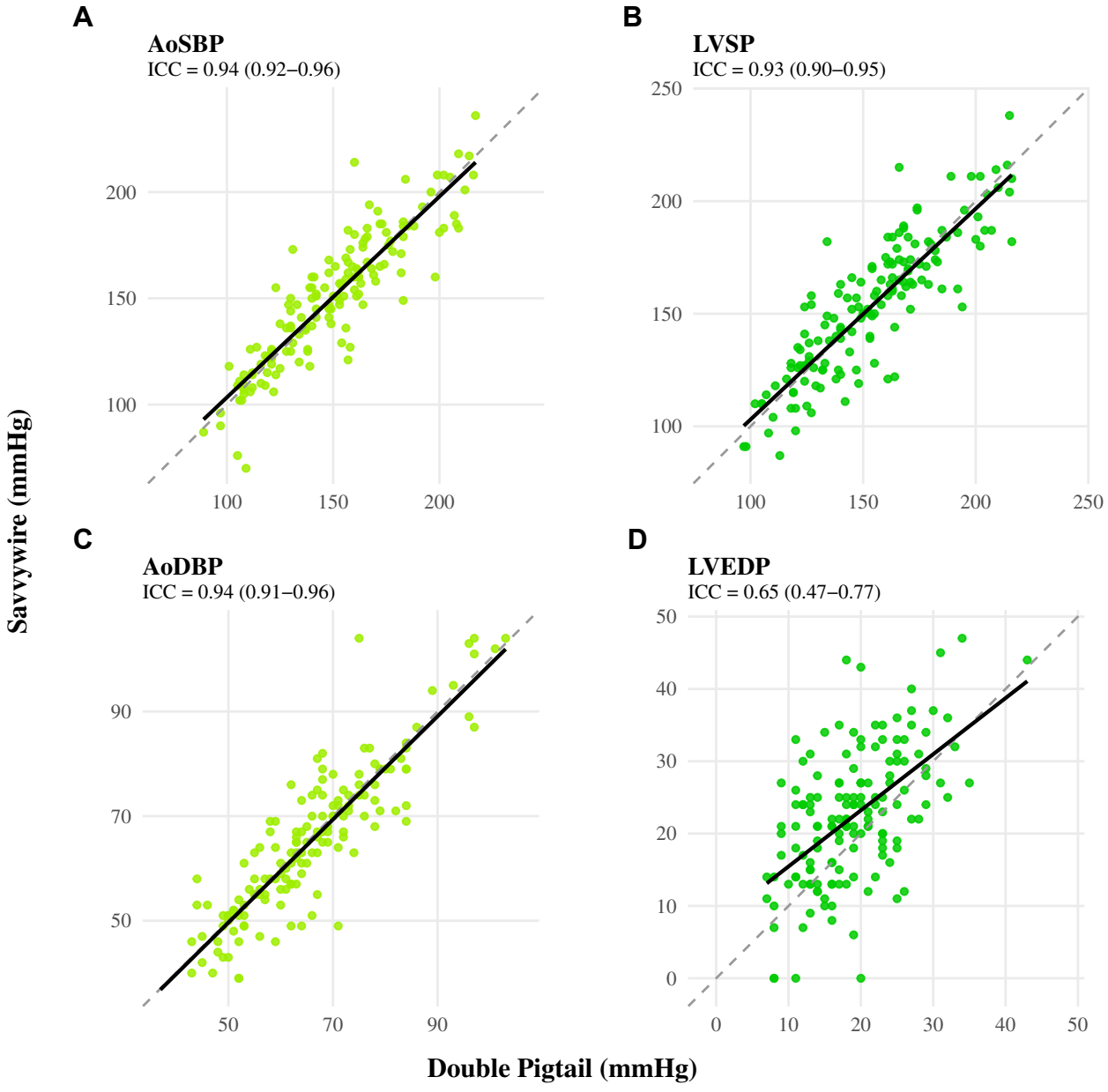
AoDBP = aortic diastolic blood pressure; AoSBP = aortic systolic blood pressure; ARI = aortic regurgitation index; DD = diastolic delta; HR-DD = heart rate-adjusted diastolic delta; ICC = intraclass correlation coefficient; LVEDP = left ventricular end-diastolic pressure; LVSP = left ventricular systolic pressure; other abbreviations as in Tables 1 and 2.

(Supplemental Figure 1). When assessed against a predefined clinically relevant cutoff of 10 mm Hg, the mean PG measurements from both modalities were concordant in 131/150 cases (87%). All discordant measurements were clustered near the treatment threshold (Supplemental Table 1) and did not result in additional postdilation. A magnitude-based sensitivity analysis, independent of the 10 mm Hg boundary, showed 90.0% concordance using a fixed >5 mm Hg cutoff; 15 of 19 threshold-based discordances (78.9%) reflected differences ≤5 mm Hg near the 10 mm Hg boundary, whereas converse discrepancies (threshold-concordant pairs differing by >5 or >4 mm Hg, the latter corresponding to the 75th percentile of observed differences) rarely involved measurements both at or above the clinical threshold (Supplemental Table 2).

INDICES OF PARAVALVULAR REGURGITATION. We found good overall agreement between both modalities when assessing hemodynamic indices of PVR (**Figure 5**). Following replacement, ICCs between both modalities were 0.87 (95% CI: 0.77-0.92) for DD, 0.82 (0.72-0.88) for heart rate-adjusted DD, and 0.81 (0.66-0.89) for ARI. In contrast, the ICC for the ARI-ratio reflected moderate agreement between modalities (ICC: 0.63 [0.45-0.75]) post-TAVR (**Table 3**). When stratified by LVEDP bias, agreement between modalities for PVR indices progressively decreased with increasing LVEDP bias (Supplemental Table 3).

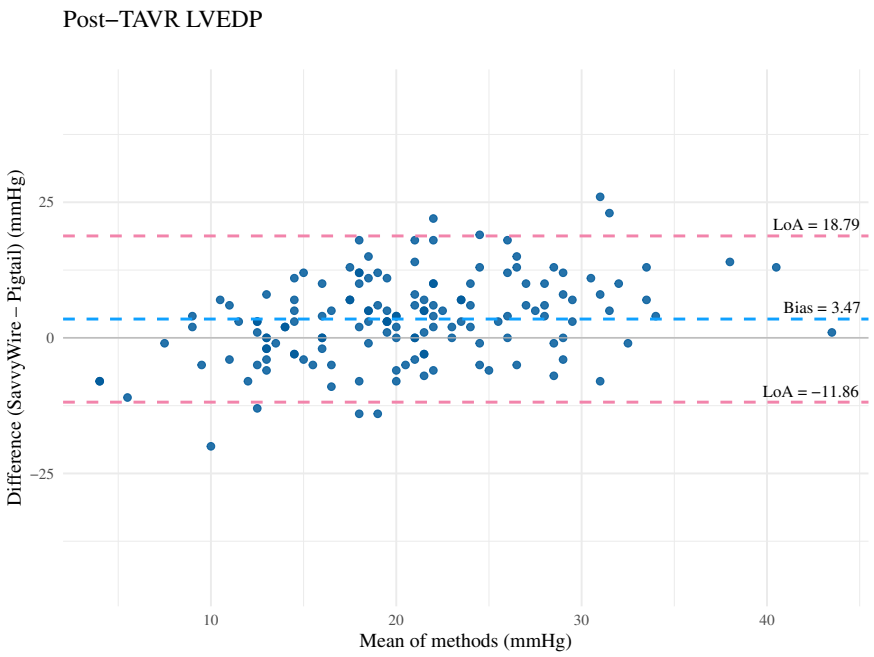
PRESSURE SIGNAL QUALITY AND AUTOMATED ALGORITHM ANALYSIS. Automated analysis[21] of raw pressure signals from the fiberoptic guidewire and double pigtail catheters resulted in the exclusion of

FIGURE 1 Agreement Between Fiberoptic Guidewire and Double Pigtail-Derived Isolated Pressure Measurements Post-Transcatheter Aortic Valve Replacement



Scatterplots showing fiberoptic guidewire and double pigtail catheter measurements for post-TAVR isolated pressures including: (A) aortic systolic blood pressure (AoSBP), (B) left ventricular systolic pressure (LVSP), (C) aortic diastolic blood pressure (AoDBP), and (D) left ventricular end-diastolic pressure (LVEDP).
ICC = intraclass correlation coefficient.

FIGURE 2 Comparison of Fiberoptic Guidewire and Double Pigtail Measurements of Post-TAVR Left Ventricular End-Diastolic Pressure

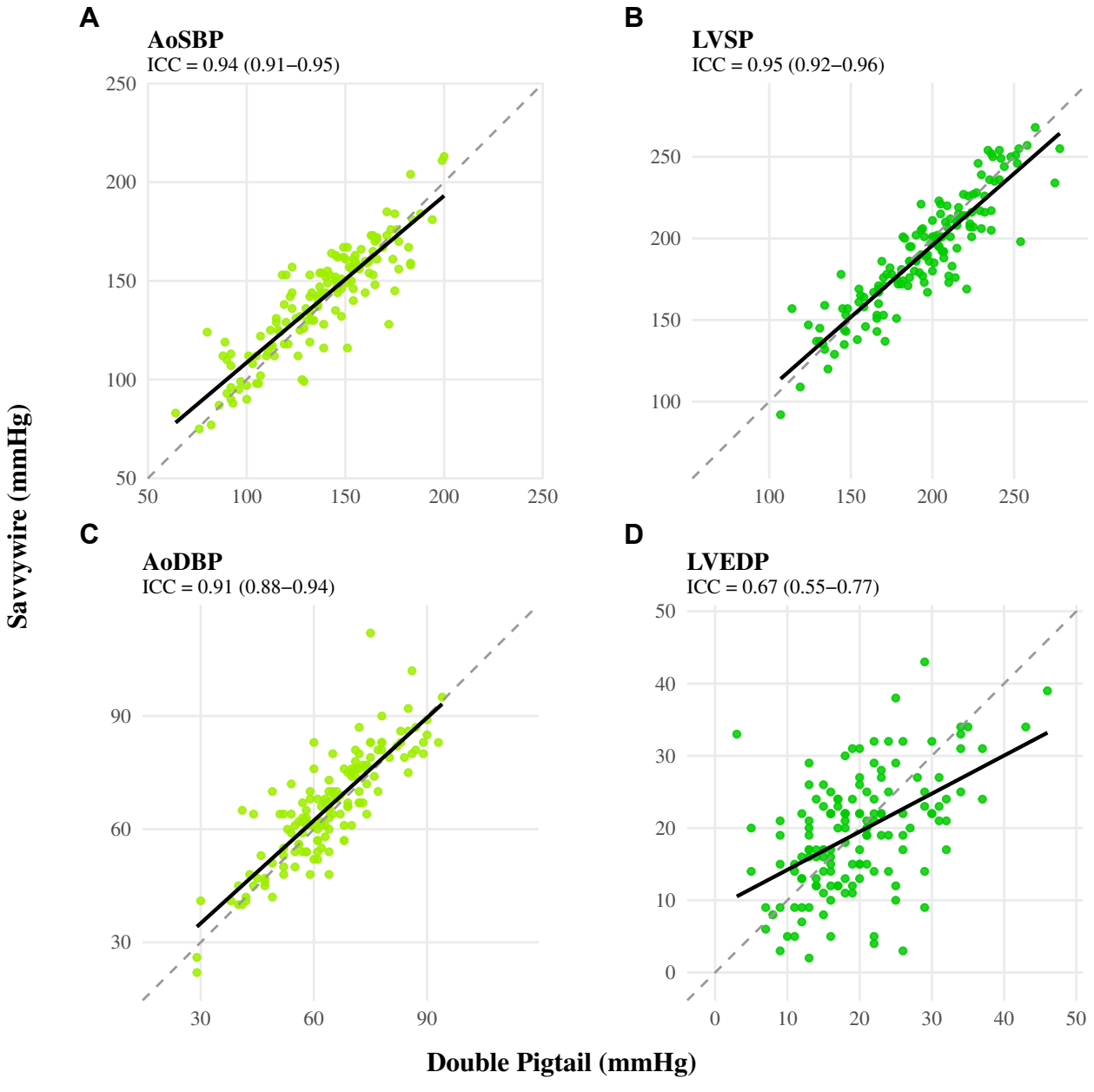


Bland-Altman plot displaying post-TAVR left ventricular end-diastolic pressures (LVEDP) obtained using the fiberoptic guidewire and double pigtail catheters, with dotted lines representing bias (blue) and limits of agreement (LoA) (pink). TAVR = transcatheter aortic valve replacement.

23 patients due to rhythm and pressure artefacts (Supplemental Table 4). After further automated exclusion of signals with calibration errors, a total of 25 patients were excluded based on fiberoptic guidewire signals and 39 patients based on double pigtail catheter signals (P = 0.048). A sensitivity analysis using the remaining algorithm-derived mean PG calculations at progressively stricter calibration-error thresholds (−2 to 0 mm Hg; n = 100-74) demonstrated improved construct validity of fiberoptic guidewire measurements of mean PG, with ICCs ranging from 0.80 to 0.85 and overlapping confidence intervals across thresholds (Supplemental Table 5). Further sensitivity analyses evaluated agreement under varying signal quality thresholds, including all patients regardless of rhythm or pressure artefacts and accepting all calibration errors (ICC: 0.70 [95% CI: 0.58-0.78], n = 149; 1 patient excluded due to inability to select a region of interest), and excluding patients with rhythm or pressure artefacts while retaining calibration errors (ICC: 0.72 [95% CI: 0.60-0.80]; n = 127).

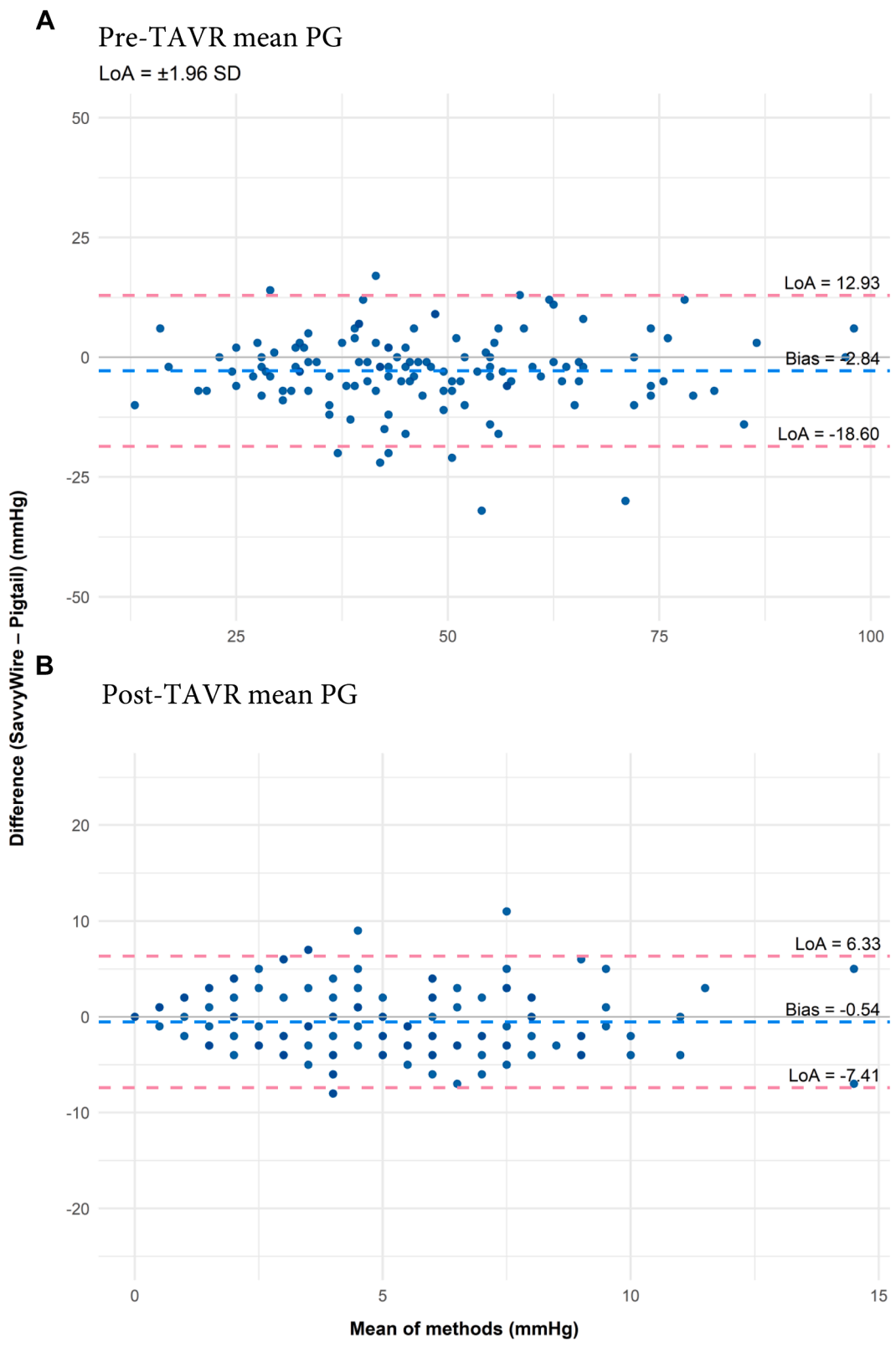
EFFICACY AND SAFETY ENDPOINTS. Efficacy and safety endpoints are presented in **Table 4**. Successful pacing capture was achieved in all patients, with only 1 instance of temporary procedural loss of capture following valve replacement, which was successfully resolved using a bailout temporary pacing lead. In total 15 patients (10.0%) required a bailout pacing lead, primarily due to high-degree conduction disturbances postreplacement. In these patients the fiberoptic guidewire provided adequate pacing support up until placement of the temporary lead. Technical success was achieved in 148 patients (98.7%), with no complications related to the fiberoptic guidewire. All-cause mortality, stroke, and major vascular complication rates were 0.7%, 4.7%, and 5.3%, respectively. TTE follow-up at 30 days revealed a mean PG of 7.1 ± 3.2 mm Hg, with only 5 patients (3.3%) showing moderate PVR. Comparing mean transvalvular gradients from post-TAVR invasive measurements with noninvasive TTE follow-up gradients revealed a low correlation for fiberoptic guidewire measurements (Pearson r = 0.30;

FIGURE 3 Agreement Between Fiberoptic Guidewire and Double Pigtail-Derived Isolated Pressure Measurements Pre-Transcatheter Aortic Valve Replacement



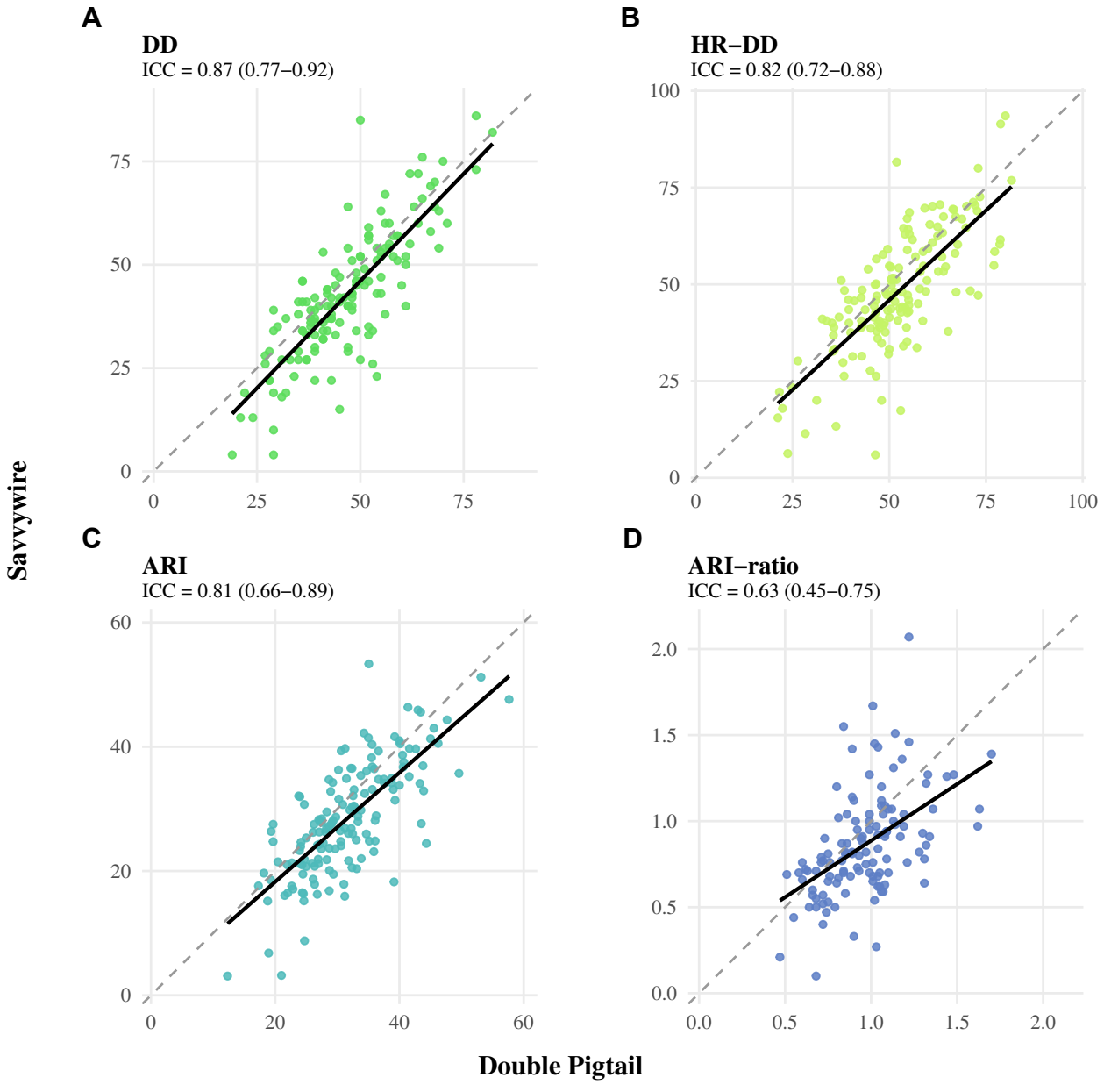
Scatterplots showing fiberoptic guidewire and double pigtail catheter measurements for pre-TAVR isolated pressures including: (A) aortic systolic blood pressure (AoSBP), (B) left ventricular systolic pressure (LVSP), (C) aortic diastolic blood pressure (AoDBP), and (D) left ventricular end-diastolic pressure (LVEDP). Abbreviation as in Figure 1.

FIGURE 4 Comparison of Fiberoptic Guidewire and Double Pigtail Measurements for Mean Pressure Gradients



Bland-Altman plots displaying mean pressure gradients obtained using the fiberoptic guidewire and double pigtail catheters: (A) pre-TAVR and (B) post-TAVR, with dotted lines representing bias (blue) and limits of agreement (LoA) (pink). PG = pressure gradient; other abbreviation as in Figure 2.

FIGURE 5 Agreement Between Fiberoptic Guidewire and Double Pigtail-Derived Measurements for Indices of PVR Post-TAVR



Scatterplots showing fiberoptic guidewire and double pigtail catheter measurements for post-TAVR indices of PVR, including (A) diastolic delta (DD), (B) heart rate-adjusted DD (HR-DD), (C) aortic regurgitation index (ARI), (D) ARI-ratio. Abbreviation as in Figure 1.

TABLE 4 Fiberoptic Guidewire Efficacy and Safety Outcomes (N = 150)

Efficacy outcomes	
Successful pacing capture, n (%)	150 (100)
Bailout pacing lead placed, n (%)	15 (10.0)
Technical success (VARC-3), n (%)	148 (98.7)
Fiberoptic guidewire safety outcomes	
Procedural loss of capture, n (%)	1 (0.7)
Complication related to the fiberoptic guidewire, n (%)	0 (0.0)
30-day safety outcomes	
All-cause mortality, n (%)	1 (0.7)
Conversion to surgery, n (%)	1 (0.7)
Stroke, n (%)	7 (4.7)
Major bleeding (VARC type ≥2), n (%)	6 (4.0)
Major vascular complication, n (%)	8 (5.3)
Acute kidney injury stage ≥3, n (%)	0 (0.0)
Permanent pacemaker implantation, n (%)	12 (8.0)
30-day valve performance	
TTE-derived mean PG, mm Hg	7.1 ± 3.2
Degree of PVR on TTE	
No/trace	85 (56.7)
Mild	47 (31.3)
Moderate	5 (3.3)
Severe	0 (0.0)

Values are n (%).
TTE = transthoracic echocardiogram; VARC = Valve Academic Research Consortium; other abbreviations as in Tables 1 and 2.

$P < 0.001$) and a very low correlation for double pigtail measurements (Pearson r = 0.06; $P = 0.48$).

DISCUSSION

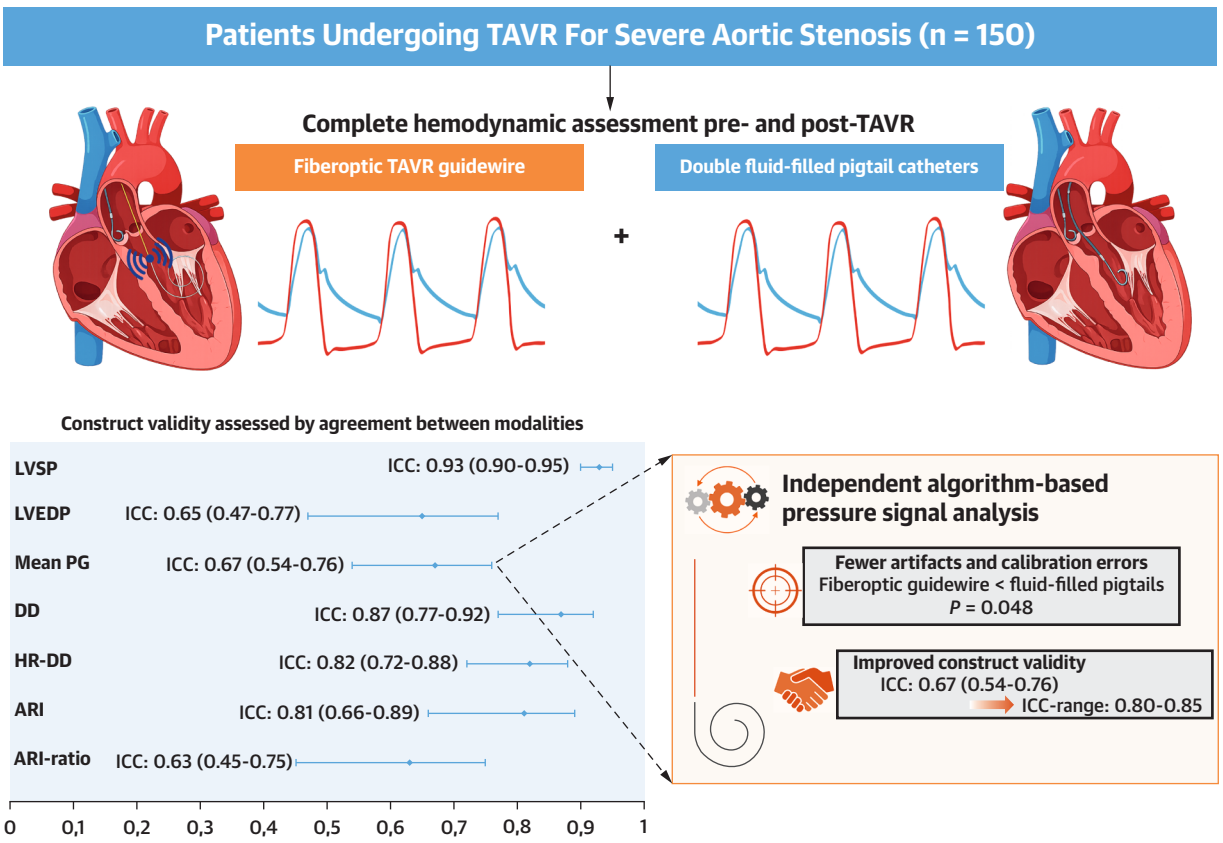
In this investigator-initiated, prospective, real-world registry, we evaluated the construct validity of hemodynamic measurements from a novel fiberoptic guidewire (ie, SavvyWire) compared with conventional double fluid-filled pigtail catheter measurements during TAVR (Central Illustration). Key findings can be summarized as follows. First, the construct validity of the fiberoptic sensor guidewire shows moderate to excellent correlation in terms of overall pressure measurements when compared to the current reference standard of double pigtail measurements, with clinically nonsignificant SEMs. Second, post-TAVR invasive pressure measurements showed moderate and good agreement for mean PG and PVR respectively, with excellent agreement in classifying clinically relevant residual transvalvular gradients. Third, the fiberoptic guidewire produced pressure signals with fewer pressure artefacts and calibration errors compared to the current reference standard of double pigtail measurements. Moreover, the construct validity of fiberoptic guidewire-derived mean PG measurements improved following standardization of calculation methods and the elimination of rhythm and pressure artefacts as well as calibration errors. Finally, the wire exhibited an excellent efficacy and safety profile. Collectively, these findings underscore the potential of fiberoptic guidewires for guiding contemporary TAVR procedures.

CONSTRUCT VALIDITY OF THE FIBEROPTIC TAVR GUIDEWIRE. Our study is the first large-scale prospective study investigating the construct validity of the fiberoptic guidewire's hemodynamic measurements in a real-world TAVR cohort. Based on the ICCs, the newly introduced guidewire exhibited moderate to excellent agreement compared to double pigtail catheters. The observed excellent agreement of LVSP measurements pre- and post-TAVR indicates that the fiberoptic sensor can measure invasive pressures in a real-world setting with high fidelity.

When focusing on post-TAVR residual transvalvular gradients a moderate agreement was observed. However, the observed mean absolute difference between measurements was small and most likely not clinically significant. Moreover, no systematic measurement bias was observed and the fiberoptic guidewire produced mean PG measurements that were highly concordant with double pigtail catheter measurements when assessed against a clinically relevant cutoff. These findings demonstrate the potential of the fiberoptic guidewire to directly evaluate residual transvalvular pressure gradients. Compared with TTE-derived follow-up mean pressure gradients, our findings are consistent with previous studies, demonstrating higher TTE gradients and poor correlation with invasive measurements.[5] This discrepancy likely reflects limitations of TTE, including reliance on the simplified Bernoulli equation,[24] and underscores the value of invasive assessment of residual post-TAVR gradients.

Besides gradients, this study also evaluated PVR measurements, demonstrating good overall agreement between the fiberoptic guidewire and pigtail catheters for PVR indices. However, a bias was observed in LVEDP measurements. Specifically, the novel fiberoptic guidewire tended to record higher LVEDPs compared with pigtail catheter measurements, which may be due to increased interaction of the stiffer LV guidewire with the prosthetic neoleaflets. This interference may have potentially induced some degree of temporary iatrogenic central aortic regurgitation in our patient cohort, leading to an increase in ventricular end-diastolic pressures.

CENTRAL ILLUSTRATION **Construct Validity of a Fiberoptic TAVR Guidewire for Hemodynamic Guidance During Transcatheter Aortic Valve Replacement**



Versteeg GAA, et al. JACC Adv. 2026;5(10):103219.

Created with BioRender. ARI = aortic regurgitation index; DD = diastolic delta; HR-DD = heart rate-adjusted diastolic delta; ICC = intraclass correlation coefficient; LVEDP = left ventricular end-diastolic pressure; LVSP = left ventricular systolic pressure; PG = pressure gradient; TAVR = transcatheter aortic valve replacement.

The LVEDP measurement bias corresponded with catheterization laboratory observations, where angiography occasionally revealed increased (valvular) regurgitation, which was observed in 9 of 28 patients (32.1%) in whom angiography was performed with the fiberoptic guidewire still in situ (Supplemental Table 6, Supplemental Figure 2). When observed, aortic regurgitation could be decreased by either relief of manual pressure, repositioning, or complete removal of the TAVR guidewire. Thus, caution should be exercised when assessing the degree of PVR solely based on invasive measurements obtained with the fiberoptic guidewire. When results from contemporary modalities and fiberoptic guidewire measurements are inconsistent and/or inconclusive, or when fiberoptic guidewire measurements demonstrate an increased LVEDP and decreased DD (Supplemental Figure 2), repeat assessment with pigtail catheters and additional contrast injections, after guidewire removal, should be considered.

Until now, data on the hemodynamic measuring performance of the fiberoptic TAVR guidewire have been limited, with only 1 study comparing a fiberoptic pressure sensor on a percutaneous coronary intervention (PCI) guidewire to fluid-filled pigtail catheters.[4] This study demonstrated feasibility of performing hemodynamic measurements with a fiberoptic PCI guidewire (OptoWire), that uses the same fiberoptic pressure sensor as adopted in our present study (ie, SavvyWire). However, our study should not be directly compared with the aforementioned study. Primarily, the PCI guidewire used has significantly different physical properties to the wire used in the present study. As a result, this reduces the PCI guidewire's likelihood of causing arrhythmia or leaflet interaction. Therefore, these previous

findings cannot be extrapolated to a real-world TAVR cohort where the sensor-embedded TAVR guidewire is used simultaneously for prosthesis guiding and left-ventricular pacing. In addition, the previous study was conducted in a small cohort of patients that were all treated under general anesthesia, further limiting its generalizability. In contrast, our study is the first study to assess construct validity of the fiberoptic TAVR guidewire's hemodynamic measurements in a large real-world TAVR cohort.

ALGORITHM-BASED PRESSURE SIGNAL ANALYSIS. Repeating our analysis using our validated automated algorithm[21] to assess invasive hemodynamic measurements and pressure signal quality is a strength of the current study, allowing for objective comparison of fiberoptic guidewire and double pigtail catheter measurements. The automated algorithm allowed standardization of mean PG calculations between the 2 modalities, which differed in methodology. In addition, our algorithm allowed for the selection of cardiac cycles that were free from rhythm and pressure artefacts, which were present despite rigorous measuring methodology. Notably, pressure signals from the double pigtail catheters were more frequently excluded due to artefacts or calibration errors compared to the novel fiberoptic guidewire, suggesting the fiberoptic guidewire is less susceptible to mechanical artefacts. A potential reason for this is that the guidewire has a stiffer design, which reduces movement artefacts and oscillations. Moreover, unlike fluid-filled pigtail catheters, the sensor is likely less susceptible to signal disruption by blood clots. This observed improvement in signal quality with fewer artefacts and calibration errors, highlights the robustness of the novel fiberoptic guidewire compared to conventional fluid-filled pigtail catheters (Supplemental Material). Moreover, repeat analysis of algorithm-derived parameters from artefact- and calibration error-free signals using standardized calculations resulted in a marked improvement in construct validity, with ICCs approaching excellent. These findings suggest that the initial differences in mean PG were partly attributable to differences in calculation methods and signal artefacts, rather than true measurement discrepancies.

EFFICACY, SAFETY, AND FUTURE DIRECTIONS. The efficacy and safety of the fiberoptic guidewire have previously been assessed in the SAFE-TAVR trial,[2] and the present study reinforces these findings by demonstrating that the wire is both safe and effective. Pacing capture was achieved in all patients, and a bail-out pacing lead was successfully inserted in all patients who developed high-degree conduction disturbances. Furthermore, technical success was achieved in almost all patients, with no complications observed related to the fiberoptic guidewire. Together, these findings suggest that the wire can be safely adopted as a workhorse TAVR guidewire, with its continuous hemodynamic monitoring providing a foundation for further investigative studies.

The observed 30-day stroke (4.7%) and major vascular complication (5.3%) rates were somewhat higher than those reported in comparative cohorts (Evolut Low Risk trial; 30-day stroke 3.4%; major vascular complication 3.8%[25]). This difference may in part reflect the real-world, single-center registry design of the present study compared with a controlled trial setting. Although a prolonged intraventricular dwell time of the fiberoptic guidewire, required for hemodynamic measurement, could theoretically carry additional thromboembolic risk, dwell times were not recorded in this study. Conversely, in scenarios where the fiberoptic guidewire eliminates the need for a separate LV pigtail catheter, this may reduce the number of intracardiac catheter exchanges and the associated thromboembolic and vascular access risk.

From a cost perspective, the SavvyWire is positioned as a premium TAVR guidewire and is considerably more expensive relative to conventional options, including Confida Brecker Guidewire (Medtronic) and SAFARI² Pre-Shaped Guidewire (Boston Scientific). In addition to its excellent safety profile, the SavvyWire offers practical clinical advantages as the first dedicated ready-to-use TAVR pacing guidewire integrating a fiberoptic pressure sensor. This design reduces catheter exchanges and may improve pacing performance. The ongoing SAPPHIRE registry (NCT07366671) will evaluate its real-world impact on TAVR workflow, including pacing performance and procedural efficiency. Together with our findings of high-quality and reliable hemodynamic measurements, this study will help define the added clinical value of the SavvyWire. Future research could explore whether continuous measurements obtained during valve deployment can further guide and optimize prosthesis placement and prospective studies should investigate whether procedural hemodynamic-guided optimization leads to improved patient outcomes.

STUDY LIMITATIONS. Some limitations should be addressed. First, this single-center registry was conducted by clinicians and nurses with limited prior experience using the fiberoptic guidewire. Although this likely has resulted in underestimating the true

construct validity, this does enhance the generalizability of the findings, as the data are more likely to reflect real-world conditions. Second, almost all patients were treated using a self-expanding device. Although invasive pressure measurements were compared within patients, differences in post-TAVR gradients and PVR patterns between platforms limit generalizability to balloon-expandable platforms. Furthermore patients undergoing a valve-in-valve procedure were excluded, precluding conclusions about the wire's measurement accuracy in valve-in-valve patients. Third, the majority of patients enrolled were considered low- or intermediate-risk. Therefore, the efficacy and safety outcomes should be interpreted in this context. Fourth, as described previously, the current fiberoptic method for calculating mean pressure gradients differs from conventional calculation methods, which may reduce the accuracy of mean PG measurements. Further software improvements could easily overcome this limitation. Fifth, the fiberoptic guidewire may induce temporary iatrogenic aortic regurgitation through interaction with the prosthetic neo-leaflets, observed in a meaningful proportion of angiographically assessed cases in this study (9/28, 32.1%). However, pigtail catheter confirmation of (para)valvular regurgitation requires guidewire removal regardless, and regurgitation frequently diminished on removal of the guidewire alone. This observed phenomenon nonetheless represents a practical limitation of the fiberoptic guidewire as a standalone "all-in-one" replacement for pigtail catheters when it comes to invasive hemodynamic measurements. Future engineering refinements and improved operator experience could improve the wire's accuracy in measuring hemodynamic parameters associated with PVR.

CONCLUSIONS

The fiberoptic TAVR guidewire (ie, SavvyWire) enables continuous hemodynamic monitoring during TAVR, with invasive pressure measurements consistent with fluid-filled pigtail catheters. Agreement for residual pressure gradients was moderate, although the wire reliably distinguished clinically relevant gradients. Assessment of PVR using the fiberoptic guidewire appears feasible, although caution is warranted in cases of significant aortic regurgitation, which may reflect wire-induced leaflet interaction. In-depth signal analysis revealed fewer pressure artefacts and calibration errors with the fiberoptic guidewire than with pigtail catheters; repeat analysis markedly improved construct validity, suggesting that the moderate agreement observed for mean pressure gradients partly reflects suboptimal comparator signal quality rather than the guidewire's true performance. Collectively, this study offers proof-of-concept evidence that the fiberoptic guidewire enables feasible, high-fidelity hemodynamic monitoring during TAVR, warranting further hemodynamic validation in larger cohorts. Broader insights into the wire's real-world performance are anticipated from the ongoing SAPPHIRE registry.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: The use of a fiberoptic guidewire for procedural invasive measurements may complement traditional pigtail catheter-derived strategies. This study demonstrated that the fiberoptic guidewire produced reliable invasive measurements of mean gradient with fewer signal artefacts and calibration errors, while simultaneously providing a guidewire platform for safe valve delivery and pacing. While assessment of paravalvular regurgitation using the guidewire is feasible, caution is advised in cases of significant aortic regurgitation, as wire-induced leaflet interaction may influence measurements.

TRANSLATIONAL OUTLOOK: The fiberoptic TAVR guidewire offers a platform for streamlined procedural workflow, combining pacing, valve delivery, and hemodynamic assessment within a single device. Further studies are needed to evaluate its integration into routine procedural practice and its potential to reduce reliance on separate invasive catheters.

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APPENDIX For supplemental tables and figures, please see the online version of this paper.