RESEARCH ARTICLE

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Impact of Transcatheter Aortic Valve Replacement in Cases with Bicuspid Aortic Valve Stenosis Compared with Tricuspid Aortic Valve Stenosis

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Abstract

Background and Aim: Transcatheter aortic valve implantation (TAVI) is a well-established intervention for severe aortic stenosis (AS). The bicuspid aortic valve (BAV) continues to pose a technical challenge because of altered valve geometry, asymmetric calcification, and larger annular dimensions. Objectives to compare the early in-hospital clinical and procedural outcomes of TAVI in patients with bicuspid versus tricuspid aortic valve (TAV) stenosis using new-generation self-expanding Evolut R and Evolut PRO valves. We hypothesized that early in-hospital outcomes would be broadly comparable between the two groups despite the more complex bicuspid anatomy.

Materials and Methods: This prospective observational cohort study enrolled 60 patients with significant symptomatic AS who underwent TAVI and were categorized by valve morphology into a BAV group (n=15) and a TAV group (n=45).

Results: Diabetes mellitus was more prevalent in the TAV group than the BAV group (64.4% vs. 33.3%, $P = 0.035$; odds ratio 0.28, 95% confidence interval 0.08-0.95, favoring a lower prevalence in the BAV group). Annular dimensions, including the minimum, maximum, and mean annular diameters, the derived perimeter, and the annular area, were significantly larger in the BAV group (all $P < 0.05$). Post-procedural conduction abnormalities, complete heart block, atrial fibrillation, aortic regurgitation, and paravalvular leak did not differ significantly between groups. Mean and maximal pressure gradients after TAVI were significantly higher in the BAV group. Early adverse events were infrequent overall, with vascular complications and stroke occurring in 3.3% and 1.7% of the whole cohort, respectively, and did not differ significantly between groups.

Conclusion: TAVI using contemporary self-expanding valves produced early in-hospital outcomes in BAV patients that were statistically comparable to those in TAV patients, despite significantly greater anatomical complexity, thereby supporting the feasibility of TAVI in carefully selected bicuspid patients. These early, hypothesis-generating findings from a two-center cohort warrant confirmation in larger, adequately powered, multicenter studies with longer follow-up.

Keywords: TAVI, bicuspid aortic valve, tricuspid aortic valve, aortic stenosis, Evolut PRO

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is now a well-established therapeutic option for patients with severe aortic stenosis (AS).[1]

Since its introduction, TAVI has undergone remarkable advancement, with over 300,000 procedures performed and an annual growth rate of approximately 40% reported by 2016.[2]

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Bicuspid aortic valve (BAV) is the most common congenital heart defect in adults, affecting approximately 0.5-2% of the general population, and is closely linked to the development of AS, a condition that often necessitates intervention.[3]

Patients with BAV frequently have enlarged annular dimensions, may show variations in coronary architecture, often have bulky, calcified and irregular aortic valve leaflets, and exhibit altered aortic geometry and haemodynamics. [4]

Multiple randomized trials have shown that transcatheter aortic valve replacement (TAVR) is effective for patients with symptomatic severe AS across surgical-risk categories. Although patients with BAV anatomy were excluded from these trials, the use of TAVR in BAV-associated AS has increased over time, and recent observational studies suggest that outcomes after TAVR are broadly similar in patients with BAV-AS and those with tricuspid aortic valve (TAV) stenosis.[5]

Compared with early-generation devices, TAVI with new-generation valves in BAV patients is associated with better postprocedural results and a lower incidence of paravalvular leak (PVL).[6]

The Valve Academic Research Consortium (VARC)-2 provides standardized definitions for the complications most frequently encountered in this field. Although post-procedural conduction abnormalities may not be the strongest predictor of mortality, they can substantially affect long-term prognosis and quality of life.[6]

This study assessed the early in-hospital clinical impact of the latest-generation self-expanding prostheses, Evolut PRO and Evolut R, in patients with BAV compared with patients with TAV stenosis.

We hypothesized that using these contemporary self-expanding valves, early in-hospital procedural and clinical outcomes of TAVI would be broadly comparable between patients with bicuspid and TAV stenosis, notwithstanding the greater anatomical complexity of the bicuspid valve. This was formulated and tested as a descriptive comparison rather than as formal non-inferiority or superiority hypotheses, as the study was not powered for either.

METHODS

Study Design and Population

This prospective observational cohort study was conducted according to routine clinical practice and did not require ClinicalTrials registration; it included 60 patients who underwent TAVI in the Cardiology Departments of Nasr City Insurance Hospital and Benha University Hospital between April 2024 and April 2025.

Patients presenting to the heart valve team at both centers who met the eligibility criteria below were enrolled prospectively and consecutively; those excluded by the heart valve team for the anatomical or clinical reasons detailed in the eligibility criteria were not entered into the registry. Screening and enrollment followed a standardized clinical pathway through the heart valve team, described above under eligibility criteria. A formal STROBE-style numerical flow diagram was not part of the original data-collection instrument but will be incorporated into the prospective case-report form for future cohorts from this registry.

Ethical Statement

The study received ethical clearance from the Research Ethics Committee of the Faculty of Medicine, Benha University (approval code: M.S 15-2-2024, date: 27.05.2026) and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants after a thorough explanation of the study's nature and objectives.

Eligibility Criteria

Inclusion criteria comprised patients with a clinical indication for TAVI due to symptomatic, severe AS, pathologically defined by constriction of the aortic orifice causing left ventricular outflow obstruction and risk of heart failure.[7] Patient selection followed the European Society of Cardiology (ESC) guidelines, which prioritize TAVI over surgical aortic valve replacement (SAVR) in patients older than 70 years with high-risk features, such as a porcelain aorta, previous chest radiation, or significant comorbidities (e.g., severe pulmonary, hepatic, or renal disease). Exclusion criteria comprised elevated frailty scores, limited life expectancy (<1-2 years), severe irreversible left ventricular systolic dysfunction, or anatomical features favoring SAVR, including complex coronary artery disease, unsuitable annular dimensions, or the need for concomitant myomectomy.

Grouping

Patients were categorized into two groups according to valve morphology: Group A: patients with BAV (n=15); Group B: patients with TAV (n=45).

Study Protocol

The indication for TAVI was established by the heart valve team, in line with current guidelines and technical suitability. Baseline assessment, performed by an experienced TAVI cardiologist, included frailty evaluation (Short Physical Performance Battery), cognitive screening (Mini-Mental State Examination), and nutritional assessment, in collaboration with a geriatric specialist. Patients with major comorbidities,

marked frailty, projected life expectancy of less than 1-2 years, severe cognitive impairment, or anatomical/technical contraindications were not offered TAVI and were excluded from the registry. Demographic, clinical, electrocardiographic, echocardiographic, and multislice CT (MSCT) data were collected prospectively at baseline.

Study Procedure

All patients gave written informed consent and underwent comprehensive history-taking, physical examination, laboratory testing, baseline electrocardiography (ECG), baseline echocardiography, baseline MSCT, and in-hospital monitoring after TAVI. The medical history included the following: age, sex, smoking status, hypertension (HTN), diabetes mellitus (DM), prior cardiac intervention, chronic kidney disease (CKD) or chronic liver disease (CLD), prior cerebrovascular accident, prior coronary artery disease, and AS-related symptoms.

Clinical Definitions and Medical History

The 2024 ESC Guidelines define HTN as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg on repeated measurement.[8] DM was defined per standard glycaemic thresholds: fasting plasma glucose ≥126 mg/dL (7.0 mmol/L), 2-hour oral glucose tolerance test glucose ≥200 mg/dL (11.1 mmol/L), HbA1c ≥6.5%, or random plasma glucose ≥200 mg/dL with classic symptoms.[9]

Particular attention was paid to AS-related symptoms, including chest tightness, signs of heart failure, and syncope. Clinical assessment included measurement of pulse and blood pressure, cardiopulmonary auscultation for signs of pulmonary venous congestion, and functional classification according to the New York Heart Association system. Cardiac auscultation was performed to assess murmurs (e.g., ejection systolic murmur) and additional heart sounds (e.g., fourth heart sound). Laboratory testing included complete blood count, serum urea, and serum creatinine.

Baseline ECG and Echocardiography

A standard 12-lead ECG was obtained for every patient before the procedure to assess baseline rhythm and conduction (PR interval, QRS duration).

Transthoracic echocardiography was performed before and during TAVI using a Vivid Ultra Edition ultrasound system with an M5Sc-D matrix probe and simultaneous ECG recording. In accordance with the 2021 ESC/EACTS Guidelines for valvular heart disease, patients were assessed using two-dimensional and color Doppler echocardiography in the left lateral decubitus position. Ejection fraction was measured by M-mode (parasternal long-axis view) and Simpson's method (apical four-chamber view). Left ventricular mass, left atrial diameter, aortic root diameter, and septal and posterior wall thicknesses (PWT) were also recorded. Diastolic function was assessed using E/e' and E/A ratios. Additional measurements included left ventricular end-diastolic and end-systolic dimensions, mean and peak transaortic pressure gradients, maximum transaortic velocity, stroke volume, and aortic valve area.

Aortic valve area was derived using the continuity equation. The left ventricular outflow tract (LVOT) diameter was measured at the aortic annulus in mid-systole. Pulsed-wave Doppler in the LVOT provided the velocity-time integral (VTI), peak velocity, and stroke volume (LVOT-VTI×LVOT area). Continuous-wave Doppler across the aortic valve was used to determine peak aortic jet velocity, peak and mean pressure gradients, and aortic valve area.

Baseline Multislice Computed Tomography

A baseline MSCT was performed before the procedure. This study used 320-slice MSCT technology, which provides accurate whole-heart coverage in a single rotation and is advantageous for functional and perfusion imaging. Dual-source CT, which uses two X-ray tubes and detectors aligned at 90 degrees, can further improve temporal resolution, particularly at higher heart rates.

Patient Preparation for MSCT

Before coronary/cardiac CT angiography, the procedure, potential risks, and the need to comply with breath-holding instructions were explained, and informed consent was obtained. Contraindications assessed included iodinated-contrast allergy, renal failure, pregnancy, and severe arrhythmia. Patients fasted for 4-6 hours before scanning, with permission to ingest small amounts of water, to reduce the risk of aspiration and to improve image quality.

A target heart rate of ≤60 beats per minute was sought using oral or intravenous metoprolol where not contraindicated (e.g., by asthma, high-grade atrioventricular block, or hypotension), with ivabradine as an alternative when beta-blockers were unsuitable. Sublingual nitroglycerin 0.4 mg was commonly administered before scanning to improve coronary visualization, unless contraindicated by hypotension, severe AS, allergy, or recent phosphodiesterase-5-inhibitor use. An 18-20G intravenous cannula was placed in the antecubital vein for high-flow contrast injection (typically 80-100 mL at 4-6 mL/s), and a saline flush was then administered to reduce artifacts. During acquisition, patients avoided speaking, moving, or swallowing and held their breath for 8-12 seconds. Renal function (serum creatinine, estimated glomerular filtration rate) was checked before contrast administration; patients with thyroid disease had thyroid function assessed, and metformin was withheld on the day of the scan and for 48 hours afterward

in patients with renal impairment, per ESC/European Society of Radiology guidance.[10]

MSCT Measurements and Anatomical Assessment

Aortic annular mean diameter, perimeter, and area were measured using MSCT. On modified coronal views, the heights of the left main and right coronary ostia and the length of the membranous septum were measured. The aortic valvular complex was characterized by leaflet-sector involvement, and the extent of basal septal and aortic-valve calcification was graded using a threshold of 850 Hounsfield units.

Aortic valve calcification was graded II-IV in this cohort. Sievers classification, raphe-specific calcification, calcium-asymmetry scoring, and eccentricity index were beyond the scope of the anatomical protocol used for this registry and are identified below as priorities for the prospective, dedicated bicuspid-imaging protocol now being implemented at our center.

Procedural Characteristics

Valve size was selected according to manufacturer-recommended annular sizing charts; balloon pre-dilatation and post-dilatation were performed at the operator's discretion, and final implantation depth was confirmed by fluoroscopy and transthoracic echocardiography prior to closure. Formal quantitative summaries of prosthesis oversizing, implantation depth, fluoroscopy time, contrast volume, total procedural duration, valve-repositioning frequency, cerebral embolic protection use, and vascular closure technique are being compiled for a dedicated analysis of procedural characteristics and are not included as a separate results table in the present manuscript, which was designed and powered to compare early clinical and anatomical outcomes rather than procedural technique. This scope is clarified in the Study Limitations section.

In-hospital Follow-up and Outcomes

After TAVI, patients were monitored in the hospital to assess early post-procedural and procedure-related outcomes, focusing on conduction abnormalities, PVL, and the post-procedural mean pressure gradient across the implanted valve.

The primary endpoint was the composite incidence of early (in-hospital) VARC-2-defined procedure-related adverse events, comprising permanent pacemaker implantation (PPI) for high-grade conduction disturbance, moderate-or-greater PVL, major vascular complication, stroke, and death. Secondary endpoints were the individual components of this composite, together with the post-procedural mean and peak transvalvular pressure gradients. The safety and efficacy of TAVI in BAV stenosis relative to TAV stenosis, as assessed against these endpoints, were the study's primary objectives.

Sample Size Calculation

The minimum required sample size was estimated using Cochran's formula, informed by the methodology of Nanjundeswaraswamy and Divakar,[11] to characterize the expected prevalence of BAV among patients undergoing TAVI for severe AS. In this calculation, Z is the z-score for the selected confidence level (1.96 for 95% confidence), P is the estimated population proportion (0.151, based on prior reported BAV prevalence among TAVI recipients[8]), and E is the margin of error (0.05).

This calculation estimates the sample size required to characterize a population prevalence and is not, by itself, a power calculation for the subsequent between-group (BAV vs. TAV) outcome comparisons reported in Results; no dedicated effect size, expected event rate, alpha, or power specific to those comparisons were pre-specified. This is acknowledged as a limitation, and the resulting BAV subgroup (n=15) should be understood as prevalence-driven rather than power-driven, which materially limits the ability to detect true between-group differences and increases the risk of Type II error.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows (version 27.0; IBM Corp., Armonk, NY, USA). Continuous variables are reported as mean ± standard deviation (SD) and range; categorical variables as frequencies and percentages. Normality of continuous data was assessed using the one-sample Kolmogorov-Smirnov test.

The Kolmogorov-Smirnov test has reduced power to detect departures from normality in small samples, such as the 15-patient BAV group, and the Shapiro-Wilk test would have been more appropriate for this subgroup. This is noted as a methodological limitation of the original analysis, and Shapiro-Wilk testing is recommended for future adequately powered analyses of this cohort.

Categorical variables were compared using the chi-square test or Fisher's exact test when expected cell counts were below 5. Normally distributed continuous variables were compared between the two independent groups using the independent-samples t-test. Statistical significance was defined as $P < 0.05$, and results were reported with a 95% confidence interval (CI) and a 5% margin of error.

Group comparisons were performed using univariate methods appropriate to this cohort size. Multivariable adjustment (e.g., logistic regression, propensity-score matching, or inverse-probability weighting) was carefully considered and deliberately not pursued: the limited number of events for several outcomes (e.g., stroke, n=1; vascular complications, n=2; moderate PVL,

n=1) relative to the number of candidate covariates would not support stable, generalizable model estimates, and an unstable adjusted model was judged less informative—and potentially misleading—than the transparent unadjusted comparisons reported here. The prevalence of DM and several annular dimensions differed significantly between groups at baseline and were identified as potential confounders to be considered when interpreting the univariate findings. No correction for multiple testing was applied across the comparisons performed, and *P*-values are, accordingly, best interpreted as hypothesis-generating, consistent with the exploratory intent of this early comparative cohort.

RESULTS

Patients were categorized by aortic valve morphology into two groups: Group A, 15 patients with BAV; and Group B, 45 patients with TAV.

There were no statistically significant differences between the two groups in gender distribution and age ($P = 0.283$ and 0.213, respectively), nor in weight, height, or BMI ($P = 0.087$, 0.585 and 0.208, respectively). DM was significantly more prevalent in Group B (29/45, 64.4%) than in Group A (5/15, 33.3%; $P = 0.035$). Groups did not differ significantly in the proportion of smokers or in the prevalence of HTN, chronic coronary syndrome, CKD, prior cerebrovascular/cardiovascular disease, or CLD (all $P > 0.05$), nor in other clinical or laboratory parameters ($P > 0.05$; Table 1).

Regarding pre-TAVI ECG findings, there were no significant between-group differences in atrial fibrillation, QRS morphology, or the proportion of patients with prolonged QRS ($P = 0.619$, 0.080, and 0.230, respectively). On pre-TAVI echocardiography, Group A had a significantly greater mean PWT than Group B (13.53±1.41 mm vs. 12.27±1.84 mm; $P = 0.018$; mean difference 1.26 mm, 95% CI 0.22-2.30 mm), with no significant between-group difference in other echocardiographic parameters ($P > 0.05$; Table 2).

On CT aortography, the minimum annular diameter, maximum annular diameter, derived perimeter, mean annular diameter and annular area were all significantly greater in Group A than Group B (minimum diameter 22.29±2.45 vs. 20.55±2.41 mm, $P = 0.019$; maximum diameter 28.45±2.99 vs. 26.83±2.35 mm, $P = 0.035$; perimeter 24.8±2.6 vs. 23.38±1.97 mm, $P = 0.029$; mean diameter 25.51±2.46 vs. 23.8 ± 2.02 mm, $P = 0.011$; area 533.1±35.3 vs. 473.8±54.3 mm^2, $P < 0.001$). There were no significant between-group differences in left main and right coronary ostial heights ($P = 0.235$ and 0.572, respectively; Table 3).

No statistically significant between-group differences were observed in the incidence of early in-hospital adverse events after the procedure ($P > 0.05$; Table 4).

The occurrence of post-TAVI PVL did not differ significantly between patients receiving Evolut R and those receiving Evolut PRO ($P = 0.509$; Table 5).

Table 1. Comparison between Group A (bicuspid aortic valve) and Group B (tricuspid aortic valve) regarding baseline demographic and clinical characteristics

Variable		Group A (BAV), n=15	Group B (TAV), n=45	Test value	*P*-value	Sig.
Gender	Male	11 (73.3%)	26 (57.8%)	1.152*	0.283	NS
	Female	4 (26.7%)	19 (42.2%)			
Age (years)	Mean ± SD	73.47±4.12	75.22±4.84	-1.260•	0.213	NS
Weight (kg)	Mean ± SD	83.27±11.09	77.42±11.29	1.744•	0.087	NS
Height (cm)	Mean ± SD	168.93±8.71	167.49±8.85	0.549•	0.585	NS
BMI (kg/m^2)	Mean ± SD	29.14±4.67	27.59±3.86	1.272•	0.208	NS
Smoking	Yes	7 (46.7%)	10 (22.2%)	3.311*	0.069	NS
Diabetes mellitus	Yes	5 (33.3%)	29 (64.4%)	4.434*	0.035	S
Hypertension	Yes	10 (66.7%)	38 (84.4%)	2.222*	0.136	NS
CCS	Yes	7 (46.7%)	26 (57.8%)	0.561*	0.454	NS
CKD	Yes	1 (6.7%)	7 (15.6%)	0.769*	0.380	NS
Prior CVS event	Yes	0 (0%)	3 (6.7%)	1.053*	0.305	NS
CLD	Yes	3 (20%)	5 (11.1%)	0.769*	0.380	NS
NYHA class III-IV	Yes	11 (73.3%)	35 (77.8%)	1.788*	0.617	NS

*: Chi-square test; •: Independent-samples t-test, BAV: Bicuspid aortic valve, TAV: Tricuspid aortic valve, NS: Not significant ($P > 0.05$); S: Significant ($P < 0.05$), SD: Standard deviation, CCS: Chronic coronary syndrome, CKD: Chronic kidney disease, CVS: Cerebrovascular, CLD: Chronic liver disease, NYHA: New York Heart Association

Table 2. Comparison between Group A and Group B regarding pre-TAVI electrocardiographic and echocardiographic parameters

Variable		Group A (BAV), n=15	Group B (TAV), n=45	Test value	*P*-value	Sig.
Prolonged QRS	Yes	2 (13.3%)	4 (8.9%)	0.247*	0.619	NS
QRS morphology	Normal	12 (80%)	40 (88.9%)	6.769*	0.080	NS
Atrial fibrillation (pre-TAVI)	Yes	4 (26.7%)	6 (13.3%)	1.440*	0.230	NS
Ejection fraction (%)	Mean ± SD	61.80±9.63	62.51±9.72	-0.246•	0.807	NS
SWT (mm)	Mean ± SD	13.67±1.76	12.84±1.78	1.552•	0.126	NS
PWT (mm)	Mean ± SD	13.53±1.41	12.27±1.84	2.435•	0.018	S
LVEDD (mm)	Mean ± SD	50.13±6.57	50.93±8.02	-0.349•	0.729	NS
LVESD (mm)	Mean ± SD	33.40±7.15	33.44±7.45	-0.020•	0.984	NS
PPG (mmHg)	Mean ± SD	90.27±18.76	81.04±19.48	1.602•	0.115	NS
MPG (mmHg)	Mean ± SD	56.93±8.05	50.44±13.01	1.813•	0.075	NS
Aortic valve area (cm^2)	Mean ± SD	0.69±0.09	0.74±0.13	-1.197•	0.236	NS
Significant AR	Yes	6 (40%)	11 (24.4%)	1.341*	0.247	NS

*: Chi-square test; •: Independent-samples t-test, BAV: Bicuspid aortic valve, TAV: Tricuspid aortic valve, NS: Not significant, S: Significant, TAVI: Transcatheter aortic valve implantation, SWT/PWT: Septal/posterior wall thickness, LVEDD/LVESD: Left ventricular end-diastolic/systolic dimension, SD: Standard deviation, PPG/MPG: Peak/mean pressure gradient, AR: Aortic regurgitation

Table 3. Comparison between Group A and Group B regarding CT aortographic (annular) parameters

Variable	Group A (BAV), n=15	Group B (TAV), n=45	Test value	*P*-value	Sig.
Minimum annular diameter (mm)	22.29±2.45	20.55±2.41	2.412•	0.019	S
Maximum annular diameter (mm)	28.45±2.99	26.83±2.35	2.158•	0.035	S
Annular derived perimeter (mm)	24.80±2.60	23.38±1.97	2.235•	0.029	S
Mean annular diameter (mm)	25.51±2.46	23.80±2.02	2.615•	0.011	S
Aortic annular area (mm^2)	533.07±35.31	473.79±54.31	3.946•	<0.001	HS
Aortic valve calcification grade II-IV	Predominantly III-IV	Predominantly II-III	-	-	-
LMCA height (mm)	14.27±4.68	13.14±2.48	1.201•	0.235	NS
RCA height (mm)	16.19±2.51	15.71±2.91	0.568•	0.572	NS

•: Independent-samples t-test, CT: Computed tomography, BAV: Bicuspid aortic valve, TAV: Tricuspid aortic valve, NS: Not significant; S: Significant, HS: Highly significant ($P < 0.01$), LMCA/RCA: Left main/right coronary artery

Sievers classification, raphe status, calcium-asymmetry and eccentricity index were not systematically recorded for this cohort (see Limitations)

Table 4. Comparison between Group A and Group B regarding early in-hospital adverse events after TAVI

Variable		Group A (BAV), n=15	Group B (TAV), n=45	Test value	*P*-value	Sig.
Conduction abnormality	Any	6 (40%)	11 (24.4%)	3.795*	0.285	NS
	CHB	2 (13.3%)	3 (6.7%)			
Permanent pacemaker	Yes	2 (13.3%)	4 (8.9%)	0.247*	0.619	NS
Paravalvular leak	Any	2 (13.3%)	3 (6.7%)	1.721*	0.423	NS
Vascular complication	Yes	0 (0%)	2 (4.4%)	0.690*	0.406	NS
Hb drop	Yes	0 (0%)	2 (4.4%)	0.690*	0.406	NS
Renal impairment	Yes	0 (0%)	2 (4.4%)	0.690*	0.406	NS
Stroke	Yes	0 (0%)	1 (2.2%)	0.339*	0.560	NS
Death (in-hospital)	Yes	0 (0%)	0 (0%)	-	-	-

*: Chi-square/Fisher's exact test as appropriate, BAV: Bicuspid aortic valve, TAV: Tricuspid aortic valve, NS: Not significant, CHB: Complete heart block, TAVI: Transcatheter aortic valve implantation

Table 5. Comparison between Evolut R and Evolut PRO regarding incidence of paravalvular leak					
	Evolut R, n=40	**Evolut PRO, n=20**	**Test value**	***P*-value**	**Sig.**
Paravalvular leak, no	36 (90.0%)	19 (95.0%)	0.436*	0.509	NS
Paravalvular leak, yes	4 (10.0%)	1 (5.0%)			
*: Chi-square test, NS: Not significant ($P > 0.05$)					

Effect Sizes for the Principal Significant Comparisons

To supplement the *P*-values above, mean differences (for continuous variables) and an odds ratio (for DM prevalence) with 95% CIs were derived from the reported group means, SDs, group sizes, and test statistics, assuming the pooled-variance independent t-test that was used for the original comparisons: PWT, mean difference 1.26 mm (95% CI 0.22-2.30); minimum annular diameter, 1.74 mm (0.30-3.18); maximum annular diameter, 1.62 mm (0.12-3.12); annular derived perimeter, 1.42 mm (0.15-2.69); mean annular diameter, 1.71 mm (0.40-3.02); annular area, 59.3 mm^2 (29.2-89.4); and DM, odds ratio 0.28 (95% CI 0.08-0.95) for Group A relative to Group B (equivalently, a risk difference of -31.1%, 95% CI -58.8% to -3.5%). All CIs exclude the null value, consistent with the $P < 0.05$ findings reported above. However, the intervals are wide, reflecting the small BAV sample.

DISCUSSION

After the procedure and during the hospital stay, most patients maintained normal conduction; conduction abnormalities included right bundle branch block, left bundle branch block (LBBB), intraventricular conduction delay, and complete heart block (CHB) at rates consistent with prior reports. These findings are broadly in line with Zaid et al.,[12] who reported new-onset LBBB rates of 20.6% and 17.8% after Evolut R and Evolut PRO implantation, respectively, and with Forrest et al.,[8] who reported 30-day PPI rates of 19.6% and 17.1% for Evolut R and Evolut PRO, respectively.

CHB occurred in 5 patients (8.3%) in our cohort, consistent with Al-Ogaili et al.,[13] who reported CHB in 10.4% of 35,500 TAVR procedures, with a significant increase in incidence from 8.4% to 11.8% between 2012 and 2014.

CHB did not differ significantly between BAV and TAV patients in our study (13.3% vs. 6.7%, respectively; Table 4). PPI was required in 6 patients overall (10.0%), comparable to rates reported in the PARTNER trial.[14] Prior studies suggest pacemaker implantation after TAVI may be more frequent in BAV patients, with large series reporting rates of 17-29%;[15] however, direct comparisons with TAV patients are limited, and many earlier reports used older-generation devices, complicating interpretation.[16] The non-significant difference observed here may reflect the small sample size and the use of newer-generation self-expanding prostheses.

Most patients had no postoperative PVL (91.7% no leak, 6.7% mild PVL, and 1.7% moderate PVL). Reported PVL rates after TAVI vary widely (7-40%), depending on imaging modality, timing, and grading method.[1] Earlier observational studies reported moderate-or-greater PVL in 10-25% of patients, and randomized trials reported approximately 12%; this variability largely reflects the absence of uniform grading in earlier work. Contemporary studies more commonly apply VARC-2 criteria, which grade PVL by the circumferential extent of the regurgitant jet.[17]

The low rate of moderate PVL observed here is consistent with Popma et al.[18] The mild-PVL rate in our cohort was lower than reported elsewhere (29% with balloon-expandable and 36% with self-expanding valves at 30 days),[19] which may reflect differences in assessment timing, valve type, grading method, and patient operative risk.

PVL did not differ significantly between BAV and TAV patients in our cohort (13.3% vs. 6.7%, respectively), in contrast to Montalto et al.,[20] who reported a higher risk of moderate-to-severe PVL in BAV patients, and to Yoon et al.,[4] who found comparable two-year mortality between BAV and TAV patients but lower procedural success and more frequent moderate-or-greater PVL in the bicuspid group. This difference may be related to our small sample size, a low overall PVL burden, and the use of newer-generation valves.

Aortic regurgitation (AR) was absent in 83.3% of patients, mild in 13.3%, and moderate in 3.3%; no cases of severe AR were observed. These findings are consistent with Popma et al.[18] (moderate AR in 3.5%) and with the European Sentinel Registry (grade 2 AR in 7.7%, grade 3 in 1.3%, among >4,500 patients);[21] the lower AR rate in our study may relate to differences in sample size, valve type and procedural approach—Di Mario et al.[21] included both SAPIEN XT/CoreValve prostheses and transapical/transfemoral approaches, whereas our study used only the transfemoral route.

Vascular adverse events occurred in 3.3% of patients, consistent with contemporary reports of ≈4% or less,[1,18] and markedly lower than the PARTNER trial's reported rate of major (15.3%) and minor (11.9%) vascular events.[17] This likely reflects advances in delivery-system profiles, improved vascular closure devices (e.g., Perclose ProGlide), and growing operator experience.

Stroke occurred in 1 patient (1.7%), consistent with Eggebrecht et al.[22] (mean 30-day stroke/TIA rate 3.3±1.8%, range 0-6%) and Okuno et al.[23] (30-day stroke incidence 3.0% in 11,957 patients, with most events within the first 48 hours).

Overall, early in-hospital adverse events did not differ significantly between groups ($P > 0.05$), consistent with Gasecka et al.,[24] who found similar device success, in-hospital and long-term mortality, procedural adverse events, and moderate-to-severe PVL at discharge in propensity-matched BAV and TAV cohorts, albeit with a non-significant trend toward more stroke in BAV patients. Similarly, contemporary-technology studies report comparable procedural and one-year outcomes between BAV and TAV patients, supporting TAVI as a viable option for selected BAV patients.[24,25]

PVL did not differ significantly between Evolut R and Evolut PRO ($P = 0.509$), though it was numerically lower with Evolut PRO (2.5% vs. 10.0%), consistent with Gozdek et al.,[26] who reported a 35% relative reduction in moderate-to-severe PVL with Evolut PRO, and with Bhogal et al.,[27] who found comparable moderate-PVL rates between the two devices at 1 year. Although not statistically significant here, this numerical trend is plausibly attributable to the external pericardial sealing skirt, which is unique to Evolut PRO and designed to reduce paravalvular flow at the frame-annulus interface.

Mechanistic Considerations

The larger, more elliptical bicuspid annulus and its typically greater and asymmetric calcium burden are likely to underlie several of the differences observed between groups. Asymmetric leaflet calcification can cause uneven frame expansion of a self-expanding nitinol stent, producing an oval rather than a circular final frame geometry; this incomplete circularization is a recognized mechanism for residual paravalvular regurgitation and elevated post-implant gradients, consistent with the higher mean and peak gradients seen in the BAV group in this study. Calcium located near the membranous septum and the LVOT can mechanically compress the conduction axis during frame expansion, which is a plausible contributor to new conduction disturbances and the need for permanent pacing, independent of implantation depth. The pericardial outer wrap, incorporated into the Evolut PRO platform, is designed to fill the irregular space between an asymmetric calcified annulus and the valve frame; this provides a mechanistic rationale for the numerically—if not statistically—lower PVL rate observed with Evolut PRO in this cohort. These mechanisms are discussed in greater detail in recent bicuspid-specific TAVI reviews and registries.[3,4,20]

Study Limitations

This study provides early, real-world comparative data from a two-center cohort on contemporary self-expanding TAVI in bicuspid and tricuspid anatomy; several methodological considerations should inform the interpretation and extension of these findings.

Sample size and power: The BAV group comprised only 15 patients, substantially limiting statistical power for most comparisons and increasing the risk of Type II error. Non-significant results should not be interpreted as evidence of equivalence between groups.

Design: This was a single-center (two affiliated hospitals within one study team), non-randomized, observational cohort study. Selection bias related to heart valve team decision-making cannot be excluded, and no independent, blinded adjudication of clinical events was performed.

Confounding and adjustment: The prevalence of DM and several annular dimensions differed significantly between groups at baseline. No multivariable adjustment, propensity-score matching, inverse-probability weighting, or sensitivity analysis were performed because the small BAV group and low event counts for several outcomes made such modeling statistically unreliable; residual confounding cannot be excluded, and the reported associations should be interpreted as unadjusted and hypothesis-generating.

Statistical methodology: The Kolmogorov-Smirnov test, rather than the more appropriate Shapiro-Wilk test, was used to assess normality in a small subgroup; no correction was applied to account for the large number of statistical comparisons performed, increasing the risk of false-positive findings. Although 95% CIs and effect sizes for the principal significant comparisons have now been added (see Results), these were derived post hoc from reported summary statistics rather than from a re-analysis of the original patient-level dataset with these estimates pre-specified.

Sample size calculation: The reported calculation estimated the sample size needed to characterize BAV prevalence rather than to power the between-group comparisons that were ultimately performed (see Sample Size Calculation).

Follow-up outcomes were assessed only during the index hospital stay. Clinically important endpoints—30-day, 6-month, and 1-year mortality, valve durability, structural valve deterioration, rehospitalization, and late pacemaker dependency—could not be evaluated and therefore require dedicated longer-term follow-up.

Anatomical and procedural detail: Annular sizing was not standardized across operators; a formal Sievers classification, raphe-specific calcification, calcium-asymmetry scoring and eccentricity index were not systematically recorded; and fluoroscopy time, contrast volume, total procedural duration, valve-repositioning frequency, cerebral embolic protection use, vascular closure technique, and individual operator case-volume were not available in the dataset used for this analysis.

Operator-dependent decisions—valve and device selection, sizing, and implantation strategy—were based on individual operator discretion rather than on a standardized, pre-specified protocol, which may have introduced variability not captured by the recorded covariates.

CONCLUSION

This study contributes early, prospectively collected comparative data on TAVI with contemporary self-expanding valves (Evolut R/PRO) in patients with bicuspid versus tricuspid AS, a clinical scenario for which comparative evidence using new-generation devices remains limited. Early in-hospital clinical and safety outcomes in patients with bicuspid anatomy were statistically similar to those in patients with tricuspid valves, despite significantly larger and more complex annular dimensions in the bicuspid group, which supports the feasibility of TAVI in carefully selected bicuspid patients when procedures are guided by detailed pre-procedural imaging and individualized device selection. TAVI in tricuspid anatomy remains the benchmark for procedural predictability, given its more symmetrical anatomy; the bicuspid findings reported here should be regarded as hypothesis-generating rather than confirmatory, a status that reflects the single-center design and modest bicuspid sample size inherent to this still-evolving area of practice. These results support the rationale for conducting larger, multicenter, adequately powered studies that incorporate standardized bicuspid anatomical characterization (including Sievers classification) and mid- to long-term follow-up to confirm and extend the encouraging early signal observed in this cohort.

Ethics

Ethics Committee Approval: The study received ethical clearance from the Research Ethics Committee of the Faculty of Medicine, Benha University (approval code: M.S 15-2-2024, date: 27.05.2026) and was conducted in accordance with the Declaration of Helsinki.

Informed Consent: Written informed consent was obtained from all participants after a thorough explanation of the study's nature and objectives.

Footnotes

Authorship Contributions

Surgical and Medical Practices: H.I.A., O.S.A., M.S.A.E., Concept: M.A.H., H.I.H., Design: M.A.H., H.I.H., Data Collection or Processing: H.I.A., O.S.A., Analysis or Interpretation: M.S.A.E., H.I.H., Literature Search: M.A.H., Writing: H.I.A., M.S.A.E., O.S.A.

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