

## Concomitant Percutaneous Left Atrial Appendage Closure and Transcatheter Aortic Valve Implantation: Double Hit Combo in Atrial Fibrillation

### ABSTRACT

**Background:** Patients with atrial fibrillation (AF) undergoing transcatheter aortic valve implantation (TAVI) often require long-term oral anticoagulation (OAC), which may not be appropriate for those at high bleeding risk. Performing left atrial appendage closure (LAAC) during TAVI can reduce the risk of thromboembolism while avoiding the need for prolonged anticoagulation.

**Methods:** This single-center study included 5 consecutive patients with severe aortic stenosis and AF who underwent same-session TAVI and LAAC between October 2024 and March 2025. All had contraindications to OAC or high bleeding risk. Procedural details and early outcomes were recorded. Technical success was defined according to Valve Academic Research Consortium-3 (VARC-3) (TAVI) and Munich/The Society for Cardiovascular Angiography & Interventions (SCAI) and the Heart Rhythm Society criteria (LAAC). Continuous variables are presented as mean  $\pm$  SD or median interquartile range (IQR), and categorical variables as n (%).

**Results:** Mean age was  $75.6 \pm 8.4$  years; 40% were male. The median Society of Thoracic Surgeons score was 6.0% [IQR 5.5-7.0], median CHA<sub>2</sub>DS<sub>2</sub>-VA was 4 [4-5], and median hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile INR, elderly, drugs/alcohol concomitantly was 3 [3-4]. All patients received a Meril valve; LAAC devices included Amulet (n=3) and LAMBE (n=2). Technical success was achieved in all cases. There were no intra-periprocedural complications, major bleeding (Bleeding Academic Research Consortium  $\geq 3$ ), stroke/transient ischemic attack, or vascular complications. But Kidney Disease: Improving Global Outcomes stage 1 acute kidney injury was observed only in 1 (20%) patient. The median hospital stay was 4 [IQR 3-6] days.

**Conclusion:** In this study, same-session TAVI and LAAC in AF patients with high bleeding risk were technically feasible and showed an acceptable short-term safety profile. Larger, prospective studies with longer follow-up are needed to confirm these results.

**Keywords:** Concomitant procedure, high bleeding risk, left atrial appendage closure, transcatheter aortic valve implantation

### INTRODUCTION

Severe aortic stenosis (AS) presents a significant procedural challenge, especially in elderly patients with atrial fibrillation (AF), a subgroup characterized by both thromboembolic and hemorrhagic risks.<sup>1,2</sup> Transcatheter aortic valve implantation (TAVI) has become a preferred alternative to surgical valve replacement in high-risk and inoperable patients, with expanding indications beyond traditional high-risk cases. However, the concurrent presence of AF complicates management, as these patients need effective stroke prevention with oral anticoagulation (OAC), which can increase both periprocedural and long-term bleeding risks, particularly when antiplatelet therapy is also involved.<sup>3</sup>

Patients with AF who are poor candidates for OAC due to either prior major bleeding, frailty, or inability to tolerate therapy remain at high risk for stroke and vulnerable to hemorrhagic complications. LAAC offers a non-pharmacological

### ORIGINAL INVESTIGATION

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Received: October 22, 2025

Accepted: November 19, 2025

Available Online Date: December 29, 2025

Cite this article as: Kıvrak A, Ateş AH, Doğan M, et al. Concomitant percutaneous left atrial appendage closure and transcatheter aortic valve implantation: double hit combo in atrial fibrillation. *Anatol J Cardiol.* 2026;30(4):242-247.



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DOI:10.14744/AnatolJCardiol.2025.5937

alternative by eliminating the primary source of thrombus formation in non-valvular AF and is particularly useful in those with contraindications to OAC or a high bleeding risk (HAS-BLED score of  $\geq 3$ ).<sup>4</sup> In TAVI candidates, who are often elderly and have comorbidities, the combined approach of LAAC and TAVI in a single session has demonstrated technical feasibility and safety in small case series, especially in OAC-ineligible patients.<sup>5</sup>

The concept of performing TAVI and LAAC in a single session aims to minimize procedural burden, reduce cumulative exposure to anesthesia and vascular access, and potentially shorten hospital stay. Several small case series and observational studies have reported high technical success rates with acceptable complication profiles, suggesting that the approach may be a viable option for selected high-risk patients.<sup>3,5,6</sup> Nonetheless, data remain limited, and most available reports involve heterogeneous patient populations, varied procedural sequences, and different device types, underscoring the need for additional evidence from real-world practice.

Given the lack of data from real-world cohorts and the limited representation of OAC-ineligible patients in larger trials, further evidence is required to define the procedural feasibility and short-term safety of same-session TAVI and LAAC. In this study, a single-center experience with 5 high-risk AF patients who underwent combined TAVI and LAAC in a single session was reported. All patients had contraindications to long-term OAC due to major bleeding events or thromboembolic events occurring while on therapy. The primary objective of this study was to assess technical success, while secondary endpoints focused on in-hospital complications and early post-procedural outcomes.

## METHODS

### Study Population

This was a single-center, retrospective, observational study including 5 consecutive patients with severe, symptomatic

## HIGHLIGHTS

- The combined transcatheter aortic valve implantation–left atrial appendage closure (TAVI-LAAC) procedure was technically successful in all 5 patients (100%) with no procedural complications, demonstrating the safety and feasibility of this approach.
- Median procedure time was 72 minutes with a contrast volume of 65 mL, indicating that the combined procedure can be performed efficiently without excessive procedural burden.
- No major adverse events, including stroke, major bleeding, or pericardial complications, occurred during the index hospitalization, supporting the early safety profile of simultaneous TAVI-LAAC.
- This combined approach may be particularly beneficial for high-risk elderly patients with atrial fibrillation requiring both TAVI and stroke prevention, potentially reducing the need for multiple procedures and prolonged anticoagulation.

AS and coexisting AF who underwent combined TAVI and LAAC in a single procedural session between October 2024 and March 2025. All patients were ineligible for long-term OAC due to a history of major bleeding (e.g., gastrointestinal or ocular hemorrhage) or thromboembolic events occurring while on therapeutic OAC. The decision to perform combined TAVI and LAAC was made by the institutional Heart Team, based on clinical presentation and comorbidities. The study was conducted in accordance with the principles of the Declaration of Helsinki. The protocol was approved by the Hacettepe University Health Sciences Research Ethics Committee (Date: August 26, 2025; Decision number: 2025/16-61; Study registration number: SBA 25/746). Waived by the ethics committee for this retrospective analysis of anonymized medical records.

### Pre-procedural Evaluation

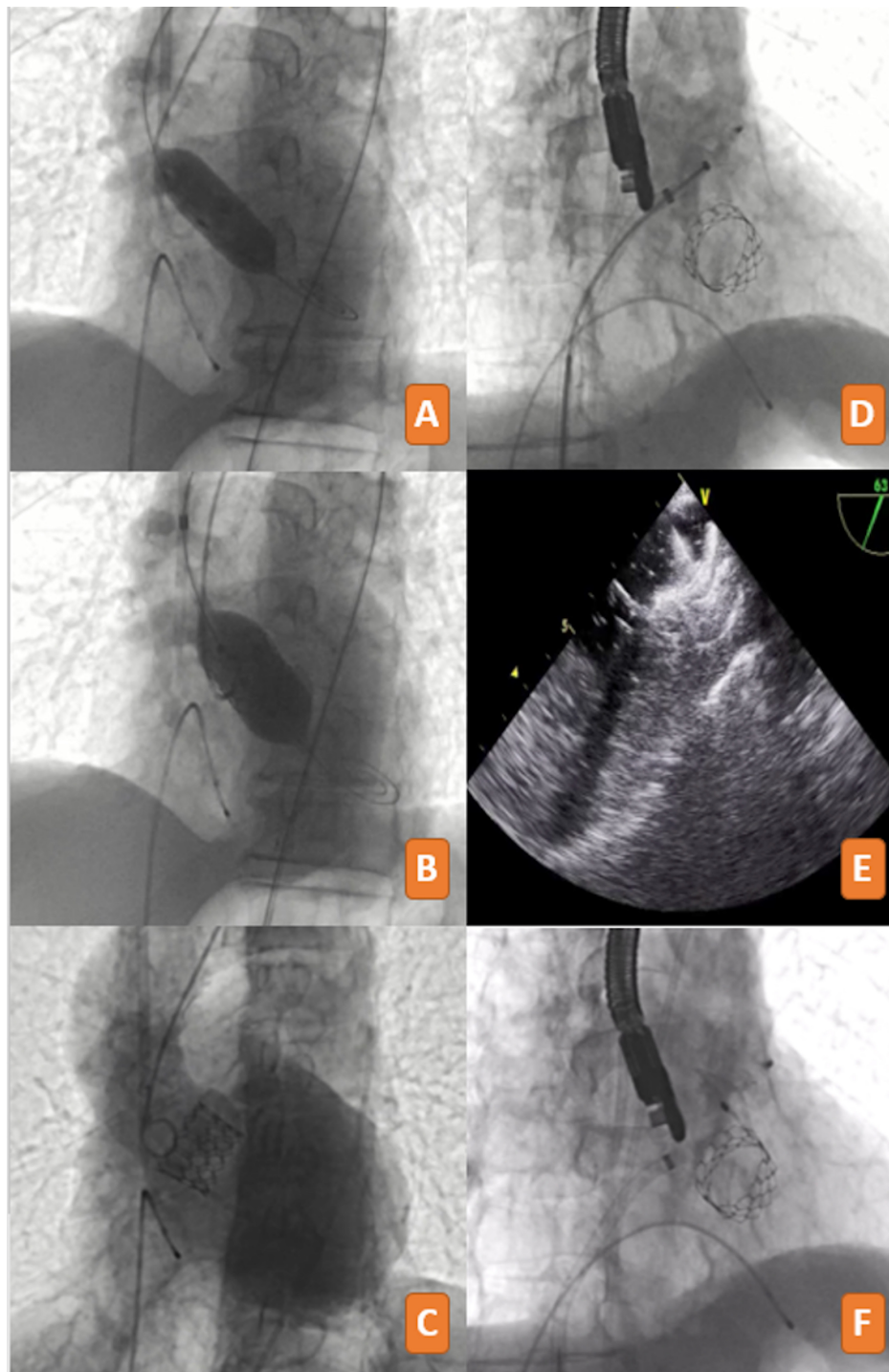
All patients underwent a comprehensive pre-procedural assessment, including detailed clinical history, physical examination, laboratory testing, transthoracic echocardiography, and multislice computed tomography (CT) for annular sizing and vascular access evaluation. Transesophageal echocardiography (TEE) was performed to assess the morphology and dimensions of the left atrial appendage (LAA) and to exclude pre-existing thrombus. Echocardiographic parameters, including peak and mean transvalvular gradients and aortic valve area measurements, confirmed the severity of AS in accordance with current guidelines. Risk stratification was performed using the Society of Thoracic Surgeons (STS) score, CHA<sub>2</sub>DS<sub>2</sub>-VA, and HAS-BLED scores, calculated from baseline clinical and echocardiographic data.

### Procedural Details

All procedures were performed under general anesthesia in a cardiac catheterization laboratory. Following sterile preparation and obtaining vascular access, transfemoral TAVI was performed using the balloon-expandable Myval transcatheter heart valve (Meril Life Sciences, Vapi, India), with device size selection based on pre-procedural multislice CT annular measurements. After successful valve implantation, TEE was introduced for LAAC planning. Venous access was obtained via the contralateral femoral vein, and transeptal puncture was performed at the inferoposterior aspect of the interatrial septum under fluoroscopic and TEE guidance. Device sizing and selection were based on TEE measurements of the LAA landing zone and ostium. Zero-contrast LAAC was performed using Amulet LAA Occluder (Abbott, Chicago, IL, USA) in 3 patients and LAmbre LAA Closure System (Lifetech Scientific, Shenzhen, China) in 2 patients. Devices were deployed under fluoroscopic and TEE visualization, ensuring optimal position and seal before release, as described in previous studies (Figure 1).<sup>7,8</sup> Final TEE and fluoroscopy confirmed stable device position, absence of peri-device leak, and no pericardial effusion.

### Study Endpoints

The primary endpoint was technical success, defined as successful deployment of both the transcatheter aortic valve and the LAAC device in the intended position, with no need for additional unplanned interventions and without



**Figure 1. Stepwise fluoroscopic and echocardiographic images of the same-session TAVI and LAAC. (A, B) Balloon valvuloplasty and transcatheter aortic valve deployment. (C) Final valve position without paravalvular leak. (D) Fluoroscopic view of LAA occluder positioning. (E) TEE confirmation of correct device placement without leak. (F) Final fluoroscopic image showing a stable valve and occluder.**

in-hospital mortality. For the TAVI procedure, technical success was defined according to the Valve Academic Research Consortium-3 (VARC-3) criteria, which include the absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location, and intended valve performance with no prosthesis-patient mismatch or significant paravalvular leak at hospital discharge.<sup>9</sup>

For the LAAC procedure, technical success was defined based on the Munich Consensus Document, which provides standardized definitions for procedural outcomes, endpoints, and data collection in clinical studies.<sup>10</sup> These criteria require successful device deployment with complete LAAC or residual peri-device leak  $\leq 5$  mm, stable device position confirmed by imaging, and no device embolization or surgical intervention.

Secondary endpoints included the occurrence of vascular complications (major or minor) according to VARC-3, major bleeding events defined as Bleeding Academic Research Consortium (BARC) type  $\geq 3$ <sup>11</sup> pericardial effusion or tamponade requiring intervention, stroke or transient ischemic attack (TIA), new permanent pacemaker implantation, and acute kidney injury (AKI) according to the Kidney Disease: Improving Global Outcomes (KDIGO) classification.

### Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for distribution using the Shapiro–Wilk test. Given the small sample size and non-normal distribution of most variables, continuous data are presented as median [interquartile range (IQR)], and categorical data are presented as counts and percentages. No imputation was performed for missing data. Descriptive statistics were used to summarize baseline characteristics, procedural details, and outcomes.

### RESULTS

The study included 5 patients with a mean age of  $75.6 \pm 8.4$  years, of whom 2 (40.0%) were male. The mean body mass index was  $24.45 \pm 2.11$  kg/m<sup>2</sup>. Four patients (80.0%) had a

history of coronary artery disease and hypertension, and 1 patient (20.0%) had diabetes mellitus. Non-paroxysmal AF was documented in 4 patients (80.0%). The median STS score was 6.0 (IQR 5.5-7.0). The median CHA<sub>2</sub>DS<sub>2</sub>-VA and HAS-BLED scores were 4 (IQR 4-5) and 3 (IQR 3-4), respectively. The primary indications for LAAC included gastrointestinal bleeding in 2 patients (40.0%), ischemic stroke despite OAC in 2 patients (40.0%), and systemic embolism (retinal artery occlusion) despite OAC in 1 patient (20.0%) (Table 1).

All procedures were completed in a single session without intraprocedural complications. The median procedural time was 72 minutes (IQR 68-78), and the median contrast volume was 65 mL (IQR 60-70), reflecting the use of a zero-contrast strategy for LAAC with TEE and fluoroscopic guidance. All TAVI procedures were performed using balloon-expandable Myval valves (Meril Life Sciences, Gujarat, India), and LAAC was achieved with either Amulet (Abbott, Chicago, IL, USA) or LAmbre (Lifetech Scientific, Shenzhen, China) devices.

Postprocedural antithrombotic therapy at discharge involved clopidogrel alone in 2 patients (40.0%) due to prior gastrointestinal bleeding, and aspirin plus apixaban in the remaining 3 patients (60.0%) who had a history of thromboembolism despite OAC, as shown in Table 2.

During the in-hospital period, no deaths, myocardial infarctions, or strokes were recorded. There were no cases of

**Table 1. Baseline Characteristics of the Study Population**

Characteristic	Value (n = 5)
<b>Demographics</b>	
Age, years	75.6 ± 8.4
Male sex, n (%)	2 (40.0)
BMI, kg/m <sup>2</sup>	24.45 ± 2.11
<b>Risk factors and comorbidities</b>	
Ex-smoker, n (%)	2 (40.0)
History of CAD, n (%)	4 (80.0)
Diabetes mellitus, n (%)	1 (20.0)
Hypertension, n (%)	4 (80.0)
STS score, %	6.0 (IQR 5.5-7.0)
CHA <sub>2</sub> DS <sub>2</sub> -VA score	4 (IQR 4-5)
HAS-BLED score	3 (IQR 3-4)
<b>Atrial fibrillation type</b>	
Non-paroxysmal AF, n (%)	4 (80.0)
Paroxysmal AF, n (%)	1 (20.0)
<b>Indication for LAAC</b>	
Gastrointestinal bleeding, n (%)	2 (40.0)
Ischemic stroke on apixaban, n (%)	1 (20.0)
Ischemic stroke on warfarin, n (%)	1 (20.0)
Retinal artery occlusion on rivaroxaban, n (%)	1 (20.0)

Data are presented as mean ± SD for continuous variables and as number (percentage) for categorical variables. AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; CHA<sub>2</sub>DS<sub>2</sub>-VA, congestive heart failure, hypertension, age  $\geq 75$  years, diabetes, stroke/TIA, vascular disease, age 65–74 years, sex category; HAS-BLED, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile International Normalized Ratio, elderly, drugs/alcohol concomitantly; IQR, interquartile range; LAAO, left atrial appendage closure; STS, Society of Thoracic Surgeons.

**Table 2. Procedural Characteristics**

Characteristic	Value (n = 5)
<b>TAVI procedure</b>	
Valve type	Meril (Meril Life Sciences, India): 5 (100.0)
Valve size, mm	25.7 ± 2.2
Peak gradient, mm Hg	74.0 ± 22.8
Mean gradient, mm Hg	42.6 ± 12.0
Aortic valve area, cm <sup>2</sup>	0.79 ± 0.16
<b>LAAC procedure</b>	
Amulet (Abbott, USA), n (%)	3 (60.0)
Lambre (Lifetech Scientific, China), n (%)	2 (40.0)
Device size, mm	22, 22/28, 22, 24, 25
Total procedure time, min	72 (IQR 68-78)
Contrast volume, mL	65 (IQR 60-70)
<b>Procedural outcome</b>	
Technical success, n (%)	5 (100.0)
Any procedural complication, n (%)	0 (0.0)
<b>Discharge antithrombotic regimen</b>	
ASA + OAC (apixaban)	3 (60.0)
Clopidogrel only	2 (40.0)
<b>Duration of Index Hospitalization</b>	
Median hospital stays, days	4 (IQR 3-6)

Data are presented as mean ± SD, median [interquartile range (IQR)], or number (percentage). ASA, acetylsalicylic acid; IQR, interquartile range; LAAC, left atrial appendage closure; OAC, oral anticoagulant; TAVI, transcatheter aortic valve implantation.

**Table 3. Early Clinical Outcomes**

Variables	Value (n = 5)
Clinical outcomes	
Stroke/TIA, n (%)	0 (0.0)
Major bleeding (BARC $\geq$ 3), n (%)	0 (0.0)
Pericardial effusion/tamponade, n (%)	0 (0.0)
Vascular complication (VARC-3), n (%)	0 (0.0)
Permanent pacemaker implantation, n (%)	0 (0.0)
Acute kidney injury (KDIGO), n (%)	1 (20.0)

Data are presented as number (percentage) unless otherwise indicated.

BARC, Bleeding Academic Research Consortium; KDIGO, Kidney Disease: Improving Global Outcomes; TIA, transient ischemic attack; VARC, Valve Academic Research Consortium.

device embolization, pericardial effusion, or major vascular complications. One patient developed AKI, which was classified as stage 1 according to the KDIGO criteria, and was managed conservatively without the need for renal replacement therapy. No major or life-threatening bleeding events were observed, and there were no cases of clinically significant paravalvular leak after TAVI or residual peri-device leak following LAAC (Table 3).

## DISCUSSION

Performing TAVI and LAAC simultaneously has become a viable treatment option for patients with AF and severe AS who are at high risk for repeated procedures. This combined approach may help reduce risks associated with multiple interventions, such as repeated anesthesia, longer hospital stays, vascular access issues, and increased contrast use. Previous studies, including the randomized study reported by Kapadia et al,<sup>6</sup> have shown promising results in terms of procedural success and early safety.<sup>3,12</sup> In the present cohort, combining both structural interventions into a single session was accomplished with high technical success and low complication rates, supporting the use of this approach in carefully selected high-risk patients.

An increasing amount of evidence shows that performing both TAVI and LAAC in a single session is feasible and can help avoid repeated anesthesia and vascular access, which is especially important in high-risk patients. In the authors' experience, this combined approach was further supported by using a zero-contrast method for LAAC, relying on TEE and fluoroscopic guidance. This minimized renal risk while ensuring procedural safety. On the other hand, cardiovascular interventions using general anesthesia are generally safe, but cumulatively are associated with cognitive decline and neurodegeneration in the elderly. Perioperative brain health should be prioritized for older and vulnerable patients, particularly those who have multiple interventional procedures using anesthesia.<sup>13</sup> These findings align with previous reports of technical success and positive early outcomes in similar populations.<sup>6,12</sup>

Our findings support previous observational and randomized studies indicating that concomitant TAVI and LAAC are both feasible and safe in selected high-risk patients. The

"One-Stop Shop" study showed comparable 30-day outcomes with combined versus isolated TAVI,<sup>3</sup> while Kleinecke et al<sup>14</sup> found no increase in complications when LAAC was performed with other structural interventions. More recently, the WATCH-TAVR trial confirmed that the combined approach is not inferior in terms of death, stroke, and major bleeding at 2 years.<sup>6</sup> Collectively, this data support LAAC integration during TAVI as a viable alternative for AF patients with high bleeding risk or contraindications to OAC.

An essential part of this study is the use of a zero-contrast strategy during LAAC, which led to a relatively low median contrast volume compared to larger cohorts. In WATCH-TAVR, the excessive contrast used for the combined procedure was about 119 mL, significantly higher than the median 65 mL reported in the present cohort. Excessive contrast exposure is a known factor contributing to AKI after TAVI, especially in elderly patients with baseline renal dysfunction. Previous consensus statements have highlighted strategies for kidney protection, including reducing contrast and relying on echocardiographic guidance whenever possible.<sup>15</sup> Based on the authors' experience, only 1 patient developed stage 1 AKI and was managed conservatively, highlighting the potential benefit of a contrast-sparing approach in high-risk groups.

In this cohort, there were no major periprocedural complications such as device embolization, pericardial effusion, stroke, or major bleeding, which aligns with findings from prior series. The case series by Freire et al<sup>5</sup> reported 7 patients undergoing concomitant TAVR and LAAC, all with successful implantation and no major adverse events during follow-up. Similarly, a meta-analysis including 482 patients indicated that combined procedures did not significantly raise the risk of stroke, bleeding, or death compared to isolated TAVR. However, a higher rate of vascular complications was observed.<sup>16</sup> These results suggest that although the overall safety profile of simultaneous TAVI and LAAC is acceptable, managing vascular access remains crucial, especially considering the added procedural complexity and the common frailty in this patient group.

The best antithrombotic strategy after combined TAVI and LAAC remains uncertain. Current European Society of Cardiology guidelines recommend lifelong OAC for AF after TAVI, but the high bleeding risk in elderly and frail patients challenges this approach.<sup>17</sup> By eliminating the need for long-term anticoagulation, LAAC provides a potential advantage in this subgroup. Kapadia et al<sup>6</sup> demonstrated in the WATCH-TAVR trial that dual antithrombotic therapy after combined procedures offered acceptable thromboembolic protection and a lower bleeding risk compared with OAC. The present practice of using short-term dual antithrombotic treatment followed by single antiplatelet therapy aligns with this evidence. This indicates that a personalized antithrombotic regimen after combined procedures can be both safe and effective.

These findings contribute to the growing evidence supporting the feasibility of performing concomitant TAVI and LAAC in selected patients with severe AS and AF who are

at high risk of bleeding. While previous studies have mostly included diverse patient populations or single-center experiences,<sup>3,5,6,12</sup> the present study offers further insight into procedural strategies such as contrast minimization and stepwise antithrombotic management.

This study is limited by its single-center, retrospective design and relatively small sample size, which may restrict the generalizability of the findings. Additionally, the short follow-up duration prevents definitive conclusions about long-term outcomes, and the lack of a control group limits direct comparisons with isolated TAVI or LAAC procedures. Despite these limitations, these results support the feasibility and short-term safety of performing TAVI and LAAC together in carefully selected high-risk patients with severe AS and AF. These findings suggest that the combined approach could be a reasonable treatment option for patients with contraindications to long-term anticoagulation, warranting validation in larger multicenter studies with longer follow-up.

**Ethics Committee Approval:** This retrospective study was conducted in accordance with the Declaration of Helsinki and approved by the Hacettepe University Health Sciences Research Ethics Committee (Date: August 26, 2025; Decision no.: 2025/16-61; Study registration number: SBA 25/746).

**Informed Consent:** Verbal and written informed consent was obtained from the patients who agreed to take part in the study.

**Peer-review:** Internally peer-reviewed.

**Author Contributions:** Concept – A.K., M.D.; Design – A.H.A., U.C.; Supervision – K.A., E.B.K., H.Y.; Resources – A.K., U.N.K., C.Ç.; Materials – A.K., M.D., H.Y.; Data Collection and/or Processing – A.H.A., C.Ç.; Analysis and/or Interpretation – N.Ö., M.L.Ş.; Literature Search – A.K., E.B.K., H.Y.; Writing – A.K., M.D.; Critical Review – H.Y., M.L.Ş., K.A.

**Declaration of Interests:** U.C. is an Associate Editor of the Archives of the Turkish Society of Cardiology. N.Ö. is an Associate Editor; H.Y. and E.B.K. are members of the International Editorial Board of The Anatolian Journal of Cardiology. Given the affiliation between these journals/societies, this relationship is declared for transparency; however, it had no influence on the peer-review process or the decision to publish. The other authors have no conflicts of interest to declare.

**Funding:** The authors declare that this study received no financial support.

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