



Optimizing antithrombotic therapy after Transcatheter Aortic Valve Implantation (TAVI): A review of current evidence and guidelines

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Introduction

Transcatheter Aortic Valve Implantation (TAVI) has emerged as a transformative approach in the management of severe aortic stenosis, particularly for patients who are high-risk or unsuitable for conventional Surgical Aortic Valve Replacement (SAVR). While TAVI has significantly improved clinical outcomes, it also presents challenges, particularly in the management of thromboembolic complications such as ischemic stroke, valve thrombosis, and systemic embolization. Reported stroke rates post-TAVI range from 3-5% within the first 30 days, with persistent risks beyond this period [1]. Additionally, subclinical leaflet thrombosis, identified as Hypo Attenuated Leaflet Thickening (HALT) on computed tomography, has been detected in up to 15% of patients, raising concerns about long-term valve durability and overall patient prognosis [2,18].

Given these risks, optimizing Antithrombotic Therapy (ATT) following TAVI is crucial. However, achieving the ideal balance between thromboembolic prevention and bleeding complications remains a complex challenge. Initial post-TAVI management strategies were influenced by data from Percutaneous Coronary Interventions (PCI), favoring Dual Antiplatelet Therapy (DAPT) with aspirin and clopidogrel. However, growing evidence has questioned the necessity of DAPT, particularly due to its association with increased bleeding risks. Recent clinical trials have driven a shift toward Single Antiplatelet Therapy (SAPT) in many patient populations, reducing bleeding complications without compromising thromboembolic protection [3,4]. Meanwhile, patients with Atrial Fibrillation (AF) or high thromboembolic risk require Oral Anticoagulation (OAC), but debate continues regarding whether Vitamin K Antagonists (VKAs) or Direct Oral Anticoagulants (DOACs) offer the best safety and efficacy profile [5,6].

This article explores the evolving landscape of ATT post-TAVI, examining the latest clinical evidence and guideline recommendations. It discusses

Abstract

Transcatheter Aortic Valve Implantation (TAVI) has revolutionized the management of severe aortic stenosis, particularly in patients at high surgical risk. However, the procedure is associated with thromboembolic and bleeding complications, necessitating optimal Antithrombotic Therapy (ATT) to balance these risks. This review explores the evolving landscape of ATT post-TAVI, focusing on Single Antiplatelet Therapy (SAPT) versus Dual Antiplatelet Therapy (DAPT), the role of Oral Anticoagulation (OAC) in Atrial Fibrillation (AF) patients, and the safety of Direct Oral Anticoagulants (DOACs). Recent clinical trials, including Popular-TAVI, ARTE, and GALILEO, have reshaped ATT strategies, favoring SAPT over DAPT and restricting DOAC use to AF patients. Current guidelines advocate an individualized approach based on thrombotic and bleeding risk profiles. As the field progresses, further research is required to refine ATT strategies for improved patient outcomes.

Keywords: Transcatheter Aortic Valve Implantation (TAVI); Anti-thrombotic therapy; Dual Antiplatelet Therapy (DAPT); Single Anti-Platelet Therapy (SAPT); Direct Oral Anti-Coagulant (DOAC).

Article Details

Received: Aug 26, 2026

Accepted: Sep 29, 2026

Published: Oct 06, 2026

Annals of Cardiology - www.anncardiology.org

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Citation: Ismat M, Gunarathne S, Gunarathne A. Optimizing antithrombotic therapy after transcatheter aortic valve implantation (TAVI): A review of current evidence and guidelines. Ann Cardiol. 2026; 3(2): 1025.

the risks and benefits of SAPT versus DAPT, the role of OAC in AF patients, and the limitations associated with DOAC use following TAVI. Additionally, the article highlights the importance of an individualized approach in ATT, considering both thromboembolic risk and bleeding potential to optimize patient outcomes.

Epidemiology and evolution of TAVI

Aortic stenosis remains the most prevalent valvular heart disease in developed countries and represents a major cause of morbidity and mortality among older adults. Its prevalence increases substantially with age, affecting approximately 3-5% of individuals older than 75 years. Untreated severe symptomatic aortic stenosis carries a poor prognosis, with mortality approaching 50% within two years following symptom onset.

Historically, Surgical Aortic Valve Replacement (SAVR) represented the standard treatment for severe aortic stenosis. However, many elderly patients and those with multiple comorbidities were considered unsuitable candidates for open-heart surgery due to prohibitively high operative risk. The development of Transcatheter Aortic Valve Implantation (TAVI) has transformed the management of this patient population. Since the first successful TAVI procedure performed by Cribber in 2002, technological advancements and growing operator experience have expanded indications beyond inoperable and high-risk groups to include intermediate- and low-risk patients.

As increasingly younger patients undergo TAVI, long-term outcomes including prosthetic valve durability, thromboembolic events, and optimal antithrombotic management have become increasingly important. This evolution has intensified interest in refining post-procedural antithrombotic strategies that effectively prevent thromboembolic complications while minimizing bleeding risk.

Pathophysiology of thromboembolic complications following TAVI

Several mechanisms contribute to thromboembolic complications following TAVI. During valve implantation, manipulation of heavily calcified native valve leaflets and the aortic arch can lead to embolization of debris, increasing the risk of cerebrovascular events. Furthermore, implantation of a bioprosthetic valve creates a thrombogenic environment characterized by endothelial disruption, altered blood flow patterns, and exposure of prosthetic material to circulating blood components.

Subclinical leaflet thrombosis has emerged as a significant concern in recent years. Hypo Attenuated Leaflet Thickening (HALT), detected through multidetector computed tomography, may impair leaflet motion and potentially affect long-term valve performance. Although the clinical significance of HALT remains incompletely understood, its association with valve thrombosis has contributed to ongoing debate regarding optimal antithrombotic therapy after TAVI.

Bleeding risk following TAVI

Bleeding complications remain among the most common adverse events after TAVI. The typical TAVI population is elderly and frequently presents with multiple comorbidities including chronic kidney disease, frailty, anemia, and the need for concomitant anticoagulation due to atrial fibrillation. These factors substantially elevate bleeding risk.

Major bleeding events have been consistently associated with increased mortality, prolonged hospitalization, and reduced quality of life. Consequently, modern post-TAVI antithrombotic strategies aim to minimize bleeding while maintaining adequate protection against stroke, valve thrombosis, and systemic embolization.

Literature search methodology

A narrative review of the contemporary literature was undertaken to evaluate current evidence regarding antithrombotic therapy following Transcatheter Aortic Valve Implantation (TAVI). Electronic databases including PubMed, MEDLINE, Embase and Google Scholar were searched for relevant studies published from January 2017 to March 2025. Search terms included combinations of “transcatheter aortic valve implantation”, “transcatheter aortic valve replacement”, “antithrombotic therapy”, “single antiplatelet therapy”, “dual antiplatelet therapy”, “oral anticoagulation”, “direct oral anticoagulants”, “vitamin K antagonists”, “atrial fibrillation”, “leaflet thrombosis”, and “hypo attenuated leaflet thickening”.

Priority was given to randomized controlled trials, meta-analyses, systematic reviews, large observational studies, and contemporary guideline documents produced by the European Society of Cardiology (ESC), European Association of Percutaneous Cardiovascular Interventions (EAPCI), American College of Cardiology (ACC), and American Heart Association (AHA). Additional studies were identified through manual screening of reference lists from relevant publications. Articles were selected based on their relevance to post-TAVI antithrombotic management, clinical outcomes, bleeding risk, thromboembolic events, and evolving guideline recommendations.

Thromboembolic risk and the role of antithrombotic therapy post-TAVI

Patients undergoing TAVI are at risk for thromboembolic complications, including ischemic stroke, valve thrombosis, and systemic embolization. Reported stroke rates post-TAVI range from 3-5% within 30 days, with ongoing risk beyond this period [1]. Additionally, subclinical leaflet thrombosis, identified as HALT on computed tomography, has been observed in 10-15% of patients, raising concerns about its impact on valve durability and long-term outcomes [2].

SAPT vs. DAPT in antithrombotic therapy post-TAVI: The debate over the use of single versus dual antiplatelet therapy post-TAVI has been significantly influenced by clinical trials, which have demonstrated that SAPT is safer while maintaining similar efficacy in preventing thromboembolic complications.

Study design

Popular-TAVI Trial (2020) was a multicenter, Randomized Controlled Trial (RCT) that enrolled patients undergoing TAVI without an indication for long-term Oral Anticoagulation (OAC). It compared SAPT (aspirin alone) versus DAPT (aspirin + clopidogrel).

Key Findings were Major or life-threatening bleeding occurred in 15.1% of patients in the SAPT group compared to 26.6% in the DAPT group. No significant difference was observed in ischemic events (e.g., stroke, myocardial infarction) between the two groups. SAPT significantly reduced the rate of non-procedural bleeding, reinforcing its role as the preferred approach for patients without an OAC indication [3]. The

consensus out of the UK and Ireland has suggested that the duration of SAPT should be modified to personal risk profile of each patient for example, those with high bleeding risk may require a 3–12 month duration of treatment with SAPT however those with concomitant coronary artery disease may require longer durations of treatment [18].

ARTE Trial (2017) was a prospective, randomized study that assessed DAPT versus SAPT in TAVI patients without an indication for OAC. Key Findings where Major bleeding was significantly higher in the DAPT group (10.8%) compared to the SAPT group (3.6%). No significant difference in ischemic stroke or myocardial infarction rates was observed between the two groups. The results strongly suggested that the additional use of clopidogrel in DAPT increases bleeding risk without providing additional thromboembolic protection, further supporting the move toward SAPT [7,19].

Several contemporary meta-analyses have consistently demonstrated that SAPT is associated with significantly lower bleeding risk compared with DAPT without increasing rates of stroke, myocardial infarction, or mortality. These findings have reinforced the shift toward SAPT as the preferred strategy in patients without an indication for long-term anticoagulation.

Both Popular-TAVI and ARTE trials clearly indicate that DAPT offers no added benefit in terms of thromboembolic prevention but substantially increases bleeding risk. As a result, current guidelines strongly favor SAPT over DAPT for most patients undergoing TAVI without a specific indication for OAC [4,8].

Role of Oral Anticoagulation (OAC) post-TAVI

For patients with Atrial Fibrillation (AF) or other high thromboembolic risk factors, OAC remains necessary. However, whether vitamin K antagonists (VKAs, e.g., warfarin) or direct oral anticoagulants (DOACs, e.g., apixaban, rivaroxaban) are the best choice has been a subject of extensive investigation.

GALILEO Trial (2019) evaluated the routine use of a DOAC (rivaroxaban 10 mg daily) versus standard antiplatelet therapy in TAVI patients without an indication for long-term OAC. The trial was stopped prematurely due to higher mortality rates in the DOAC group (7.7% vs. 4.5% in the antiplatelet group). Major bleeding was significantly more common in the DOAC group (4.3% vs. 2.8%). Stroke rates did not significantly differ between the two groups. These findings firmly discouraged the routine use of DOACs for thromboprophylaxis in patients without AF [9,19].

ATLANTIS Trial (2021) trial compared apixaban (a DOAC) Versus Warfarin (VKA) in patients undergoing TAVI, including both those with and without AF. There was no significant difference in thromboembolic outcomes (stroke, valve thrombosis) between apixaban and warfarin. Major bleeding was slightly lower in the apixaban group, suggesting a potentially safer profile for DOACs over VKAs in AF patients. The subgroup of patients without AF had worse outcomes with DOACs, aligning with the GALILEO findings. Based on these results, DOACs are now considered an alternative to warfarin in AF patients post-TAVI, but not for patients without AF [11].

The ENVISAGE-TAVI AF trial evaluated deoxidant compared with vitamin K antagonists in patients with atrial fibrillation undergoing TAVI. Although deoxidant demonstrated non-inferiority regarding composite thromboembolic outcomes, a

higher incidence of major bleeding was observed, particularly gastrointestinal bleeding. These findings highlighted the importance of individualized anticoagulant selection rather than assuming a class-wide advantage for all direct oral anticoagulants.

The ADAPT-TAVR study investigated whether anticoagulation could reduce subclinical leaflet thrombosis when compared with dual antiplatelet therapy. Although anticoagulation resulted in lower rates of leaflet thrombosis detected by imaging, the reduction did not translate into significant improvements in clinical neurological outcomes. These findings emphasize the continuing uncertainty surrounding the clinical relevance of HALT and the optimal treatment approach.

For AF Patients, DOACs (e.g., apixaban) are a viable alternative to warfarin, potentially with a better safety profile. For Non-AF Patients, DOACs should not be used routinely, as they increase bleeding and mortality risks.

Subclinical leaflet thrombosis

The increasing use of high-resolution cardiac computed tomography has led to the recognition of subclinical leaflet thrombosis as an important phenomenon following TAVI. This condition is characterized by Hypo Attenuated Leaflet Thickening (HALT) and reduced leaflet motion that may occur in the absence of clinical symptoms.

Studies suggest that HALT may be identified in approximately 10-20% of TAVI recipients during follow-up imaging. While many cases remain clinically silent, concerns have been raised regarding possible associations with cerebrovascular events, valve dysfunction, and reduced prosthetic durability [20,21].

Evidence indicates that oral anticoagulation is generally more effective than antiplatelet therapy in reducing imaging evidence of leaflet thrombosis. Nevertheless, routine anticoagulation solely for prevention of HALT is not currently recommended because the potential reduction in leaflet thrombosis must be weighed against the increased risk of major bleeding. Further studies are required to clarify whether treatment of imaging-detected HALT translates into meaningful improvements in clinical outcomes.

Guideline recommendations

The 2021 European Society of Cardiology (ESC) and European Association of Percutaneous Cardiovascular Interventions (EAPCI) guidelines recommend: SAPT with aspirin alone for most post-TAVI patients without an indication for OAC [8]. DAPT is generally not advised due to increased bleeding risk [4,8]. For patients with AF, OAC is required, with DOACs preferred over VKAs except in cases of mechanical valves or severe mitral stenosis [8]. Routine DOAC use in patients without AF is contraindicated based on the findings of GALILEO [2,9]. This is in slight contrast to the 2021 ACC/AHA guidelines which recommend that a 3-6 month period of treatment with Dual Anti-Platelet Therapy with Aspirin 75 mg daily and Clopidogrel 75 mg daily followed by lifelong Single Anti-Platelet Therapy with Aspirin 75 mg daily for patients with low bleeding risk and no other indications for anticoagulation. For patients undergoing TAVI who are at a higher risk of bleeding, the same guidelines recommend Single Anti-Platelet Therapy with Aspirin 75 mg daily for life [10,19].

Application of current evidence in clinical practice

Current evidence supports a patient-centered approach to antithrombotic therapy following TAVI.

Patients without atrial fibrillation

For patients who do not have atrial fibrillation or another indication for anticoagulation, lifelong single antiplatelet therapy, usually aspirin, is generally recommended [14]. Dual antiplatelet therapy should be avoided unless another clinical indication exists, such as recent coronary stent implantation.

Patients with atrial fibrillation

Patients with atrial fibrillation require lifelong oral anticoagulation for stroke prevention. Contemporary evidence supports the use of either direct oral anticoagulants or vitamin K antagonists depending on individual patient characteristics, bleeding risk, renal function, and clinician preference [17].

Patients with recent percutaneous coronary intervention

Patients requiring both anticoagulation and antiplatelet therapy represent a particularly challenging group. Treatment duration should be individualized, aiming to minimize exposure to combination therapy while ensuring adequate protection against coronary thrombotic events [7,14].

Patients at high bleeding risk

For patients with advanced age, frailty, previous bleeding events, or significant renal dysfunction, simplified

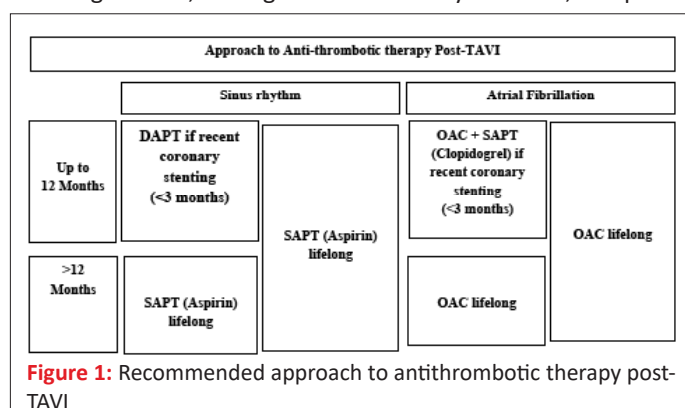


Figure 1: Recommended approach to antithrombotic therapy post-TAVI

antithrombotic regimens should be considered. These patients may derive particular benefit from SAPT and avoidance of unnecessary combination therapies [6,12,13].

Future perspectives in antithrombotic therapy after TAVI

Despite substantial advances in post-TAVI management, several important questions remain unanswered.

Personalized antithrombotic therapy

Future management strategies are likely to focus on individualized treatment plans guided by validated risk prediction models. Integration of clinical, imaging, and biomarker data may enable more accurate assessment of both thrombotic and bleeding risks.

Artificial intelligence and precision medicine

Artificial intelligence and machine learning systems may facilitate more precise risk stratification by identifying complex patterns that are not apparent using conventional clinical scoring systems. Such technologies could support selection of the most appropriate antithrombotic regimen for individual patients.

New-generation valve technologies

Continued development of transcatheter valve platforms may reduce thrombogenicity through improved leaflet design, enhanced haemodynamic, and more biocompatible materials. These innovations could eventually reduce the need for intensive antithrombotic therapy.

Long-term clinical outcomes

Most randomized studies currently provide follow-up periods of one to three years. Longer-term data are required to determine the effects of various antithrombotic strategies on valve durability, structural valve deterioration, and lifetime cerebrovascular risk.

Management of leaflet thrombosis

The significance of HALT remains incompletely understood. Ongoing studies will help determine whether routine imaging surveillance or targeted anticoagulation can improve long-term outcomes in selected patients.

Table 1: Summary of key clinical trials on antithrombotic therapy post-TAVI.

Trial	Study design	Comparison groups	Key findings	Clinical implications
POPular-TAVI (2020) [14]	Multicenter RCT	SAPT (aspirin) vs. DAPT (aspirin + clopidogrel) in TAVI patients without an OAC indication	- Major bleeding: 15.1% (SAPT) vs. 26.6% (DAPT) - No difference in thromboembolic events (stroke, MI)	SAPT is preferred over DAPT, as it reduces bleeding risk without increasing ischemic events [6].
ARTE (2017) [15]	RCT	SAPT vs. DAPT in TAVI patients without an OAC indication	- Major bleeding: 10.8% (DAPT) vs. 3.6% (SAPT) - No difference in ischemic stroke or MI	DAPT is not necessarily post-TAVI; SAPT is safer with less bleeding risk [13].
GALILEO (2019) [16]	Multicenter RCT	DOAC (rivaroxaban 10 mg) vs. standard antiplatelet therapy in non-AF patients	- Higher mortality in DOAC group: 7.7% vs. 4.5% (antiplatelet) - Increased major bleeding: 4.3% (DOAC) vs. 2.8% (antiplatelet) - No significant stroke reduction	DOACs should not be used routinely post-TAVI in patients without AF due to increased mortality and bleeding risk [4].
ATLANTIS (2021) [17]	RCT	DOAC (apixaban) vs. VKA (warfarin) in both AF and non-AF patients	- No significant difference in thromboembolic events (stroke, valve thrombosis) - Lower bleeding risk in DOAC group (particularly in AF patients)	DOACs are a safer alternative to VKAs in AF patients post-TAVI but should not be used in non-AF patients [11].

Conclusion

The management of antithrombotic therapy following TAVI has undergone substantial evolution over the past decade. Contemporary evidence demonstrates that single antiplatelet therapy offers a superior balance between efficacy and safety compared with dual antiplatelet therapy for most patients without an indication for oral anticoagulation. In patients with atrial fibrillation, oral anticoagulation remains essential, with direct oral anticoagulants representing an effective alternative to vitamin K antagonists in appropriately selected individuals.

Randomized trials including Popular-TAVI, ARTE, GALILEO, ATLANTIS, and ENVISAGE-TAVI AF have significantly influenced modern practice by highlighting the importance of minimizing bleeding complications while maintaining protection against thromboembolic events. Furthermore, growing recognition of subclinical leaflet thrombosis has expanded understanding of post-TAVI pathophysiology and generated important new avenues of investigation.

Nevertheless, significant uncertainties remain regarding the optimal duration of therapy, management of HALT, selection of anticoagulant agents, and treatment of increasingly diverse TAVI populations. Future research should focus on individualized risk stratification models, long-term valve durability, emerging valve technologies, and precision medicine approaches to antithrombotic management.

Ultimately, successful post-TAVI care requires a multidisciplinary and patient-centred strategy that carefully balances thromboembolic protection with bleeding risk. Ongoing clinical trials and technological advancements are expected to further refine treatment recommendations and improve long-term outcomes for patients undergoing TAVI.

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