Antithrombotic Therapy Post-TAVR

BACKGROUND

TAVR carries some unavoidable bleeding and thrombotic events during the interventional period as well as long-term follow up. Several aspects related to this subject still lack established randomized clinical trials with long term follow up.

Risk of stroke at 30 days ranges from 0% to 5% based on several clinical factors. Role of cerebral protection devices is still being studied. New onset, persistent or permanent atrial fibrillation increases the risk of stroke in these patients.

Association between thromboembolic events and subclinical leaflet thrombosis, characterized by 4-dimensional computed tomography as hypo-attenuated leaflet thickening (HALT) and reduced leaflet motion, is controversial.

Risk of myocardial infarction ranges between 0% and 2.8% at 30 days.

Rates of serious bleeding range from 2.4% and 41.7% at 30 days and between 3.2% and 46.1% at 1 year. There is an increase in late non-access-site-related bleeding which has not been tracked well. Its risk is higher in patients who are on the higher surgical risk spectrum. Both access site and non-access bleeding increase the risk of death. In general, the risk of serious bleeding event was generally higher than the risk for having a major stroke in all risk categories, but the difference between risks attenuated from the higher to the lower risk categories.

The impact of preloading with antiplatelet/oral anticoagulant (OAC) agents on procedural and long-term complication has not been studied.

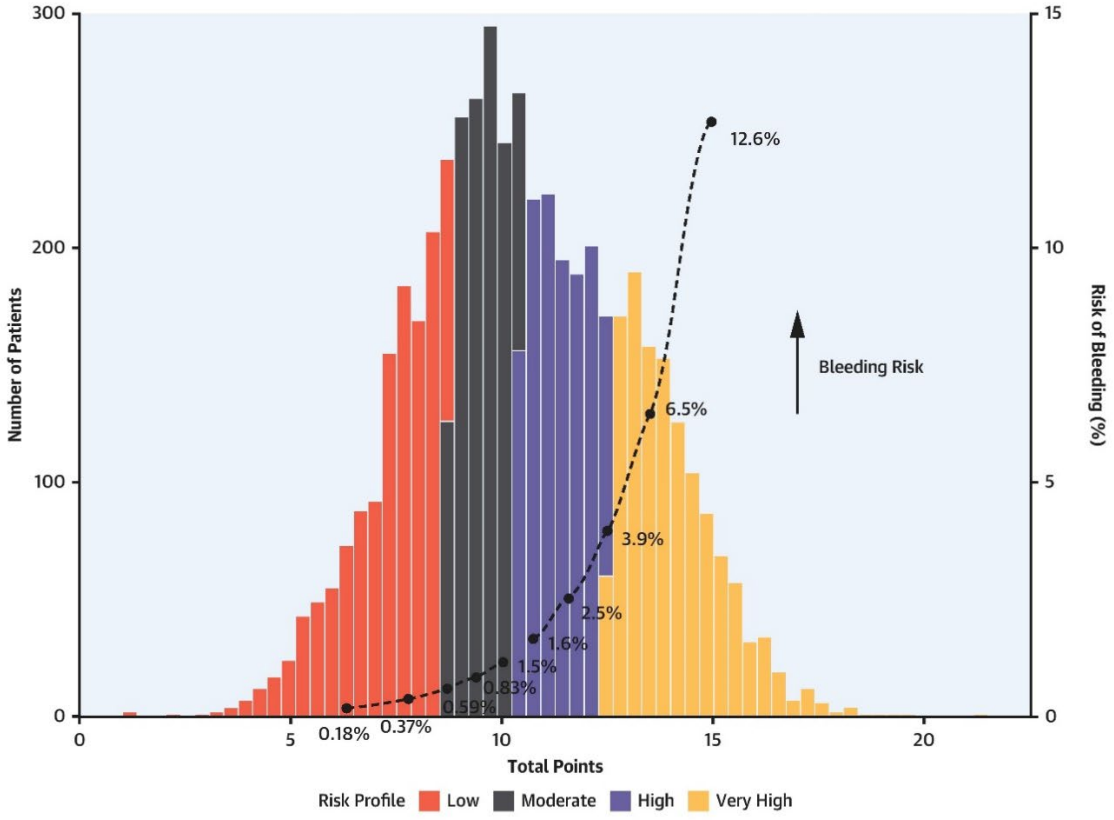
Both patient and procedural factors have to be kept in mind. Factors which increase bleeding risk include age, sex, history of bleeding events, peripheral vascular disease, chronic kidney disease, need for concomitant anticoagulants, acquired von Willebrand factor deficiency, acquired thrombocytopenia, access site complications and injury to cardiac structures.

PREDICTIVE MODEL FOR BLEED RISK

The paper, “Development and Validation of a Practical Model to Identify Patients at Risk of Bleeding After TAVR” (see References), provides a predictive model to identify patients at higher bleeding risk and can be used in risk stratification.

CENTRAL ILLUSTRATION: 30-Day Bleeding Probabilities After Transcatheter Aortic Valve Replacement Across PREDICT-TAVR Quartiles

PREDICT-TAVR Score			
Variables	Points	Total Score	Risk
Oral anticoagulant therapy	0-2	≤8	Low
Hemoglobin	0-10		
Common femoral artery diameter	0-3	>8 and ≤10	Moderate
Dual antiplatelet therapy	0-2		
Serum Iron	0-5	>10 and ≤12	High
Creatinine clearance	0-3		
		>12	Very High



Navarese, E.P. et al. J Am Coll Cardiol Intv. 2021;14(11):1196-206.

Table 1 Academic Research Consortium (ARC) Major and Minor Criterion For High Bleeding Risk

Major	Minor
	Age ≥ 75 years
Anticipated use of long-term oral anticoagulation*	
Severe or end-stage CKD (eGFR <30 mL/min)	Moderate CKD (eGFR 30-59 mL/min)
Hemoglobin <11 g/dL	Hemoglobin 11-12.9 g/dL for men and 11-11.9 g/dL for women
Spontaneous bleeding requiring hospitalization or transfusion in the past 6 months, or any time, if recurrent	Spontaneous bleeding requiring hospitalization or transfusion within the past 12 months not meeting the major criterion
Moderate or severe baseline thrombocytopenia (platelet count <100x10^9/L)	
Chronic bleeding diathesis	
Liver cirrhosis with portal hypertension	
	Long term use of oral NSAIDs or steroids
Active malignancy (excluding nonmelanoma skin cancer) within the past 12 months	
Previous spontaneous intracranial hemorrhage	
Previous traumatic intracranial hemorrhage within the past 12 months	
Presence of brain AVM	
Moderate or severe ischemic stroke (NIHSS score ≥ 5) within the past 6 months	Any ischemic stroke at any time not meeting the major criterion
Nondeferrable major surgery on DAPT	
Recent major surgery or major trauma within 30 days before PCI	

* Excludes vascular protection doses.
AVM, arteriovenous malformation; CKD, chronic kidney disease; DAPT, dual antiplatelet therapy; eGFR, estimated glomerular filtration rate; NIHSS, National Institute of Health Stroke Scale; PCI, percutaneous coronary intervention; NSAIDs, nonsteroidal anti-inflammatory drugs.
Table reprinted from Urban P, Mehran R, Colleran R, et al. Defining high bleeding risk in patients undergoing percutaneous coronary intervention: a consensus document from the Academic Research Consortium for High Bleeding Risk. *Eur Heart J* 2019;40:2632-53.

TAVR patients without concurrent indications for OAC

Preferred antiplatelet strategy for patients without indications for OAC undergoing TAVR may be simplified to aspirin alone, for safety reasons. (However, based on findings from the recent OCEAN TAVI registry, no antithrombotic strategy may be a safe alternative.)

If a patient undergoes TAVR in the context of a recent or concomitant PCI, a mandatory period of DAPT is required based on the clinical presentation (e.g., 6 months after elective PCI, 12 months after PCI for acute coronary syndromes, with halved durations in patients at high bleeding risk).

TAVR patients with concurrent indications for OAC

Patients with atrial fibrillation (AF) undergoing TAVR have a higher risk for mortality than those without AF, and patients requiring anticoagulation have a higher risk for mortality after TAVR.

In patients with AF undergoing TAVR, combining a VKA plus 1 or 2 antiplatelet agents resulted in a higher risk for major or life-threatening bleeding. Risk of ischemic or thrombotic events was not different between VKA monotherapy and a VKA plus 1or 2 antiplatelet agents.

CURRENT APPROACH

Answer two questions:

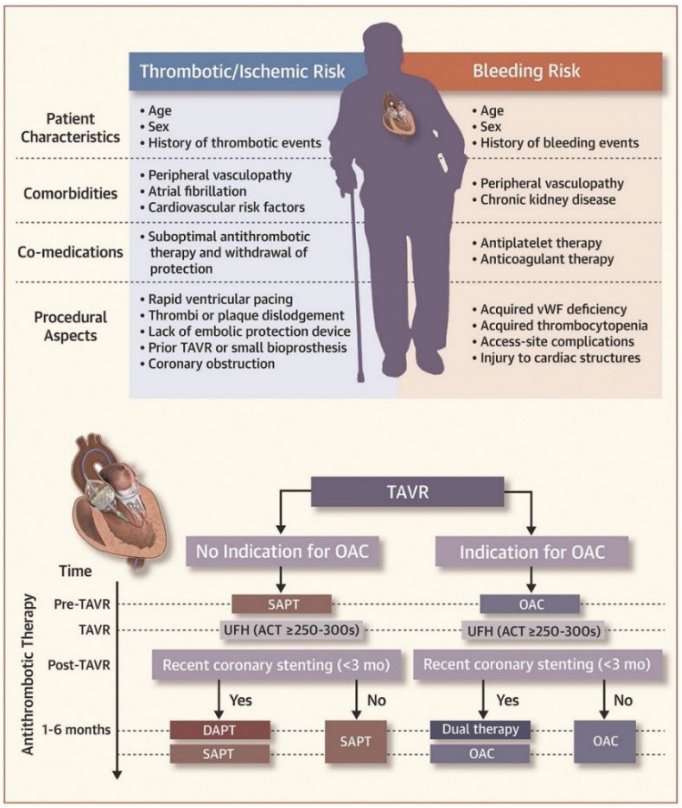
1. Is there an ongoing indication for OAC?
2. Has the patient had a recent coronary stent (less than 3 months)?

Clinical factors to consider:

a) Are there any factors increasing the risk of thrombotic/ischemic events?
b) Are there any factors which will increase bleeding risk? (Consider using PPI in patients with high bleeding risk)

Use the illustration to choose the best antithrombotic regimen:

CENTRAL ILLUSTRATION: Determinants of Thrombotic, Ischemic and Bleeding Risk and Best Practices for Antithrombotic Therapy in Patients Undergoing TAVR



Capodanno, D. et al. J Am Coll Cardiol Intv. 2021;14(15):1688-703.

LIMITATIONS

Controversial issues related to antithrombotic therapy remain. This document will be updated as MISHC consensus is reached on those issues (i.e., need, initiation, duration, use of DAPT, bridging, follow up care).

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DISCLAIMER

Michigan TAVR Best Practice Protocols are based on consortium-wide consensus at the time of publication. Protocols will be updated regularly, and should not be considered formal guidance, and do not replace the professional opinion of the treating physician.

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