Clinical Practice Guideline

Thai Guidelines for Transcatheter Aortic Valve Implantation, TAVI 2021

Mann Chandavimol MD[1], Wacin Buddhari MD[2], Pranya Sakiyalak MD[3], Sirichai Cheewatankornkul MD[4], Vorarit Lertsuwunseri MD[2], Noppon Taksaudom MD[5], Chanapong Kittayarak MD[2], Narathip Chunhamaneewat MD[3], Suphot Srimahachota MD[2]

[1] Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

[2] King Chulalongkorn Memorial Hospital, Chulalongkorn University, Bangkok, Thailand

[3] Siriraj Hospital, Mahidol University, Bangkok, Thailand

[4] Songklanagarind Hospital, Prince of Songkla University, Songkhla, Thailand

[5] Chaing Mai University Hospital, Chiang Mai University, Chiang Mai, Thailand

Thai Guidelines for Transcatheter Aortic Valve Implantation (TAVI) were initiated by the Thai Heart Association, Society of Thoracic Surgeons of Thailand, and Cardiovascular Intervention Association of Thailand. There are several factors in Thailand that differ from western countries, such as patient life expectancy, the types of available TAVI valves, socio-economic status, and experiences in TAVI. Therefore, Thailand-specific guidelines would be of great benefit for Thai patients. The objectives of the guidelines are to provide update recommendations regarding best practice in patients undergoing TAVI in Thailand, to emphasize the importance of a multidisciplinary heart valve team, and to emphasize the importance of data collection and follow up in patients undergoing TAVI for quality improvement. Classes of recommendation were based on standard classification and level of evidence. Recommendations were categorized into recommendation for multidisciplinary heart valve team, for perioperative risk assessment, for patient selection, for antithrombotic treatment after TAVI, for hospital and operator requirement, and for TAVI data collection.

Keywords: Aortic stenosis; Transcatheter aortic valve implantation (TAVI)

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Severe aortic stenosis (AS) is a serious cardiac condition with a high mortality rate if left untreated by valve replacement. Surgical aortic valve replacement (SAVR) has traditionally been the standard treatment. However, there are a significant number of patients in whom the procedure cannot be performed due to the risk involved. Thus, transcatheter aortic valve implantation (TAVI) has been developed as an alternative treatment.

The PARTNER trial consisted of a randomized sample of patients with high surgical risk [the Society of Thoracic Surgeon predicted risk of operative mortality (STS) greater than 15%] and found that treatment with TAVI using a balloon-expandable valve yielded results comparable to standard SAVR in terms of overall mortality[1]. Another cohort using a randomized sample of inoperable patients found that treatment with TAVI was significantly superior to conservative treatment in terms of overall mortality[2].

The PARTNER 2 trial, in which patients with intermediate surgical risk at STS of more than 4% but less than 8%, were randomized to either SAVR or TAVI treatment, reported that overall morality and stroke were comparable between the two treatment groups. Risk of acute kidney injury, new atrial fibrillation, and severe bleeding were significantly lower in the TAVI group, but paravalvular aortic regurgitation and major vascular complications were higher[3].

The SURTAVI trial, using a self-expandable valve, also in patients with intermediate surgical risk randomized to undergo either SAVR or TAVI, reported no difference in mortality rate between the two groups. The incidence of stroke, acute kidney injury, new onset atrial fibrillation, and the

Correspondence to:

Srimahachota S.

King Chulalongkorn Memorial Hospital, Chulalongkorn University, Bangkok 10330, Thailand.

Phone: +66-2-2564291, **Fax**: +66-2-2564291

Email: s_srimahachota@yahoo.co.th

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Table 1. Important recommendations regarding the multidisciplinary heart team

Recommendations	Class	Level
All institutions must set up a multidisciplinary heart team for TAVI	I	C
Patients with severe AS must be evaluated by a multidisciplinary heart team to decide treatment options and plans	I	C

TAVI=transcatheter aortic valve implantation

need for blood transfusion were significantly lower in the TAVI group, but paravalvular leak and the need for permanent pacemaker implantation were higher[4].

The PARTNER 3 trial, conducted in aortic stenosis patients with low surgical risk, reported that TAVI yielded superior outcomes to SAVR in terms of composite endpoints such as death, stroke, and rehospitalization at 1 year[5]. The EVOLUT trials in low-risk patients also demonstrated comparable overall mortality and stroke outcomes between the two treatments[6].

The above studies show that TAVI has comparable short- and medium-term outcomes when compared with SAVR in patient at all levels of risk.

As low-risk patients are often, but not always, younger, TAVI valve durability becomes an even more important factor in this group. Based on bench testing, the SAPIEN 3 valve has the same longevity at 25 years, as the Magna Ease valve[7]. A real-world report found bioprosthetic valve failure (BVF) to be low in the SAPIEN 3 at 4.7% at 8 and 6.5% at 10 years[8]. The NOTION study in low-risk AS patients found that the self-expandable Core Valve had a low rate of structural valve deterioration (SVD) and similar rate of BVF compared to a surgical bioprosthetic valve[9]. In addition, in 2021, standardized criteria for TAVI and SAVR endpoints were developed using an updated definition and published by the Valve Academic Research Consortium 3[10].

In 2017, the ESC/EACTS guidelines for the management of valvular heart disease recommended performing TAVI in patients with moderate risk of STS at 4% or greater, severe comorbidity, age over 75, previous chest surgery, high frailty score, favorable access for transfemoral (TF) TAVI, and porcelain aorta[11]. The 2020 ACC/AHA Guidelines for the management of patients with valvular heart disease[12] also recommend TF TAVI in high-risk patients of STS at greater than 8%, 2 or higher Frailty score, age 80 years or older, or age 65 to 80, in whom the procedure is feasible. There are several factors in Thailand that differ from in the U.S. or Europe such as patient life expectancy, the types of TAVI valves available, socio-economic status, as the cost of TAVI valves is higher than that of surgical bioprosthetic valves, and TAVI experience. The authors thus developed these Thailand-specific guidelines for TAVI treatment.

Objective

1. Provide recommendations regarding best practice in patients undergoing TAVI in Thailand
2. Emphasize the importance of a multi-disciplinary heart valve team.
3. Emphasize the importance of data collection and follow-up in patients undergoing TAVI for quality improvement.

Classes of recommendation and level of evidence

Classes of recommendation

Class I: "Is recommended or is indicated": Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, or effective.

Class IIa: "Should be considered": Weight of evidence/opinion is on usefulness/efficacy.

Class IIb: "May be considered": Usefulness/efficacy is less well established by evidence/opinion.

Class III: "Is not recommended": Evidence or general agreement that the given treatment or procedure is not useful/effective and, in some cases, may be harmful.

Level of evidence

A: Data derived from multiple randomized clinical trials or meta-analyses.

B: Data derived from a single randomized clinical trial or large non-randomized studies.

C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Recommendations for a multidisciplinary heart valve team

A multidisciplinary heart valve team is central in the treatment of AS and should include cardiologists, interventional cardiologists, cardiovascular thoracic surgeons, radiologists, anesthesiologists, nurses, coordinators, and social welfare staff (Table 1).

Table 2. Patient risk assessment and recommendations for aortic valve replacement in patients with aortic stenosis

Recommendation	Class	Level
1. Patients with symptomatic severe AS age over 80 and life expectancy/acceptable QoL more than 1 year and anatomical suitable for TF TAVI, preferred TAVI over SAVR.	I	A
2. Patients with symptomatic severe AS with high (STS >8%) predicted surgical risk or frailty (evaluated by severe frail score >6 or Katz index with 5-meters walk test) or more than 2 organs system disorder and life expectancy more than 1 year after treatment, preferred TAVI over SAVR.	I	A
3. Patients with symptomatic severe AS, age over 80 and life expectancy/acceptable QoL less than 1 year after treatment, should be considered for palliative care.	I	A
4. In asymptomatic severe AS and required valve replacement, SAVR Should be considered.	I	A
5. Patient with asymptomatic AS and age >70 years-old and has anatomy that is suitable for TF TAVI, may consider TAVI but has to be evaluated by multidisciplinary heart team	IIb	C
6. Patients with symptomatic severe AS, age 70 to 80 with low (STS <4%) or intermediate (STS 4-8%) predicted surgical risk for mortality, TF TAVI and SAVR are equivalent base on clinical, anatomical and procedural factors that influence the choice of treatment modality for an individual patient (Table 3) and require decision by multidisciplinary heart team.	I	A
7. Patients with symptomatic severe AS, age <70 is recommended for SAVR, however, should evaluate by multidisciplinary heart team.	I	A
8. If TF access is not possible and patients have intermediate (STS 4% to 8%) predicted surgical risk for mortality or age >80 or high frailty score, alternative access TAVI in experience center can be considered.	IIa	C
9. Patients with degenerated surgical bioprothesis aortic valve (AV) and high risk for re-do operation, TAVI should be considered after multidisciplinary heart team evaluation.	IIa	C

AS=aortic stenosis; QoL=quality of life; TF=transfemoral; TAVI=transcatheter aortic valve implantation; SAVR=surgical aortic valve replacement

Recommendations regarding perioperative risk assessment

Preoperative risk assessment is a basic requirement before SAVR or TAVR in severe AS patients. Although the assessment has some limitations, it can provide important information to guide the multidisciplinary heart team in choosing proper treatment strategies.

Risk assessment includes

1. STS/Euroscore II score to predict risk of death
2. Frailty scale
3. Cardiac or other organ system involved
4. Individual risk assessment

Recommendations for patient selection

TAVI is recommended in patients with symptomatic severe AS according to the following guidelines (Figure 1 and Table 2).

1. In patients over 80 years of age with life expectancy/acceptable QoL more than 1 year and anatomical suitability for TF TAVI, TAVI is preferred over SAVR.

2. In patients with high predicted surgical risk for mortality with STS greater than 8%, frailty or with a FRAIL score greater than 6 or severe Katz index with a five-meter walk test, or disorders in more than two organ systems and life expectancy more than one year after treatment, TAVI is preferred over SAVR.

3. In patients over 80 years of age with life expectancy/acceptable QoL less than one year after treatment, palliative care should be considered.

4. In patients with asymptomatic severe AS who require valve replacement, SAVR should be considered.

5. In patients aged 70 to 80 years with low or intermediate predicted surgical risk for mortality at STS lower than 4% or STS at 4% to 8%, respectively, TF TAVR and SAVR are equivalent. The multidisciplinary heart team should choose the treatment modality for the individual patient based on clinical, anatomical and procedural factors (Table 3).

6. In patients aged younger than 70 years SAVR is recommended. However, the patient should be evaluated by the multidisciplinary heart team.

7. If TF access is not possible and the patient has intermediate predicted surgical risk for mortality STS at 4% to 8%, age older than 80 years, or a high frailty score, alternative access TAVI performed by an experienced team should be considered over SAVR (class IIa).

8. In patients with a regenerated surgical bioprosthetic aortic valve (AV) and high risk for reoperation, TAVI should be considered after evaluation by the multidisciplinary team (class IIa).

Patients must meet all the following criteria:

1. Anatomical suitability for TF TAVI, evaluated based on CTA TAVI protocol for aortic annulus and aortic valve complex, calcification in the AV and left ventricular outflow tract, aorta from ascending to femoral artery.

2. Life expectancy/acceptable QoL more than one year.

3. No indication for open-heart surgery such as aortic aneurysm, severe coronary artery disease not

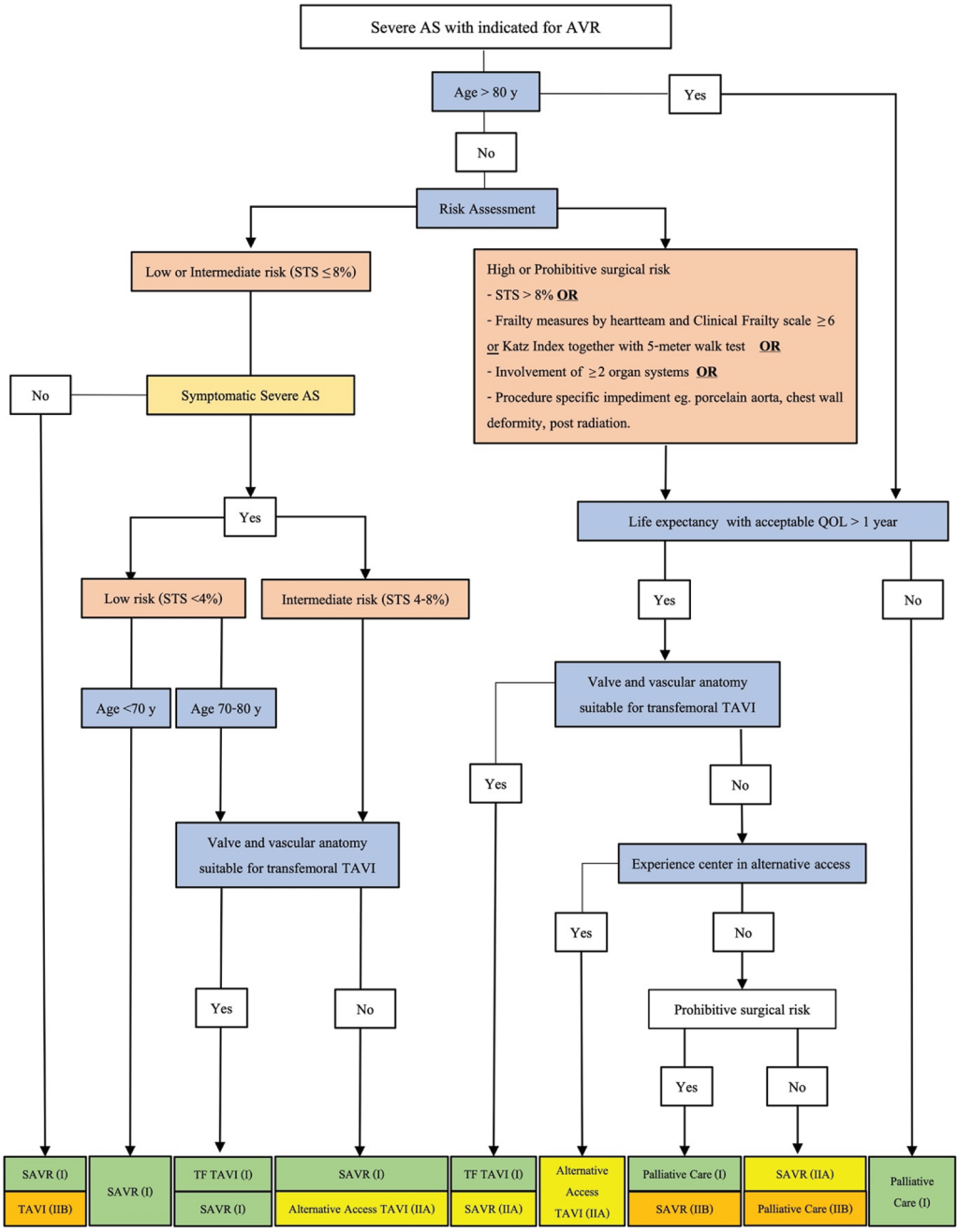


Figure 1. Algorithm for management of patients with severe aortic stenosis.

suitable for percutaneous coronary intervention.

Recommendations regarding antithrombotic treatment after TAVI

The early experience TAVI trial protocols recommend three to six months of dual antiplatelet therapy (DAPT) with aspirin and clopidogrel followed by daily low-dose aspirin for thromboembolic prevention. However, this treatment has never been proven by randomized trials. Future trials are required to find the optimal antithrombotic regimen for these patients[1-6].

The benefits of using DAPT over single antiplatelet therapy (SAPT) has been challenged by an early small clinical trial by Ussia et al[13], followed by two other clinical trials, the SAT-TAVI (Single

Table 3. Clinical, anatomical, and procedural factors that influence the choice of treatment modality for an individual patient (modified from the 2017 ESC guidelines for the management of valvular heart disease)

	Favors TAVI	Favors SAVR
Clinical characteristics		
STS/Euroscore II <4%		+
STS/Euroscore II >4%	+	
Serious comorbid disease	+	
: Age <70 years		+
: Age >80 years	+	
Previous cardiac surgery	+	
Severe frailty	+	
Problems with ambulation after surgery	+	
Suspected of infective endocarditis		+
Anatomy and technical aspects		
: TAVI feasible via the transfemoral approach	+	
: Transfemoral access challenging or impossible		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Patent coronary artery bypass graft	+	
High chance of patient-prosthesis mismatch	+	
Severe chest wall deformity	+	
Low coronary height with high risk of coronary occlusion		+
Aortic annular dimensions unsuitable for available TAVI devices		+
Aortic root not suitable for TAVI		+
Valve morphology not suitable for TAVI		+
Thrombus at aortic valve		+
Concomitant cardiac conditions requiring intervention		
Severe CAD required CABG		+
Severe primary mitral valve or tricuspid valve requiring correction		+
Aneurysm of ascending aorta		+
Septal hypertrophy required myectomy		+

TAVI=transcatheter aortic valve implantation; SAVR=surgical aortic valve replacement; CAD=coronary artery disease; CABG=coronary artery bypass grafting

Antiplatelet Therapy for TAVI) trial and ARTE (Aspirin versus Aspirin+Clopidogrel Following Transcatheter Aortic Valve Implantation) trials. In contrast, using DAPT post TAVI was associated with increased risk of bleeding[14,15]. A recent network meta-analysis by Kuno et al suggested the same finding about bleeding risk associated with DAPT[16].

The GALILEO (Global Study Comparing a Rivaroxaban-based Antithrombotic Strategy to an Antiplatelet-based Strategy After TAVR to Optimize Clinical Outcomes) study[17] randomized patients without indication for anticoagulation to receive either rivaroxaban at 10 mg daily plus aspirin or DAPT (aspirin plus clopidogrel) for three months. The results showed that routine use of rivaroxaban was associated with worse outcomes, including increased risk of death and major bleeding events, without reduction in thromboembolic events.

The POPULAR-TAVI (Antiplatelet Therapy for Patients Undergoing Transcatheter Aortic-Valve Implantation) trial was a parallel-design trial involving two cohorts. Cohort A included 331 patients without an indication for anticoagulation and compared aspirin + clopidogrel versus single antiplatelet therapy with low-dose aspirin. The primary endpoint of a bleeding event occurred in 15.1% of the single antiplatelet therapy group versus 26.6% of the DAPT group (p=0.001). There was no statistically significant difference between groups in terms of death, stroke, or myocardial infarction[18]. Cohort B included patients with an indication for anticoagulation and enrolled 313 patients undergoing TAVI to receive oral anticoagulation alone or anticoagulation plus clopidogrel for three months. The results showed bleeding events in 21.7% of the oral anticoagulation-alone group versus 34.6% of the anticoagulation plus clopidogrel group (p=0.01). The secondary composite outcome of cardiovascular death as non-procedure-related bleeding, stroke, myocardial infarction in 12 months, occurred in 31.2% of the oral anticoagulation-alone group versus 45.5% in the oral anticoagulation plus clopidogrel group[19].

The ATLANTIS (Anti-Thrombotic Strategy After Trans-Aortic Valve Implantation for Aortic Stenosis) trial randomized patients to either a full dose apixaban-based strategy (Apixaban 5 mg bid) or the standard of care strategy to reduce the risk for post-TAVR thromboembolic and bleeding complications. Randomization was stratified according to the baseline need for OAC. Stratum 1 included 451 patients that underwent TAVI with an indication for anticoagulation who received apixaban or VKA. Stratum 2 included 1,049 patients without indication for anticoagulation who received apixaban and an antiplatelet strategy as single or dual therapy with clopidogrel, were compared. The primary endpoint, a composite of death, stroke, MI, systemic emboli, intracardiac or valve thrombosis, deep vein thrombosis or pulmonary embolism, and major bleeding, did not differ between apixaban and the standard of care at 18.4% versus 20.1%. No statistically significant difference was observed in either stratum from stratum 1 with apixaban versus warfarin at 21.9% versus 21.9% or stratum 2 with apixaban versus antiplatelet at 16.9%

Table 4. Recommendations for antithrombotic therapy after transcatheter aortic valve implantation

Recommendations	COR	LOE
Patient undergoing TAVI with no indication for anticoagulation		
1. Aspirin 75 to 100 mg daily is recommended lifelong	I	C
2. Clopidogrel 75 mg daily should be considered lifelong in case of aspirin allergy	IIa	C
3. DAPT (aspirin 75-100 mg daily and clopidogrel 75 mg daily) may be considered for the first 3 months following TAVI followed by aspirin 75 to 100 mg daily lifelong in patients with low risk of bleeding	IIb	C
4. In patients undergoing TAVI treated with DAPT after PCI, the duration of DAPT depends on PCI indication. After completion of DAPT, low-dose aspirin should then be continued indefinitely.		
For ACS PCI, continuation of DAPT for 12 months post PCI is recommended (6 months for patients who are at high risk of bleeding)	IIa	C
For elective PCI, continuation of DAPT for 6 months post PCI is recommended (3 months for patients who are at high risk of bleeding)		
Patients undergoing TAVI with an indication for anticoagulation		
1. Anticoagulation with a warfarin or direct oral anticoagulation without additional antiplatelet therapy is recommended	IIa	C
2. In patients undergoing TAVI with recent PCI with an indication for anticoagulation, the duration of dual antithrombotic therapy should be determined based on PCI indication. After completion of dual therapy, single oral anticoagulation with VKA or DOAC should then be continued indefinitely.		
For ACS PCI, continuation of dual therapy (OAC with clopidogrel or aspirin) for 12 months post PCI is recommended (6 months for patients who are at high risk of bleeding)	IIa	C
For elective PCI, continuation of dual therapy (OAC with clopidogrel or aspirin) for 6 months post PCI is recommended (3 months for patients who are at high risk of bleeding)		

COR=class of recommendation; LOE=level of evidence; TAVI=transcatheter aortic valve implantation; DAPT=dual antiplatelet therapy; PCI=percutaneous coronary intervention; ACS=acute coronary syndrome; VKA=vitamin K antagonist; DOAC=direct oral anticoagulant; OAC=oral anticoagulant

versus 19.3%. The antiplatelet strategy group had a higher incidence of bioprosthetic valve thrombosis in exploratory analysis of secondary outcomes, which was mostly subclinical at 1.1% versus 4.7% ($p<0.05$). The rate of bleeding complications such as life threatening, disabling or major bleeding, did not differ between groups[20].

The ENVISAGE-TAVI AF (Edoxaban versus Standard of Care and Their Effects on Clinical Outcomes in Patients Having Undergone Transcatheter Aortic Valve Implantation-Atrial Fibrillation) trial was a prospective, randomized trial comparing Edoxaban at 60 mg once daily with VKA (warfarin) in 1,426 patients with atrial fibrillation post-TAVI. The rate of net adverse clinical events defined as the composite of death from any cause, myocardial infarction, ischemic stroke, systemic thromboembolic event, valve thrombosis, or major bleeding [International Society on Thrombosis and Hemostasis definition] at one and three years did not differ significantly (HR 1.05, 95% CI 0.85 to 1.31). The rate of major bleeding was significantly higher in the Edoxaban group (HR 1.40, 95% CI 1.03 to 1.91). In this cohort, concomitant antiplatelet therapy was used in about 46% of the patients in the Edoxaban group and 50.4% in the warfarin group[21].

Considering the updated clinical trials mentioned above, the 2021 expert consensus document by the ESC Working Group on Thrombosis and the European Association of Percutaneous Cardiovascular Interventions and endorsed by the ESC Counsel on Valvular Heart Disease provided updated therapeutic insights on antithrombotic treatment during and after TAVR[22].

Recommendations for using antithrombotic therapy post-TAVI in Thailand are listed in Figure 2 and Table 4.

Other recommendations

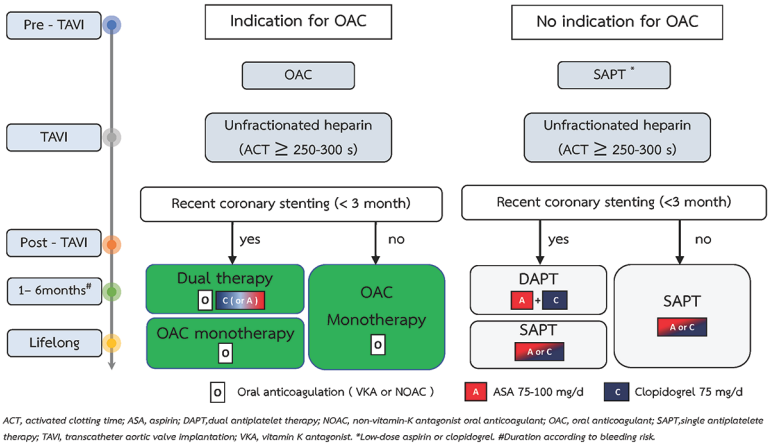
The cardiac center at which transcatheter aortic valve implantation (TAVI) is performed should have the following:

Service standards

1. Imaging service and imaging specialists for diagnosis and TAVI procedural planning such as echocardiography and computerized axial tomography.
2. Electrophysiology service and capability to implant a permanent pacemaker.
3. Nephrology service and capability to perform hemodialysis.
4. Neurology service.
5. Cardiac care unit.
6. Hematology and blood bank service.
7. Operating room in which emergency open heart surgery can be performed.

Equipment standards

1. Digital fluoroscopy and archiving system.



*ACT, activated clotting time; ASA, aspirin; DAPT,dual antiplatelet therapy; NOAC, non-vitamin-K antagonist oral anticoagulant; OAC, oral anticoagulant; SAPT,single antiplatelete therapy; TAVI, transcatheter aortic valve implantation; VKA, vitamin K antagonist. *Low-dose aspirin or clopidogrel. #Duration according to bleeding risk.*

Figure 2. Recommendations for antithrombotic therapy after transcatheter aortic valve implantation.

2. Real-time blood pressure monitoring and electrocardiogram with at least two sets of blood pressure transducers and a 3-lead electrocardiogram.

3. All necessary transcatheter equipment, such as vascular sheath, catheter, and guidewire, including equipment that may be needed in an emergency situation such as stent graft, coronary guidewire, and coronary stent.

4. Cardiopulmonary resuscitation set that is readily available, including biphasic defibrillator, temporary pacemaker, extracorporeal membrane oxygenation (ECMO), and pericardiocentesis kit.

Heart team and operator standards

1. Operators must be certified intervention cardiologists or cardiothoracic surgeons.

2. The team must perform TAVI in least ten patients per year or have a proctoring system to ensure the highest standards.

3. The heart team must be multidisciplinary and should be composed of a cardiologist, intervention cardiologist, cardiothoracic surgeon, radiologist, anesthesiologist, registered nurse, and social worker.

Data management standards

1. Patient data record.

2. Procedural data record.

3. Record of procedural outcomes and complications.

4. All data must be stored for a minimum of five years.

TAVI device standards

1. Consider using TAVI devices that have more than five years of follow-up data if TAVI was to be performed in patients under 75 years of age.

Recommendation for data collection and TAVI registry

1. TAVI data registration in the national database.

Conflicts of interest

The authors declare no conflict of interest.

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