

# Incidence and Clinical Outcomes of Thrombocytopenia after Transcatheter Aortic Valve Replacement in Thai Patients

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**Background:** Post-transcatheter aortic valve replacement (TAVR) thrombocytopenia has been reported to be a predictor of higher mortality and worse clinical outcomes in published studies mostly from Western countries; however, data from Asian countries are generally limited, while data from Thai population are lacking.

**Objective:** To evaluate the incidence and outcomes of Thai patients who developed thrombocytopenia after TAVR.

**Materials and Methods:** The present research was a retrospective observational study. The authors collected data from patients underwent TAVR at Siriraj Hospital between 2009 and 2019. The patients were stratified into four groups according to nadir platelet count, no thrombocytopenia with platelet of 150,000/uL or more, mild with platelet of 100,000 to 149,999/uL, moderate at 50,000 to 99,999/uL and severe at less than 50,000/uL. In addition, the patients with moderate to severe thrombocytopenia were stratified into two groups according to the percentage decline in platelet count (DPC) post procedure as DPC of less than 50% or DPC of 50% or more from the baseline platelet count.

**Results:** Eighty-three patients were reviewed. One patient who died intraoperatively was excluded. Thrombocytopenia occurred in 62 patients (75.6%), in which 36.6% (n=30) of the cases were classed as moderate, and 8.5% (n=7) as severe thrombocytopenia. The platelet count returned to baseline before discharge or during the follow-up period in 83.8% (n=52) of patients. The incidence of in-hospital mortality was significantly higher in patients with severe thrombocytopenia than those with mild thrombocytopenia at 28.6% versus 4% (p=0.011). The duration of admission, length of stay in the CCU, incidence of life-threatening bleeding, clopidogrel discontinuation, platelet transfusion, rate of infection, shock, and acute kidney injury were also significantly higher in patients with moderate to severe thrombocytopenia.

**Conclusion:** Acquired thrombocytopenia after TAVR is a common phenomenon in Thai patients (75%) but usually transient with a nadir platelet count greater than 50,000/uL. Most patients had spontaneous platelet recovery. The presence of severe thrombocytopenia with a nadir platelet count of less than 50,000 is a red flag sign for concomitant infection. The severity of thrombocytopenia is significantly associated with higher mortality and post-procedural adverse events.

**Keywords:** Thrombocytopenia; Transcatheter aortic valve replacement (TAVR)

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Transcatheter aortic valve replacement (TAVR) is currently the standard treatment for severe symptomatic aortic stenosis patients who are prohibited or intermediate to high surgical risk<sup>(1)</sup>. From a recent meta-analysis, TAVR was found to be associated with a reduction in all-cause mortality and major bleeding compared to surgical aortic valve replacement (SAVR). This effect was consistent across all the whole spectrum of surgical risk<sup>(2)</sup>, also with a significant decrease in mortality, but suboptimal outcomes are still found in a proportion of patients. Several studies have reported the

possibility of a negative impact of blood disorder on the TAVR outcome<sup>(3)</sup>. In the present study, the authors specifically focused on thrombocytopenia, defined as a platelet count of 150,000 or less per uL, since it is a common phenomenon post TAVR, reportedly occurring in 40% to 87% of patients<sup>(4-7)</sup>, and has been described as a predictor of higher mortality, higher major vascular complications, and major bleeding<sup>(8)</sup>.

The occurrence and consequence of thrombocytopenia have been demonstrated in several published studies from Western countries. However, data in Asian populations are limited, and furthermore, this subject has never been explored in the Thai population. Due to the distinct anatomical features of Asian patients, such as a smaller iliofemoral and aortic root dimension, the risk of vascular complications and mortality might be potentiated, if thrombocytopenia occurred<sup>(9-11)</sup>. Consequently, the aim of the present study was to evaluate the incidence and clinical outcomes of acquired thrombocytopenia after TAVR in Thai patients.

## Materials and Methods

### Data collection and clinical follow-up

The present research was a single-center, retrospective observational study, conducted between July 1, 2018 and January 31, 2020. The study protocol was approved by the Siriraj Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University (COA no. Si 438/2018). Inclusion criteria were all patients that underwent TAVR at Siriraj Hospital between January 2009 and December 2019. Exclusion criteria were the patients with intraoperative death. The data of all the patients were reviewed. The researchers retrospectively collected the patients' baseline demographics, medical information, procedural data, and clinical outcomes. Platelet counts and clinical outcomes were studied retrospectively, with available data analyzed from pre-procedure, until hospital discharge, at 30-day and 1-year post procedure. Assessment of any clinical outcomes will be obtained by reviewing the patients' medical record. Clinical outcomes included post-procedural complications and in-hospital outcomes, such as stroke, myocardial infarction, vascular complication, infection, shock, bleeding, in-hospital mortality, 30-day mortality, and 1-year mortality. Most of the clinical endpoints were defined in accordance with the Valve Academic Research Consortium-2 (VARC-2) consensus document<sup>(12)</sup>.

For the baseline laboratory values, the tests prior to the TAVR procedure were recorded. The nadir

platelet count was defined as the lowest platelet value during hospitalization. Patients who expired before follow-up laboratory examination were excluded from the analyses.

Patients were stratified into four groups according to their nadir platelet count, no thrombocytopenia at platelet of 150,000 or more per uL, as mild at 100,000 to 149,999/uL, as moderate at 50,000 to 99,000/uL, and as severe at less than 50,000/uL. In addition, the patients with moderate and severe thrombocytopenia were stratified into two groups according to the percentage decline in platelet count (DPC) post procedure, DPC of less than 50% or of 50% or more. The percentage DPC was calculated as baseline platelet count minus nadir platelet count over baseline platelet count time 100.

The definition of baseline thrombocytopenia is platelet before TAVR of less than 150,000/uL. The definition of significant thrombocytopenia is nadir platelet count post TAVR in moderate to severe thrombocytopenia group or platelet during post-procedural hospitalization of less than 100,000/uL.

### Statistical analysis

Categorical data were presented as frequency and percentage values. Continuous variables were reported as mean  $\pm$  standard deviation. Categorical data were compared using chi-square test or Fisher's exact test, and continuous data were compared using One-way ANOVA (normality). A p-value of less than 0.05 was considered statistically significant. All the statistical analyses were performed using PASW Statistics, version 18.0 (SPSS Inc., Chicago, IL, USA).

## Results

Eighty-three patients who underwent TAVR at Siriraj Hospital between January 2009 and 2019 were examined. One patient who died intraoperatively was excluded. Overall, 80 patients were diagnosed as symptomatic severe aortic stenosis with 78 tricuspid and two bicuspid, and another two patients had a degenerated bioprosthetic surgical aortic valve with severe intra-valvular aortic regurgitation. The transfemoral approach was mainly used in 60 procedures (73.2%), while the rest of the procedures (26.8%) were conducted via a transapical approach. We routinely administered unfractionated heparin in all procedures. All the patients also received aspirin 81 mg plus clopidogrel 75 mg daily for three to six months afterward if they had no indications with long-term anticoagulants.

**Table 1.** Baseline characteristics classified by nadir platelet count

Clinical characteristics	Nadir platelet count; n (%)				p-value
	Normal ≥150,000 (n=20)	Mild 100,000 to 149,999 (n=25)	Moderate 50,000 to 99,999 (n=30)	Severe <50,000 (n=7)	
Age (year); mean±SD	84.0±6.0	82.9±6.5	84.9±7.0	84.3±7.7	0.737
Male	3 (15.0)	13 (52.0)	14 (46.7)	2 (28.6)	0.044
DM	10 (50.0)	13 (52.0)	6 (20.0)	3 (42.9)	0.051
HT	19 (95.0)	24 (96.0)	28 (93.3)	6 (85.7)	0.692
DLP	18 (90.0)	20 (80.0)	25 (83.3)	6 (85.7)	0.866
Liver disease	0 (0.0)	0 (0.0)	2 (6.7)	1 (14.3)	0.130
COPD	0 (0.0)	0 (0.0)	5 (16.7)	1 (14.3)	0.028
CAD	14 (70.0)	15 (60.0)	23 (76.7)	5 (71.4)	0.608
Previous PCI	11 (55.0)	10 (40.0)	13 (43.3)	3 (42.9)	0.789
Previous CABG	3 (15.0)	4 (16.0)	8 (26.7)	1 (14.3)	0.769
LV ejection fraction (%); mean±SD	62.5±18.1	65.3±10.2	65.6±14.4	65.6±19.2	0.886
AVA (cm <sup>2</sup> ); mean±SD	0.7±0.1	0.7±0.2	0.8±0.4	0.7±0.1	0.226
AV gradient (mmHg); mean±SD	55.1±15.3	51.9±14.2	49.4±19.7	50.0±16.6	0.701
NYHA III-IV (%)	8 (40.0)	12 (48.0)	15 (50.0)	5 (71.4)	0.581
STS Mortality score; mean±SD	6.9±3.3	6.6±6.1	8.6±8.4	9.1±3.6	0.591
Transapical access	8 (40.0)	4 (16.0)	8 (26.7)	2 (28.6)	0.352
Transfemoral access	12 (60.0)	21 (84.0)	22 (73.3)	5 (71.4)	0.352
Balloon expandable prosthesis	16 (80.0)	18 (72.0)	24 (80.0)	5 (71.4)	0.828
Self-expandable prosthesis	4 (20.0)	7 (28.0)	6 (20.0)	2 (28.6)	0.828
Post dilatation	4 (20.0)	9 (36.0)	6 (20.0)	1 (16.7)	0.525
OR time (minute); mean±SD	104.7±40.8	100.2±34.4	106.5±28.0	143.3±104.8	0.172
X-ray time (minute); mean±SD	24.3±10.7	20.6±7.1	24.3±14.5	24.2±15.4	0.855
Contrast volume (mL); mean±SD	105.9±46.5	115.0±68.2	103.9±65.3	147.5±159.1	0.834

DM=diabetes mellitus; HT=hypertension; DLP=dyslipidemia; COPD=chronic obstructive pulmonary disease; CAD=coronary artery disease; PCI=percutaneous coronary intervention; CABG=coronary artery bypass grafting; LV=left ventricular; AVA=aortic valve area; AV=aortic valve; NYHA=New York Heart Association; STS=Society of Thoracic Surgeons; OR=operating room; SD=standard deviation

A p<0.05 indicates statistical significance

In the present study, 19 patients (23.2%) had baseline thrombocytopenia and included three patients with liver cirrhosis and three patients with suspected myelodysplastic syndrome. The median baseline platelet count was 208,000/uL with a minimum of 96,000/uL and a maximum of 924,000/uL. During post-procedural hospitalization, thrombocytopenia occurred in 62 patients (75.6%), in which 36.6% (n=30) of the cases were classed as moderate and 8.5% (n=7) as severe thrombocytopenia. The median nadir platelet count was 104,500/uL, ranging from 22,000 to 520,000/uL. The median time to the nadir platelet count could not be precisely estimated due to the lack of consecutive daily platelet count evaluation. However, from the existing data, the authors estimated the median time to the platelet nadir was three days, ranging from 1 to 10 days. Most patients (83.8%,

n=52) had platelet recovery before discharge or during the follow-up period. Ten patients did not have platelet recovery as one patient had baseline thrombocytopenia from liver cirrhosis, one patient had uncontrolled infection, one patient was followed for one year and found that platelet did not return to normal, and the other patients had follow up of platelet for a short time and had no platelet value after discharge.

Patients were stratified into four groups according to their nadir platelet count as normal (n=20), mild (n=25), moderate (n=30), or severe thrombocytopenia (n=7). The patients' baseline characteristics, as shown in Table 1, were mostly similar among the groups. Age, co-morbidities, New York Heart Association (NYHA) classification, left ventricular ejection fraction (LVEF), aortic valve area (AVA), and Society

**Table 2.** Baseline laboratory values classified by nadir platelet count

	Nadir platelet count; mean±SD				p-value
	Normal ≥150,000 (n=20)	Mild 100,000 to 149,999 (n=25)	Moderate 50,000 to 99,999 (n=30)	Severe <50,000 (n=7)	
Baseline hematocrit (%)	32.7±4.0	33.6±5.3	33.5±3.6	31.1±8.1	0.611
Baseline leukocyte (/uL)	6776.5±2341.8	6452.0±2112.9	6443.3±2617.7	5431.4±1426.0	0.631
Baseline thrombocytopenia; n (%)	0 (0.0)	4 (16.0)	12 (40.0)	3 (42.9)	0.002
Baseline creatinine (mg/dL)	1.2±0.6	1.3±0.4	1.9±1.8	1.5±1.1	0.118

SD=standard deviation

A p&lt;0.05 indicates statistical significance

**Table 3.** Clinical outcomes classified by nadir platelet count

	Nadir platelet count; n (%)				p-value
	Normal ≥150,000 (n=20)	Mild 100,000 to 149,999 (n=25)	Moderate 50,000 to 99,999 (n=30)	Severe <50,000 (n=7)	
30-day All-cause mortality	1 (5.0)	0 (0.0)	1 (3.3)	0 (0.0)	0.774
In-hospital mortality	0 (0.0)	1 (4.0)	0 (0.0)	2 (28.6)	0.011
1-year cardiovascular death	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1.000
1-year non-cardiovascular death	1 (5.0)	4 (16.0)	1 (3.3)	2 (28.6)	0.097
Myocardial infarction	1 (5.0)	0 (0.0)	1 (3.3)	2 (28.6)	0.033
Stroke	0 (0.0)	1 (4.0)	0 (0.0)	1 (14.3)	0.101
Major vascular complication	1 (5.0)	0 (0.0)	6 (20.0)	2 (28.6)	0.020
Minor vascular complication	1 (5.0)	0 (0.0)	1 (3.3)	0 (0.0)	0.774
Infection	6 (30.0)	5 (20.0)	8 (26.7)	6 (85.7)	0.014
Shock	0 (0.0)	2 (8.0)	5 (16.7)	3 (42.9)	0.021
Life-threatening bleeding	1 (5.0)	1 (4.0)	4 (13.3)	3 (42.9)	0.047
Major bleeding	0 (0.0)	4 (16.0)	7 (23.3)	0 (0.0)	0.068
Minor bleeding	11 (55.0)	11 (44.0)	13 (43.3)	3 (42.9)	0.869
Bleed at low platelet	0 (0.0)	1 (4.0)	3 (10.0)	2 (28.6)	0.077
Platelet transfusion	0 (0.0)	1 (4.0)	2 (6.7)	3 (42.9)	0.009
PRC transfusion	0 (0.0)	1 (4.0)	5 (16.7)	3 (42.9)	0.009
Number of PRC transfusions; mean±SD	1.3±1.9	1.2±1.4	1.9±1.7	3.7±3.5	0.013
Discontinuation of ASA	0 (0.0)	2 (8.0)	1 (3.3)	2 (28.6)	0.066
Discontinuation of clopidogrel	0 (0.0)	1 (4.0)	0 (0.0)	2 (28.6)	0.011
Discontinuation of OAC	0 (0.0)	2 (8.0)	1 (3.3)	0 (0.0)	0.711
Acute kidney injury	6 (30.0)	7 (28.0)	3 (10.0)	4 (57.1)	0.039
Moderate to severe PVL	2 (10.0)	3 (12.0)	2 (6.7)	0 (0.0)	0.939
Reintervention for valve dysfunction	0 (0.0)	0 (0.0)	2 (6.7)	0 (0.0)	0.443
Index length of stay (day); mean±SD	9.8±15.1	9.5±13.1	9.8±7.2	35.4±42.3	0.002
Length of stay in CCU (day); mean±SD	1.5±0.8	1.8±1.4	2.4±2.1	4.6±3.2	0.005
1-year Rehospitalization	4 (20.0)	4 (16.0)	7 (23.3)	2 (28.6)	0.863
1-year All-cause mortality	1 (5.0)	4 (16.0)	2 (6.7)	2 (28.6)	0.226

PRC=packed red cell; ASA=aspirin; OAC=oral anticoagulant; PVL=paravalvular leak; CCU=critical care unit; SD=standard deviation

A p&lt;0.05 indicates statistical significance

of Thoracic Surgeons (STS) mortality score were not significantly different. The baseline laboratory results

are presented in Table 2.

Data on the clinical outcomes, which were

**Table 4.** Baseline characteristics and clinical outcomes compared between DPC <50% and DPC ≥50%

	Decline in platelet count; n (%)		p-value
	<50% (n=11)	≥50% (n=26)	
Age (year); mean±SD	80.9±7.1	86.4±6.5	0.030
STS score; mean±SD	8.9±10.2	8.5±6.5	0.863
Balloon-expandable valve	9 (81.8)	20 (76.9)	1.000
30-day All-cause mortality	1 (9.1)	0 (0.0)	0.297
In-hospital mortality	0 (0.0)	2 (7.7)	1.000
Major vascular complications	3 (27.3)	5 (19.2)	0.672
Infection	3 (27.3)	11 (42.3)	0.477
Shock from any cause	2 (18.2)	6 (23.1)	1.000
Intubation	1 (9.1)	7 (26.9)	0.391
Life-threatening bleeding	0 (0.0)	7 (26.9)	0.080
Major bleeding	3 (27.3)	4 (15.4)	0.403
PRC transfusion	1 (9.1)	7 (26.9)	0.391
Acute kidney injury	1 (9.1)	6 (23.1)	0.649
Duration of admission (day); mean±SD	8.4±6.9	17.3±24.4	0.246
Length of stay in the CCU (day); mean±SD	1.6±0.9	3.2±2.7	0.072

DPC=decline in platelet count; STS=Society of Thoracic Surgeons; PRC=packed red cell; CCU=critical care unit  
A p<0.05 indicates statistical significance

stratified according to the nadir platelet count, are listed in Table 3. The incidence of in-hospital mortality was significantly higher in patients with severe thrombocytopenia than in those with mild thrombocytopenia at 28.6% versus 4% (p=0.011). The two patients in the present study with severe thrombocytopenia in-hospital and at 1-year follow up were the non-cardiovascular mortality, died from sepsis. The duration of admission, length of stay in the critical care unit (CCU), incidence of life-threatening bleeding, clopidogrel discontinuation, platelet transfusion, rate of infection, shock, acute kidney injury, and major vascular complications were also significantly higher in patients with moderate to severe thrombocytopenia. There was no difference in the one-year all-cause mortality rates or in moderate to severe paravalvular leakage among the groups.

Additionally, the patients with moderate to severe thrombocytopenia were stratified into two groups according to the percentage DPC post procedure as DPC of less than 50% and DPC of 50% or more from the baseline platelet count. The clinical outcomes were not significantly different between these two groups. Full details are shown in Table 4.

## Discussion

The present study is the first study reporting the incidences and outcomes of post-TAVR

thrombocytopenia in the Thai population. The incidence of acquired thrombocytopenia in the present study was similar to the reported data from China (63%)<sup>(13)</sup>, but higher than the studies from the USA and Europe<sup>(5,6,14-17)</sup>.

The present study has three main findings that are consistent with the previous published studies. First, acquired thrombocytopenia after TAVR was usually transient, and mostly resolved before discharge or during the follow-up period. Second, significant thrombocytopenia, with platelet of less than 100,000/uL, was common and occurred in more than one-third of the patients. Lastly, severe thrombocytopenia after TAVR was associated with worse clinical outcomes<sup>(3,8,14,15)</sup>.

Although the authors could not analyze the association between the severity of thrombocytopenia and adverse events because of small sample size, post-procedural complications, such as life-threatening bleeding, need for blood transfusion, duration of admission, and length of stay in the CCU were significantly higher in patients with moderate to severe thrombocytopenia than those with mild thrombocytopenia.

The rate of major vascular complications and acute kidney injury were significantly different among the present study groups stratified according to the nadir platelet count. This finding is similar to

the prior concern of raising vascular complications if thrombocytopenia occurred in an Asian population. However, the rates of moderate to severe paravalvular leakage was not statistically significantly different. The present study also did not find a correlation between nadir platelet count and the amount of contrast applied during the procedure or a longer procedural time as reported in some studies from Europe<sup>(15,16)</sup>.

Interestingly, the patients with DPC of 50% or more, post procedure, had trend toward more infections, while less infections occurred in the other group. This finding revealed a possible association between severe thrombocytopenia and post-procedural concomitant infection. From a large observational study<sup>(8)</sup>, it was hypothesized that patients with a latent infection prior to the procedure, manifested only as leukocytosis, might suffer from significant thrombocytopenia and infection after TAVR. Until now, the mechanism of thrombocytopenia after TAVR remained unclear and heterogeneity. The possible mechanism included increased consumption mainly due to the prosthesis induced platelet activation and aggregation, vessel and tissue injury initiated thrombo-inflammatory mechanism, pharmacotherapy induced thrombocytopenia from heparin, antiplatelets, and decreased platelet production<sup>(7)</sup>.

Most patients (77%) in the present series were considered inoperable or at high surgical risk for SAVR by the present study heart team<sup>(18,19)</sup>. There was a trend of a higher STS score in correlation with the nadir platelet count severity. The median STS score was 9.1 in patients with severe thrombocytopenia, while the median STS score was 6.9 in patients without thrombocytopenia. When dealing with patients with multiple co-morbidities who are inoperable or at a high risk of needing SAVR, even when we corrected the aortic valve successfully, their co-morbidities remained the same. Frailty and functional impairment increase the risk of subsequent infection. Even though, the rate of 30-day all-cause mortality was not significantly different between groups, the patients with severe thrombocytopenia had significant higher in-hospital mortality and a trend for higher 1-year non-cardiovascular mortality. The two patients in the present study with severe thrombocytopenia in-hospital and at 1-year follow up were the non-cardiovascular mortality, died from sepsis.

Infection-induced platelet consumption and platelet destruction were considered as a possible cause of severe thrombocytopenia. Severe thrombocytopenia is probably a marker of severe general

homeostasis impairment, a final common pathway of several death correlations in critically ill patients, rather than being a direct cause of death<sup>(3)</sup>.

Even though acquired thrombocytopenia after TAVR is quite common, benign, mostly transient, and involves a nadir platelet count of more than 50,000, the presence of severe thrombocytopenia with a nadir platelet count of less than 50,000 in patients with multiple co-morbidities should alert clinician to search for secondary infection that could have occurred after the procedure or in subsequent admission.

### **Limitation**

As a single-center, retrospective observational study, the conclusions from the present study might not be generalizable. In addition, the sample size was inadequate to do multivariate analysis or allow to examine the predictors for severe thrombocytopenia. Furthermore, the researchers could not precisely report the time to the nadir platelet count due to lack of consecutive daily platelet evaluation.

### **Conclusion**

Acquired thrombocytopenia after TAVR is a common phenomenon in Thai patients (75%), but usually transient with a nadir platelet count greater than 50,000. Most patients in the present study had spontaneous platelet recovery. The presence of severe thrombocytopenia with a nadir platelet count of less than 50,000 is a red flag sign for infection. The severity of thrombocytopenia is significantly associated with higher mortality and post-procedural adverse events.

### **What is already known on this topic?**

Post-TAVR thrombocytopenia has been reported in the Western countries as occurring in 40% to 87% of patients. It is a predictor of higher mortality and major adverse cardiac events.

### **What does this study add?**

Post-TAVR thrombocytopenia in Thai patients occurred in 75%. It is usually transient with a nadir platelet count of more than 50,000. Almost all the patients in this study had spontaneous platelet recovery. The presence of severe thrombocytopenia with a nadir platelet count of less than 50,000 is a red flag sign for secondary infection.

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### Conflicts of interest

All the authors declare they have no personal or professional conflicts of interest and received no financial support from the companies that produce or distribute the drugs, devices, or materials described in the present report.

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