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ORIGINAL RESEARCH

Use of Thrombus Aspiration for Patients With Acute Coronary Syndrome: Insights From the Nationwide J-PCI Registry

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BACKGROUND: There is significant regional or institutional variation in the use of thrombus aspiration (TA) in patients undergoing percutaneous coronary intervention (PCI). We investigated the temporal trend in TA use and its association with clinical outcomes in acute coronary syndrome using the nationwide J-PCI (Japanese PCI) registry.

METHODS AND RESULTS: Between 2016 and 2018, patients with acute coronary syndrome undergoing PCI (n=282 606; median age, 71.0 years; interquartile range, 62.0–79.0 years; women, 24.7%) at 1124 hospitals were stratified on the basis of whether TA was performed (TA and non-TA). The patients were subdivided according to clinical presentation (ST-segment–elevation myocardial infarction, non–ST-segment–elevation myocardial infarction, and unstable angina). Successful PCI, defined as the achievement of TIMI (Thrombolysis in Myocardial Infarction) 3 flow, and in-hospital mortality were assessed. During the study period, 83 422 patients (29.5%) underwent TA (52.9%, 23.5%, and 5.2% for ST-segment–elevation myocardial infarction, non–ST-segment–elevation myocardial infarction, and unstable angina, respectively), and the TA implementation rate remained relatively stable throughout. Patients treated with TA had higher rate of successful PCI than non-TA (98.7% versus 97.8%; $P<0.001$). TA was not associated with in-hospital death among patients with ST-segment–elevation myocardial infarction (adjusted odds ratio [aOR], 1.02 [95% CI, 0.94–1.12]). However, TA use was associated with higher rates of in-hospital death in patients with non–ST-segment–elevation myocardial infarction (aOR, 1.51 [95% CI, 1.23–1.86]) or unstable angina (aOR, 1.95 [95% CI, 1.37–2.79]).

CONCLUSIONS: In our retrospective analysis of the nationwide PCI registry, TA use was associated with a higher achievement of successful PCI without impairing in-hospital mortality among patients with ST-segment–elevation myocardial infarction. Nevertheless, its use should be cautioned in less-established indications (eg, non–ST-segment–elevation myocardial infarction and unstable angina).

Key Words: acute coronary syndrome ■ myocardial infarction ■ percutaneous coronary intervention ■ thrombus aspiration

See Editorial by Pruthi et al.

Coronary vessel occlusion with thrombus formation attributable to plaque rupture is the underlying pathophysiology of acute coronary syndrome (ACS), and thrombus aspiration (TA) was considered to be a promising strategy to reduce distal embolization.[1] However, 2 recent large-scale randomized controlled trials that evaluated the efficacy and safety of TA, TASTE (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) and TOTAL (Trial of Routine Aspiration Thrombectomy With PCI [Percutaneous Coronary Intervention] Versus PCI Alone in Patients With STEMI [ST-Segment–Elevation Myocardial Infarction], consistently failed to show the benefit of routine use of TA in patients with STEMI

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CLINICAL PERSPECTIVE

What Is New?

- In a clinical practice in Japan, although in a decreasing trend, thrombus aspiration remained a dominant strategy for treating ST-segment elevation myocardial infarction and was also used for >20% percutaneous coronary interventions for non–ST-segment–elevation myocardial infarction and >5% percutaneous coronary interventions for unstable angina, with a significant interinstitutional variation.
- Thrombus aspiration use was associated with a higher achievement of successful percutaneous coronary intervention without impairing in-hospital mortality among patients with ST-segment elevation myocardial infarction; however, the association between thrombus aspiration use and the risk of in-hospital mortality was significant in patients with non–ST-segment–elevation myocardial infarction and unstable angina.

What Are the Clinical Implications?

- Thrombus aspiration could be a promising strategy to treat patients with ST-segment elevation myocardial infarctiongiven its higher achievement of TIMI (Thrombolysis in Myocardial Infarction) 3 flow; however, its use should be cautioned in less-established indications (eg, non–ST-segment–elevation myocardial infarction and unstable angina).

Nonstandard Abbreviations and Acronyms

J-PCI	Japanese Percutaneous Coronary Intervention
TA	thrombus aspiration
TASTE	Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia
TATORT	Thrombus Aspiration in Thrombus Containing Culprit Lesions
TIMI	Thrombolysis in Myocardial Infarction
TOTAL	Trial of Routine Aspiration Thrombectomy With PCI Versus PCI Alone in Patients With STEMI
UA	unstable angina
VAMPIRE	Vacuum Aspiration Thrombus

undergoing PCI.[2,3] On the basis of these findings, recommendations in the clinical practice guidelines for the routine use of TA for STEMI have been downgraded from class IIa to class III.[4,5]

However, among patients with a heavy thrombus burden, TA is considered a class IIb indication, indicating potential room for using selective TA in primary PCI (ie, with careful patient and lesion selection). TA is still frequently used in clinical practice in Japan.[6] TA is also frequently applied to patients with non–ST-segment–elevation myocardial infarction (NSTEMI) or unstable angina (UA), as most of these patients display a relevant thrombus burden.[7] In the most updated statistical report from the Japanese Association of Cardiovascular Interventional Therapeutics, TA was used in ≈20% of PCIs for NSTEMI.[6]

Given the frequent use and potential risk associated with the use of TA outside of guideline recommendations, we aimed to assess the temporal trend and institutional variability in the use of TA during PCI for ACS and the association between TA use and in-hospital outcomes according to the type of ACS, using the nationwide J-PCI (Japanese PCI) registry.

METHODS

The data, analytic methods, and study materials will not be made publicly available to other researchers for the purpose of reproducing the results or replicating the procedure.

Data Source

The cohorts analyzed in this study were obtained from the J-PCI registry. The J-PCI registry is a prospective Japanese nationwide multicenter registry sponsored by the Japanese Association of Cardiovascular Intervention and Therapeutics and designed to collect clinical variables and in-hospital outcome data on consecutive patients undergoing PCI, which covers ≈90% of all PCIs performed in Japan.[8,9]

Cardiac catheterization procedures are performed in both publicly and privately funded hospitals in Japan, and because registration in the J-PCI registry is mandatory for board certification and renewal under both systems, data completeness is high. Furthermore, since January 2013, the J-PCI registry has been incorporated into the National Clinical Data system, a nationwide prospective web-based registry linked to board certification. Each hospital has a data manager responsible for collecting PCI data and entering them into a computer database. The Japanese Association of Cardiovascular Intervention and Therapeutics holds an annual meeting of data managers to secure appropriate data collection and performs random audits (20 institutions annually) to check the quality of the abstracted data.

The definitions of variables in the J-PCI registry are available online (http://www.cvit.jp/files/registry/j-pci-definition.pdf, last accessed on September 27, 2021). The study protocol of the J-PCI registry was approved by the Institutional Review Board Committee of the

Network for Promotion of Clinical Studies, a nonprofit organization affiliated with Osaka University Graduate School of Medicine, Osaka, Japan. Written informed consent specified for the present study was waived because of the retrospective analyses and observational study design.

Study Population

For the present study, we extracted data of the patients who underwent PCI between January 2016 and December 2018 from the J-PCI registry (n=761 177). We excluded patients who had missing data for age or sex (n=7), were aged <20 >100 years (n=246), had missing data for in-hospital outcomes (n=89), and whose clinical presentation was other than ACS (n=478 229) as well as those presenting with ACS undergoing PCI. The study population (n=282 606) was used to evaluate the temporal trends in the use of TA and the association between its use and clinical outcomes, according to the patients' clinical presentations (UA, NSTEMI, or STEMI) (Figure 1). Then, for the subgroup analysis of patients presenting with STEMI, we excluded patients whose clinical presentations were other than STEMI (n=153 138), who had missing data for door-to-balloon time (n=28 941), and whose door-to-balloon time was <30 or >120 minutes (n=15 685).

Definitions and Clinical Outcomes

In the J-PCI registry, definitions of categories on clinical presentation, including STEMI, NSTEMI, and UA, have been previously published.[8] Cardiogenic shock was defined as a sustained episode of systolic blood pressure <80 mm Hg and a cardiac index <1.8 L/min per m^2, which was determined to be secondary to cardiac dysfunction. This episode could have required parenteral inotropic or vasopressor agents or mechanical support, including an intra-aortic balloon pump, to maintain blood pressure and cardiac index above the specified levels within 24 hours before the PCI procedures. Acute heart failure (HF) was defined as a symptom of HF within 24 hours before PCI. These symptoms included dyspnea on mild activity, orthopnea, body fluid retention, moist rales, neck vein distension, and pulmonary edema, which are equivalent to class IV congestive HF in the New York Heart Association functional classification. In this registry, chronic kidney disease was defined as the presence of proteinuria, serum creatinine ≥1.3 mg/dL, or estimated glomerular filtration rate ≤60 mL/min per 1.73 m^2, according to guidelines from the Japanese Society of Nephrology. Successful PCI was defined as the achievement of TIMI (Thrombolysis in Myocardial Infarction) flow grade 3 with residual stenosis ≤25% in the target lesion.

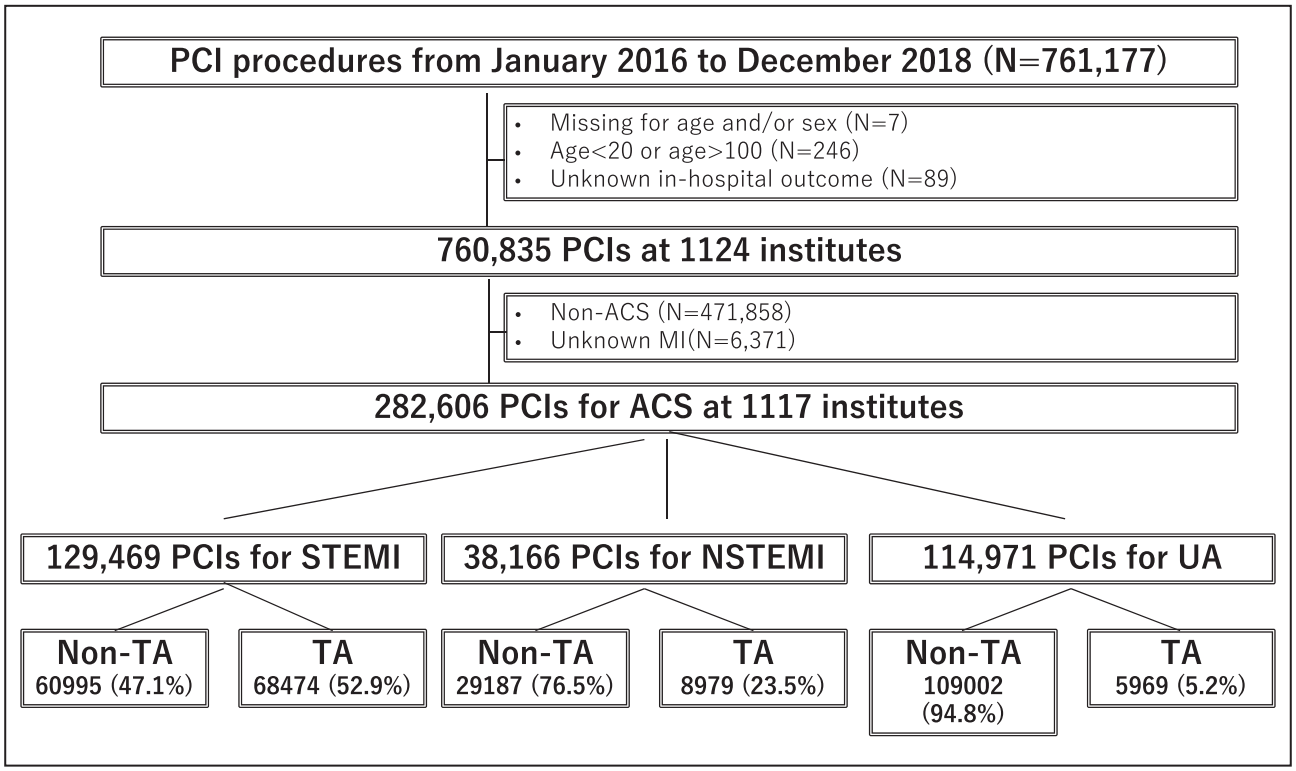

Figure 1. Study flowchart.
ACS indicates acute coronary syndrome; MI, myocardial infarction; NSTEMI, non–ST-segment–elevation MI; PCI, percutaneous coronary intervention; STEMI, ST-segment–elevation MI; TA, thrombus aspiration; and UA, unstable angina.

The outcomes analyzed in this study included in-hospital all-cause mortality, procedure-related complications, and bleeding complications. Procedure-related complications included in-hospital death within 30 days of PCI, periprocedural myocardial infarction, cardiac tamponade, cardiogenic shock during and after PCI, emergency operations, bleeding, and other complications. Bleeding complications were defined as bleeding events during or after PCI that required blood transfusion, including access and non–access site bleeding. Full definitions of these J-PCI registry variables are available online (http://www.cvit.jp/registry/jpci_definition.pdf).

Statistical Analysis

The patients were stratified into 2 groups based on whether TA was performed during PCI. The data are presented as mean±SD or median (25th–75th percentile) for continuous variables. Descriptive statistics were presented as frequencies (percentages) for categorical data. Patient characteristics, clinical presentation, lesion and procedural details, and in-hospital outcomes were compared using the χ^2 test for categorical variables and the Student unpaired *t* test for continuous variables.

To compare in-hospital outcomes, logistic regression models were used to adjust for differences in baseline characteristics between patients treated with and without TA. Covariates for adjustment included age, sex, previous PCI, previous coronary artery bypass grafting, hypertension, dyslipidemia, diabetes, smoking status, chronic kidney disease, hemodialysis, peripheral artery disease, previous HF, cardiogenic shock within 24 hours before the procedure, acute HF within 24 hours before the procedure, cardiopulmonary arrest within 24 hours before the procedure, 3-vessel disease, left main trunk or proximal left anterior descending artery disease, approach site, drug-eluting stent use, and institutional annual PCI volume. The adjusted associations between TA use and in-hospital outcomes were also evaluated according to clinical presentation (STEMI, NSTEMI, or UA).

To evaluate the impact of institutional variability in TA use on in-hospital outcomes, institutions were categorized into quartiles based on the volume of TA cases performed between 2016 and 2018 (first quartile, 0–16; second quartile, 17–27; third quartile, 28–38; and fourth quartile, 39–100). In each quartile, the association between TA use and in-hospital outcomes was evaluated and the interaction between institutional variability and TA use was tested.

In the subgroup analysis of patients with STEMI, we hypothesized that the relationship between TA use and in-hospital outcomes might be influenced by door-to-balloon time. Thus, we tested and evaluated this association according to door-to-balloon time (30–60, 60–75, 75–90, and 90–120 minutes).

All variables that were included in the logistic regression models had <1% missing data. Because of the small percentage of missing data, imputation was not used. Statistical tests were 2 tailed, and statistical

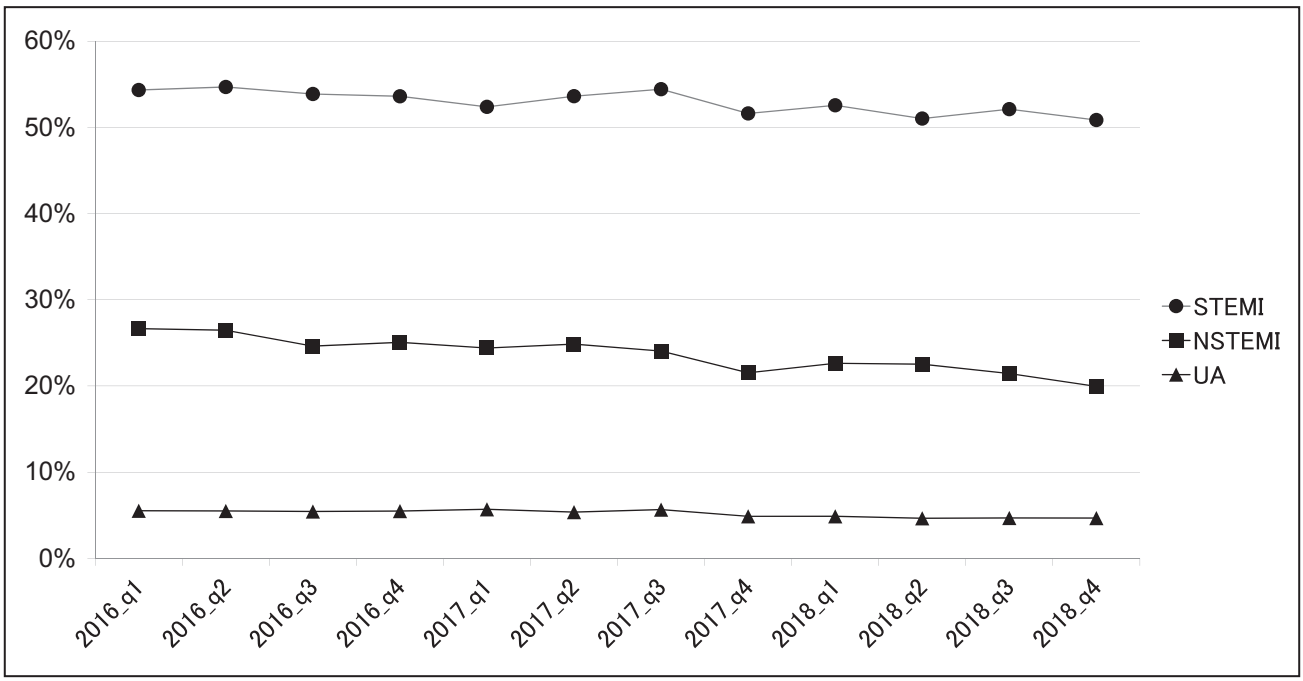

Figure 2. Temporal trends in the use of thrombus aspiration.
NSTEMI indicates non–ST-segment–elevation myocardial infarction; q, quartile; STEMI, ST-segment–elevation myocardial infarction; and UA, unstable angina.

significance was set at $P<0.05$. All statistical calculations and analyses were performed using the R statistical software, version 4.0.5 (Free Software Foundation, Boston, MA).

RESULTS

A total of 761 177 patients underwent PCI at 1124 hospitals participating in the J-PCI registry (Figure 1). After applying the exclusion criteria, 282 606 eligible patients with ACS who underwent PCI at 1117 institutes were identified and analyzed. Among them, 83 422 (29.5%) underwent TA, 52.9% had STEMI, 23.5% had NSTEMI, and 5.2% had UA.

Trends in the Use of TA, According to Clinical Presentations

Among patients presenting with ACS and treated with PCI, trends in the use of TA according to clinical presentation by quarter are summarized in Figure 2. Regardless of clinical presentation, the rates of TA use showed a slight decreasing trend, most prominently in patients with NSTEMI (STEMI: 54.3% in quartile 1 of 2016 to 50.9% in quartile 4 of 2018; NSTEMI: 26.6% in quartile 1 of 2016 to 20.0% in quartile 4 of 2018; UA: 5.5% in quartile 1 of 2016 to 4.7% in quartile 4 of 2018).

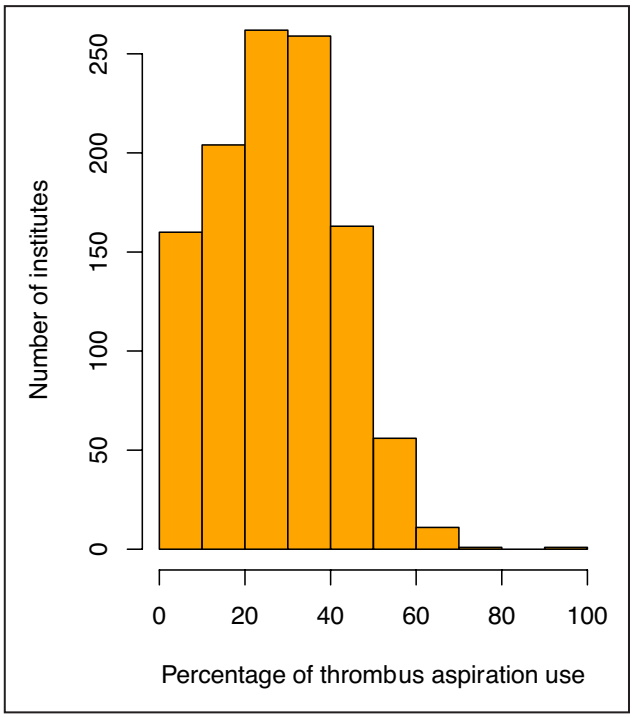

Figure 3. Variability of thrombus aspiration use among institutes.
Median percentage of thrombus aspiration use was 27.5% (interquartile range, 16.2%–38.3%).

Baseline Characteristics and Procedural Details

Among those presenting with ACS who underwent PCI, there was significant variation in the use of TA among institutes (median, 27.5%; interquartile range, 16.2%–38.3%) (Figure 3). TA was never used by 45 institutes (4.0%).

Characteristics according to the use of TA are summarized in Table 1. Compared with patients without TA, those treated with TA were younger, more likely to be men, and more likely to have a history of smoking. Patients treated with TA were less likely to have a history of revascularization and myocardial infarction and were more likely to have 1-vessel disease and culprit lesions in their right coronary artery. Patients treated with TA were also more likely to concomitantly use distal protection devices. Characteristics based on clinical presentation are summarized in Table S1. Compared with those with NSTEMI and UA, patients presenting with STEMI were more likely to have cardiogenic shock and/or cardiopulmonary arrest within the 24 hours before PCI and 1-vessel disease with the right coronary artery as a culprit lesion.

In-Hospital Outcomes

A comparison of in-hospital outcomes between patients treated with and without TA is summarized in Table 2. Patients treated with TA had a higher achievement of successful PCI than those without TA (98.7% versus 97.8%, respectively; $P<0.001$).

When confined to patients presenting with STEMI, those treated with TA had a lower incidence of in-hospital deaths than those without TA (2.5% versus 3.0%, respectively; $P<0.001$). The crude rate of composite of procedure-related complications was not different between those treated with TA and those without TA (5.9% versus 5.9%; $P=0.848$), although patients with TA had higher rates of stent thrombosis than those without TA (0.5% versus 0.3%; $P<0.001$) and higher rates of shock requiring inotropes and/or mechanical support devices (3.0% versus 2.6%; $P<0.001$) (Table 3).

After adjustment, the use of TA was not associated with an increased risk of in-hospital death in patients with STEMI compared with those without TA (2.5% versus 3.0%; respectively; adjusted odds ratio [aOR], 1.02 [95% CI, 0.94–1.12]) (Figure 4). However, the associations were significant in patients with NSTEMI (2.2% versus 2.0%; aOR, 1.51 [95% CI, 1.04–1.86]) and UA (0.8% versus 0.4%, respectively; aOR, 1.95 [95% CI, 1.37–2.79]). In terms of procedure-related complications, the use of TA was consistently associated with an increased risk of procedure-related complications, regardless of clinical presentation (STEMI: aOR, 1.17 [95% CI, 1.11–1.24]; NSTEMI: aOR, 1.39 [95% CI, 1.21–1.60]; UA: aOR, 2.11 [95% CI, 1.75–2.55]) (Figure 4).

Table 1. Baseline Characteristics and Procedure Details

Variables	Non-TA (N=199184)	TA (N=83422)	*P* value
Clinical characteristics			
Age, median (IQR), y	72.00 (64.00–80.00)	69.00 (59.00–77.00)	<0.001
Women, n (%)	51407 (25.8)	18408 (22.1)	<0.001
History of PCI, n (%)	65407 (33.0)	9648 (11.6)	<0.001
History of CABG, n (%)	6673 (3.4)	820 (1.0)	<0.001
Prior myocardial infarction, n (%)	34876 (17.7)	7050 (8.5)	<0.001
Diabetes, n (%)	80834 (40.6)	27940 (33.5)	<0.001
Hypertension, n (%)	143983 (72.3)	54402 (65.2)	<0.001
Dyslipidemia, n (%)	121830 (61.2)	47784 (57.3)	<0.001
Smoking, n (%)	62883 (31.6)	33985 (40.7)	<0.001
Renal dysfunction, n (%)	35127 (17.6)	11035 (13.2)	<0.001
Dialysis, n (%)	11905 (6.0)	1318 (1.6)	<0.001
Chronic obstructive lung disease, n (%)	4595 (2.3)	1799 (2.2)	0.015
Peripheral artery disease, n (%)	11026 (5.5)	2199 (2.6)	<0.001
Prior heart failure, n (%)	22810 (11.6)	3881 (4.7)	<0.001
Institutional PCI volume quantile, n (%)			<0.001
Quantile 1 (lowest)	52010 (26.1)	18427 (22.1)	
Quantile 2	49102 (24.7)	22350 (26.8)	
Quantile 3	47368 (23.8)	22223 (26.6)	
Quantile 4 (highest)	50702 (25.5)	20422 (24.5)	
Presentation, n (%)			
Cardiopulmonary arrest within 24 h	6245 (3.2)	4947 (6.0)	<0.001
Cardiogenic shock within 24 h	11493 (5.8)	9709 (11.7)	<0.001
Acute heart failure within 24 h	16056 (8.1)	9694 (11.7)	<0.001
1-Vessel disease	115740 (58.1)	52491 (62.9)	<0.001
2-Vessel disease	52597 (26.4)	20484 (24.6)	<0.001
3-Vessel disease	30036 (15.1)	10151 (12.2)	<0.001
Left main trunk disease	9802 (4.9)	2390 (2.9)	<0.001
Lesion and procedural characteristics, n (%)			
Right coronary artery	64760 (32.5)	36257 (43.5)	<0.001
LMT or LAD	110528 (55.5)	40533 (48.6)	<0.001
Left circumflex artery	49283 (24.7)	13650 (16.4)	<0.001
Graft	1087 (0.5)	271 (0.3)	<0.001
Procedure details, n (%)			
Access site			<0.001
Femoral	55050 (27.6)	30562 (36.6)	
Other	9228 (4.6)	2014 (2.4)	
Radial	134906 (67.7)	50846 (61.0)	
Drug-eluting stent	171105 (85.9)	72070 (86.4)	0.001
Bare metal stent	2879 (1.4)	1758 (2.1)	<0.001
Rotablator	4966 (2.5)	207 (0.2)	<0.001
Drug-eluting balloon	20517 (10.3)	3266 (3.9)	<0.001
Distal protection device	6161 (3.1)	8256 (9.9)	<0.001

CABG indicates coronary artery bypass grafting; IQR, interquartile range; LAD, left anterior descending; LMT, left main trunk; PCI, percutaneous coronary intervention; and TA, thrombus aspiration.

Table 2. In-Hospital Outcomes

Outcomes	Non-TA (N=199184)	TA (N=83422)	*P* value
In-hospital death, n (%)	2853 (1.4)	1988 (2.4)	<0.001
Procedure-related myocardial infarction, n (%)	865 (0.4)	232 (0.3)	<0.001
Tamponade, n (%)	349 (0.2)	188 (0.2)	0.006
Shock requiring mechanical support or inotropes, n (%)	2833 (1.4)	2331 (2.8)	<0.001
Stent thrombosis, n (%)	296 (0.1)	386 (0.5)	<0.001
Emergency operation, n (%)	284 (0.1)	146 (0.2)	0.049
Bleeding, requiring transfusion, n (%)	966 (0.5)	507 (0.6)	<0.001
Access site bleeding, n (%)	514 (0.3)	242 (0.3)	0.143
Non–access site bleeding, n (%)	483 (0.2)	278 (0.3)	<0.001
Radiation time, median (IQR), min	24.00 (16.00–37.00)	24.00 (17.00–35.00)	0.639
Successful PCI, n (%)	194897 (97.8)	82379 (98.7)	<0.001

IQR indicates interquartile range; PCI, percutaneous coronary intervention; and TA, thrombus aspiration.

After classifying the institutes into quartiles based on the volume of TA cases performed during the 3 observed years, the use of TA was associated with an increased risk of in-hospital death and procedure-related complications regardless of institutional TA volume. More important, their associations were more prominent in institutes with a smaller TA volume (Figure 5).

Subgroup Analysis, According to Door-to-Balloon Time

For the subgroup analysis investigating the relationship between the use of TA and door-to-balloon time, we excluded patients who had missing data on door-to-balloon time or whose door-to-balloon time was <30 or >120 minutes. As a result, 83305 patients with STEMI (63.6%) from 1041 sites were eligible for subgroup analysis. Of these patients with STEMI, 49 025 (58.8%) were treated with TA during PCI, with greater institutional variation (median, 59.7%; interquartile range, 41.6%–73.6%) (Figure S1).

We classified the 83305 eligible patients into 4 categories, according to their door-to-balloon time (30–60 minutes, 28679 patients; 60–75 minutes, 22243 patients; 75–90 minutes, 18372 patients; and 90–120 minutes, 14011 patients). The procedure-related complication rate was higher in TA use than non-TA use in patients with STEMI treated with PCI for the patients in the category of door-to-balloon time 75 to 90 and 90 to 120 minutes, albeit there was no interaction between TA use and door-to-balloon time in terms of in-hospital death and procedure-related complications (*P* for interaction >0.05) (Table S2).

DISCUSSION

Using a large nationally representative cohort of patients undergoing PCI, we evaluated the contemporary use of TA and its impact on in-hospital clinical outcomes, leading to several major findings. First, although in a decreasing trend, TA remained a dominant strategy for treating STEMI and was also used for >20% PCIs for NSTEMI and >5% PCIs for UA. Second, there was significant interinstitutional variation in the use of TA. Third, patients treated with TA had a higher rate of successful PCI. The association between TA use and the risk of in-hospital mortality was not significant in patients with STEMI; however, the association was significant in patients with NSTEMI and UA. Fourth, the association of TA use with an increased risk of in-hospital death and procedure-related complications was consistent regardless of the institutional TA volume; however, the associations were more prominent in the institutes with a smaller TA volume. Fifth, in patients with STEMI, there was no apparent interaction between the use of TA and door-to-balloon time in terms of in-hospital mortality.

Despite the results of the TASTE and TOTAL trials and recommendations from updated clinical practice guidelines, TA is still widely used in Japan.[2,3] There was a slightly decreasing trend in the use of TA between 2016 and 2018; however, more than half of the patients presenting with STEMI who underwent PCI were still concomitantly treated with TA. This trend contrasts a report from Sweden, which stated that after the publication of the TASTE trial, the rate of TA use significantly decreased from ~40% in 2012 to ~10% in 2018, according to their nationwide registry.[10] More important, the decrease in TA use did not affect the trends in the rate of all-cause death and definite stent thrombosis 30 days after the procedure. The significant gap in the prevalence of TA between countries may reflect differences in guideline recommendations. In the European guidelines published in 2017 on the management of patients with STEMI, routine TA use was downgraded from stage IIa to III (not recommended).[4] However, in

Table 3. In-Hospital Outcomes by Clinical Presentations

Outcomes	STEMI			NSTEMI			UA		
	Non-TA (N=60995)	TA (N=68474)	*P* value	Non-TA (N=29187)	TA (N=8979)	*P* value	Non-TA (N=109002)	TA (N=5969)	*P* value
In-hospital death, n (%)	1804 (3.0)	1743 (2.5)	<0.001	575 (2.0)	200 (2.2)	0.142	474 (0.4)	45 (0.8)	<0.001
Procedure-related myocardial infarction, n (%)	135 (0.2)	116 (0.2)	0.04	135 (0.5)	27 (0.3)	0.049	595 (0.5)	89 (1.5)	<0.001
Tamponade, n (%)	175 (0.3)	167 (0.2)	0.147	56 (0.2)	15 (0.2)	0.736	118 (0.1)	6 (0.1)	1
Shock requiring mechanical support or inotropes, n (%)	1610 (2.6)	2040 (3.0)	<0.001	564 (1.9)	200 (2.2)	0.089	659 (0.6)	91 (1.5)	<0.001
Stent thrombosis, n (%)	179 (0.3)	332 (0.5)	<0.001	40 (0.1)	33 (0.4)	<0.001	77 (0.1)	21 (0.4)	<0.001
Emergency operation, n (%)	136 (0.2)	124 (0.2)	0.106	56 (0.2)	15 (0.2)	0.736	92 (0.1)	7 (0.1)	0.538
Bleeding, requiring transfusion n (%)	408 (0.7)	427 (0.6)	0.326	211 (0.7)	61 (0.7)	0.721	347 (0.3)	19 (0.3)	1
Access site bleeding, n (%)	193 (0.3)	207 (0.3)	0.684	105 (0.4)	27 (0.3)	0.465	216 (0.2)	8 (0.1)	0.345
Non–access site bleeding, n (%)	233 (0.4)	233 (0.3)	0.228	108 (0.4)	34 (0.4)	0.985	142 (0.1)	11 (0.2)	0.351
Radiation time, median (IQR), min	24.00 (16.00–37.00)	24.00 (16.00–35.00)	<0.001	26.00 (17.00–40.00)	25.00 (17.00–36.00)	<0.001	23.00 (15.00–36.00)	25.00 (18.00–37.00)	<0.001
Successful PCI, n (%)	59372 (97.3)	67620 (98.8)	<0.001	28306 (97.0)	8848 (98.5)	<0.001	107219 (98.4)	5911 (99.0)	<0.001

IQR indicates interquartile range; NSTEMI, non–ST-segment–elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment–elevation myocardial infarction; TA, thrombus aspiration; and UA, unstable angina.

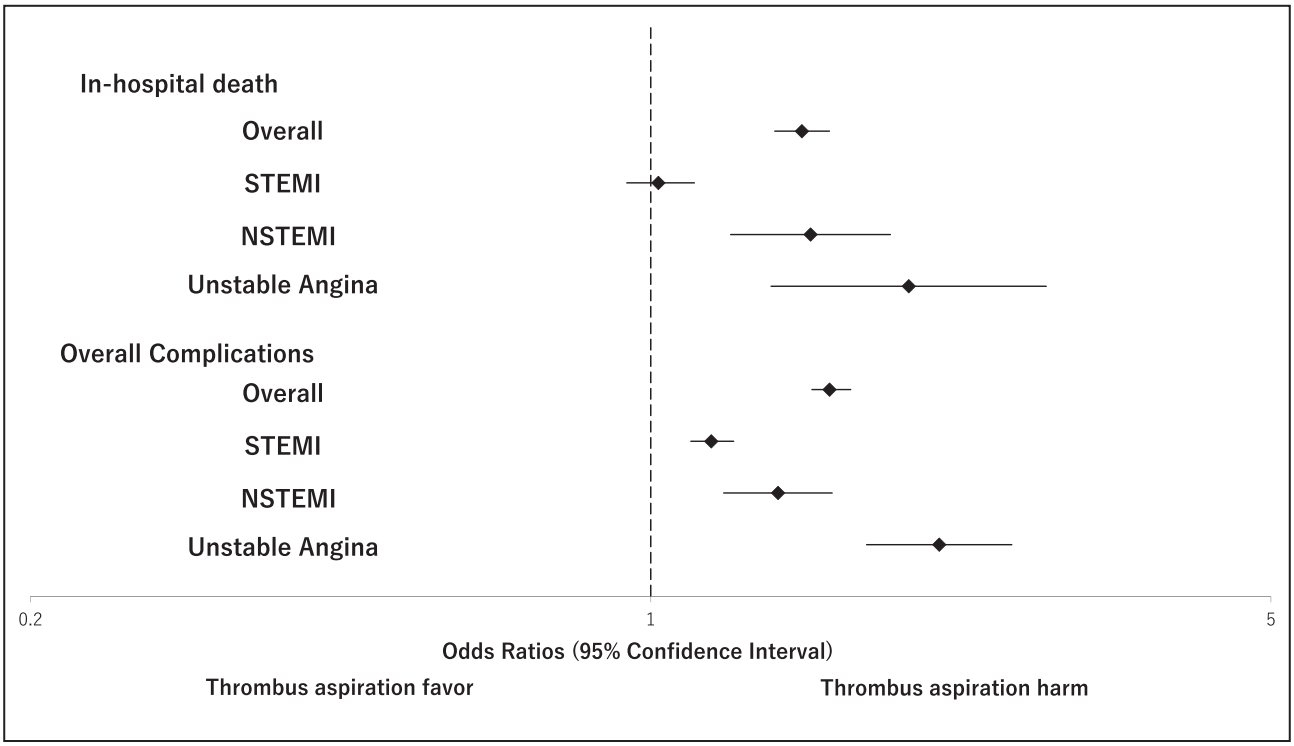

Figure 4. Adjusted impacts of thrombus aspiration use on in-hospital mortality and procedure-related complications by clinical presentations.
Overall complications were defined as a composite of in-hospital deaths within 30 days of percutaneous coronary intervention (PCI), periprocedural myocardial infarction, cardiac tamponade, cardiogenic shock during and after PCI, emergency operations, bleeding, and other complications. NSTEMI indicates non–ST-segment–elevation myocardial infarction; and STEMI, ST-segment–elevation myocardial infarction.

the latest Japanese guidelines, TA use in primary PCI is recommended as a class IIa indication with level of evidence of B.[11] The favorable statement in the Japanese guidelines is mainly based on the findings of the VAMPIRE (Vacuum Aspiration Thrombus) study, which randomized patients presenting with STEMI to primary PCI with and without upfront TA and showed a lower incidence of slow or no reflow in TA use.[12] The present study confirmed the results of the VAMPIRE study, and the achievement rate of TIMI grade 3 flow was higher in patients treated with TA. In Japan, glycoprotein IIb/IIIa inhibitors, a bailout therapy in the event of angiographic evidence of a large thrombus, a slow or no-reflow phenomenon, are not commercially available; therefore, the role of TA could be different from that in Western countries. Intravascular ultrasound guidance during primary PCI is popular in Japan and could facilitate the identification of high-risk plaque characteristics to prevent slow-flow phenomena and serious adverse cardiac events with the use of TA and distal protection devices.[13] Further investigations are needed to evaluate whether the higher achievement of TIMI 3 flow by TA use could contribute to beneficial effects on long-term mortality.

In the current guidelines, there are no statements about the recommendations for TA use in patients presenting with NSTEMI or UA. The TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) trial, a randomized controlled trial comparing adjunctive TA with conventional PCI in patients presenting with NSTEMI, showed that TA use did not lead to a reduction in microvascular obstruction and adverse cardiovascular events.[14,15] In our study, TA was used in >20% of patients presenting with NSTEMI, although its rate showed a significant decreasing trend. Furthermore, in the present study, TA was used for >5% of PCIs for UA, and no previous studies have evaluated the impact of TA on clinical outcomes in patients presenting with UA who underwent PCI. Given that our findings show prominent associations between the use of TA and the increased risk of in-hospital death and procedure-related complications in NSTEMI and UA, the indication for TA needs to be carefully determined in clinical situations outside the guideline recommendations, such as NSTEMI and UA. However, most important, because of the nonrandomized nature of our study, the association between the use of TA and the increased risk of in-hospital adverse events does not ensure the causation. This association could be caused by the more severe clinical profile of patients who underwent TA, rather than the procedure itself. Among our

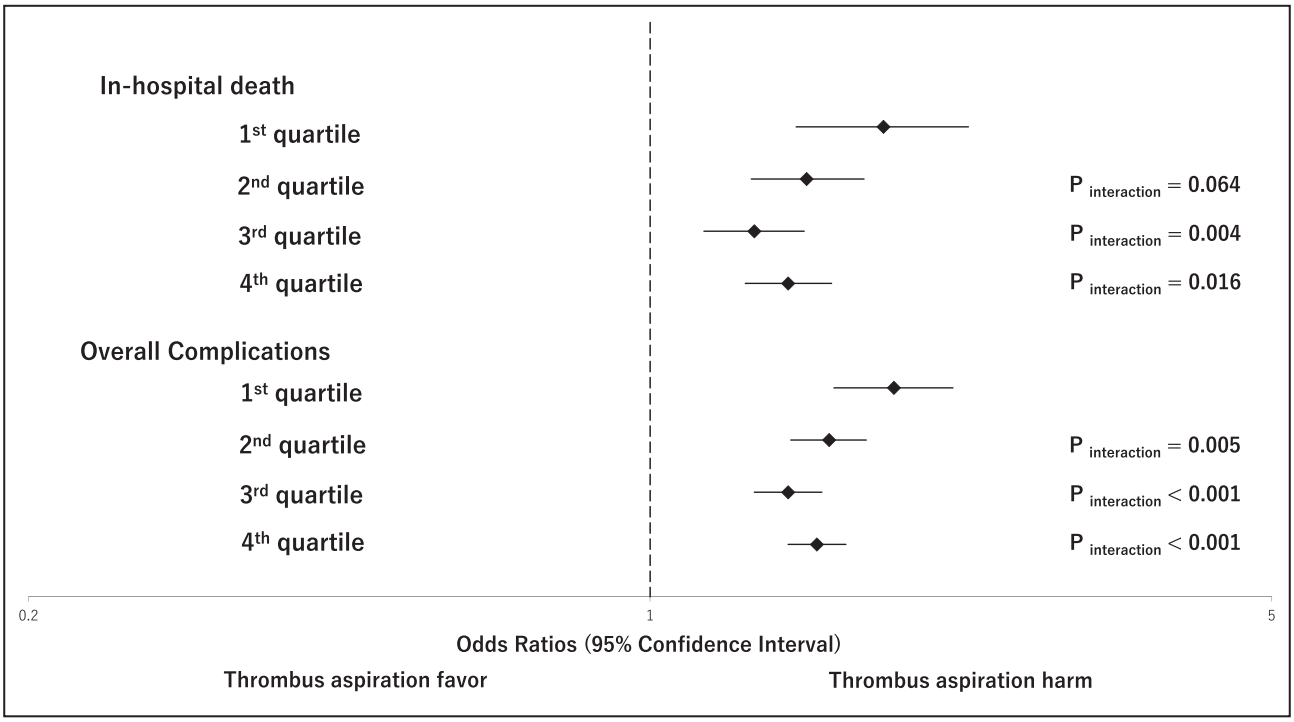

Figure 5. The association between the use of thrombus aspiration (TA) and in-hospital outcomes, according to the institutional volume of TA cases performed during the study period (between 2016 and 2018).
Overall complications were defined as a composite of in-hospital death within 30 days of PCI, periprocedural myocardial infarction, cardiac tamponade, cardiogenic shock during and after PCI, emergency operations, bleeding, and other complications. The precise numbers of TAs performed for each quartile were as follows: first quartile, 0 to 16; second quartile, 17 to 27; third quartile, 28 to 38; and fourth quartile, 39 to 100.

patients presenting with NSTEMI or UA, those who underwent TA were more likely to have 1-vessel disease with a culprit lesion in their right coronary artery, which is a feature of high thrombus burden.[16] It is well known that a high thrombus burden is associated with a subsequent cardiovascular adverse event, which could be applicable to our study population with TA.

The volume-outcome relationship in PCI is a well-known phenomenon.[17] Our findings imply that this relationship could apply to TA; the institutes with more experience in TA were more likely to have better clinical outcomes compared with institutes with a smaller TA volume. Given that the inverse association of TA use and in-hospital clinical outcomes was consistently confirmed regardless of institutional experience in TA, routine use of TA is not recommended; however, there may be situations where the use of TA is justified, as long as it is performed in experienced centers.

There is a hypothesis that TA is beneficial for patients with STEMI who present early; however, a subanalysis of the TOTAL trial showed that TA did not appear to be associated with an improvement in clinical outcomes regardless of ischemic time.[18] Our study expanded this finding and demonstrated that there was no interaction between TA use and door-to-balloon time in terms of reduction of in-hospital death. Furthermore, the increased risk of procedure-related complications was more prominent in cases with a door-to-balloon time of >75 minutes than in those with a door-to-balloon time of <75 minutes. This implies that, in patients with STEMI who require a longer door-to-balloon time, the risk-benefit of TA use should be more cautiously evaluated.

Our study had several limitations. First, despite the use of rigorous statistical methods to adjust for potential confounders, residual and/or unmeasured confounding factors may exist. The present study is an observational one, and the use of TA was not randomized; therefore, the association between TA use and subsequent clinical outcomes does not imply causation. Second, information on stroke and/or transient ischemic stroke, an important clinical outcome in studies related to TA, was not available in the J-PCI registry. The TOTAL trial demonstrated a higher stroke rate among patients using TA.[3] Given the potential risks related to TA use, its indications should be assessed more carefully. Third, the thrombus burden was not assessed in the J-PCI registry. Thrombus burden might be greater in patients with TA than in those without TA, which may explain the poor clinical outcomes in patients with NSTEMI or UA with TA.

CONCLUSIONS

TA was used in over half of the ACS-related cases in a nationwide cohort of Japanese patients undergoing PCI. Overall, its use was associated with a higher achievement of TIMI 3 flow, contributing to the beneficial effects exclusively in patients with STEMI. Given the significant association between TA use and in-hospital mortality in patients with less-established indications (NSTEMI and UA), caution should be exercised in these circumstances, and further investigation of long-term outcomes is needed.

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Supplemental Material

Tables S1–S2
Figure S1

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SUPPLEMENTAL MATERIAL

Table S1. Baseline Characteristics and Procedure Details by Clinical Presentations

Variables	STEMI			NSTEMI			UA		
	Non TA N=60995	TA N=68474	p	Non TA N=29187	TA N=8979	p	Non TA N=109002	TA N=5969	p
Clinical Characteristics									
Age (years), median [IQR]	71.00 [62.00, 80.00]	69.00 [59.00, 77.00]	<0.001	72.00 [64.00, 80.00]	69.00 [59.00, 77.00]	<0.001	72.00 [64.00, 79.00]	69.00 [60.00, 78.00]	<0.001
Female, n (%)	15690 (25.7)	15321 (22.4)	<0.001	7289 (25.0)	1874 (20.9)	<0.001	28428 (26.1)	1213 (20.3)	<0.001
History of PCI, n (%)	11574 (19.1)	6798 (10.0)	<0.001	8129 (27.9)	1350 (15.1)	<0.001	45704 (42.2)	1500 (25.3)	<0.001
History of CABG, n (%)	819 (1.4)	462 (0.7)	<0.001	1026 (3.5)	169 (1.9)	<0.001	4828 (4.5)	189 (3.2)	<0.001
Prior myocardial infarction, n (%)	8487 (14.1)	5047 (7.4)	<0.001	6265 (21.7)	1061 (11.9)	<0.001	20124 (18.7)	942 (16.0)	<0.001
Diabetes, n (%)	22361 (36.7)	22630 (33.0)	<0.001	12329 (42.2)	3028 (33.7)	<0.001	46144 (42.3)	2282 (38.2)	<0.001
Hypertension, n (%)	41493 (68.0)	44142 (64.5)	<0.001	21527 (73.8)	6045 (67.3)	<0.001	80963 (74.3)	4215 (70.6)	<0.001
Dyslipidemia, n (%)	33952 (55.7)	38568 (56.3)	0.017	17832 (61.1)	5394 (60.1)	0.085	70046 (64.3)	3822 (64.0)	0.728
Smoking, n (%)	21770 (35.7)	28226 (41.2)	<0.001	9897 (33.9)	3549 (39.5)	<0.001	31216 (28.6)	2210 (37.0)	<0.001
Renal dysfunction, n (%)	9163 (15.0)	8916 (13.0)	<0.001	6180 (21.2)	1293 (14.4)	<0.001	19784 (18.2)	826 (13.8)	<0.001
Dialysis, n (%)	1955 (3.2)	932 (1.4)	<0.001	1713 (5.9)	182 (2.0)	<0.001	8237 (7.6)	204 (3.4)	<0.001
Chronic obstructive lung disease, n (%)	1292 (2.1)	1426 (2.1)	0.669	810 (2.8)	221 (2.5)	0.117	2493 (2.3)	152 (2.5)	0.209
Peripheral artery disease, n (%)	2091 (3.4)	1655 (2.4)	<0.001	1752 (6.0)	319 (3.6)	<0.001	7183 (6.6)	225 (3.8)	<0.001
Prior heart failure, n (%)	4208 (7.0)	2784 (4.1)	<0.001	4087 (14.2)	601 (6.8)	<0.001	14515 (13.5)	496 (8.5)	<0.001
Institutional PCI volume quantile, n (%)			<0.001			<0.001			<0.001
quantile_1 (lowest)	15661 (25.7)	15112 (22.1)		6853 (23.5)	1917 (21.3)		29496 (27.1)	1398 (23.4)	
quantile_2	17038 (27.9)	18680 (27.3)		7056 (24.2)	2255 (25.1)		25008 (22.9)	1415 (23.7)	
quantile_3	14599 (23.9)	18165 (26.5)		8122 (27.8)	2423 (27.0)		24647 (22.6)	1635 (27.4)	
quantile_4 (highest)	13697 (22.5)	16517 (24.1)		7156 (24.5)	2384 (26.6)		29849 (27.4)	1521 (25.5)	
Presentation									
Cardiopulmonary arrest within 24 hours, n (%)	4027 (6.6)	4418 (6.5)	0.28	1381 (4.7)	443 (4.9)	0.46	837 (0.8)	86 (1.5)	<0.001
Cardiogenic shock within 24 hours, n (%)	7421 (12.2)	8756 (12.9)	0.001	2445 (8.4)	785 (8.8)	0.296	1627 (1.5)	168 (2.8)	<0.001
Acute heart failure within 24 hours, n (%)	8552 (14.1)	8429 (12.4)	<0.001	4083 (14.1)	1000 (11.2)	<0.001	3421 (3.2)	265 (4.5)	<0.001
1-vessel disease, n (%)	34979 (57.3)	43493 (63.5)	<0.001	14409 (49.4)	5195 (57.9)	<0.001	66352 (60.9)	3803 (63.7)	<0.001
2-vessel disease, n (%)	16140 (26.5)	16621 (24.3)	<0.001	8497 (29.1)	2411 (26.9)	<0.001	27960 (25.7)	1452 (24.3)	0.023
3-vesel disease, n (%)	9588 (15.7)	8084 (11.8)	<0.001	6112 (20.9)	1353 (15.1)	<0.001	14336 (13.2)	714 (12.0)	0.008

Left main trunk disease, n (%)	2783 (4.6)	1897 (2.8)	<0.001	1883 (6.5)	316 (3.5)	<0.001	5136 (4.7)	177 (3.0)	<0.001
Lesion and procedural characteristics									
Right coronary artery, n (%)	21753 (35.7)	30744 (44.9)	<0.001	8567 (29.4)	3087 (34.4)	<0.001	34440 (31.6)	2426 (40.6)	<0.001
LMT or LAD, n (%)	35463 (58.1)	34360 (50.2)	<0.001	15325 (52.5)	3305 (36.8)	<0.001	59740 (54.8)	2868 (48.0)	<0.001
Left circumflex artery, n (%)	11204 (18.4)	8964 (13.1)	<0.001	10090 (34.6)	3541 (39.4)	<0.001	27989 (25.7)	1145 (19.2)	<0.001
Graft, n (%)	142 (0.2)	113 (0.2)	0.007	199 (0.7)	71 (0.8)	0.315	746 (0.7)	87 (1.5)	<0.001
Procedure details									
Access site			<0.001			<0.001			<0.001
Femoral	22132 (36.3)	26642 (38.9)		8381 (28.7)	2494 (27.8)		24537 (22.5)	1426 (23.9)	
Other	1896 (3.1)	1554 (2.3)		1191 (4.1)	240 (2.7)		6141 (5.6)	220 (3.7)	
Radial	36967 (60.6)	40278 (58.8)		19615 (67.2)	6245 (69.6)		78324 (71.9)	4323 (72.4)	
Drug eluting stent, n (%)	53075 (87.0)	59421 (86.8)	0.211	24520 (84.0)	7522 (83.8)	0.604	93510 (85.8)	5127 (85.9)	0.834
Bare metal stent, n (%)	1233 (2.0)	1507 (2.2)	0.026	456 (1.6)	144 (1.6)	0.82	1190 (1.1)	107 (1.8)	<0.001
Rotablator, n (%)	666 (1.1)	128 (0.2)	<0.001	769 (2.6)	29 (0.3)	<0.001	3531 (3.2)	50 (0.8)	<0.001
Drug eluting balloon, n (%)	3551 (5.8)	2296 (3.4)	<0.001	2954 (10.1)	535 (6.0)	<0.001	14012 (12.9)	435 (7.3)	<0.001
Distal protection device, n (%)	1586 (2.6)	6532 (9.5)	<0.001	815 (2.8)	743 (8.3)	<0.001	3760 (3.4)	981 (16.4)	<0.001

Abbreviations: STEMI, ST-elevation myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction; UA, unstable angina; TA, thrombus aspiration; IQR, interquartile range; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; LMT, left main trunk; LAD, left anterior descending

Table S2. Sub-group Analysis According to Door-to-balloon Time

In-hospital death

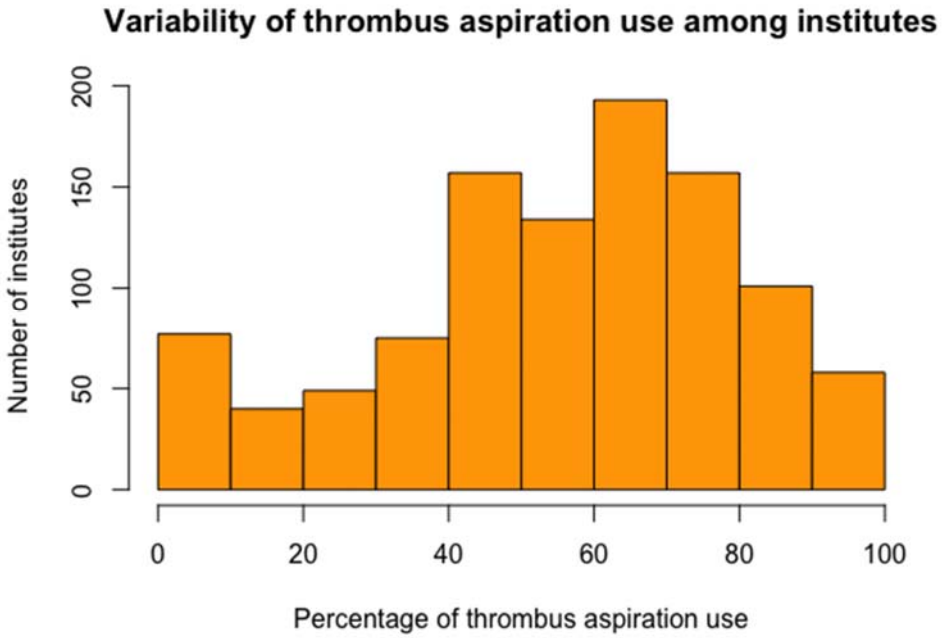
	Non TA PCI	TA PCI	TA PCI vs. Non-TA PCI (reference)				
			Adjusted ORs	95%CI		P	P for interaction
Overall	813/33800 (2.4)	1005/48565 (2.1)	1.044	0.931	1.171	0.465	NA
D2B 30-60	185/10937 (1.7)	269/17495 (1.5)	1.054	0.841	1.32	0.65	Reference
D2B 60-75	195/8852 (2.2)	217/13145 (1.7)	0.937	0.737	1.191	0.595	0.299
D2B 75-90	184/7724 (2.4)	256/10431 (2.5)	1.211	0.96	1.529	0.107	0.275
D2B 90-120	249/6287 (4.0)	263/7494 (3.5)	1.046	0.841	1.301	0.688	0.507

Composite of procedure-related complications

	Non TA PCI	TA PCI	TA PCI vs. Non-TA PCI (reference)				
			Adjusted ORs	95%CI		P	P for interaction
Overall	1702/33800 (5.0)	2446/48565 (5.0)	1.175	1.089	1.267	<0.001	NA
D2B 30-60	461/10937 (4.2)	747/17495 (4.3)	1.145	0.994	1.32	0.061	Reference
D2B 60-75	419/8852 (4.7)	567/13145 (4.3)	1.043	0.897	1.214	0.582	0.451
D2B 75-90	387/7724 (5.0)	589/10431 (5.6)	1.281	1.091	1.504	0.002	0.191
D2B 90-120	435/6287 (6.9)	543/7494 (7.2)	1.276	1.086	1.501	0.003	0.153

Abbreviations: TA, thrombus aspiration; PCI, percutaneous coronary intervention; D2B, door-to-balloon time; OR, odds ratio; CI, confidence interval; NA, not applicable

Figure S1. Variability of Thrombus Aspiration Use Among Institutes in Patients Presenting With STEMI



Median percentage of thrombus aspiration use was 59.7% (IQR, 41.6%–73.6%).

Abbreviation: IQR, interquartile range