HUE UNIVERSITY

UNIVERSITY OF MEDICINE AND PHARMACY

NGUYEN TUAN ANH

IMPACT OF THROMBUS ASPIRATION IN PATIENTS WITH ACUTE ST-ELEVATION MYOCARDIAL INFARCTION WITH HIGH THROMBUS BURDEN UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

Major: INTERNAL MEDICINE

Code: 9 72 01 07

SUMMARY OF MEDICAL DOCTORAL DISSERTATION

HUE - 2023

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INTRODUCTION

1. Rationale for the study

Thrombosis plays a central role in the pathophysiology of ST-segment elevation myocardial infarction. Recognotion and management of thrombosis have a crucial role in optimizing the door-to-balloon time in percutaneous coronary intervention (PCI) for acute ST-elevation myocardial infarction patients. Even with planned PCI, thrombosis management remains challenging to interventional cardiologists. Thrombus burden is associated not only with the risk of acute embolism, lower procedural success, higher rates of in-hospital complications, including mortality and myocardial infarction, but also increases the risk of requiring emergency coronary bypass surgery.

Thrombus aspiration prior to coronary stenting is cost-effective in reducing the burden of thrombosis. The benefits of thrombosis aspiration include: (1) removal of thrombus (which play a role in pre-coagulation, promoting vasoconstriction and platelet aggregation); (2) reducing the risk of embolization or distal embolization; (3) restoring downstream flow, improve myocardial perfusion index; (4) helps to accurately assess the pattern of atheroma underlying a thrombus and the degree of stenosis; (5) facilitating stent implantation; (6) allowing for selective use of fibrinolytics, platelet aggregation inhibitors, and vasodilators through the device.

At present, there are still gaps of knowledge regarding the role of thrombectomy in special cases in daily clinical practice when patients have a large thrombus burden on angiography. Studies specialized on thrombosis aspiration in this group of patients have shown positive initial results. In Vietnam, the treatment of thrombosis in ST-elevation MI patients with large thrombus burden by primary PCI still often performed but its effectiveness has not been evaluated. Therefore, we conducted research entitled “Impact of

thrombus aspiration in patients with acute ST-elevation myocardial infarction undergoing primary percutaneous coronary intervention" with the following objectives:

(1) To describe clinical and subclinical characteristics of ST-segment elevation myocardial infarction with high thrombus burden in patients undergoing selective thrombosis aspiration during primary PCI compared with PCI alone.

(2) To compare outcomes of primary PCI, cardiovascular events and mortality between two study groups during hospital stay and 1 year after hospital discharge.

(3) To examine some factors related to outcomes of primary PCI, cardiovascular events and mortality between two study groups.

2. Scientific contributions and practical implications

This study helps to determine the benefit of thrombectomy and clinical prognostic factors in subgroups of patients with ST-segment elevation myocardial infarction with a high thrombus burden. Findings of this research help to identify the group of subjects that should receive thrombectomy during primary PCI in order to reduce mortality as well as major cardiovascular events.

3. Contributions of the dissertation

This is one of the first studies in Vietnam on thrombosis aspiration in ST-segment elevation myocardial infarction patients with high thrombus burden. Thrombosis aspiration in this subgroup of patients improves myocardial perfusion (TMP), reduces ST-segment elevation on electrocardiogram, and in-hospital mortality. These findings have implied for clinical practice so that interventional physicians have a basis to decide to perform thrombosis aspiration during primary PCI in ST-segment elevation myocardial infarction patients with high thrombus burden.

Chapter 1
LITERATURE REVIEW

1.1. OVERVIEW OF ACUTE ST-ELEVATION MYOCARDIAL INFARCTION

1.1.1. Definition

The 4th universal definition of acute myocardial infarction (MI): There is acute myocardial injury with clinical evidence of acute myocardial ischemia and with detection of a rise and/or fall of cardiac troponin (cTn) values with at least one value exceeding the 99th percentile URL and at least one of the following symptoms:

- Symptoms of myocardial ischemia;
- New ischemic changes on electrocardiogram (ECG);
- Development of pathological Q waves;
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality in a pattern consistent with ischemic etiology;
- Identification of coronary thrombosis by angiography or autopsy.

ST-elevation MI (STEMI) is a type of acute MI and characterized by symptoms of myocardial ischemic accompanied by a persistent elevation of ST-segment on the ECG. The new ST segment elevation is defined as:

- New ST elevation at the J-point in two contiguous leads with the cut-point ≥ 1 mm except V2 and V3.
- In leads V2 and V3, the J- point elevation is ≥ 2mm in men ≥ 40 years old; ≥ 2.5 mm in men <40 years old; or ≥ 1.5 mm in women regardless of age.

1.1.2. Epidemiology of ST-elevation myocardial infarction

STEMI is a major health problem in developed countries and is becoming increasingly important in developing countries. However, the actual prevalence of MI is difficult to determine because of the variability from different study data (Table 1.1).

In Vietnam, there are no specific statistics on the prevalence of MI, however, the trend of cardiovascular disease and especially acute coronary syndrome (ACS) has been increasing.

Table 1.1. Estimates of the proportion of patients with ST-elevation myocardial infarction

Registry	Proportion
National Registry of Myocardial Infarction (NRMI-4)	29%
AHA	32%
Global Registry of Acute Coronary Event (GRACE)	38%

1.1.3. Pathology of ST-elevation myocardial infarction

Based on studies conducted since the 1970s, we now know that most cases of ACS are caused by coronary atherosclerotic disease associated with coronary thrombosis following by rupture or erosion of atherosclerotic plaque.

Atherosclerotic plaque rupture exposes substances that promote platelet activation and aggregation, thrombin formation, and ultimately thrombus formation. Thrombosis cuts off coronary flow and causes an imbalance between oxygen supply and demand, if this condition persists and gets worse, myocardial necrosis will occur.

1.2. PERCUTANEOUS CORONARY INTERVENTION IN ST-ELEVATION MYOCARDIAL INFARCTION

1.2.1. Primary percutaneous coronary intervention

Before coronary intervention, fibrinolytic therapy played a crucial role in the treatment of STEMI. However, limitations to its use include relative or absolute contraindications to fibrinolysis; life-threatening major bleeding complications in elderly patients; narrow therapeutic window due to relatively short duration of effective treatment; low chance of re-establishing of blood flow in the culprit artery even when timely administered, frequent re-occlusion of the culprit artery which can lead to recurrent ischemia or re-infarction MI in the following months. Contrary to the above disadvantages,

primary PCI has advantages over fibrinolysis including (1) restoration of TIMI 3 flow with higher rates of infarct-related artery patency; this benefit is relatively independent of the time of onset and duration of symptoms due to the stability of the blood vessels after catheterization; (2) preserve more myocardial mass; (3) delineate coronary anatomy and hemodynamic status, help stratify patient risk, and (4) provide better cardiac care for patients and to be discharged earlier.

The American Heart Association (AHA) suggests primary PCI at class of recommendation I for STEMI patients who (1) present with ischemic symptoms within 12 hours (level of evidence A); (2) present with ischemic symptoms within 12 hours and contraindications to fibrinolytic therapy regardless of the time delay from first medical exposure (level of evidence B) ; and (3) present with cardiogenic shock or severe heart failure irrespective of time delay from MI onset (level of evidence B). The European Society of Cardiology (ESC) guidelines recommend reperfusion therapy for all STEMI patients within 12 hours of onset at recommendation level I (level of evidence A). Primary PCI is the strategy that should be used (level I) if performed by an experienced team within 120 minutes of first medical contact (level of evidence A). In addition, coronary stenting is the preferred approach (level I indication, level of evidence A) over balloon angioplasty alone.

1.2.2. Rescue percutaneous coronary intervention

Rescue PCI was defined as intervention within 12 hours of failure of fibrinolytic therapy in patients who were still symptomatic or had recurrent ischemic symptoms. In the non-coronary angiography setting, the ST-segment elevation on ECG is less than 50%, progressive chest pain and/or hemodynamic instability and heart failure – although known to be vague – but the above symptoms are still used as an indicator of fibrinolytic failure. Even with the most recent generations, fibrinolysis only restores TIMI 3 flow to the epicardial coronary arteries in more than half of MI patients.

Furthermore, approximately 5% to 10% of patients will undergo re-occlusion after successful fibrinolysis. At present, rescue PCI improves clinical outcomes and should be recommended in STEMI patients with evidence of failed reperfusion after fibrinolytic therapy.

1.3. EFFECTS OF THROMBUS BURDEN IN PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

1.3.1. Relationship between thrombus burden and distal embolization

Distal embolization due to thrombus, plaque debris has been identified as a major impediment to primary PCI in STEMI patients. It reduces myocardial reperfusion efficiency, leading to more extensive myocardial damage and a worse prognosis. The angiographically visible distal embolization was found in 6% to 15% of STEMI patients with primary PCI.

Experimental studies suggest that thromboembolism and atherosclerotic plaques occur during primary PCI, and distal embolization accounts for a small number of embolization cases observed in most patients. However, its burden and clinical harm is largely based on the amount of thrombus: greater thrombus burden lead to greater the likelihood of distal embolism and higher risk of microvascular occlusion. According to these observations, patients presenting with a high thrombus burden tend to have more extensive necrosis even if distal embolization is undetectable on angiography.

1.3.2. Effect of distal embolization on myocardial injury and clinical outcomes

Distal embolization reduces the effectiveness of reperfusion within the first 6 hours and enhances greater myocardial damage within the first 3 hours. This may help explain some of the poor results expected of mechanical assist devices on infarct size in large studies in which patients were recruited usually after 3 hours after symptoms onset.

Other relevant factors influencing the effect of distal embolization on reperfusion and myocardial damage in STEMI patients are thrombus burden and myocardial area at risk. In fact, studies of high thrombus burden on myocardial and microvascular injury during reperfusion have shown that the presence of a large thrombus burden not only causes more embolism, but also affects the degree of myocardial perfusion, regardless of whether or not an embolism is detected.

1.4. CLASSIFICATION OF THROMBOSIS

The most widely used classification is the TIMI flow grading system published in 1985 by the TIMI research group (Table 1.4).

Table 1.4. TIMI thrombus grade

Definition	
0	No thrombus on angiogram
1	Possibility of thrombus. Angiography showing reduced contrast density, opacity, irregular lesion contour, or smooth convexity at the site of complete occlusion also suggests thrombus but is uncertain.
2	Definite thrombus present in multiple angiographic projections, irregular lesion contour with marked defects, small size: the largest size of thrombus is less than or equal to half of vessel diameter
3	Definite thrombus appears, medium size: greatest dimension from >1/2 to <2 vessel diameters)
4	Large size thrombus present: same as grade 3 but greater than or equal to 2 times the vessel diameter
5	Completely thrombotic occlusion of a vessel; a convex edge that stains with contrast and persists for several cardiac cycles

1.4.1. Thrombotic storm

Characteristic of thrombotic storm is sudden, acute onset, accumulation of large thrombus to cause clinical instability. This prothrombotic phenotype may form as a result of sudden rupture of the atherosclerotic plaque or of mechanical impulses during coronary

interventions such as guidewire and/or other devices during the passage of the plaque.

1.5. STUDIES RELATED TO THROMBOSIS ASPIRATION

In 2016, investigators of TAPAS, TOTAL, and TASTE conducted a systematic review involving approximately 18,000 MI patients from these three studies. The study authors' conclusion was that routine thrombectomy during PCI did not improve clinical outcomes, however, there was a trend towards reduced mortality in patients with high thrombus burden.

Studies on patients with high thrombus burden have shown that thrombosis aspiration (TA) can help reduce in-hospital mortality, reduce slow flow, improve left ventricular ejection fraction (LVEF), reduce ST segment elevation, and cardiac enzyme concentrations.

Chapter 2
METHODOLOGY

2.1. STUDY SUBJECTS

Study participants were patients with acute STEMI who underwent angiography and emergency PCI, with TIMI thrombus grade 4 or 5 after having passed the wire through the culprit lesion. Details criteria for emergency PCI were based on the 2017 ESC guidelines.

2.2. RESEARCH METHODOLOGY

2.2.1. Study design

Registry for longitudinal study compared the proportion of major cardiovascular events and mortality in STEMI patients with high thrombus burden undergoing emergency PCI with and without thrombosis aspiration.

2.2.2. Study time and settings

The study was conducted at the Department of Interventional Cardiology, Cho Ray Hospital from September 2018 to December 2021.

2.2.3. Sample size and sampling method

Sample size: The estimated sample size of each group was 73 patients. The actual sample size collected in the TA and the balloon angioplasty (BA) group was 71 and 76, respectively. Out of a total of 147 patients enrolled in the study, there were 18 deaths, of which two died during the procedure, 7 deaths during hospital stay and 9 deaths during follow-up after hospital discharge. Surviving patients at hospital discharge were followed up from the date of discharge to the end of the study (December 15, 2021) or until patient's death. In this study, there were 21 cases that were lost to follow-up and 19 patients who did not have enough follow-up period of one year.

***Sampling method*:** We employed convenience sampling to recruit study participants.

2.3. DATA COLLECTION

2.3.1. Data collection tools

Including prepared questionnaires and CDs that stored patients' images of angiography and PCI.

2.3.2. Research procedure

A total of 147 patients were enrolled in the study and were divided into aspiration (n = 71) and a control (explosion) group (n = 76). The patients were followed up at procedure, in-hospital and after 1 year.

2.3.3. Describe the technique of thrombus suction

PCI were performed after the patients underwent coronary angiography to identify the culprit artery. A 6F guiding catheter was inserted into the culprit coronary artery (usually JR4 6F for the right coronary artery (RCA) and CLS3 or BL3 6F for the left coronary artery (LCA)). Contrast was injected into the coronary artery through a catheter to visualize the thrombus and coronary arteries. An

interventional lead will be guided through the thrombus lesion to the coronary artery. After confirmation that the guidewire was indeed in the true lumen of the coronary artery, high thrombus burden was classified, the TA group would proceed to the procedure of thrombectomy, while the other group was underwent balloon angioplasty.

The guiding catheter was flushed with 0.9% normal saline and heparin to prevent microthrombosis from adhering to the surface. The catheter is then connected to the 50cc syringe with a lock connector. The plunger of the syringe was pulled back and locked to create negative pressure in the catheter lumen. The catheter was then inserted into the coronary artery through a guide wire system to the lesion. TA was started when the catheter was 2cm in front of the lesion through the unlocking of the guide catheter to pressure the thrombus into the lumen of the catheter and the 50cc syringe. The catheter was moved slowly and sometimes stopped at the site of the thrombus, suction pressure should be maintained continuously during aspiration and during removal of the suction device and should be done to the distal location of the occlusion if possible. When flow from catheter was slow or cease, there was a possibility that thrombus obstructed the catheter, then the catheter would be pulled out slowly and still maintained a constant suction pressure and keep the catheter a little deeper into the coronary lumen to prevent the clot from falling out of the catheter. After complete withdrawal, the catheter was flushed through the filter tray to note whether or not large thrombus was aspirated.

TA procedure should be performed two to three times. Thrombectomy was considered successful in the presence of thrombus in the aspirated fluid.

2.4. Data analysis

Data were entered and analyzed using SPSS statistical software version 20.0. Qualitative data were described as frequency (n) and percentage (%). Quantitative variables were tested for normal

distribution by the Kolmogorov-Smirnov or Shapiro-Wilk test and described as mean, standard deviation if normally distributed; median, Q1, Q3, minimum and maximum if non-normally distributed.

We employed Chi-squared test or Fisher's Exact test in case of violation of Chi-squared test's assumption to compare the proportions. Independent sample t-test or Mann-Whitney U-test was used to compare two means; one-way ANOVA test or Kruskal-Wallis test to compare three means.

Multivariable logistic regression was used to calculate the OR and 95% confidence interval (CI) to identify some factors related to the prognosis of ST-segment elevation recovery, optimal reperfusion after intervention, and suboptimal flow.

A p-value of <0.05 is considered statistically significant.

2.5. Research ethics

The research protocol was approved by the Ethical Committee of Hue University of Medicine and Pharmacy and Cho Ray Hospital. Study subjects were fully informed about the purposes, benefits, and risks of participating in the study. Participation in this study was completely voluntary and participants may refuse to participate in the study at any time without any coercion. All information of patients in the study was processed and published in the form of data, ensuring respect for the patient's privacy.

Chapter 3
RESULTS

3.1. GENERAL CHARACTERISTICS OF STUDY POPULATION

3.1.1. Demographic characteristics and cardiovascular risk factors

The proportion of male in TA group was 81.7%, higher than in the BA group (75%) but the difference was not statistically

significant (p>0.05). The mean age of the two study groups was similar, specifically, the mean age of TA group was 60.6 ± 11.2 years and of BA group was 62.8 ± 12.2 years old. The proportion of male were higher than female in both groups.

Patients' history such as previous cerebrovascular accident, previous MI, previous PCI and heart failure were low and similar in both study groups (p>0.05).

Dyslipidemia and hypertension were the two most common coronary risk factors in both groups. However, there was no statistically significant difference in coronary risk factors between two groups.

3.1.2. Clinical and subclinical features of the study population

There were no significant differences in clinical and subclinical characteristics between two study groups.

3.1.3. Characteristics of coronary angiography

RCA was the main culprit artery in both study groups (55.3% in BA group and 63.4% in TA group). The rate of multivessel coronary disease in BA group was significantly higher than that of TA group (61.8% vs. 21%, p< 0.001).

There was about 1/3 of the study subjects of each group received the intervention after 12 hours.

The radial artery was the most commonly used access site for coronary procedure (86.8% in the BA group and 97.2% in the TA group).

There was no significant difference in the fluoroscopic time or radiation doses used in the procedure.

There were 2 cases in each group requiring only BA or TA and no stenting.

The median diameter of stents used in the thrombectomy group was statistically significantly larger than the control group [3 (2.8 – 3.5) mm vs. 3 (3 – 3.5) mm, p=0.001).

All patients received general pharmacologic therapy for ACS including anticoagulation, antiplatelet agents, and statins.

3.2. OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION

Table 3.1. Short-term outcomes of primary percutaneous coronary intervention

Short-term outcomes	Total (n=147)	BA group (n=76)	TA group (n=71)	p
	n (%)	n (%)	n (%)	
Reduction >50% of ST elevation	71 (48.3%)	30 (39.5%)	41 (57.7%)	0.027
Suboptimal flow (TMI <3 or presence of residual thrombosis)	58 (39.5%)	36 (47.4%)	22 (31%)	0.042
Optimal perfusion index after PCI (TMP=3)	107 (72.8%)	50 (65.8%)	57 (80.3%)	0.049

Comment:

- The proportion of patients with reduction over 50% of ST segment elevation and TMP=3 in the thrombectomy group was statistically significantly higher than in the control group.

- The proportion of patients with suboptimal flow (TIMI=3 and/or presence of residual thrombosis) was significantly lower in the TA group than in the control group.

Table 3.2. Cardiovascular events during hospital stay

Cardiovascular events during hospital stay	Total (n=147)	BA group (n=76)	TA group (n=71)	
	n (%)	n (%)	n (%)	p
Major adverse cardiovascular events	60 40.8%)	35 (46.1%)	25 (35.2%)	0.181
Heart failure	53 (36.1%)	29 (38.2%)	24 (33.8%)	0.583
Stroke	2 (1.4%)	2 (2.6%)	0 (0%)	0.497
Recurrent MI	1 (0.7%)	1 (1.3%)	0 (0%)	1
Target lesion revascularization	1 (0.7%)	1 (1.3%)	0 (0%)	1
Mortality	9 (6.1%)	8 (10.5%)	1 (1.4%)	0.034

Comment:

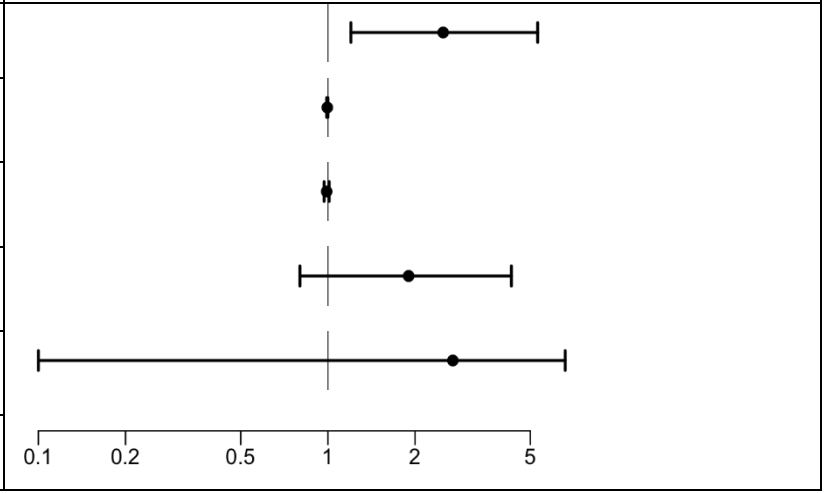
- The proportion of in-hospital mortality was significantly lower in TA group than the control group.
- There was no difference in procedure-related complications between the two study groups.
- There was no significant difference in adverse cardiovascular events or mortality in the two study groups after one year of follow-up.

3.3. FACTORS RELATED TO OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION, CARDIOVASCULAR EVENTS AND MORTALITY

Factors considered related to perfusion outcomes of PCI including ST segment reduction, cardiovascular events, and mortality.

Table 3.3. Factors related to the ST-segment recovery after PCI in study subjects (logistics regression model)

Characteristic	Adjusted OR (95%CI)	p
TA vs. BA	2.5 (1.2 – 5.3)	0.019
Pre-procedural CKMB (U/L)	0.995 (0.99 - 1)	0.066
Pre-procedural Tnl (ng/ml)	0.99 (0.97 – 1.01)	0.413
Inferior vs. Anterior MI	1.9 (0.8 – 4.3)	0.119
PCI ≤12 hours vs. >12 hours	2.7 (1.1 – 6.6)	0.034

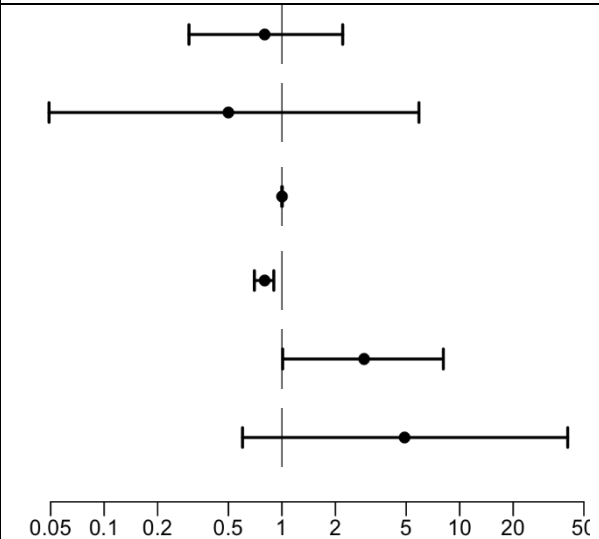


Comment:

The group receiving thrombectomy had 2.5 times higher ST segment recovery than patients treated with BA and the difference was statistically significant.

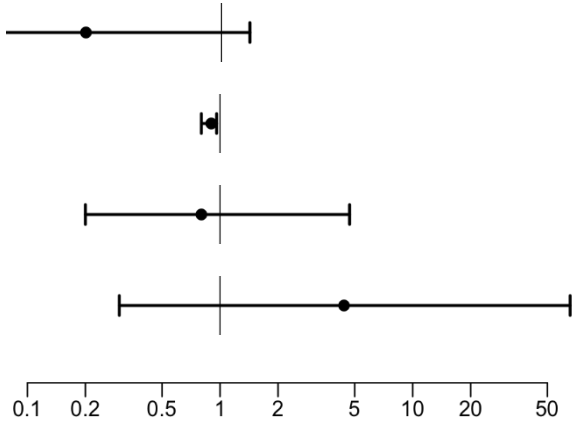
Table 3.4. Factors related to major cardiovascular events in study subjects during hospital stay (logistics regression model)

Characteristic	Adjusted OR (95%CI)	p
TA vs. BA	0.8 (0.3 – 2.2)	0.712
Previous MI Yes vs. No	0.5 (0.049 – 5.9)	0.61
Pre-procedural CKMB (U/L)	1.002 (0.997 – 1.006)	0.432
LVEF (%)	0.8 (0.7 – 0.9)	<0.001
LAD vs RCA	2.9 (1.01 – 8.1)	0.048
LCX vs RCA	4.9 (0.6 – 40.5)	0.141



Comment: LVEF was associated with major cardiovascular events during hospital stay.

Table 3.5. Factors related to mortality during hospital stay in study subjects (logistics regression model)

Characteristic	Adjusted OR (95%CI)	p	
TA vs. BA	0.2 (0.02 – 1.4)	0.099	
LVEF (%)	0.9 (0.8 – 0.96)	0.009	
LAD vs RCA	0.8 (0.2 – 4.7)	0.847	
LCX vs RCA	4.4 (0.3 – 65.7)	0.288	

Comment:

LVEF was associated with mortality during hospital stay.

Chapter 4
DISCUSSION

4.1. GENERAL CHARACTERISTICS OF STUDY POPULATION

4.1.1. Demographic characteristics and cardiovascular risk factors

The mean age of BA and TA groups were 62.8 ± 12.2 and 60.6 ± 11.2, respectively, which was in line with previous research.

The proportion of male and female in BA group were 75% and 25%, in TA group were 81.7% and 18.3%, respectively. The proportion of male having MI was three times higher than that of women. This was similar to other MI studies worldwide.

Hypertension and dyslipidemia were the two characteristics that accounted for the highest proportion, the rate of hypertension in BA and TA group was 57.9% and 59.2%, respectively; the rate of dyslipidemia was 59.2% and 60.6%, respectively. These rates were higher than that of previous MI studies.

4.1.2. Clinical and subclinical characteristics of the study subjects

The proportion of inferior MI was highest in this study, accounted for 60.5% in control group and 66.2% in TA group. Although the rate of anterior myocardial infarction was lower, mortality still occurred more in this group, specifically among 11 deaths in our study, anterior MI accounted for 6 cases and inferior MI accounted for 5 cases. This was also consistent with previous literature showing that anterior MI had a higher risk of mortality compared with other infarct sites despite undergoing intervention.

The median time from symptom onset to hospital admission and diagnosis of MI was 8 hours (480 minutes) for both study groups, which was quite high compared to previous TA studies.

In general, the parameters of complete blood count, liver enzymes, fasting blood sugar of our two study groups were not significant differences and fluctuated within normal limits. Changes

in these parameters mainly reflect inflammation in MI and have been rarely studied in the pathology of STEMI, most of the studies on these parameters were aimed at assessing prognosis.

The mean ejection fraction in our study was 43.4 ± 10.4% in the control group and 44.9 ± 9% in the TA group, belonging to the palliative classification according to the European Society of Cardiology. This finding was similar to previous TA studies conducted in Europe, but lower than studies from China.

4.2. OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION, CARDIOVASCULAR EVENTS AND MORTALITY IN TWO STUDY GROUPS DURING HOSPITAL STAY AND 1-YEAR FOLLOW-UP

4.2.1. Subclinical outcomes related to primary PCI

Tests to assess injury in MI including creatine kinase (CK), creatine kinase-myocardial band (CK–MB), Troponin I (TnI) and Troponin T (TnT) have prognostic value for the degree of necrosis, left ventricular function and post-infarction cardiovascular events for patients have been studied and used for a long time. At Cho Ray hospital, we use CK-MB and Troponin I to diagnose and monitor patients.

The median pre-procedural CK-MB concentration in our study was 92.4 (51.4 - 181) (U/L) in the control group, 88.2 (49.4 - 183.9) (U/L) in the thrombectomy group and there was no significant difference between these two groups.

The median troponin I concentration before the procedure was 7 (1 - 43.4) ng/ml in the control group and 7 (1.2 - 42.2) ng/ml in the TA group and there was a statistically significant difference.

Renal function measured through blood creatinine value reflects the possibility of acute kidney injury after intervention is also a factor of interest in coronary intervention procedures. To compare safety of BA and TA approach on renal function, we compared post-procedural creatinine levels between these two groups and found that there was not significant difference. The median creatinine

concentration obtained within 24 hours after the intervention in the BA and TA group was 0.9 (0.8 - 1.1) mg/dl and 0.9 (0.8 - 1) mg/dl, respectively.

4.2.2. Features of coronary angiography and percutaneous coronary intervention

RCA as culprit artery was accounted for the highest percentage in our study, with the proportion of 55.3% in the control group and 63.4% in the TA group. According to the literature, of the three main coronary arteries of the heart, RCA has fewer branches which enhance thrombus form and accumulate here easier.

The median fluoroscopy time of the control group and the thrombectomy group in our study was 7.6 (4.8 - 10.4) and 7.6 (5.5 - 11.1) minutes, respectively. There was no significant difference between the two groups although BA usually only needs to be performed once to open the occluded branch, TA usually requires 2 to 3 aspiration or more to ensure maximal aspirated thrombus.

The median amount of contrast (ml) used in our study of BA and TA group was 100 (90 – 120) and 100 (80 – 120), respectively, with no significant difference between the two groups. Although we performed a flow check after each thrombectomy and this can be more frequent than the BA. approach.

The median diameter of stent for the culprit lesion was significantly larger in the TA group than in the control group (3 (3 - 3.5) (mm) vs. 3 (2.8 - 3.5) (mm), $p = 0.001$). This result was in line with previous studies which also illustrated that the stent diameter or equivalent values such as the maximum stent diameter after intervention, the diameter of blood vessels after the intervention... were significantly higher in TA than the control group.

4.2.3. Characteristics of medical treatment after intervention

Approximately 99% study participants were treated with antiplatelet drugs, anticoagulants and statins after the intervention. These are the general pharmacological therapy in the treatment of acute MI with the goals of antithrombotic, stabilizing inflammation,

and protecting stents according to the guidelines of the ESC and AHA.

4.2.4. Characteristics associated with reperfusion and clinical outcomes

The rate of reduction of ST segment elevation in our thrombectomy group was 57.7%, significantly higher than that of the control group, 39.5%, p=0.027. Thus, for patients with huge thrombus burden, the thrombectomy procedure also resulted in significant ST-segment elevation reduction which was in line with other studies.

We evaluated suboptimal flow rates including cases with TIMI flow ≤ 2 and/or residual thrombosis between the two study groups. Our finding indicated that the TA group had a statistically significant lower suboptimal flow rate than the control group (31% vs. 47.4%, p = 0.042). Thus, overall, in patients with high thrombus burden, TA is still significant to reduce the rate of TIMI flow ≤ 2 and/or residual thrombosis after intervention.

In our study, the rate of TMP = 3 in the TA group was 80.3% significantly higher than that in the control group of 65.8%. This result was consistent with previous studies showing that TA improved myocardial perfusion.

4.2.5. Cardiovascular events and mortality

The proportion of major cardiovascular events including heart failure, MI, stroke, and target lesion revascularization were not significantly different between the two study groups during hospital stay and 1-year follow-up. However, in-hospital mortality rate in the TA group was statistically significantly lower than in the conventional intervention group (1.4% vs 10.5%, p = 0.034). This figure was similar to previous studies which were conducted on patients with high thrombus burden.

In our study, there were two cases of cerebrovascular accident occurred in the control group and there was no case in the TA group,

there was no significant difference between these two groups. This finding was in line with other recent studies.

4.3. FACTORS RELATED TO OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION, CARDIOVASCULAR EVENTS AND MORTALITY IN TWO STUDY GROUPS

Results from our logistics regression model showed that TA and PCI before 12 hours were associated with an improvement of ST segment reduction.

In our study, left ventricular systolic function and the culprit artery were two factors associated with in-hospital cardiovascular events (including heart failure, cerebrovascular accident, re-infarction, target vascular revascularization), however, only left ventricular systolic function was associated with risk of cardiovascular events after 1-year follow-up. Only left ventricular systolic function was associated with in-hospital mortality as well as mortality after 1-year follow-up. These findings were consistent with previous literature.

CONCLUSION

Through the study of 147 acute STEMI patients with high thrombus burden underwent angiography and primary PCI combined with thrombectomy compared to PCI with BA from September 2018 to July 2021, we draw the following conclusions:

1. Clinical and subclinical characteristics of ST-segment elevation myocardial infarction patients with high thrombus burden undergoing primary percutaneous coronary intervention in the group with and without selective thrombosis aspiration

- Most of the patients were male with a mean age of 60.
- Dyslipidemia and hypertension were the two most common cardiovascular risk factors.

- Inferior MI accounted for the highest proportion.

- Duration of onset of symptoms to hospital admission of patients was still high compared to other studies worldwide, the median time was 8 hours.

- There was no significant difference in the dose of contrast used between the TA and BA group [100 ml (80 - 120) versus 100 (90 - 120) ml, respectively; p=0.435]; post-procedural serum creatinine level [0.9 (0.8 - 1) mg/dl vs. 0.9 (0.8 - 1.1) mg/dl, p=0.845]; fluoroscopic time [7.6 (5.5 - 11.1) minutes vs. 7.6 (4.8 - 10.4) minutes, p=0.476].

- The TA group had a significantly larger stent diameter than the control group [3 (3 - 3.5) mm vs. 3 (2.8 - 3.50) mm, p = 0.001].

2. Outcomes of primary percutaneous coronary intervention, cardiovascular events and mortality in the two study groups during hospital stay and one year after discharge

- The TA group had a significantly higher rate of achieving myocardial perfusion TMP = 3 than the BA group (80.3% vs. 65.8%, p = 0.049).

- The TA group had a significantly higher rate of ST-segment elevation reduction on ECG after PCI than the control group (57.7% vs. 39.5%, p = 0.027).

- The proportion of suboptimal blood flow (including TIMI flow $\leq$ 2 and/or residual thrombus) was significantly lower in the TA group than in the BA group (31% vs. 47.4%, p = 0.042).

- There was no significant difference in the proportion of cardiovascular events (heart failure, re-MI, stroke, target lesion revascularization) during hospital stay and one year of follow-up.

- The TA group had a significantly lower in-hospital mortality rate than the control group (1.4% vs. 10.5%, p=0.034).

- There was no significant difference in mortality between the two groups after one year of follow-up.

3. Factors related to outcomes of primary percutaneous coronary intervention, cardiovascular events and mortality in the two study groups

- In the regression model to evaluate the reduction of ST segment after intervention, we noted that aspiration thrombosis and PCI before 12 hours were the factors that helped to improve the ST segment reduction.
- Left ventricular systolic function and the culprit artery were two factors that were correlated in the regression analysis of in-hospital cardiovascular events (including heart failure, cerebrovascular accident, re-myocardial infarction, targeted revascularization) in our study, however, only left ventricular systolic function was correlated with cardiovascular events after 1 year.
- Left ventricular systolic function is a factor associated with in-hospital mortality and one year mortality after discharge.

RECOMMENDATION

Based on study's findings, we would like to suggest the following recommendations:

1. Aspiration thrombectomy in ST-segment elevation myocardial infarction patients with high thrombus burden can reduce the risk of in-hospital mortality, achieve higher myocardial perfusion ratio of TMP = 3 and a higher rate of ST segment resolve after intervention.

2. - The burden of thrombosis is considered high according to our study when the culprit coronary artery thrombosis is still at TIMI 4 or 5 after passing the guidewire through the lesion.

3. - Patients with reduced left ventricular systolic function and the culprit artery being the left anterior descending need attention during follow up and treatment because these patients are high risk with cardiovascular events and mortality.

LIST OF RELATED SCIENTIFIC WORKS THAT HAD BEEN PUBLISHED

1. Nguyen Tuan Anh, Vo Thanh Nhan, Hoang Anh Tien (2019), "Study on thrombosis aspiration in emergency intervention in ST-segment elevation myocardial infarction patients with high thrombus burden". *Journal of Medicine and Pharmacy - Hue University of Medicine and Pharmacy*, 9 (6 + 7).

2. Nguyen Tuan Anh, Nguyen Thuong Nghia (2022), "Study on in-hospital outcomes in ST-segment elevation myocardial infarction patients with high thrombus burden receiving thrombosis aspiration during primary percutaneous coronary intervention". *Journal of Vietnamese Medicine*, 515 (1).

3. Nguyen Tuan Anh, Hoang Anh Tien (2022), "Study on benefits of thrombosis aspiration in ST-segment elevation myocardial infarction patients with high thrombus burden undergoing primary percutaneous coronary intervention". *Journal of Clinical Medicine*, 7.