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In-hospital outcomes of patients undergoing manual thrombus aspiration in primary PCI for acute STEMI with high thrombus burden.

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Abstract

Background: Routine thrombus aspiration during primary PCI does not improve clinical outcomes. However, the outcomes of manual thrombus aspiration for patients undergoing primary PCI for acute STEMI with high thrombus burden are still unclear.

Objective: Evaluate the in-hospital outcomes of using manual thrombus aspiration in STEMI patients undergoing primary PCI and showing a high thrombus burden.

Methods: Intervention prospective study.

Results: 147 STEMI patients with high thrombus burden in coronary angiography divides into thrombus aspiration and PCI (n=71) or conventional PCI (n=76). The ST-segment resolution and TIMI myocardial perfusion grading (TMP=3) were significantly higher in the aspiration+PCI group compared with the conventional PCI group. The in-hospital mortality rate was lower in the aspiration+PCI group compared with the conventional PCI group (10.5% versus 1.4%; P=0.034). There were no significant differences in the incidence of stroke between the two groups.

Conclusion: In STEMI patients with high thrombus burden, manual thrombus aspiration improved in-hospital mortality, ST-segment resolution, and TIMI myocardial perfusion grading.

Keywords: ST-segment elevation myocardial infarction, Aspiration thrombectomy, High thrombus burden.
Abbreviations: STEMI: ST Elevation Myocardial Infarction; PCI: Primary Coronary Intervention.

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Introduction

Despite advances in diagnosis and treatment, acute ST-elevation myocardial infarction remains a major health problem in industrialized countries and increases in developing countries. The process of formation and progression of atherosclerosis, along with events of gradual erosion or cracking of atherosclerotic plaque with clot (Thromboembolism) that partially or completely occludes the lumen of the coronary arteries, is the primary mechanism of the disease, so early reperfusion is the most effective treatment to improve patient survival. It is recommended at the top of the European Heart Association treatment guidelines [1].

Whether emergency or elective coronary interventions, thrombus burden management remains challenging for interventional cardiologists. The burden of thrombosis increases the risk of acute embolism, reduces the likelihood of procedure success, and increases the incidence of complications during hospitalization, including death and myocardial infarction, and the incidence of emergency coronary bypass surgery [2].

Manual thrombus aspiration before coronary stenting is a simple but effective measure of reducing the burden of thrombosis. The benefits of manual thrombus aspiration include: (1) Elimination of thrombosis (which plays a role in causing pre-coagulation, promoting vasoconstriction and platelet aggregation); (2) Reduce the risk of embolism of distal blood flow; (3) Restore downstream flow, improve myocardial blood perfusion ; (4) Helps to accurately assess the type of atheroma below the thrombus and the degree of stenosis; (5) Facilitate stenting; (6) Allows the selective use of fibrinolytic, platelet aggregation inhibitors, and vasodilators. The TAPAS study is one of the early studies on thrombotic aspiration, showing manual thrombus aspiration to improve myocardial perfusion and mortality. However, the TASTE (2013) and TOTAL

(2015) studies of over 7,000 patients per study found that routine manual thrombus aspiration did not improve clinical outcomes when compared to routine coronary interventions [3,4]. In 2016, researchers from the TAPAS, TOTAL, and TASTE study conducted a meta-analysis of 18,000 ST-elevation myocardial infarction patients. The study results showed no statistically significant difference in cardiovascular mortality within 30 days between the conventional coronary intervention group (2.4%) and the manual thrombus aspiration group (2.9%) (P=0.06). The stroke or transient ischemic attack incidence was 0.8% in the thrombus aspiration group and 0.5% in the routine coronary intervention group (P=0.06), respectively. This result is similar to previous results on routine thrombosis aspiration strategies. However, subgroup analyses based on thrombotic burden showed that the group with a large thrombotic burden (defined as TIMI thrombosis score>3) showed that manual thrombus aspiration tended to improve clinical outcomes at 30 days; 30-day cardiovascular mortality in the thrombus aspiration group with a large thrombotic burden was 2.5% compared to the conventional coronary intervention group of 3.1% with P=0.03; 30-day all-cause mortality between the two groups was 2.6% and 3.1% with P=0.04, respectively. The study authors conclude that routine thrombus aspiration in primary coronary interventions does not improve clinical outcomes; however, reducing mortality in the subgroup with large thrombotic burden patients suggests new research directions and technical improvements for thrombus suction devices. That could benefit this high-risk subgroup.

The American and European Heart Association guidelines do not allow routine manual thrombus aspiration in emergency coronary interventions in patients with ST myocardial infarction due to a lack of clinical benefit evidence. However, manual thrombus aspiration may be helpful in some particular cases, such as large thrombotic burden or salvage after stenting, and is still allowed with the level of evidence (IIb) [1].

To answer the question of whether manual thrombus aspiration during primary coronary intervention in the subgroup of ST myocardial infarction patients with a large thrombotic burden is clinically beneficial, we conducted a study about the inpatient outcomes of primary coronary intervention in ST-elevation myocardial infarction patients with a large thrombotic burden undergoing primary coronary intervention.

Materials and Methods

The criteria for selecting a specific emergency coronary intervention based on ESC/EACTS 2017 guidelines include patients with symptoms from onset to hospitalization<12 hours and with persistent ST elevation myocardial infarction or new left branch blocks in ECG or patients who are late after 12 hours but still have symptoms and signs that show progressive ischemia or life-threatening arrhythmias.

The study selected patients with acute ST-elevation myocardial infarction with complete occlusion of the culprit artery who underwent emergency coronary angiography and PCI. The procedures were performed as primary coronary intervention routinely. The coronary guide wires were passed through the lesion, and then images of the coronary arteries were taken to classify the extent of the thrombus burden. The patients with large thrombus burden (TIMI 4-5 grade) will be recruited to the study and approached by either balloon angioplasty with stenting /direct stenting procedure (routine) or manual thrombus aspiration, then stenting procedure.

The criteria for exclusion are acute myocardial infarction patients with cardiogenic shock, mechanical complications, and severe comorbidities that lead to poor expectations, such as cancer. The study method is interventional, prospective research.

147 subjects who met the large thrombosis criteria were admitted to the study, the group approached by balloon angioplasty had 76 patients, and the group approached by thrombus aspiration had 71 patients. During the procedure, there were 8 patients in the balloon angioplasty group who had to perform salvage manual thrombus aspiration and 4 patients in the manual thrombus aspiration group who needed supportive balloon angioplasty.

Patients were monitored and collected subclinical, clinical data on cardiovascular events, including heart failure, death, cerebrovascular accidents, and coronary revascularization during hospitalization and 6 months later.

Statistical processing procedures

Data is entered and analyzed using SPSS statistical software version 20.0.

Results

There were no statistically significant differences in age, sex, and ethnicity between the control group *vs.* the manual thrombus aspiration group (Table 1).

There were no statistically significant differences in cardiovascular risk factors and cardiac ejection fraction between the two groups: control group *vs.* manual thrombus aspiration group (Table 2).

Kidney function in both groups does not differ significantly before and after PCI (Table 3).

Most cases underwent PCI *via* radial vascular access, but in the manual thrombus aspiration group, were performed *via* radial vascular access (97.2%) more than in the control group (86.8%) (Table 4).

The decrease in ST elevation by more than 50% and the improvement of myocardial perfusion after intervention (TMP ≥ 3) was significantly higher in the manual thrombus aspiration group than in the non-thrombectomy group statistically (Table 5).

Table 1. *Population characteristics.*

Population characteristics		Control group (n=76)	Thrombus suction (n=71)	P
		n (%)	n (%)	
Gender	Male	57(75%)	58(81.7%)	0.326*
	Female	19(25%)	13(18.3%)	
Ethics	Vietnamese	73(96.1%)	68(95.8%)	1**
	Others	3(3.9%)	3(4.2%)	
Age	Mean (SD)	62.8(12.2)	60.6(11.2)	0.259***
	min-max	27-86	31-86	
Age group	<65	40(52.6%)	46(64.8%)	0.135*
	≥ 65	36(47.4%)	25(35.2%)	

Note:*Pearson Chi-Square, **Fisher's Exact Test, ***Independent Samples Test

Table 2. *Ejection fraction characteristics.*

Ejection fraction characteristics	Control group (n=76)	Thrombus suction (n=71)	P
LVEF (%) Mean (SD)	43.4(10.4)	44.8(9)	0.362*

Note:*Independent Samples Test

Table 3. *Kidney function before and after the intervention procedure.*

Kidney function before and after the intervention procedure	n	Balloon angioplasty group	n	Thrombus suction group	P
Creatinine (before the procedure)[b]	74	1(0.8-1.3)	70	0.9(0.8-1.1)	0.147*
Creatinine (after the procedure)[b]	68	0.9(0.8-1.1)	62	0.9(0.8-1)	0.845*

Note: [b]Presented as Median (Q1-Q3), *Independent-Samples Mann-Whitney U Test

Table 4. *Features of intervention procedures.*

Features of intervention procedures		Control group (n=76)	Thrombus suction group (n=71)	P
		n (%)	n (%)	
Time from admission to intervention (hours)[a]		10(8-13)	9(7-13)	0.234*
PCI ≤ 12 hours	No	26(34.2%)	18(25.4%)	0.241**
	Yes	50(65.8%)	53(74.6%)	
Vascular access PCI	Radial	66(86.8%)	69(97.2%)	0.022**
	Femoral	10(13.2%)	2(2.8%)	
Duration of intervention (minute)[a]		7.6(4.8-10.4)	7.6(5.5-11.1)	0.476*
Amount of contrast used (ml)[a]		100(90-120)	100(80-120)	0.435*

Note: [a]Presented as median (Q1-Q3), *Independent-Samples Mann-Whitney U Test, **Pearson Chi-Square

Table 5. *Early result after PCI on ECG. TMP Grade.*

Features of early results after intervention	Both (n=147)	Control group (n=76)	Thrombus suction group (n=71)	P
	n (%)	n (%)	n (%)	
ST elevation reduce >50%	71(48.3%)	30(39.5%)	41(57.7%)	0.027*
Optimal post-intervention reperfusion (TMP ^{3} 3)	107(72.8%)	50(65.8%)	57(80.3%)	0.049*

Note: *Pearson Chi-Square

The prevalence of major cardiovascular events in the hospital (Stroke, Recurrent MI, Re-PCI, and Death) in the manual thrombus aspiration group and the control group is 15.8%, 1.4%, respectively. But there were no statistically significant differences. The prevalence of heart failure in the manual thrombus aspiration group and the control group is respectively 38.2%, 33.8%. But there were no statistically significant differences (P=0.583). There may be that all acute myocardial infarction patients recruited in the study come to the cath lab a little bit late somewhat (about 10 hours after chest pain). So, a lot of myocardia were lost. It is easy for patients to have a high risk of heart failure (Tables 6 and 7).

Table 6. *Major cardiovascular events during hospitalization.*

Major cardiovascular events during hospitalization	Both (n=147)	Balloon angioplasty group (n=76)	Thrombus suction group (n=71)	P
	n (%)	n (%)	n (%)	
Major cardiovascular events	13(8.8%)	12(15.8%)	1(1.4%)	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 myocardial infarction	1(0.7%)	1(1.3%)	0(0%)	1**
Coronary re-intervention culprit lesion	1(0.7%)	1(1.3%)	0(0%)	1**
Death	9(6.1%)	8(10.5%)	1(1.4%)	0.034**

Note: *Pearson Chi-Square, **Fisher's Exact Test

Table 7. *Major cardiovascular events after 12 months.*

Major cardiovascular events after 12 months	Both (n=127)	Balloon angioplasty group (n=65)	Thrombus suction group (n=62)	P
	n (%)	n (%)	n (%)	
Major cardiovascular events	23(18.1%)	17(26.2%)	6 (9.8%)	0.137*
Heart failure	53(39.8%)	29(42.0%)	24 (37.5%)	0.594*
Stroke	2(1.6%)	2(3.0%)	0 (0%)	0.497**
Recurrent myocardial infarction	2(1.6%)	2(3.0%)	0 (0%)	1**
Coronary re-intervention culprit lesion	1(0.8%)	1(1.5%)	0 (0%)	1**
Death	18(14.3%)	12(18.5%)	6(9.8%)	0.167**

Note: *Pearson Chi-Square, **Fisher's Exact Test

Discussion

Our study's main findings were that compared to conventional interventions, in the subgroup of patients with a large thrombotic burden, primary PCI procedures combined with manual thrombus aspiration have improved clinical outcomes, including reducing ST by ≥ 50%, improved myocardial perfusion index, and in-hospital mortality.

To compare the safety and efficacy of the two approaches, we compared the fluoro time and the total amount of contrast between the two groups of subjects. The timing of the fluoro time during the intervention reflects the efficacy of manual thrombus aspiration compared to the balloon angioplasty only. The total amount of contrast and serum creatinine after the procedure reflects the renal safety of the two procedures.

The median fluoro time (minutes) of the control group and the manual thrombus aspiration group in our study was 7.6 minutes (4.8-10.4) and 7.6 minutes (5.5-11.1), respectively, with no significant difference between the two groups.

The median contrast (ml) used in our study was 100 ml (90-120) and 100 ml (80-120), respectively, for the control group and the thrombus aspiration group, with no significant difference between the two groups.

The median value of blood creatinine taken within 24 hours after the intervention was 0.9(0.8-1.1) mg/dl and 0.9(0.8-1) mg/dl in the control and thrombolytic groups, respectively, with no statistically significant difference. The results showed no effect on the kidneys between the two approaches in our study.

A decreased elevation of the ST segment on an electrocardiogram indirectly indicates that it is a successful reperfusion. The TAPAS, DEAR-MI study showed that manual thrombus aspiration in patients with ST-elevated acute myocardial infarction reduced ST segment elevation with a statistically significant difference [5,6]. Our results also showed a 50% reduction in the ST segment in the manual thrombus aspiration, much more than in the control group with statistically significant differences respectively (57.7% *vs.* 39.5%, P=0.027).

Similar to the reduction in ST difference on the electrocardiogram, myocardial perfusion index (TMP) improved significantly compared to the non-thrombotic aspiration group in this study. The myocardial perfusion index was associated with a higher mortality rate of ST-elevated acute myocardial infarction patients undergoing emergency coronary artery revascularization. The association of TMP with death rate was studied and approved by Michael Gibson *et al*., in 762 patients with acute myocardial infarction. The results of that study showed that the mortality rate was lowest in the group with TMP=3(2%), average at TMP=2(4%), and highest in the group with TMP group 0 or 1 (6%) [7]. In our

study, the percentage of TMP 3 achieved in the thrombus aspiration group was higher than in the control group, with a statistically significant difference, respectively (80.3% *vs.* 65.8%, P=0.049).

The in-hospital cardiac major events were less considered in the three large TAPAS, TASTE, and TOTAL studies. But in several studies and our study, it was noted in the manual thrombus aspiration studies that focused on subgroups of ST elevated acute myocardial infarction patients with a large thrombotic burden and showed positive outcomes.

In our study, in-hospital mortality in the manual thrombus aspiration group of 1.4% was significantly lower than the control group of 10.5%, with P=0.034. This result is similar to some of the results of recent manual thrombus aspiration studies in ST-elevated myocardial infarction patients with a large thrombotic burden. The registry statistics from Shiraishi J *et al*., on ST elevated myocardial infarction patients with complete occlusion of the culprit artery showed that in-hospital mortality in the manual thrombus aspiration group was 7.4% compared to 12% of the control group, P=0.028 [8]. The study by Ehab Mohamed Elfekky *et al*., also showed that in-hospital mortality in the large thrombotic burden group of patients undergoing primary PCI was 2.7% versus 11.8% of the control group, P=0.02 [9].

In the study, we did not note a difference in the rates of stroke in the two groups.

Conclusion

Although manual thrombosis aspiration should not be routinely performed in emergency primary PCI, it may still be effective in some ST elevated myocardial infarction patients with a large thrombotic burden in the culprit's vessel. Manual aspiration of thrombus on coronary arteries with a large thrombotic burden in patients with ST elevated acute myocardial infarction is a simple method that does not take much time and has less contrast than balloon angioplasty in primary PCI. Nevertheless, it improves hospital major cardiac outcomes, including reducing ST-segment elevation as well as improving myocardial perfusion index (TMP=3) and mortality rate with a statistically significant difference (P<0.05).

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