

Patients' Complications in ST Segment Elevation Myocardial Infarction Managed with Primary Percutaneous Coronary Intervention with and without Thromboaspiration

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ABSTRACT

Introduction: One of the biggest challenges for interventional cardiologist is subsequent distal embolization and disturbance in microvascular perfusion after a Percutaneous Coronary Intervention (PCI). Theoretically, manual thromboaspiration might be a useful way to prevent this complication. According to recent studies, the use of thromboaspiration does not have a significant effect.

Aim: To compare the clinical outcomes of patients managed with Primary PCI (PPCI) with and without thromboaspiration, based on coronary arteries flow and thrombus burden before the procedure.

Materials and Methods: A total of 249 patients who were admitted with ST Segment Elevation Myocardial Infarction (STEMI) to Farshchian Heart Center, Hamadan, Iran, during 2015-2017 were enrolled in our study. Patients were managed with PPCI with and without thromboaspiration and were classified as case and control groups, respectively. In the follow-up course of 30 days, complications including mortality, Major Adverse Cardiovascular Events (MACE) and stroke were evaluated. After collecting data, analysis was done with statistical software

SPSS 18. Chi-square test and independent t-test were used for analysis. All statistical analyses were carried out at 95% confidence level.

Results: A total of 58 and 191 patients were managed with PPCI with and without thromboaspiration (case and control groups respectively). There was no significant difference in the occurrence of primary outcomes including mortality (1.72% vs. 2.62%, p-value=0.697), MACE (0 vs. 0.52%, p-value=0.581) and stroke (1.72% vs. 0.52%, p-value=0.370) in case and control groups respectively. Thrombolysis in Myocardial Infarction (TIMI) grade flow before the procedure was significantly higher in case group (p-value=0.01), but postprocedural TIMI grade flow was the same (p-value=0.450).

Conclusion: One-month clinical complications including mortality, MACE and stroke were similar in both the groups. Despite the lower TIMI grade flow before the procedure in the case group compared to the control group, a similar TIMI grade flow after the procedure was achieved, which indicate the usefulness of thromboaspiration in the patients with lower TIMI grade flow at presentation.

Keywords: Acute coronary syndrome, Angioplasty, Balloon, Coronary artery disease, Myocardial revascularization

INTRODUCTION

PPCI is a routine method of revascularization in the management of patients diagnosed as Acute Myocardial Infarction (AMI) except some situations such as anatomical involvement not suitable for PCI [1], or lack of interventional compliance. Approximately, 600,000 PPCI cases are performed annually in the United States [2]. The pathological mechanisms in STEMI include the disruption and erosion of atherosclerotic plaque with subsequent thrombus formation, which eventually leads to occlusion and necrosis [3].

One of the most important limitations of PPCI is the probability of embolization to the distal part of the coronary artery during the procedure that may deteriorate the microvascular perfusion [4]. Thromboaspiration seems to decrease the rate of distal embolization, improve the perfusion, decrease the thrombus burden, and subsequently reduce the stent deployment complications. Various thromboaspiration devices including manual and mechanical thromboaspiration are used to prevent distal embolization. Mechanical thromboaspiration is associated with higher mortality rate compared to the non-thromboaspiration strategy [5]. Manual thromboaspiration before stenting is a way to decrease the probability of distal embolization and improve the microvascular perfusion [6,7]. Manual thromboaspiration with aspiration catheters has been widely used in large trials with favorable results. Based on previous studies, the use of thrombus aspiration before stenting can

cause better reperfusion, preserve microvascular integrity, and have better clinical outcomes [6,8,9].

TASTE and TOTAL trials which were published recently, showed different results compared to previous studies. These studies revealed non-significant difference in short and long term clinical outcomes between the STEMI patients who were managed with and without thromboaspiration, but there was higher risk of stroke rate in the thromboaspiration group [10-14].

According to these studies, routine thromboaspiration during PPCI is not recommended, but in some cases based on angiographic characteristics such as thrombus burden, thromboaspiration is still efficient. This study tried to clarify this issue and the stroke rate in these patients.

MATERIALS AND METHODS

Study Population

This mixed cohort study was conducted between December 2015 to December 2017 at Farshchian Heart Center, Hamadan, Iran. Study protocol was approved by the local institutional review board and Ethics Committee of the Hamadan University of Medical Sciences by letter number p/16/35/1/775. Informed written consent were taken from all patients before the procedure. We enrolled the patients based on census sampling, which according to inclusion and exclusion criteria were 249 patients.

We included all the patients between 18 to 75-year-old diagnosed as STEMI with suggestive symptoms of AMI, ECG findings showing ST segment elevation ≥ 1 mm in 2 adjacent extremity leads or ≥ 2 mm in 2 adjacent precordial leads or new left bundle branch block with cardiac enzyme rising.

The exclusion criteria were: patients managed with fibrinolytic drugs, pharmacoinvasive strategy (PCI 3-24 hours after taking fibrinolytic therapy) or rescue PCI (PCI following unsuccessful fibrinolytic therapy), patients with chronic kidney disease, patients with Cardiac Resynchronization Therapy (CRT) or Implantable Cardioverter-Defibrillator (ICD), pregnant women and anatomic involvement of coronary arteries which was not suitable for PCI. All patients with symptoms onset within 12 hours and ECG findings suggestive of STEMI were revascularized.

Before conducting the procedure, TIMI grade flow of all patients was specified according to angiographic study. Total 58 and 191 consecutive patients were enrolled as case and control groups, respectively. Decision making for using thromboaspiration was based on interventional cardiologist's opinion. The TIMI grade flow after the procedure was also specified.

TIMI grade flow as a scale showing the blood flow through coronary arteries [15] were as follows:

Grade 0 (no perfusion): Total occlusion, the absence of contrast flow after thrombus

Grade 1 (penetration without perfusion): Partial penetration of contrast beyond the obstruction without complete distal filling

Grade 2 (partial perfusion): Patency with opacification distal to obstruction but accompanying delayed filling or washout time compared to normal

Grade 3 (complete perfusion): Normal flow

Procedure

In the case group, thromboaspiration was used before PPCI, in which after passing the guide wire, thromboaspiration device was crossed over the guide wire. Throughout the procedure, the guiding catheter's tip was fully engaged in order to decrease the risk of systemic embolization and stroke. Aspiration was started at the site proximal to the occlusion. Subsequently, the catheter was pushed through the lesion. Negative pressure was performed throughout the procedure from crossing the lesion until the withdrawal of the

catheter. Thromboaspiration was followed by PPCI in this group. While in the control group, patients were managed with PPCI without thromboaspiration. Medications used before the procedure for both groups were similar and included Aspirin (PO, a loading dose of 325 mg), Heparin (IV injection, 100 IU/kg), and Clopidogrel (PO, a loading dose of 600 mg).

The primary outcome included total mortality; MACE and stroke during 30 days follow-up of patients after discharge. MACE consisted of cardiac death, non-fatal MI and Target Vessel Revascularization (TVR). TVR was defined as reperfusion of ischemic region in the territory of previously revascularized artery.

STATISTICAL ANALYSIS

Comparison of continuous data was performed with independent t-test. Categorical variables expressed as number, percentages and comparison performed with χ^2 test or Fisher-exact test. All p-values were 2 tailed, with statistical significance at <0.05 . SPSS 18 software was used for statistical analysis.

RESULTS

Of the 249 consecutive patients eligible for management with PPCI, 58 (23/29%) and 191 (76.71%) patients were managed with PPCI with and without thromboaspiration, respectively.

Baseline characteristics including BMI, gender, diabetes, hypertension, and hyperlipidemia were comparable in the two groups, except for the age and proportion of smokers, which was significantly higher in the case group and the history of cerebrovascular disease that was lower in the case group (5.2% vs. 16.8%, p-value=0.026) [Table/Fig-1].

The data related to the procedure are shown in [Table/Fig-2]. Drug eluting stents were used for all of the patients. Other stent characteristics including stent brand names, total stent length, and diameter of the stent were similar.

The important point here was TIMI grade flow before and after the procedure in the two groups. Despite the difference in TIMI grade flow before the procedure, (p-value=0.001), the same results were achieved in the two groups in terms of postprocedural TIMI grade flow (p-value=0.450).

As shown in [Table/Fig-3] during one month follow-up, there were 6 (2.4%) cases of mortality including 1 (1.72%) in case and 5 (2.62%) in control group (p-value=0.697). MACE occurred in

Variables	Total		PPCI with thromboaspiration	PPCI without thromboaspiration	p-value
	N (%)				
Age (years)			60.10 \pm 12.32	57.65 \pm 12.27	<0.001
BMI (kg/m ²)	≥ 30	95 (38.2%)	21 (36%)	74 (38.7%)	0.728
	<30	154 (61.8%)	37 (63.8%)	117 (61.3%)	
Gender	Male	194 (77.91%)	44 (75.86%)	150 (78.53%)	0.667
	Female	55 (21.09%)	14 (14.24%)	41 (21.47%)	
Smoking	Never	172 (69.1%)	32 (55.2%)	140 (73.3%)	0.009
	Current user or positive history	77 (30.9%)	26 (44.8%)	51 (26.7%)	
Diabetes	No	188 (75.5%)	41 (70.7%)	147 (77.0%)	0.331
	Yes	61 (24.5%)	17 (29.3%)	44 (23.0%)	
Hypertension	No	178 (71.5%)	43 (74.1%)	135 (70.7%)	0.610
	Yes	71 (28.5%)	15 (25.9%)	56 (29.3%)	
Hyperlipidemia	No	184 (73.9%)	44 (75.9%)	140 (73.3%)	0.697
	Yes	65 (26.1%)	14 (24.1%)	51 (26.7%)	
Previous MI	No	223 (89.6%)	52 (89.7%)	171 (89.5%)	0.978
	Yes	26 (10.4%)	6 (10.3%)	20 (10.5%)	
Previous cerebrovascular disease	No	213 (85.9%)	55 (94.8%)	159 (83.2%)	0.026
	Yes	35 (14.1%)	3 (5.2%)	32 (16.8%)	

[Table/Fig-1]: Characteristics of patients.

Data are presented as mean \pm standard deviation or number (percentage), PPCI: Primary percutaneous coronary intervention, MI: Myocardial infarction, BMI: Body mass index

Variables			Total	PPCI with thromboaspiration	PPCI without thromboaspiration	p-value
			N (%)			
TIMI grade flow	Before procedure	0	181 (72.7%)	50 (86.2%)	131 (68.6%)	<0.001
		1	33 (13.3%)	2 (3.4%)	31 (16.2%)	
		2	7 (2.8%)	4 (6.9%)	3 (1.6%)	
		3	28 (11.2)	2 (3.4%)	26 (13.6%)	
	Post procedure	0	2 (0.8%)	0 (0%)	2 (1%)	0.450
		1	5 (2%)	1 (1.7%)	4 (2.1%)	
		2	26 (10.4%)	9 (15.5%)	17 (8.9%)	
		3	216 (86.7%)	48 (82.8%)	168 (88%)	
PCI access	Femoral	65 (26.10%)	17 (29.31%)	48 (25.13%)	0.473	
	Radial	184 (73.9%)	41 (70.68%)	143 (74.86%)		
Stent brand name	Xience	66 (26.5%)	10 (17.2%)	56 (29.3%)	0.059	
	Resolute	67 (26.9%)	21 (36.2%)	46 (24.1%)		
	Biomatrix	80 (32.12%)	22 (37.9%)	58 (30.4%)		
	Ultimaster	36 (14.45%)	5 (8.6%)	31 (16.2%)		

[Table/Fig-2]: Procedure data.

Data are presented as number (percentage). TIMI: Thrombolysis in Myocardial infarction, PPCI: Primary percutaneous coronary intervention

Variables			Total	PPCI with thromboaspiration	PPCI without thromboaspiration	p-value
			N (%)	N (%)	N (%)	
Mortality	Yes	6 (2.4%)	1 (1.72%)	5 (2.62%)	0.697	
	No	243 (97.6%)	57 (98.28%)	186 (97.38%)		
Major cardiac event	Yes	1 (0.40%)	0 (0%)	1 (0.52%)	0.581	
	No	248 (99.6%)	58 (100%)	190 (99.48%)		
Target vessel revascularization	Yes	23 (9.23%)	6 (10.34%)	17 (8.9%)	0.739	
	No	226 (90.77%)	52 (89.66%)	174 (91.1%)		
Rehospitalization due to reinfarction	Yes	1 (0.4%)	0 (0%)	1 (0.5%)	0.581	
	No	248 (99.6%)	58 (100%)	190 (99.5%)		
Stent thrombosis	Yes	1 (0.4%)	0 (0%)	1 (0.5%)	0.581	
	No	248 (99.6%)	58 (100%)	190 (99.5%)		
Stroke	Yes	2 (0.80%)	1 (1.72%)	1 (0.52%)	0.370	
	No	247 (99.2%)	57 (98.28%)	190 (99.48%)		

[Table/Fig-3]: Outcome and follow-up.

Data are presented as number (percentage). PPCI: Primary percutaneous coronary intervention

1 (0.40%) patient which was in case group (p-value=0.581). Stroke was occurred in two of the patients including 1 (1.72%) in case and 1 (0.52%) in control group (p-value=0.370). One month clinical follow-up showed similar outcomes.

DISCUSSION

According to the results of our study, the use of thromboaspiration along with PPCI had no preference over PPCI alone in 30-day mortality, MACE and stroke. Considering most of the studies which were conducted before 2014, thromboaspiration was a helpful additive procedure to PPCI in patients diagnosed with STEMI and planned to be managed with PPCI [8,9]. One of the most remarkable and large trials was TAPAS that demonstrated better reperfusion and clinical outcome in a 30-day follow-up and a lower risk of mortality and nonfatal reinfarction during the one-year follow-up in groups of people managed with thromboaspiration and PPCI compared to PPCI alone [9]. According to EXPIRA study, thromboaspiration prevents distal thrombus embolization and preserves the microvascular integrity, which eventually leads to decreased infarct size [6]. Based on ACC/AHA 2013 and ESC/EACTS guidelines, manual thromboaspiration is classified as class IIa and IIb, respectively which supports the fact that it is a helpful adjunctive action [16,17].

Moreover, based on a meta-analysis, thromboaspiration results in a decrease in 6-12-month risk of MACE [18]. More recent meta-analyses also showed better myocardial reperfusion and

minimal reduction in mortality despite an increase in the risk of stroke [19,20].

In contrast to what is mentioned above, other studies proved the inefficiency of thromboaspiration as an additional strategy. Based on TASTE trial, routine thromboaspiration with PPCI compared to PPCI alone, made no significant difference in the rate of 30-day mortality, 1-year rate of mortality, stent thrombosis, target vessel revascularization, and rehospitalization due to reinfarction [10,11].

TOTAL trial results showed no significant difference for thromboaspiration strategy with PPCI compared to PPCI alone in 180-day rate of cardiovascular death, recurrent MI, cardiogenic shock, and heart failure but it was associated with the increased risk of stroke in 30-day, 180-day, and 1-year follow-ups (particularly the risk of stroke was higher in 48-h post procedure). In addition, it was mentioned that routine thromboaspiration did not improve TIMI grade flow or microvascular perfusion despite reducing rates of distal embolization [12-14].

Without considering the result of studies that are somewhat contradictory, they have all been shown myocardial perfusion improvement and reduction in distal embolization [21,22].

A recent meta-analysis of available randomised trials around this aspect also showed no significant reduction in the rate of mortality, reinfarction and TVR in long-term follow-ups. Furthermore, they demonstrated the increased rate of stroke [23,24]. A comprehensive meta-analysis of TAPAS, TASTE, and TOTAL trial published in 2017

showed no significant difference in all-cause and cardiovascular mortality but in the high thrombus burden group, a reduced rate of mortality and increased rate of stroke were seen [25].

Moreover, regarding the ACC/AHA/SCAI 2015 and ESC 2017 guidelines, routine thromboaspiration is classified as class III, but as mentioned in the 2017 ESC guideline, in cases of high thrombus burden, using thromboaspiration still is based on the interventional cardiologist opinion, and in cases of opening coronary arteries via guide wire or balloon with large residual thrombus burden, thromboaspiration may be useful [26,27].

Despite the limited number of cases, the results obtained from our study were consistent with the latest guidelines. Two major distinct results were achieved in our study. First, no difference in the risk of stroke was observed between the two groups. The occurrence of stroke within 30 days of post procedure is more related to the adverse effects of the procedure itself. However, late-onset strokes are probably more attributed to procedure-independent factors. Thus, in order to compare the efficacy of thromboaspiration and non-thromboaspiration strategies, the results achieved in a 30-day follow-up are more reliable. Our method of thrombus aspiration procedure is considered the reason for this result. In order to use manual thromboaspiration for our patients, first, we passed the guide wire through the target lesion. The thromboaspiration device crossed over the guide wire. Through the whole time of the procedure, guiding catheter's tip was fully engaged. That is, the point thought to decrease the rate of embolization to blood vessels and hence, lowering the rate of stroke. The second difference was, lower TIMI grade flow before the procedure in case group which proved the usefulness of thromboaspiration in patients with lower TIMI grade flow (i.e., high thrombus burden). According to our results, despite the significantly lower TIMI grade flow before the procedure in the case group, the same results were achieved based on TIMI grade flow after the procedure. The later one was inconsistent with the data achieved from the subgroup analysis of TASTE and TOTAL trials [10,12]. In those studies, a subgroup was formed based on thrombus burden. Finally, despite the higher thrombus burden, the same results were seen, which meant that even in cases of higher thrombus burden, routine thromboaspiration was not recommended.

STRENGTH AND LIMITATION

The main limitation of this study was the small sample size. On the other hand, focusing on the impact of thrombus burden and the efficacy of thromboaspiration and more precious look for the relationship between stroke and the procedure itself was the strength of our study.

The present results were collected in a STEMI setting with major resources, including trained physicians and nurses; therefore, the results may not be generalizable to other regions.

CONCLUSION

Our study showed no advantage for thromboaspiration added to PPCI, based on the clinical outcomes of a 30-day follow-up, except for patients with lower TIMI grade flow before the procedure. Therefore, it seems thromboaspiration still can be useful in the management for selected cases of high thrombus burden planned to be managed with PPCI. We recommend interventional cardiologists' consideration in these cases. However, further studies with larger sample sizes are needed to check the efficacy of this strategy.

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