The role of manual thrombectomy in cardiovascular outcome among patients with total cutoff vessel myocardial infarction undergoing primary percutaneous coronary intervention

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Original Article

Abstract

BACKGROUND: The applicability of manual aspiration thrombectomy in patients with ST-segment elevation myocardial infarction (STEMI) has been a challenging issue. This study aimed to compare the impact of additive manual thrombectomy on patients with myocardial infarction (MI) and total cutoff vessel with standard primary percutaneous coronary intervention (PPCI) with bailout thrombectomy.

METHODS: In this case-control study, 181 patients with acute STEMI were enrolled who referred to Chamran Hospital (Isfahan, Iran) between August to December 2014. The culprit lesion was treated with routine PPCI with bailout thrombectomy (111 patients) and routine primary thrombectomy then percutaneous coronary intervention [(PCI), 70 patients] during hospitalization and one month after discharge. Patients in the case group received manual thrombectomy before PPCI and patients in the control group received standard PPCI with bailout thrombectomy. Patients were followed during the study procedure, post-hospitalization and one month later for cardiovascular outcomes including death, recurrent MI, stroke, major bleeding, post PCI arrhythmia, no reflow, thrombolysis in myocardial infarction (TIMI)-flow and TIMI myocardial blush grade (TMBG), which were assessed and recorded.

RESULTS: Myocardial perfusion and angiographic outcomes had no significant differences in the two groups ($P = 0.730$). There was also no significant difference in no reflow prevalence between the two groups ($P > 0.990$). There were no significant differences for primary outcomes such as death, stroke, major bleeding and arrhythmia between the two groups ($P < 0.050$). In particular, outcomes were the same for both groups during hospitalization period and one month after discharge. Mortality rate during hospitalization was 5.7% for the control group and 4.5% for the case group ($P = 0.730$). However, one-month mortality rate was quite similar in both groups.

CONCLUSION: This study showed there is no significant difference in cardiovascular outcomes such as death, stroke, bleeding, arrhythmia, target vessel revascularization, and distal embolization during hospitalization and one month after discharge in patients with acute MI and total cutoff of the involved vessel, who underwent PPCI with and without primary Export® aspiration catheter direct thrombosuction.

Keywords: Cardiovascular Diseases, Myocardial Infarction, Percutaneous Coronary Intervention, Thrombectomy

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Introduction

Primary percutaneous coronary intervention (PPCI) had been known as one of the most effective therapeutic procedures for patients with ST-segment elevation myocardial infarction (STEMI) for restoring coronary flow to a normal thrombolysis in myocardial infarction (MI).[1,2] Poor myocardial reperfusion in some patients with STEMI causes large infarct size

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and worse clinical outcomes.[1-4] Clinicians focused their studies on distal embolization as a major determinant of poor reperfusion and clinical outcome after primary angioplasty.[1-6] Manual thrombectomy was suggested as a useful procedure for preventing distal embolization and increasing reperfusion during PPCI.[2,5]

However, the impact of manual thrombectomy on cardiovascular events compared to target vessel revascularization (TVR) is not clear. Some studies have shown that manual thrombectomy with percutaneous coronary intervention (PCI) in STEMI patients has several benefits such as improvement of reperfusion microcirculation, ST-segment resolution (STR) and reduction in mortality.[1-3,6-10] Manual thrombectomy had significant impacts on mortality in patients with STEMI due to improved myocardial perfusion and reduced distal embolization.[5,11] Recent meta-analysis has shown that overall, thrombectomy with different technique did not reduce one-month mortality rate among STEMI patients.[12] Other studies showed that routine use of manual aspiration compared with PCI alone reduced the incidence of the primary outcome of impaired microvascular perfusion and reduced mortality by 52% annually,[6,13] whereas other studies on TVR in PPCI with manual thrombectomy showed no statistically significant reduction in cardiovascular mortality compared to without manual therapy.[6,11,14] Previous studies were performed on patients with MI regardless of whether the infarcted vessel is total cutoff or not.

Complete obstruction of the infarcted vessel may have impacts on the thrombectomy results as well as its prognosis and cardiovascular disease events. So this study is the first study designed to assess and directly compare the frequency of cardiovascular outcomes and major adverse cardiac events (MACE) which consist of stroke, bleeding, MI, TVR among patients with acute MI and total occlusion of the involved artery, who underwent PPCI with and without primary Export® aspiration catheter direct thrombosuction.[4,6,10,11]

Materials and Methods

This study was designed as a case-control study in 181 patients with acute MI who referred to Chamran Hospital, Isfahan, Iran, between August 2014 and December 2014. The protocol was approved in research ethics committee of Isfahan University of Medical Sciences and written informed consent was obtained from all study participants. Inclusion criteria were having history of acute MI with ST-segment elevation in the past 24 hours with complete occlusion of infarcted artery evident in angiography. Exclusion criteria were subjects with cardiogenic shock, left main involvement, history or evidence of chronic occlusions, disturbance of consciousness, non-complete vessel occlusion, achievement of thrombolysis in myocardial infarction (TIMI) 3 after wire passage and death or other major cardiovascular event before starting the procedure. Patients were divided into two groups based on clinical condition and physician decision. In the first group (case group) PCI with manual thrombectomy was done and in the second group only PPCI was done. After enrolment of patients, a trained nurse measured weight and height (Seca, Germany). Blood pressure was measured by manual sphygmomanometer in sitting position with standard method. A questionnaire containing history of cardiovascular risk factors was filled out. In the case group, manual thrombectomy was done before PPCI and patients in the control group received standard PPCI with bailout thrombectomy. Patients were followed during the study procedure, post hospitalization and one month later for cardiovascular outcomes including death, recurrent MI, stroke, major bleeding, post PCI arrhythmia, no reflow, TIMI-flow and TIMI myocardial blush grade (TMBG), which were assessed and recorded by two cardiologists blind to study. In each visit ejection fraction was measured and recorded.

After one month, all study subjects were contacted and asked to attend the clinic visit. All cardiovascular outcomes such as recurrent MI, stroke, major bleeding, post PCI arrhythmia, no reflow, and TIMI-flow were assessed and the same cardiologist measured TMBG. Major bleeding was defined as any bleeding requiring hospitalization and/or causing 0.2 g/dl decrease in hemoglobin level and/or requiring blood transfusion that was not a hemorrhagic stroke. Hemorrhagic stroke was defined as a focal neurologic deficit of sudden onset caused by bleeding, diagnosed by a neurologist, and evident in computed tomography (CT) scan or magnetic resonance imaging (MRI), which lasted 24 hours.

TIMI-flow determination of angiographic blood flow (TIMI grade), arrhythmia, no reflow and TMBG were determined during angiography.[14]

All patients received oral aspirin (325 mg) and clopidogrel (600 mg) at the time of STEMI diagnosis. In the catheterization laboratory, intravenous boluses of unfractionated heparin (60 U/kg) and integrilin (10 mg) were administered. The PCI was performed with standard technique, with the femoral approach as the first choice. If TIMI 3 was achieved immediately after wire passage, the patient was excluded from the study. The thrombectomy was performed with Export® aspiration catheters (6 or 7 French). In the case group,

manual thrombectomy was performed first, and then the PCI was continued by balloon or stent. In the control group, firstly, primary PCI was begun and completed and thrombectomy was not performed for those who had large thrombus during procedure.

After the lesion was crossed with a guidewire, the thrombectomy catheter was inserted just proximal to the culprit lesion and was slowly pushed across the lesion for at least two passages while aspiration was done continually via thrombectomy catheter. Additional passages were performed until no further reduction in thrombus load could be obtained. If the operator was unable to cross the lesion with the thrombectomy catheter, predilatation was firstly performed with a small-diameter balloon and followed by other thrombectomy attempts. It was recommended that the guiding catheter be fully engaged with the coronary ostium during removal of the thrombectomy catheter in order to avoid embolizing thrombus to the systemic vasculature. After thrombectomy, the guiding catheter was aspirated to ensure removal of air or thrombus.[3,15] The PCI procedure was performed after thrombus aspiration was completed. Use of embolic protection devices was not allowed.

In control group we predilated the lesion and reevaluated the distal flow if the distal vessel was not appearing, and thrombectomy was done with the size of thrombus as in the case group before stenting.

Study data were entered into the SPSS software (version 15.0, SPSS Inc., Chicago, IL, USA) for statistical analysis. Qualitative and quantitative variables were presented with frequency/percentage and mean ± standard deviation, respectively. Study variables were compared between case and control groups with Student's independent t-test and chi-square tests for quantitative and qualitative variables, respectively. Logistic regression analysis was performed. All P-values less than 0.05 were considered as significant.

Results

Patient characteristics: A total of 188 patients were recruited and five patients were excluded due to TIMI 3 flow immediately after wire insertion. Furthermore, two patients were excluded due to death from perforation and stroke before initiation of the procedures. Finally, after exclusion 70 patients remained in the control group who received routine primary thrombectomy plus PCI and 111 patients remained in the case group and received PPCI and bailout thrombectomy. Table 1 shows the characteristics of the patients. Two groups were comparable except for smoking status that was higher in the control group.

Table 1. Characteristics of the patients at baseline

Characteristic	Primary thrombectomy (n = 70)	PPCI with bailout thrombectomy (n = 111)	P
Age (year)	58.5 ± 12.1	61.4 ± 14.0	0.140
Sex (male)	56 (80.0)	92 (82.9)	0.690
Medical history [n (%)]			
Diabetes mellitus	24 (34.5)	33 (29.7)	0.620
Hypertension	22 (31.9)	45 (40.9)	0.260
Smoking	22 (32.8)	49 (44.5)	0.150
CVD	16 (19.3)	24 (25.0)	0.370
Receiving thrombolytic therapy	13 (18.6)	11 (9.9)	0.110
Location of MI [n (%)]			0.110
Inferior	29 (41.4)	49 (44.1)	
Anterior	41 (58.6)	54 (48.6)	
Lateral	0 (0.0)	7 (6.3)	
Posterior	0 (0.0)	1 (0.9)	
Number of vessels involved [n (%)]			0.350
1	36 (51.4)	45 (40.5)	
2	23 (32.9)	45 (40.5)	
3	11 (15.7)	21 (18.9)	
Vessels involved [n (%)]			0.330
LAD	41 (58.6)	56 (50.5)	
CX	3 (4.3)	12 (10.8)	
RCA	26 (37.1)	42 (37.8)	
Other	0 (0.0)	1 (0.9)	
Ejection fraction < 30% [n (%)]	21 (30.0)	42 (37.8)	0.330

PPCI: Primary percutaneous coronary intervention; CVD: Cardiovascular disease; MI: Myocardial infarction; LAD: Left anterior descending artery; CX: Circumflex artery; RCA: Right coronary artery

Table 2. Study outcomes based on primary thrombectomy or primary percutaneous coronary intervention (PPCI) with bailout thrombectomy

Outcome	Primary thrombectomy (n = 70)	PPCI with bailout thrombectomy (n = 111)	P
Post primary thrombectomy TIMI flow grade			-
0	5 (7.1)	-	
1	10 (14.3)	-	
2	18 (25.7)	-	
3	37 (52.9)	-	
End TMBG [n (%)]			0.650
0	3 (4.3)	4 (3.6)	
1	8 (11.4)	20 (18.0)	
2	23 (32.9)	37 (33.3)	
3	36 (51.4)	50 (45.0)	
End TIMI flow grade [n (%)]			0.730
0	1 (1.4)	2 (1.8)	
1	3 (4.3)	5 (4.5)	
2	10 (14.3)	23 (20.7)	
3	56 (80.0)	81 (73.0)	
No reflow	6 (8.6)	11 (9.9)	> 0.990

PPCI: Primary percutaneous coronary intervention; TIMI: Thrombolysis in myocardial infarction; TMBG: TIMI myocardial blush grade

Myocardial perfusion and angiographic outcomes: There were no significant differences between the two groups regarding myocardial perfusion and angiographic outcomes such as death, stroke, bleeding, arrhythmia, TVR, and distal embolization. There was also no significant difference in no reflow prevalence between the two groups (Table 2).

Efficacy and safety: There were no significant differences for primary outcomes between the two groups. In particular, outcomes were the same for both groups during hospitalization period and one month after discharge. Mortality rate during hospitalization was 5.7% for the control group and 4.5% for the case group (P = 0.730). However, one-month mortality rate was quite similar in both groups (Table 3).

Results of logistic regression analysis: After entering demographic data into the model (age and sex), and after adjusting for known cardiovascular risk factors such as hypertension, smoking and number of involved vessels, major cardiac events were not associated with the success of manual thrombectomy during hospital stay and one month after PPCI (Tables 4 and 5).

Table 3. Association of major cardiac events (MACE) in subjects who underwent primary thrombectomy or primary percutaneous coronary intervention (PPCI) with bailout thrombectomy

Outcome	Thrombectomy (n = 70)	PPCI (n = 11)	P
During hospitalization [n (%)]			
Death	4 (5.7)	5 (4.5)	0.730
Stroke	0 (0.0)	2 (1.8)	0.520
Bleeding	2 (2.9)	3 (2.7)	> 0.990
Arrhythmia	3 (4.3)	5 (4.5)	> 0.990
TVR	0 (0.0)	0 (0.0)	-
Distal embolization	8 (11.4)	14 (12.6)	0.490
One month after discharge [n (%)]			
Death	1 (1.4)	1 (0.9)	> 0.990
Stroke	1 (1.4)	0 (0.0)	0.380
Bleeding	2 (2.9)	0 (0.0)	0.140
Arrhythmia	0 (0.0)	2 (1.8)	0.520
TVR	0 (0.0)	2 (1.8)	0.520
Distal embolization	0 (0.0)	0 (0.0)	-

PPCI: Primary percutaneous coronary intervention; TVR: Target vessel revascularization

Table 4. Odds of major cardiac events (MACE) during hospital stay in patients who underwent primary thrombectomy

Model	Odds ratio	95% CI	P
Crude Model	0.96	0.44-2.09	0.925
Adjusted Model 1	0.92	0.43-2.10	0.512
Adjusted Model 2	0.82	0.36-1.88	0.640

Model 1: Adjusted for age and sex; Model 2: Adjusted for age, sex, diabetes mellitus, hypertension, smoking and number of vessels; CI: Confidence interval

Discussion

This study showed there are no significant differences in cardiovascular outcomes such as death stroke, bleeding, arrhythmia, TVR, distal embolization during hospitalization and one month after discharge in patients with acute MI and total cutoff of the involved vessel, who underwent PPCI with and without primary Export® aspiration catheter direct thrombosuction. In the control group, patients received manual thrombectomy followed by PPCI with standard protocol and the case group received PPCI with bailout thrombectomy as needed when large thrombus was seen after balloon dilatation. Study findings suggest that major clinical outcomes such as stroke and major bleeding after PPCI did not change irrespective of adjunctive routine primary thrombectomy. The outcomes were similar within hospitalization period and one month after discharge. Furthermore, adding manual thrombectomy to the PCI did not significantly improve participants' outcomes. Although normal flow after PPCI is usually restored in epicardial vessels, in most patients, myocardial perfusion is not satisfactory due to distal embolization[1].

Table 5. Odds of major cardiac events (MACE) one month after primary thrombectomy in patients

Model	Odds ratio	95% CI	P
Crude Model	0.83	0.18-3.84	0.817
Adjusted Model 1	0.67	0.13-3.31	0.627
Adjusted Model 2	0.39	0.06-2.56	0.325

Model 1: Adjusted for age and sex; Model 2: Adjusted for age, sex, diabetes mellitus, hypertension, smoking and number of vessels; CI: Confidence interval

Therefore, a number of devices have been developed to reduce distal embolization. Several studies have been performed for assessing the impact of thrombectomy on PPCI outcomes and some of them had similar findings to our study.[8,16-28] Previous meta-analysis had similar results to our study and confirmed our findings.[1,4,11,29]

Generally, it is claimed that manual procedures are superior to mechanical procedures with respect to mortality, and markers of myocardial perfusion and mechanical procedures are recommended for management of patients who have heavy thrombus burden.[1,15] In a recent meta-analysis, Tamhane et al. reported that manual devices improved myocardial perfusion markers, where there was not a significant difference in one-month mortality between conventional PCI and PCI with thrombectomy.[30] Investigators reported that the risk of stroke increased in thrombectomy group. In contrast, we observed no difference in stroke risk; however, an insignificant reduction in myocardial perfusion markers was observed in thrombectomy group in our study. In another meta-analysis, De Luca et al. reported a significant increase in stroke risk in thrombectomy group and no differences in one-month mortality rate.[4] Another meta-analysis showed significant reductions in cardiac perfusion markers as well as mortality rate in STEMI patients who underwent both PPCI and adjunctive thrombectomy.[1] While analysis by Deng et al. showed no statistically significant differences in long-term mortality and reinfarction,[11] short-term reinfarction and long-term MACEs were significantly lower in thrombectomy group. The present study showed no significant differences between the study groups with respect to either mortality rate or cardiac perfusion markers. Subjects we considered here were total cutoff patients and the results provided new information on this group of patients. In total cutoff, distal part of vessel is not visible and thrombus burden is indistinguishable. We also compared all patients in whom thrombectomy was used (as routine primary or secondary during procedure) with patients in whom no thrombectomy was used according to above mentioned outcomes and observed no differences. Manual aspiration thrombectomy was not identified to result in notable benefits in PPCI patients. Nonetheless, the relatively short follow up period is a limitation of our study and extending this period could provide more information on long-term effects of both procedures in these patients. Use of thrombectomy remains challenging in STEMI, especially total cutoff patients and further research with larger sample sizes and longer follow-ups are warranted to give clear advice on medical practice in this regard.

For achieving accurate and interpretable results, we had to exclude some high-risk patients with cardiogenic shock. Large randomized trials are

needed for covering all patients. Although thrombosuction did not have benefit for patients, it can help operators to better visualize distal part of the artery and guide them for more precise decisions.

Our study also has limitations. First, our study is limited to a small sample size, and only applies to patients with STEMI who received PPCI. In addition, in this study, patients were followed for one month and in other similar studies, participants were followed for one year. It seems that some differences between findings of these studies and our study might be due to our short follow-up time. Moreover, most of the similar studies were performed on patients at the early hours of MI and with loose clots which are easily fragmented.

Conclusion

Findings of our study showed that adjunctive thrombectomy after PPCI did not have significant benefits to reduce cardiovascular outcomes in patients with STEMI and total cutoff culprit vessel.

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Conflict of Interests

Authors have no conflict of interests.

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