

ORIGINAL ARTICLE

Comparison of Angiographic and in Hospital Outcomes of Thrombuster Versus Pre Ballooning in Primary Percutaneous Coronary InterventionMUHAMMAD ABBAS KHAN¹, SAJJAD ALI¹, MUHAMMAD YOUSAF², INAM-U-LLAH³, MAHMOOD UL HASSAN⁴¹Fellow Interventional Cardiology, Hayatabad Medical Complex, Peshawar, Pakistan²Department of Biochemistry, Bahauddin Zakariya University, 60000, Multan, Pakistan³Department of Food Science, The University of Haripur, KPK, Pakistan⁴Professor & Head of Interventional Cardiology Dept, Hayatabad Medical Complex, Peshawar, PakistanCorresponding author: Sajjad Ali, Email: drsajjad944@yahoo.com**ABSTRACT**

Introduction: South Asian communities vary from western cultures in terms of their genetic make-up, culture, and predisposition to develop coronary artery disease (CAD). Percutaneous coronary intervention (PCI) has shown remarkable effectiveness over the last three decades. To decrease hospital outcomes, thrombus aspiration and pre ballooning are often employed during angiography.

Objectives: To evaluate the angiographic and hospital results between PCI using a thrombuster and PCI using pre-ballooning.

Methodology: This research was conducted at Hayatabad Medical Complex, Peshawar from March 2022 to September 2022. 188 patients who came in for primary PCI at the catheterization lab were included and divided into two groups: the “thrombuster group (n=96)” and the “balloon group (n=92)”. In the thrombuster group, manual thrombus aspiration was carried out with the use of a thrombuster, whereas in the balloon group, patients had primary PCI with customary pre-dilatation using a balloon and had their TIMI flow evaluated and graded again. Throughout their hospital stays, all patients were monitored, and study outcomes, such as death and post-procedure problems, were noted. The statistical study made use of SPSS (v.25), and p value less than 0.05 was established as the threshold for significant.

Results: 54 participants (26.72%) were women and 134 (71.72%) were men. A statistical study reveals a significant relationship ($p=0.027$) between gender. With a larger percentage of male patients (36.70%), the balloon group's demographics (n=92; 48.93%) differed from those of the thrombuster group (n=96; 51.06%). In balloon groups, a greater mean age (56.89 10.3) was discovered. With the exception of smoking, all clinical risk factors were greater in balloon groups than in thrombuster patients [17 (9.04%) vs. 12 (6.38%); $p=0.007$]. When compared to the balloon group (7/92), the Thrombuster groups' in-hospital mortality rate was much lower (2/96). Overall complications were also substantially greater with balloon than with thrombuster.

Conclusion: Thrombus aspiration rather than ballooning should be performed using a large lumen guiding catheter in a deep-seated position.

Keywords: angiography, coronary artery disease, thromboses, ballooning, angiography

INTRODUCTION

More than half of the world's population is Asian, and South Asian countries are home to more than a quarter of the population of the developing world.^{1,2} South Asian communities have a greater prevalence of coronary artery disease (CAD) and have distinct genetic profiles and lifestyles compared to western populations.³ Effective CAD prevention in this group is essential for reducing the worldwide disease burden. In the western population, Prevention and treatment of risk factors for coronary artery disease, such as hypertension, hypercholesterolemia, diabetes etc. have shown to be effectual preventative methods.⁴ Due to urbanisation and globalisation of eating behaviour, the south Asian population has seen a change in their food habits and lifestyle during the last two decades.⁵⁻⁷

According to the World Health Organization (WHO), cardiovascular diseases (CVD) cause about 17.8 million deaths annually worldwide, with more than 75 percent of these fatalities occurring in poorer nations.² CADs are considered a disease of old age; nonetheless, the frequency of CAD in the elder age group is increasing.^{8,9} According to a local study, growing BMI is the leading CVD risk factor among patients under the age of 45, while smoking ranks second.¹⁰ For smokers, a paradoxical phenomenon of good outcomes after acute myocardial infarction (AMI) was discovered. Later research linked this pattern to the adolescent age and less severe illness of smokers.^{11,12} It was discovered that smokers get ST-elevation myocardial infarction (STEMI) about ten years sooner than nonsmokers, and that smokers had a greater sex- and age-adjusted one-year death rate.¹³

Thrombus is a characteristic component of dynamic, unstable atherosclerotic plaques that are often seen in individuals with acute coronary syndromes.¹⁴ PCI has gained significant success rates over the last three decades, with the addition of more complicated target lesions.¹⁵ Nevertheless, thrombus continues to be a severe barrier to revascularization, despite these remarkable advancements. Thrombuster has a significant effect on

the effectiveness of main and liberate treatments. The best management of thrombotic lesions remains obscure and contentious. Still thrombus aspiration is an efficient technique for achieving good reperfusion during primary angioplasty. Patients who had primary percutaneous transluminal coronary angioplasty (PTCA) either with or without thrombus aspiration and suffered an acute STEMI were assessed.

MATERIALS AND METHODS

This research was conducted at Hayatabad Medical Complex, Peshawar from March 2022 to September 2022. ST-segment elevation myocardial infarction (STEMI) patients presenting consecutively for primary PCI with the diagnosis of STEMI were recruited. Les chest pain onset to primary PCI times for each patient were shorter than 12 hours. All patients exhibited angiographic evidence of TIMI 0 flow prior to the operation (total occlusion). Patients who refused permission and those who had previously had any cardiac intervention or surgery were excluded. According to the fourth universal definition of myocardial infarction, STEMI was diagnosed. As “thrombuster group” and “balloon group,” two separate cohorts of almost identical patient numbers were recruited. In the thrombuster group, manual thrombus aspiration was conducted using a thrombuster, while patients in the balloon group had primary PCI with traditional pre-dilatation using a balloon. The decision to employ or not utilise an export catheter was left to the discretion of the operators. Before PCI, patients received aspirin (325 mg loading dosage), heparin (6000 IU), clopidogrel (600 mg), and atorvastatin (80 mg). TIMI flow was reviewed and rated after PCI. At presentation and 90 minutes after PCI, a 12-lead ECG was obtained, and the ST segments on the postprocedural EKG were matched with those who attended the session.

Primary percutaneous coronary intervention entails conducting a coronary angiography to identify the offending artery, crossing the lesion with coronary wire, and then doing either manual thrombus aspiration or pre-balloon dilation. Then, a

coronary stent was inserted, followed by dilatation with an NC balloon.

Study outcomes, including death and post-procedure problems, were tracked for all patients during their hospitalisation. Complications after the surgery included no-reflow, contrast-induced nephropathy (CIN), and arrhythmias. During the operation, no reflow/slow flow was characterised as the TIMI flow of 1-III. CIN was defined as a 25% or 0.5 ng/dL rise in serum creatinine level 48-72 hours post-procedure, relative to baseline. During the post-procedure hospital stay, ventricular tachycardia (VT) and ventricular fibrillation (V-Fib) occurred as arrhythmias.

The research was examined and approved by the institution's ethical review committee. Regarding the patient's involvement in the research and release of anonymised forms of gathered data, verbal informed permission was obtained. All of the investigations conducted during this research were part of standard patient care.

The statistical evaluation was conducted using SPSS Version 25.0 software. Using a chi-square test, the significance of observed differences between the two techniques was determined. A probability value of less than 0.05 was deemed statistically significant.

The limitation of the research is that thrombus aspiration was conducted freely by the operator, which may have resulted in patient selection bias.

RESULTS

A total of 188 patients were recruited into two groups: the thrombuster group and the balloon group, with 134 (71.72%) men and 54 (28.72%) females. The gender relationship is statistically significant (p=0.027), according to an investigation. The demographic composition of the balloon group (n=92; 48.93%) differed from that of the thrombuster group (n=96; 51.06%), with a greater number of male patients (36.70%) and an older mean age (56.89 ± 10.3) in the balloon group. Similarly, there were significantly more smokers in the thrombuster group than in the balloon group (p=0.007). No significant correlation was identified in the Killip class (p=0.186) since both groups had comparable remaining features, such as Killip class at presentation, presentation and procedure time, risk profile, and kind of MI. Table 1 compares the demographic and clinical features of two different research groups.

Table 1: Comparison of demographic and clinical characteristics of two study groups

Characteristics	Total	Group		P-value
		Thrombuster	Balloon	
Total (N)	188	96 (51.06%)	92 (48.93%)	-
Gender				
Male	134 (71.72%)	69 (36.70%)	65 (34.57%)	0.027*
Female	54 (28.72%)	22 (11.70%)	32 (17.02%)	
Age (years)	58.37 ± 11.2	51.68 ± 13.8	56.89 ± 10.3	0.022*
≤ 65 years	125 (66.48%)	71 (37.76%)	54 (28.72%)	0.062
> 65 years	63 (33.51%)	26 (13.82%)	37 (19.68%)	
Killip Class				
I	106 (56.38%)	51 (27.12%)	55 (29.25%)	
II	47 (25%)	27 (14.36%)	20 (10.63%)	0.186
III	22 (11.70%)	8 (4.25%)	14 (7.44%)	
IV	13 (6.91%)	5 (2.65%)	8 (4.25%)	
Risk profile				
Hypertension	118 (62.76%)	53 (28.19%)	65 (34.57%)	0.473
Diabetes mellitus	54 (28.72%)	22 (11.70%)	32 (17.02%)	0.556
Smoking	29 (15.42%)	17 (9.04%)	12 (6.38%)	0.005*
Family history of IHD	6 (3.19%)	2 (1.06%)	5 (2.65%)	0.262
Chronic kidney disease	2 (1.06%)	0	2 (1.06%)	0.38
Type of myocardial infarction				
AWMI	82 (43.61%)	49 (26.06%)	33 (17.55%)	
IWMI	41 (21.80%)	20 (10.63%)	21 (11.17%)	
IPWMI	23 (12.23%)	9 (4.78%)	14 (7.44%)	0.011*
IWMI with RV	35 (18.61%)	14 (7.44%)	21 (11.17%)	
LWMI	7 (3.72%)	2 (1.06%)	5 (2.65%)	
Number of vessels involved				
Single vessel disease	81 (43.08%)	42 (22.34%)	39 (20.74%)	
Two vessel disease	38 (20.21%)	16 (8.5%)	22 (11.70%)	0.881
Three vessel disease	69 (36.70%)	35 (18.61%)	34 (18.08%)	

(*significant at 5%; IHD = ischemic heart diseases, AWMI = anterior wall myocardial infarction, IWMI = inferior wall myocardial infarction, IPWMI = inferoposterior wall myocardial infarction, RV = right ventricular, LWMI = lateral wall myocardial infarction)

The effectiveness of thrombus aspiration and stenting was compared to that of standard PCI without thrombus aspiration. Thrombus aspiration was associated with improved outcomes for the main objective, thrombolysis in myocardial infarction (TIMI) flow grade. Table 2 demonstrates a statistically noteworthy (P value 0.01) difference in TIMI flow, with TIMI flow of 3 after PCI occurring in 62 participants (32.97%) in the thrombus aspiration group and 72 participants (38.29%) in the traditional PCI group (figure 1). There were no statistically significant differences between the two groups with regard to secondary endpoints such as recurrent angina, reinfarction, heart failure, substantial bleeding, debilitating stroke, or death.

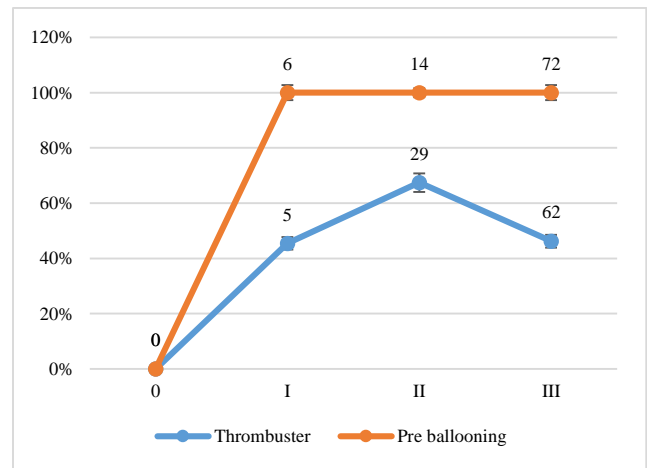


Figure 1: TIMI flow in Thrombuster vs pre ballooning in primary percutaneous coronary intervention

Table 2: Comparison of post-procedure TIMI flow in Thrombuster and pre ballooning in primary percutaneous coronary intervention

Post-procedure TIMI flow	Thrombuster (n)	%	Pre ballooning (n)	%	Total (n)	P-value
I	5	2.65	6	3.19	11	0.001
II	29	15.42	14	7.44	43	
III	62	32.97	72	38.29	134	
Total	96	51.06	92	48.93	188	

Both the traditional Pre-balloon dilatation group and the thrombus aspiration group saw no significant hospital outcomes (p values > 0.05). The in-hospital mortality rate in the Thrombuster groups (2/96) was lower than in the balloon groups (7/92), as shown in Table 3. With regard to overall consequences, reinfarction (6/96 vs 7/92, p=0.42), major bleeding (2/96 vs 5/92, p=0.29, recurrent angina pectoris (11/96 vs 15/92, p=0.32 and heart failure (16/96 vs 21/92, p=0.28) were all substantially more common with balloon than thrombuster. After a mean follow-up of 4 days, comparisons of the two research groups' in-hospital outcomes and complications did not reveal statistically significant differences in major cardiac events between the two groups (Table 2).

Table 3: Major hospital outcomes in the thrombus aspiration group and conventional Pre-balloon dilatation group

Events	Thrombuster group (n = 96)	Pre-balloon dilatation group (n = 92)	P-value
Reinfarction	6	7	0.42
Major bleeding	2	5	0.29
Recurrent angina pectoris	11	15	0.32
Heart failure	16	21	0.28
Death	2	3	0.41

DISCUSSION

Theoretical analysis and preliminary clinical data showed that thrombus aspiration during primary PCI for patients with high thrombus load might improve microvascular perfusion and decrease distal embolization.¹⁶⁻¹⁸ However, the temporal trend analysis revealed a more than 50% drop in manual thrombus aspiration during primary PCI since 2011 with less than 5% usage by mid-year 2016. This was in response to the publishing of unfavorable studies about the regular use of thrombus aspiration.¹⁹ Although the study found no therapeutic advantage of regular thrombus aspiration in terms of improving objective clinical endpoints, some positive results were shown in subgroup analyses of patients with significant thrombus load.²⁰

According to the research protocol, thrombus aspiration may have advantages and enhance primary outcomes in patients who had primary PCI and had TIMI 0 flow after a coronary wire had crossed the lesion. Similar to the findings of Kumar et al.¹⁹ the results of this investigation support thrombus aspiration over pre dilatation using a balloon catheter. In compared to the balloon pre dilatation arm, manual thrombus aspiration significantly reduced in-hospital mortality and comorbidities such slow/no reflow, contrast-induced nephropathy, and arrhythmias. Furthermore, if the export time was less than six hours, the results were better.

Due to the disparities in clinical results, presentation, and risk profile, CAD in young patients manifests in entirely distinct ways. Due to its increasing risk factors, such as smoking, diabetes, and sedentary lifestyles, CAD is no longer only an old age illness. Instead, it is becoming more common among the young population.⁸ In the present study, all clinical risk factors—17 (9.04%) vs. 12 (6.38%); $p=0.007$ —were greater in the balloon groups than in the thrombuster patients, with the exception of smoking.

Overall in-hospital mortality in this trial was 5/188 patients (2/96 in the balloon group and 3/92 in the thrombuster group). Mortality was greater in the balloon group than in the thrombuster group, however, and this group showed a negative correlation with the timing of predilatation use. Patients who attained TIMI flow I [5 (2.65%) vs 6 (3.19%)], II [29 (15.42%) vs 14 (7.44%)], and III [62 (32.97%) vs 72 (38.29%)] had significantly lower rates of overall mortality during the index hospitalisation, with a p -value of $P<0.001$. A study by Kumar et al.¹⁹ using TIMI 0 flow thrombectomy (7.3%) and a balloon (7.5%) of patients demonstrated a superior result in the thrombectomy group. In terms of 30-day mortality, adjunctive manual thrombectomy devices were significantly linked with benefits [1.7 vs. 3.1%, OR (95% CI)].²¹ However, there hasn't been a recorded research done on individuals who had TIMI 0 flow after a coronary wire crossed the lesion.

CONCLUSION

In comparison to the use of a balloon catheter, the use of a thrombuster in a limited group of patients receiving primary percutaneous coronary intervention for complete occlusion leads in a much lower complication rate and comparatively superior mortality benefits. Patients with acute myocardial infarction having primary angioplasty have a greater death rate when PCI is unsuccessful. The advantages of using thrombuster are also closely related to export speed. Therefore, in patients with complete blockage who come with chest discomfort of shorter duration, manual thrombus aspiration should be taken into consideration.

REFERENCES

- Nishtar S. Prevention of coronary heart disease in south Asia. *The Lancet*. 2002 Sep 28;360(9338):1015-8. DOI: 10.1016/S0140-6736(02)11088-9
- Ahmed S, Khowaja S, Khowaja S, Ashraf T, Aamir K, Batra MK, Karim M, Ahmedani MA, Jamal SZ. Differences in angiographic profile and immediate outcome of primary percutaneous coronary intervention in otherwise risk-free young male smokers. *Cureus*. 2020 Jun 24;12(6). DOI 10.7759/cureus.8799
- Hata J, Kiyohara Y. Epidemiology of stroke and coronary artery disease in

- Asia. *Circulation Journal*. 2013;77(8):1923-32. DOI: 10.1253/circj.13-0786
- Okrainec K, Banerjee DK, Eisenberg MJ: Coronary artery disease in the developing world. *Am Heart J*. 2004, 148:7-15. DOI: 10.1016/j.ahj.2003.11.027
- Popkin BM, Adair LS, Ng SW. Global nutrition transition and the pandemic of obesity in developing countries. *Nutrition reviews*. 2012 Jan 1;70(1):3-21. 10.1111/j.1753-4887.2011.00456.x
- Reddy KS. Cardiovascular diseases in the developing countries: dimensions, determinants, dynamics and directions for public health action. *Public health nutrition*. 2002 Feb;5(1a):231-7. DOI: 10.1079/phn2001298
- Hossain P, Kowar B, El Nahas M. Obesity and diabetes in the developing world—a growing challenge. *New England journal of medicine*. 2007 Jan 18;356(3):213-5. DOI: 10.1056/NEJMp068177
- Singh B, Singh A, Goyal A, Chhabra S, Tandon R, Aslam N, Mohan B, Wander GS. The prevalence, clinical spectrum and the long term outcome of ST-segment elevation myocardial infarction in young-a prospective observational study. *Cardiovascular Revascularization Medicine*. 2019 May 1;20(5):387-91. DOI: 10.1016/j.carrev.2018.07.020
- Liu Y, Han T, Gao M, Wang J, Liu F, Zhou S, Chen Y. Clinical characteristics and prognosis of acute myocardial infarction in young smokers and non-smokers (≤ 45 years): a systematic review and meta-analysis. *Oncotarget*. 2017 Oct 10;8(46):81195. DOI: 10.18632/oncotarget.21092
- Nadeem M, Ahmed SS, Mansoor S, Farooq S: Risk factors for coronary heart disease in patients below 45 years of age. *Pak J Med Sci*. 2013, 29:91-96. DOI: 10.12669/pjms.291.2828
- Kirtane AJ, Kelly CR. Clearing the air on the "smoker's paradox". *Journal of the American College of Cardiology*. 2015 Mar 24;65(11):1116-8. DOI: 10.1016/j.jacc.2015.01.012
- Ashraf T, Afaque SM, Aziz R, Khan MN, Achakzai AS, Lateef A, Karim M, Saghir T, Rizvi SN, Rasool SI. Clinical, angiographic characteristics and in-hospital outcomes of smoker and nonsmoker patients after primary percutaneous coronary intervention. *Global Heart*. 2019 Sep 1;14(3):335-41. DOI: 10.1016/j.gheart.2019.07.007
- Rakowski T, Siudak Z, Dziewierz A, Dubiel JS, Dudek D. Impact of smoking status on outcome in patients with ST-segment elevation myocardial infarction treated with primary percutaneous coronary intervention. *Journal of thrombosis and thrombolysis*. 2012 Oct;34:397-403. DOI: 10.1007/s11239-012-0764-0
- Chacko P, Jayaprakash K, Misriya KJ, Madhavan S, Kumary VS, Jayaprasad N, Jayaprakash VL, George R. Effect of thrombus aspiration on angiography and outcome in patients undergoing primary coronary angioplasty. *In: Baylor University Medical Center Proceedings* 2017 Jul 1 (Vol. 30, No. 3, pp. 273-275). Taylor & Francis. DOI: 10.1080/08998280.2017.11929613
- Venkitchalam L, Kip KE, Selzer F, Wilensky RL, Slater J, Mulukutla SR, Marroquin OC, Block PC, Williams DO, Kelsey SF. Twenty-year evolution of percutaneous coronary intervention and its impact on clinical outcomes: a report from the National Heart, Lung, and Blood Institute-sponsored, multicenter 1985-1986 PTCA and 1997-2006 dynamic registries. *Circulation: Cardiovascular Interventions*. 2009 Feb;2(1):6-13.
- Mahmoud KD, Zijlstra F. Thrombus aspiration in acute myocardial infarction. *Nature Reviews Cardiology*. 2016 Jul;13(7):418-28.
- Huang AL, Murphy JC, Shaw E, Kozor R, Yan W, Loxton A, Soo Hoo SY, Figtree GA, Rasmussen HH, Hansen PS, Nelson GI. Routine aspiration thrombectomy improves the diagnosis and management of embolic myocardial infarction. *Catheterization and Cardiovascular Interventions*. 2016 Mar;87(4):642-7. <https://www.nature.com/articles/nrcardio.2016.38>
- Taglieri N, Bacchi Reggiani ML, Ghetti G, Saia F, Compagnone M, Lanati G, Di Dio MT, Bruno A, Bruno M, Della Riva D, Corsini A. Efficacy and safety of thrombus aspiration in ST-segment elevation myocardial infarction: an updated systematic review and meta-analysis of randomised clinical trials. *European Heart Journal: Acute Cardiovascular Care*. 2019 Feb 1;8(1):24-38. <https://journals.sagepub.com/doi/pdf/10.1177/2048872618795512>
- Kumar D, Saghir T, Sial JA, Kumar R, Khan KA, Shah GA, Rehman ZU, Khattai S, Hussain A, Yasin U, Bai R, Wadhvani A, Qamar N. In-Hospital Outcomes of Manual Thrombus Aspiration versus Pre-Balloon Dilatation during Primary Percutaneous Coronary Intervention for Total Occlusion. *Pak Heart J*. 2022;55(03):260-265. DOI: <https://doi.org/10.47144/phj.v55i3.2291>
- Secemsky EA, Ferro EG, Rao SV, Kirtane A, Tamez H, Zakrojsky P, et al. Association of physician variation in use of manual aspiration thrombectomy with outcomes following primary percutaneous coronary intervention for ST-elevation myocardial infarction: the National Cardiovascular Data Registry CathPCI Registry. *JAMA Cardiol*. 2019;4(2):110-8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6439624/>
- Tsang M, Jolly S. Interventional strategies in thrombus management for ST elevation myocardial infarction. *Interventional Cardiology Review*. 2015 Mar;10(1):35. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5808725/>