ORIGINAL ARTICLE

IN-HOSPITAL OUTCOMES OF MANUAL THROMBUS ASPIRATION VERSUS PRE-BALLOON DILATATION DURING PRIMARY PCI FOR TOTAL OCCLUSION

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Objectives: This study was designed to compare the in-hospital outcomes of primary PCI with export vs. primary PCI with the balloon in patients with total occlusion.

Methodology: Consecutive patients with STEMI undergoing primary PCI with TA and pre-balloon dilatation were recruited in 1:1 ratio and post-procedure in-hospital mortality and complication rate (slow flow/no-reflow, contrast-induced nephropathy (CIN), and arrhythmias) were compared. Patients in the TA group were further stratified based on export time (time from onset of chest pain to the use of export) as ≤ 6 hours or > 6 hours.

Results: A total of 200:199 patients were recruited in export and balloon group. Overall complications were significantly higher in balloon group, 39.7% (79/199) vs. 23.0% (46/200); p<0.001, which included slow flow/no-reflow (24.6% vs. 14.5%; p=0.005), CIN (10.1% vs. 4.5%; p=0.022), and arrhythmias (14.6% vs. 5.5%; p=0.006) with in-hospital mortality rate of 3.0% (6/200) vs. 6.0% (12/199); p=0.153. Upon stratifications, outcomes were more favorable when export time was ≤ 6 hours as compared to > 6 hours with mortality rate of 0% vs. 6.3%; p=0.010 and complication rate of 19.2% vs. 27.1%; p=0.187.

Conclusion: TA in patients with total occlusion was associated with lesser complications and relatively better mortality benefits. The benefits of TA were directly associated with export time. Therefore, timely use of export can be considered in patients with total occlusion.

Keywords: Export catheter, Balloon catheter, primary PCI, In-hospital outcome, optimal Export time

Citation: Kumar D, Saghir T, Sial JA, Kumar R, Khan KA, Shah GA, Rehman ZU, Khatti S, Hussain A, Yasin U, Bai R, Wadhwani 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

INTRODUCTION

Primary percutaneous coronary intervention (PCI), is the most effective method of achieving reperfusion in patients with ST-segment elevation myocardial infarction (STEMI).[1] High thrombus burden and plaque rupture, the two main pathogenesis, are associated with poor myocardial reperfusion with increased risk of slow/no-reflow during primary PCI.[2] Manual thrombus aspiration or pre-balloon dilatation after passing the coronary wire are the two widely adopted clinical approaches for primary PCI of patients with thrombolysis in myocardial infarction (TIMI) flow grade of 0. However, routine manual thrombus aspiration is downgraded from class IIa to class III in the current clinical practice guidelines.[3,4] Shreds of evidence from the two major clinical trials, the trial of routine aspiration thrombectomy with PCI versus PCI alone in patients with STEMI (TOTAL)[5] and the thrombus aspiration in ST-elevation MI in Scandinavia (TASTE) trial,[6,7] failed to show promising results of manual thrombus aspiration. However, in the subgroup analysis of patients with a high thrombus burden (grade G4 or higher), the TASTE trial showed a beneficial outcome of thrombus aspiration.[7] Even though, clinical data regarding the benefit of thrombus aspiration in high thrombus burden is limited, based on our clinical observations we have postulated that primary PCI with thrombus aspiration can have a beneficial outcome as compared to primary PCI alone for patients with total occlusion after crossing the lesion with a coronary wire. Hence, this study was designed with the aim to compare the in-hospital outcomes of primary PCI with export vs. primary PCI with the balloon in patients with total occlusion and also to evaluate the impact of ischemia time (export time).

METHODOLOGY

This observational prospective cohort study was conducted at the largest tertiary care cardiac center of Pakistan between 08 July 2020 and 07 March 2021. Consecutive patients presenting to the catheterization

laboratory for primary PCI with the diagnosis of ST-segment elevation myocardial infarction (STEMI) were enrolled. All the patients had chest pain onset to primary PCI time of less than 12 hours. All the patients had angiographic evidence of pre-procedure TIMI 0 flow (total occlusion). Non-consenting patients and patients with prior history of any cardiac-related intervention or surgery were excluded. Diagnosis of STEMI was made as per the 4th universal definition of myocardial infarction. Two independent cohorts with an equal number of patients were recruited as "export group" and "balloon group". In the export group, manual thrombus aspiration was performed with the use of an export catheter, while, in the balloon group, patients received primary PCI with conventional pre dilatation with a balloon. The choice of approach, whether to use or not to use an export catheter, was at the operators' discretion. All the patients had received standard pre and post-procedure medical therapy which included taking premedications (Aspirin 300 mg, clopidogrel 600 mg, unfractionated heparin, 5000 IU and then proceeded for a procedure. During the procedure, tirofiban infusion was considered in some of the patients based on the primary physician's decision and the remaining UFH (weight-adjusted) was injected. Those patients who developed slow/no-reflow were treated with either adenosine or adrenaline based on the hemodynamic parameters. After the procedure, these patients were treated as a standard of care recommended management._

The study was reviewed and approved by the ethical review committee of the institution (approval number: ERC-29/2020). Verbal informed consent was obtained regarding the participation of the patient in the study and publication of anonymized forms of obtained data. All the investigations performed during this study were part of the routine management of the patients.

Primary percutaneous intervention procure that compiles the standard steps such as performing coronary angiogram to find a culprit artery, crossing the lesion with coronary wire followed by either manual thrombus aspiration or pre-balloon dilatation. After that inserting a coronary stent and post dilatation with an NC balloon was performed.

All the patients were followed during their hospital stay and study outcomes, including, mortality and post-procedure complications, were recorded. Post-procedure complications comprised of no-reflow, contrast-induced nephropathy (CIN), and arrhythmias. No-reflow/slow flow was defined as the TIMI flow of 0-II during the procedure. CIN was defined as either a 25% or 0.5 ng/dL increase in serum creatinine level at 48-72 hours of procedure as compared to baseline level. Arrhythmias included ventricular tachycardia (VT) or ventricular fibrillation (V-Fib) during the post-procedure hospital stay.

Collected data were analyzed with the help of IBM SPSS version 21. Export and balloon groups were compared for categorical response variables by applying the Chi-square test and continuous response variables by applying an independent sample t-test. Risk ratio (RR) along with a 95% confidence interval was computed in favor of the export group for post-procedure complications and in-hospital mortality. Patients were further stratified into two groups based on the duration between chest pain onset to the procedure, the total ischemic time, ≤ 6 hours and 6 to 12 hours and study outcomes were compared. A p-value of ≤ 0.05 was taken as a criterion for statistical significance.

RESULTS

A total of 399 patients were recruited in a 1:1 ratio of export and balloon group. The demographic construction of the balloon group was different from the export group with a higher proportion of female patients (24.6% vs. 15.0%; p=0.016) and higher mean age (57.97 ± 11.3 vs. 55.37 ± 12.16; p=0.027). Similarly, smoking was more common among the export group as compared to the balloon group (31.0% vs. 20.6%; p=0.018). Both the groups were similar on remaining characteristics which included Killip class at presentation, presentation and procedure time, risk profile, type of MI, and disease burden. A better post-procedure TIMI flow was found to be associated with the use of an export catheter with a TIMI III flow rate of 89% (178/200) vs. 78.9% (157/199); p=0.019 for export and balloon group respectively. Comparison of demographic and clinical characteristics of two study groups are presented in Table 1.

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

Characteristics	Total	Group		P-value
		Export	Balloon	
Total (N)	399	200	199	-
Gender				
Male	80.2% (320)	85% (170)	75.4% (150)	0.016*
Female	19.8% (79)	15% (30)	24.6% (49)	
Age (years)	56.66 ± 11.8	55.37 ± 12.16	57.97 ± 11.3	0.027*
≤ 65 years	78.4% (313)	82% (164)	74.9% (149)	0.083
> 65 years	21.6% (86)	18% (36)	25.1% (50)	

Chest pain to ER Time (min)	240 [160-360]	240 [135-360]	240 [180-390]	0.37
ER to Lab Time (min)	90 [70-120]	90 [67.5-110]	85 [70-130]	0.176
Total Ischemic Time (min)	360 [248-500]	338 [232.5-462.5]	368 [260-530]	0.133
Killip Class				
I	75.7% (302)	74.5% (149)	76.9% (153)	0.278
II	14% (56)	17% (34)	11.1% (22)	
III	5.3% (21)	4.5% (9)	6% (12)	
IV	5% (20)	4% (8)	6% (12)	
Risk profile				
Hypertension	54.9% (219)	52.5% (105)	57.3% (114)	0.337
Diabetes mellitus	35.8% (143)	34.5% (69)	37.2% (74)	0.576
Smoking	25.8% (103)	31% (62)	20.6% (41)	0.018*
Family history of IHD	4.5% (18)	4% (8)	5% (10)	0.622
Chronic kidney disease	1.8% (7)	1% (2)	2.5% (5)	0.25
Type of myocardial infarction				
AWMI	53.6% (214)	60.5% (121)	46.7% (93)	0.011*
IWMI	23.8% (95)	23.5% (47)	24.1% (48)	
IPWMI	8% (32)	5% (10)	11.1% (22)	
IWMI with RV	10.5% (42)	9% (18)	12.1% (24)	
LWMI	4% (16)	2% (4)	6% (12)	
Number of vessels involved				
Single vessel disease	35.1% (140)	36% (72)	34.2% (68)	0.881
2 vessel disease	30.1% (120)	29% (58)	31.2% (62)	
3 vessel disease	34.8% (139)	35% (70)	34.7% (69)	
Post-procedure TIMI flow				
0	0% (0)	0% (0)	0% (0)	0.019*
I	3% (12)	2.5% (5)	3.5% (7)	
II	13% (52)	8.5% (17)	17.6% (35)	
III	84% (335)	89% (178)	78.9% (157)	

**significant at 5%*

ER=emergency room, 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, TIMI = thrombolysis in myocardial infarction

Vaccination status and occupation, education status, and monthly income of the patients showed significant association with p=0.011, p=0.001, and p=0.001 respectively. A total of 236(70.7%) study subjects were from urban areas with the vaccination rate of 7.2% as against 6.1% or the rural residents (p=0.001).

In-hospital mortality rate was 3.0% (6/200) vs. 6.0% (12/199); p=0.153 for patients in export and balloon group. Overall complications were significantly higher with balloon as compared to export, 39.7% (79/199) vs. 23.0% (46/200); p<0.001, which included slow flow/no-reflow (24.6% vs. 14.5%; p=0.005), CIN (10.1% vs. 4.5%; p=0.022), and arrhythmias (14.6% vs. 5.5%; p=0.006). Use of export was found to be associated with lesser risk of in-hospital mortality and post procedure complications with risk ratio of 0.48 [0.18 - 1.31] and 0.45 [0.29 - 0.7] respectively. Comparisons of in hospital outcomes and complication of two study groups are presented in Table 2.

Table 2: Comparisons of in hospital outcomes and complication of two study groups

Characteristics	Total	Group		Risk Ratio [95% CI]	Chi-square P-value
		Export	Balloon¥		
Total (N)	399	200	199	-	-
Total					
Mortality	4.5% (18)	3% (6)	6% (12)	0.48 [0.18 - 1.31]	0.153
Complications	31.3% (125)	23% (46)	39.7% (79)	0.45 [0.29 - 0.7]	<0.001*
Slow flow/No-reflow	19.5% (78)	14.5% (29)	24.6% (49)	0.52 [0.31 - 0.86]	0.005*
CIN	7.3% (29)	4.5% (9)	10.1% (20)	0.42 [0.19 - 0.95]	0.022*
Arrhythmias	10% (40)	5.5% (11)	14.6% (29)	0.34 [0.17 - 0.7]	0.006*
Total Ischemic Time: ≤ 6 hours					
Mortality	4.5% (9)	0% (0)	9.4% (9)	-	0.011*
Complications	29.5% (59)	19.2% (20)	40.6% (39)	0.35 [0.18 - 0.66]	0.001*
Slow flow/No-reflow	18% (36)	9.6% (10)	27.1% (26)	0.29 [0.13 - 0.63]	0.001*
CIN	7% (14)	1% (1)	13.5% (13)	0.06 [0.01 - 0.48]	<0.001*
Arrhythmias	12% (24)	7.7% (8)	16.7% (16)	0.42 [0.17 - 1.02]	0.051
Total Ischemic Time: 6 to 12 hours					
Mortality	4.5% (9)	6.3% (6)	2.9% (3)	2.22 [0.54 - 9.15]	0.258

Complications	33.2% (66)	27.1% (26)	38.8% (40)	0.59 [0.32 - 1.07]	0.078
Slow flow/No-reflow	21.1% (42)	19.8% (19)	22.3% (23)	0.86 [0.43 - 1.7]	0.661
CIN	7.5% (15)	8.3% (8)	6.8% (7)	1.25 [0.43 - 3.58]	0.681
Arrhythmias	8% (16)	3.1% (3)	12.6% (13)	0.22 [0.06 - 0.81]	0.014*

**significant at 5%*
¥ = reference category
CI = confidence interval, CIN = contrast induced nephropathy

In-hospital outcomes were more favorable in patients with export time of ≤ 6 hours as compared to > 6 hours which included mortality (0% vs. 6.3%; p=0.010) and complications (19.2% vs. 27.1%; p=0.187) such as slow flow/no-reflow (9.6% vs. 19.8%; p=0.041) and CIN (1% vs. 8.3%; p=0.012), however rate of arrhythmias were insignificant (7.7% vs. 3.1%; p=0.157). The risk of post-procedure complications was observed to increase significantly for the patients in which export was used within six-hour of symptom onset as compared to the use of export after six-hour of symptom onset (RR: 1.56 [0.8 - 3.03]). A drastically increased risk of post-procedure CIN and no-reflow were associated with the use of export after six hours of symptom onset with RR of 9.36 [1.15 - 76.33] and 2.32 [1.02 - 5.28] respectively. Comparisons of in-hospital outcomes and complications by the time of export use are presented in Table 3.

DISCUSSION

Consideration of theoretical as well as some initial clinical evidence suggested the thrombus aspiration during primary PCI for the patients with high thrombus burden can have clinical benefits in improving microvascular perfusion, and reducing distal embolization.[8-14] However, after the publication of negative trials regarding the routine use of thrombus aspiration, the temporal trend analysis showed over 50% decline in manual thrombus aspiration during primary PCI since 2011 with less than 5% use by mid-year 2016.[15] However, the TOTAL trial showed no clinical benefit of routine thrombus aspiration in improving hard clinical endpoints, but on sub-group analysis of patients with high thrombus burden, some beneficial outcomes have been observed.[15]

Table 3: Comparisons of in-hospital outcomes and complication by the time of export use

Characteristics	Total Ischemic Time		Risk Ratio [95% CI]	Chi-square P-value
	≤ 6 hours¥	6 to 12 hours		
Total (N)	104	96	-	-
In-hospital Outcome				
Mortality	0% (0)	6.3% (6)	-	0.010*
Complications	19.2% (20)	27.1% (26)	1.56 [0.8 - 3.03]	0.187
Slow flow/No-reflow	9.6% (10)	19.8% (19)	2.32 [1.02 - 5.28]	0.041*
CIN	1% (1)	8.3% (8)	9.36 [1.15 - 76.33]	0.012*
Arrhythmias	7.7% (8)	3.1% (3)	0.39 [0.1 - 1.5]	0.157

**significant at 5%*
¥ = reference category
CI = confidence interval, CIN = contrast-induced nephropathy

In this study manual, thrombus aspiration had shown potential benefits and improved primary outcome in patients who underwent primary PCI and had TIMI 0 flow after crossing the lesion with a coronary wire. The findings in this study are favorable for thrombus aspiration as compared to pre dilatation with a balloon catheter. Manual thrombus aspiration had markedly reduced in-hospital mortality and complications including slow/no-reflow, contrast-induced nephropathy, and arrhythmias in comparison to the balloon pre dilatation arm. Moreover, outcomes were more favorable if the export time is lower than 6 hours.

In this study, overall in-hospital mortality was 3% in the export group and further categorized as 0% if export time is < 6 hours as compared to 6.3% if export time is > 6 hours. However, in the balloon group, mortality was 6% and this group had shown an inverse relationship with the time of usage of pre dilatation. In the TOTAL trial, with TIMI 0 flow thrombectomy was used in 7.3% and a balloon was used in 7.5% of patients and showed a better outcome in the thrombectomy arm.[5] Adjunctive manual thrombectomy devices were associated with significant benefits in terms of 30-day mortality [1.7 vs. 3.1%, OR (95% CI).[5] However, there is no documented study up till now on those patients who had TIMI 0 flow after crossing the lesion with a coronary wire.

Export time was proved to be a beneficial factor in determining the outcome of these patients. When the export time was < 6 hours, complications occurred in 19.2% of patients including slow/no-reflow in 9.6%, CIN in 1%. In contrast, if export time was > 6 hours

complications occurred in 27.1% of the patients with slow/no-reflow of 19.8%, CIN of 8.3%.

In clinical practice, operators' reluctance to thrombus aspiration can be due to likely difficulties such as unfavorable coronary anatomy, highly tortuous or calcified vessels, and distally located or small caliber culprit lesion. All of these situations increased the concomitant risk of vessel wall injury.[16] Ge J et al.[12] summarized available clinical literature regarding manual thrombus aspiration during primary PCI and laid out future perspectives to use of thrombus aspiration and argued the need for improvements in the algorithm of its use in primary PCI. Further, concluded that the thrombus aspiration can be a tool of consideration for STEMI patients, especially, when dealing with high thrombus burden and fresh thrombus, and highlighted the importance of the use of glycoprotein IIb/IIIa inhibitors during the procedures with manual thrombus aspiration.

To the best of our knowledge this is only specific to the quantitative evaluation of clinical outcomes of primary PCI along with thrombus aspiration strategy for patients with TIMI 0 flow grade after crossing the lesion with a coronary wire.

The key limitation is the non-randomized nature of the study where thrombus aspiration was performed voluntarily by the operator which may have a patient selection bias.

CONCLUSION

Use of export in a selective group of patients undergoing primary PCI for total occlusion after passing the coronary wire results in a significantly lesser complication rate and relatively better mortality benefits as compared to the use of a balloon catheter. Furthermore, the benefits of usage of export are directly associated with export time. Therefore, manual thrombus aspiration should be considered in patients with total occlusion who present with shorter duration of chest pain.

AUTHORS' CONTRIBUTION

DK, RK, KAK, GAS, ZUR, SK, AH, UY, AW, and RB: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. JAS, TS and NQ: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

Conflict of interest: Authors declared no conflict of interest.

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