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Deferred versus Immediate Stenting in the setting of Acute ST-Elevation Myocardial Infarction

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Abstract

Deferred stent implantation may allow time for reduction in coronary thrombus burden and recovery of microvascular function so that the likelihood of no-reflow can be reduced. We conducted a prospective study which included 100 Patients admitted to National Heart Institute and Critical Care Department, Cairo University presenting by ST elevation myocardial infarction STEMI with high thrombus burden and undergoing primary percutaneous coronary intervention PCI, they were divided into two groups (50 patients in each group) based on the strategy of management: either immediate or deferred stenting. Occurrence of major adverse cardiovascular and cerebrovascular events MACCE and angiographic outcome were observed in each group. Incidence of re-infarction, heart failure, fatal arrhythmia, stroke and target vessel revascularization in deferred stenting group was comparable to immediate stenting group with no statistically significant difference during hospital stay and 6 months follow up. Thrombolysis in myocardial infarction TIMI III flow was achieved in 43 patients (86%) in immediate stent group more than in deferred stent group 38 patients (76%) although this difference was statistically insignificant with P value=0.389. Deferred stenting strategy in patients presented with STEMI with high thrombus burden does not affect the clinical outcome.

Keywords: Myocardial Infarction; Deferred stent implantation; Microvascular Function

Full length article *Corresponding Author, e-mail: <u>drmahmoud1017@yahoo.com</u>

1. Introduction

Acute ST elevation myocardial infarction (STEMI) is currently treated with primary percutaneous coronary intervention (PCI) with stenting as soon as coronary reperfusion occurs. This procedure salvages the compromised myocardium and improves prognosis [1,2]. Acute myocardial blood flow loss in the presence of a patent epicardial coronary artery is known as "no-reflow".3 Microvascular blockage due to distal embolisation of a clot, microvascular spasm, and thrombosis are involved in the pathophysiology of no-reflow [3]. About 10% of primary PCI procedures result in no-reflow, which is linked to patient features like advanced age and delayed presentation as well as coronary abnormalities including a fully blocked culprit artery and a high thrombus burden [3-7]. There is no proven treatment for no-reflow, and the only treatments available when it does occur are intra-aortic balloon counter-pulsation therapy and the injection of vasodilator medications [2,3,8,9]. The goal of this preventative measure was to prevent the possible negative consequences of stenting right away, when there may be a higher chance of no-reflow. The possibility of no-reflow may be decreased with delayed stent implantation

because it may give time for the burden of coronary thrombus to be lowered and microvascular function to improve. We suggested that a brief postponement of stenting, following initial coronary reperfusion and the restoration of normal coronary blood flow, may decrease the incidence of noreflow in contrast to standard therapy that involves immediate stenting and enhance myocardial salvage. Using primary PCI-treated STEMI patients and their clinical sequelae at a 6month follow-up, we examined this theory in a practical clinical setting.

2. Patients and Methods

This is multi centers, prospective study which included 100 Patients admitted to Critical Care Department-Cairo University and National Heart Institute in Cairo who presented by STEMI with high thrombus burden and undergoing primary PCI, They were divided into two groups based on the strategy of management: either immediate stenting or deferred stenting.

Group 1: Included patients who treated with conventional immediate stenting (IS group).

Group 2: Included patients who treated with deferred stenting (DS group).

Inclusion criteria:

All patients with (STEMI) or new left bundle branch block undergoing primary PCI in the presence of a heavy thrombus burden in the infarct related artery (IRA) (thrombus burden score, TBS \geq 3)

Exclusion criteria:

- 1. Treatment of STEMI with thrombolytic drugs in the previous 24 hours.
- 2. TIMI grade ≤ 1 coronary blood flow after initial reperfusion with aspiration thrombectomy with or without balloon angioplasty.
- 3. Allergy to any of the drugs used (aspirin, clopidogrel, GP IIb/IIIa inhibitors)
- 4. Cardiogenic shock.
- 5. End stage liver and renal failure.
- 6. Culprit lesion in unprotected left main or saphenous venous graft.
- 7. Inability to give informed consent.

Ethical approval:

Informed consent was obtained from the patient or his first kin in case of the patient is unable to give consent. Ethical committee approved on July 23rd 2017,serial no 155432.

Methodology in details:

All patients were subjected to the following:

- 1. Thorough history taking and clinical examination.
- 2. A 12 lead Electrocardiogram.
- 3. Complete blood count, cardiac enzymes and renal profile on admission.
- 4. The patients were categorized into two groups: group II (DS) and group I (IS). Following angiography and first interventions, the IS group had stent insertion when needed right away, but the DS group had to wait 24 to 48 hours to get their stent implanted.
- 5. In the first phase of the DS group, angiography-based initial interventions were carried out immediately to achieve a TIMI flow of at least 2, which was followed by enhanced antithrombotic therapy with Glycoprotein IIb/IIIa inhibitors infusion for 24–48 hours; in the second phase, angiography was repeated 24–48 hours later, and stent implantation occurred at the operator's discretion based on the IRA's residual stenosis. Both groups were permitted to receive the initial therapies, which included manual thrombus aspiration and balloon predilation.
- 6. The decision of the interventional and coronary care unit cardiologists, based on current standards of care, regarding primary PCI with pharmacologic therapy during and after primary PCI.

7. Patients were subjected to echocardiographic evaluation to document ejection fraction and LV end systolic and end diastolic dimensions.

Patients were followed for angiographic complications and the development of major adverse cardiovascular and cerebrovascular events (MACCE) while they were in the hospital, and they were followed for six months after their discharge from the hospital.

Follow up done through clinical examination, echocardiographic evaluation and coronary angiography if indicated.

Major adverse cardiovascular events (MACCE) were defined as in stent thrombosis, non-fatal myocardial infarction, acute heart failure, stroke, arrhythmia and mortality.

Possible Risk:

In IS group there is risk of no reflow. In DS group there is risk of re-infarction after initial reperfusion.

Primary outcomes:

The primary outcomes were angiographic outcomes and occurrence of MACCE during in hospital admission and during 6 months follow up.

Secondary outcomes:

- Duration of ICU stay.
- ST segment resolution.
- Left ventricular remodeling.
- Multi organ dysfunction.

Statistical analysis:

Data were analyzed using SPSS version 23. For quantitative variables, the mean, standard deviation, minimum, and maximum were used to summarize the data; for categorical variables, the frequencies (number of cases) and relative frequencies (percentages) were used. Unpaired t tests were used to compare the groups. The Chi square (2) test was used to compare categorical data. When the anticipated frequency is less than 5, an exact test was utilized instead, and P-values less than 0.05 were regarded as statistically significant.

3. Results:

From June 2017 through March 2020, a total of 100 patients were enrolled in this study. Of these patients, 50 patients (50%) were assigned to the IS group and 50 patients (50%) were assigned to the DS group. Baseline demographic and clinical characteristics of patients were well balanced between the 2 groups. Majority of patients were males (77%) with mean age of 54 years with non-significant differences between both groups. Age, sex, risk factors, clinical presentation and diagnosis were matched in both groups (**Table 1**).

Baseline angiographic and procedure characteristics showed in Table (2). Syntax score was higher in the DS group than in the IS group (16.6 versus 13.5) respectively; P=0.012. Initial TIMI flow was comparable in both groups; (P=0.401), but regarding thrombus burden score there was significant difference between both groups (P=0.024). The left anterior descending artery was the most frequently culprit IRA with total 62 patients (62%) in both groups. PCI in the DS group was performed 24 to 48 h after initial angiography with mean duration of 36.2 h. Lesion length, stent length and stent diameter were comparable in both groups with no significantly different (P=0.93, 0.673, 0.437) respectively. Adjuvant infusion of intravenous GP IIb/IIIa inhibitors (Tirofiban or Eptifibitide) during or immediately after initial percutaneous coronary intervention in all patients in the DS only 11 patients with major thrombotic group versus complications (no or slow flow or significant distal embolization) in the IS group were received GP IIb IIIa inhibitors, this was statistically significant, (P=<0.001) (Table 3). No reflow occurred in 7 patients (14%) in the DS group versus 3 patients (6%) in the IS group but this difference was not statistically significant (P = 0.182). At the end of procedure; in the DS group TIMI flow grade III was obtained in 38 patients (76%) and TIMI flow grade II in 9 patients (18%) and TIMI flow grade I in 3 patients (6%), and zero no reflow. while in the IS group TIMI III is obtained in 43 patients (86%), TIMI II in 4 patients (8%), TIMI flow grade I in 3 patient (6%) and no reflow in 3 patients (6%) (Table 4). During hospital stay that ranged from 4 to 8 days in the IS group and from 4 to 10 days in the DS group, in the IS group re-infarction occurred in 2 patients (4%), heart failure occurred in 3 patients (6%), Target vessel revascularization was needed in only one patient (2%) due to recurrence of symptoms, Contrast induced nephropathy occurred in 1 patient (2%), Malignant arrhythmias occurred in 2 patients (4%). In the DS group re-infarction occurred in 2 patients (4%), heart failure occurred in 4 patients (8%), Target vessel revascularization was needed in 2 patient (4%) due to recurrence of symptoms, Contrast induced nephropathy occurred in 1 patient (2%), Malignant arrhythmias occurred in 3 patients (6%).No cerebrovascular stroke was reported in both groups during hospital stay (Table 5). Follow up for 6 months in the IS group re-infarction occurred in 1 patients (2%), heart failure occurred in 2 patients(4%), Target vessel revascularization was needed in only one patient (2%) due to recurrence of symptoms, death occurred in 2 patients (4%).In the DS group re-infarction occurred in 1 patients (2%), heart failure occurred in 4 patients(8%), Target vessel revascularization was needed in 3 patient (6%) due to recurrence of symptoms, death occurred in 2 patients (4%).No cerebrovascular stroke was reported in both groups during follow up period, table 6.Comparison between IS group and DS group regarding MACCE during hospital stay and after 6 months follow up is shown in Figure (1). Intensive antithrombotic therapies showed no increase in Salama et al., 2023

major or moderate bleeding in the deferred stenting group compared with the IS group. Minor hemorrhagic complications were observed in 3 patients (6%) in the DS group (two hematomata at access site and one hematuria that didn't change the hemoglobin level significantly) versus 2 patients (4%) in the IS group (hematoma at access site), P value =1.0.These hematoma did not require blood transfusion, vascular surgical intervention or causing hemodynamic instability.These hematoma were treated conservatively and GPIIb/ IIIa was hold in the patients who develops hematuria.

4. Discussion

Patients diagnosed with ST-segment elevation myocardial infarction (STEMI) are often treated with prompt primary percutaneous coronary intervention (PCI) using balloon dilatation and stent implantation [10,11]. A patent epicardial artery or complications from distal embolization, which are linked to a worse prognosis, can induce decreased coronary blood flow in certain patients, nevertheless [3,12]. According to registry data, there may be a way to conserve coronary blood flow and lower the risk of embolization by postponing or delaying stent placement after a stable blood flow has been established in the infarct-related artery. This could potentially enhance clinical outcome [13-16]. The current study showed that after initial thrombectomy or balloon dilatation in the DS group. no reflow occurred in 7 patients out of 50 (14%) compared to the IS group only 3 patients out of 50 (6%) at the end of PCI. TIMI III flow was achieved in 43 patients (86%) in the IS group more than in the DS group 38 patients (76%) although this difference was statistically insignificant with P value=0.389.The incidence of slow or no reflow varies in different studies, in Kim et al. [17], the incidence of slow or no reflow was not significantly different (occurred in 20 out of 57 patients 35.1% in the IS arm versus 13 out of 57 patients in the DS arm 22.8%; P=0.139). This result is inconsistent with Carrick et al. [18] who investigated that deferred stenting group had a significantly lower incidence of slow or no reflow after stenting (primary end point): odds ratio 0.16 (0.04, 0.59), p = 0.006. The DS group also experienced fewer distal embolizations and intraprocedural thrombotic events. The DS group had increased post-stenting TIMI grade 3 flow and myocardial blush grades. The percentage of patients in the DS group who had angiographic evidence of thrombus at the beginning of the second surgery was significantly lower than that of the first procedure (98.1% vs. 62.7%; p<0.0001). Also, Cassese et al. [19] evaluated 1,433 patients, 182 patients (12.7%) had a slow or no reflow. Patients who had postponed versus immediate stenting had a decreased risk of slow or no reflow (8.8% versus 16.6%; RR= 0.54 [0.41-0.72], p<0.001; I2=1%). In our study the Synergy between percutaneous coronary intervention with TAXUS and cardiac surgery (SYNTAX) score was higher in the DS group with mean 16.64 while in immediate stenting group was 13.55. This difference was statistically significant (P value = 0.012). Syntax score was used as predictor of no reflow in many studies, Magro et al. [20] reported that 77 patients (12%) have no reflow phenomenon. In Sahin et al. [21] showed 32.8% of patients have no reflow.

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Table 1. Baseline Clinical Characteristics of the Study Subjects

Characteristics	IS (N=50)	DS (N=50)	P-value
Mean age $\pm SD$	53.46 ± 11.71	54.56 ± 11.81	0.641 (NS)
Median (range)	60 (28 - 76)	58 (28 - 86)	0.041 (NS)
Male	39 (78%)	38 (76%)	0.812 (NS)
Female	11 (22%)	12 (24%)	
DM	21(42%)	16 (32%)	0.300 (NS)
HTN	19(38%)	20 (40%)	0.838 (NS)
Smoking	22 (44%)	24 (48%)	0.688(NS)
Dyslipidima	18(36%)	15(30%)	0.523(NS)
Prior MI	2 (4%)	5 (10%)	0.499(NS)
FH	14(28%)	15(30%)	0.826(NS)
CHF	4(8%)	5(10%)	1(NS)
CRF	1(2%)	1(2%)	1(NS)
Killip Class I	39 (78%)	40 (80%)	
			1(NS)
Class II	8 (16%)	7 (14%)	
Class III Class IV	1 (2%)	1 (2%)	
Anterior STEMI	2 (4%) 30 (60%)	2 (4%) 33 (66%)	
Inferior STEMI	20 (40%)	14 (28%)	
Posterior STEMI	0 (0%)	3 (6%)	0.138(NS)
Total ischemic time (h) Mean ± SD	7.44 ± 3.0	8.62 ± 6.08	0.000 010
Median (Range)	8(1-12)	7.5(1-36)	0.222(NS)
Chest pain resolution	45(90%)	47(94%)	0.715 (NS)
ST resolution> 50% LVEF (%)Mean ± SD	46(92%) 49.48 ±7.85	47(94%) 50.62±8.89	1(NS) 0.498 (NS)
LVEDD Mean ± SD	5.37±0.53	5.34±0.57	0.309 (NS)
LVESD Mean ± SD	3.96±0.54	3.89±0.65	0.501(NS)

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Table 2. Baseline angiographic and procedure characteristics

Initial CA data	IS (N=50)	DS (N=50)	P-value	
	Syntax s			
Mean \pm SD	13.55±5.39	16.64±6.56	0.012	
Median (Range)	13.75(7-39)	16.80(5-24)	0.012	
	Thrombus	burden		
2	1(2%)	0(0%)		
3	2(4%)	4(8%)		
4	5(10%)	5(10%)	0.024	
5	42(84%)	41(82%)		
	TIMI flow p			
TIMI 0	44(88%)	41(82%)	0.401 (NS)	
TIMI I	6(12%)	9(18%)	- 0.401 (INS)	
	Infarct relate	× /		
LM	2(4%)	0(0%)		
Proximal LAD	13(26%)	18(36%)		
Mid LAD	17(34%)	14(28%)		
Proximal LCX	0(0%)	4(8%)		
distal LCX	2(4%)	2(4%)		
Proximal RCA	6(12%)	5(10%)	0.343 (NS)	
Mid RCA	8(16%)	5(10%)		
Distal RCA	1(2%)	2(4%)		
PDA	1(2%)	0(0%)		
	Lesion leng			
Mean ± SD	25.68±9.09	25.86±11.26		
Median (Range)	24(9-60)	24(12-74)	0.930(NS)	
	Stent ler	· · · · · · · · · · · · · · · · · · ·		
Mean ± SD			0.673(NS)	
Median (Range)	28(15-66)	28(15-76)		
	Stent diar			
Mean ± SD	0.437(NS)			
Median (Range)	3.09±0.39 3(2.5-4)	3.14±0.37 3(2.5-4)	× ,	
pre dilatation	25(50%)	29(58%)	0.422 (NS)	
post dilatation	10(20%)	14(28%)	0.349 (NS)	
Aspiration Device	4(8%)	9(18%)	0.137(NS)	
•	Time to re int			
Mean ± SD		36.20 ±7.70		
Median (Range)		36(24-48)		
No reflow	3(6%)	7(14%)	0.182(NS)	

Table 3. Comparison between the studied groups regarding adjuvant infusion:

	IS (N=50)	DS (N=50)	P-value
Clopidogrel	38(76%)	45(90%)	0.062
Ticagrelor	12(24%)	5(10%)	0.029
GPIIb/IIIa inhibitor	11(22%)	50(100%)	< 0.001

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	IS (N=50)	DS (N=50)	P-value			
Final TIMI flow						
TIMI I	3(6%)	3(6%)				
TIMI II	4(8%)	9(18%)	0.389(NS)			
TIMI III	43 (86%)	38(76%)				
MBG						
0	1(2%)	0(0%)				
1	2(4%)	6(12%)	0.318(NS)			
2	18(36%)	14(28%)				
3	29(58%)	30(60%)				
Complete revascularization	41(82%)	38(76%)	0.461(NS)			

Table 4. Comparison between the studied groups regarding the final angiographic outcome.

Table 5. Comparison between the studied groups regarding the clinical outcomes during hospital stay.

	IS (N=50)	DS (N=50)	P-value
Re-infarction	2(4%)	2(4%)	1
HF	3(6%)	4(8%)	1
TVR	1(2%)	2(4%)	1
Stroke	0(0%)	0(0%)	
CIN	1(2%)	1(2%)	1
VT	1(2%)	2(4%)	1
VF	1(2%)	1(2%)	1

Table 6.	Comparison	between th	he studied	groups	regarding	the clinical	outcomes	after 6 months.

	IS (N=50)	DS (N=50)	P-value
Re-infarction	1(2%)	1(2%)	1
HF	2(4%)	4(8%)	0.678
TVR	1(2%)	3(6%)	0.617
Stroke	0(0%)	0(0%)	
Death	2(4%)	2(4%)	1

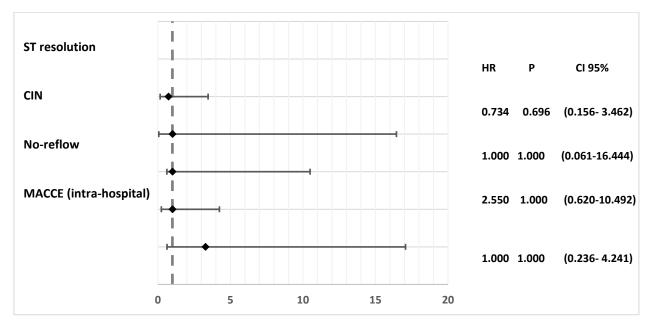


Figure 1: Forest plot comparison between IS and DS group

The no-reflow group had a mean Syntax score $(19.2\pm6.8/12.9\pm6.1, p<0.001)$ that was greater than the regular flow group's. Independent predictors of no reflow on multivariate logistic regression analysis included syntax score (β=0.872, %CI=0.845-0.899, p<0.001), diabetes (β=0.767, %CI=0.128-4.597, p=0.004), anterior myocardial infarction (β=5.421, %CI=1.369-21.469, p=0.025), and thrombus grade after wiring (β =2.537, %CI=1.506-4.273, p<0.001). For the prediction of no reflow, the threshold Syntax score (sensitivity: 70.6%, specificity: 69.4%) determined by ROC curve analysis was 19.75. Incidence of re-infarction, heart failure, fatal arrhythmia, stroke and target vessel revascularization in the DS group was comparable to the IS group during hospital stay with no statistically significant difference (P value = 1), CI= 0.620-10.492.In the IS group two patients had re-infarction, 3 patients had heart failure and 2 patients had ventricular arrhythmia. TVR was needed in only one patient in the IS group while in the DS group two patients had re-infarction, 4 patients had heart failure and 3 patients had ventricular arrhythmia. TVR was needed in 2 patients. No cerebrovascular stroke was reported in both groups during hospital stay. In Harbaoui et al. [22] included ninety-eight patients; 50 patients underwent DS and 58 patients had IS. There was no difference between the two groups in terms of overall hospital mortality (7 patients, or 7.1%; P value = 0.48). Patients with critical clinical presentations were admitted in all cases that resulted in mortality (3 patients with cardiac arrest and 4 patients with cardiogenic shocks). More precisely, one patient experienced refractory cardiogenic shock while the other two patients (5.0%) in the postponed stenting group died from brain death. In the group receiving immediate stenting, five patients (8.6%) passed away: these included two cases of acute stent thrombosis, two cases of refractory cardiogenic shock, and one case of ventricular arrhythmia. Four patients experienced a re-infarction: one at one hour in the deferred stenting group and three due to acute stent thrombosis in the immediate stenting group. In Meneveau et al. [23] revealed that patients who received immediate PCI and those who received delayed

PCI did not significantly vary in MACE (39 in the immediate PCI group and 39 in the delayed PCI group). Between the first angiography and the postponed coronary intervention, there was not a single ischemic incident in the group receiving deferred PCI. In each group, there was one patient who underwent target vessel revascularization and one patient who died. Recurrent ischemia occurred in two patients in the immediate PCI group and in one patient in the delayed PCI group. Recurrent ischemia followed PCI in all three cases (whether immediate or delayed).

The major adverse cardiovascular events were observed in the two groups during six months follow up through clinical visits, echocardiographic evaluation and coronary angiography when indicated; deferred stenting did not improve the incidence of death, development of heart failure, re-infarction, and stroke or target vessel revascularization. Death occurred in two patients (4%) in the DS group similar to the IS group. Target vessel revascularization occurred more in the DS group 3 patients (6%) versus only 1 patient (2%) in the IS group but this difference was not statistically different (P value = 0.617).Re-infarction occurred in one patient (2%) in the IS group similar to the DS group. Heart failure occurred in 4 patients (8%) in the DS group versus only 2 patients (4%) in the IS group. Kelbaek et al. [24] investigated that 109 patients (18%) in the conventional primary PCI group and 105 patients (17%) in the deferred stent implantation group noticed the composite primary endpoint of all-cause mortality, hospital admission for heart failure, recurrent infarction, and any unplanned revascularization of the target vessel. The risk ratios for each component of the composite endpoint were as follows: 1.10 (0.69-1.60; p=0.49) for non-fatal recurrent myocardial infarction, 1.70 (1.04-2.92; p=0.0342) for unplanned target vessel revascularization, 0.83 (95% CI 0.56-1.20; p=0.37) for all-cause mortality; and 0.82 (0.47-1.40; p=0.49) for hospital

admission for heart failure. The frequency of cardiac-related deaths did not significantly differ between the groups.as opposed to just one patient in the group receiving delayed PCI. Recurrent ischemia (either immediate or delayed) followed PCI in all three cases.

5. Conclusions

Deferred stenting remains an alternative safe strategy for revascularization in STEMI patients with high thrombus burden. No ischemic events or re-occlusion had occurred between the initial coronary angioplasty and the postponed coronary intervention. Thrombus burden improved significantly after initial coronary angioplasty and intense antithrombotic therapy with no increase in major or moderate bleeding; however there was no significant difference in MACCE during in hospital stay and after 6 months follows up.

List of abbreviations

STEMI: ST elevation myocardial infarction; PCI: primary percutaneous coronary intervention; MACCE: major adverse cardiovascular and cerebrovascular events; TIMI: Thrombolysis in myocardial infarction; IRA; infarct related artery; TBS: thrombus burden score.

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