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Delayed Stenting Compared with Immediate Stenting in Patients with ST-Segment Elevation Myocardial Infarction

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Keywords: Stenting; Primary percutaneous coronary intervention; ST-segment elevation myocardial infarction.

Abstract

Aims: To compare Delayed Intentional Stent Implantation (DSI) with Immediate Stent Implantation (ISI) in patients with ST-Segment Elevation Myocardial Infarction (STEMI) undergoing Primary Percutaneous Coronary Intervention (PPCI).

Background: Stenting in thrombus-laden arteries can lead to distal embolisations and microvascular obstruction, which have been associated with worse prognosis.

Methods and results: We prospectively collected data from 179 consecutive patients with acute STEMI treated by PPCI. Stent was immediately implanted (ISI) in 127 patients and delayed in 52 patients. In the DSI group, patients had a control coronary angiography performed 3-7 following the primary reperfusion A greater proportion of patients treated with DSI achieved myocardial reperfusion compared to patients treated with ISI, as measured by the ST-segment resolution ≥75%, at 60-90 minutes post-reperfusion (13.4% vs. 36.5%, adjusted odds ratio [OR]; 3.35, 95% confidence interval [CI] 1.15-9.75, p=0.03).

Fifty patients treated by DSI (96.2%) had a control angiogram , 4.3±2 days after PPCI of which only 16 (32%) required a stent implantation The rates of in-hospital infarct-related artery reocclusion were 5.5% in the ISI group compared to. 1.9% in the DSI group (OR 0.21, 95% CI 0.02-2.14, p=0.44) and the risk of major adverse cardiac events were 9.4% vs. 1.9% (p=0.11), respectively.

Conclusions: Compared to ISI, DSI is associated with improved myocardial reperfusion in patients with ST-segment treated by PPCI s and remains associated with a low incidence of infarct-related artery reocclusion.

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Introduction

Primary Percutaneous Coronary Intervention (PPCI) is the optimal reperfusion strategy in patients with ST-Segment Elevation Myocardial Infarction (STEMI) [1,2]. Even when normal coronary flow is achieved by PPCI, the myocardial reperfusion measured by ST-segment resolution remains incomplete in a high proportion of patients [3,4].

Improper ST-segment resolution has been explained by poor myocardial reperfusion due in part to distal embolization, and has been associated with major adverse outcomes [5].

Improvement in myocardial reperfusion in PPCI is challenging and needs further refinement. The Minimalist Immediate Mechanical Intervention (MIMI) strategy is a two-stage angiographic procedure [6,7], whereby reperfusion is acutely achieved with the tool least likely to harm the artery or to cause distal emboli, and where stenting is implanted only after the thrombus has reduced, typically few days following the index reperfusion [8,9]. Few studies have compared the conventional strategy with the MIMI strategy [3, 9-14]. The aim of the present study was to compare the MIMI strategy with delayed stenting to conventional immediate stenting on myocardial reperfusion in patients with STEMI treated by PPCI.

Methods

Study design and patients

A permanent registry of consecutive patients treated by PPCI for STEMI is maintained at the University Hospital Center in Blida, Algeria. Patients were eligible to the present study if presenting with STEMI of less than 12 hours since symptoms onset from April 2009 to December 2012. During this transition period, the delayed stenting was progressively implemented in our clinical practice. Patients with no indication for stent implantation and patients with conditions on the Electrocardiogram (ECG) that precluded interpretation of their ST-segment resolution (left bundle branch block (LBBB), pacing, pre-excitation, accelerated idioventricular rhythm, were excluded from the study.

The collected data included baseline, angiographic, and procedural characteristics and in-hospital clinical outcomes. Apart delaying stent implantation, all interventions were performed according to current standard guidelines [2]. All patients were loaded with aspirin (250 mg) and clopidogrel (600 mg) prior to PPCI During the index reperfusion, patients were anticoagulated with either unfractionated

heparin or enoxaparin. The use of glycoprotein IIb/IIIa inhibitor, balloon angioplasty thrombectomy and the decision to delayed stent implantation were left to the discretion of the operator. All patients had a maintenance dose of 100 mg of aspirin and 75 mg of clopidogrel for 1 year.

The study was approved by the institutional ethics committee of the Blida Hospital Centre and all patients provided written informed consent to participate.

Mimi strategy

The MIMI strategy is a provisional, Delayed Stent Implantation (DSI) technique in where a normal TIMI 3 flow is achieved in the infarct-related artery either spontaneously or after wire passage or thrombectomy Stents are only implanted 3-7 days after the index reperfusion when the control angiogram shows a residual diameter stenosis >50% on visual estimation. In the interval between the index reperfusion and the control angiogram, patients received clopidogrel 150 mg daily and subcutaneous enoxaparin (1 mg/kg if non contra indicated) or heparin (TCA in the therapeutic range).

End points

The primary endpoint was ST-segment resolution ≥75% on the 12-lead surface ECG, 60-90 minutes after primary reperfusion. Secondary endpoints included: TIMI 3 flow after the first procedure; proportion of patients implanted with a stent in the infarct related artery; in-hospital reocclusion of the infract-related artery; and in-hospital Major Adverse Cardiac Events (MACEs), defined as the composite of cardiac death, recurrent myocardial infarction, and stroke.

Electrocardiographic analysis

ST-segment measurement has been described previously [15]. Each patient had paired ECGs performed at baseline and 60-90 minutes after PPCI. The rate of ST-segment resolution was determined in the lead with the greatest baseline degree of ST-segment elevation [16].

Definitions

Thrombus burden score at the initial flow has been described previously [17]. In brief, TIMI thrombus grade 0 indicates no angiographic characteristics of thrombus are present; grade 1 indicates possible thrombus; grade 2 indicates that the greatest dimension of thrombus is up to half the vessel diameter; grade 3 indicates the greatest dimension is more than half but <2 vessel diameters; grade 4 indicates the greatest dimension is ≥2 vessel diameters; and grade 5 indicates total occlusion. TIMI flow grade has been described previously [18].

Cardiac death included causes such as but not limited congestive heart failure, Myocardial Infarction (MI), malignant ventricular arrhythmias and sudden death.

In-hospital recurrent myocardial infarction was defined as the association of acute onset of chest pain and/or typical modification on ECG (ST-segment or T-wave modification) [19] and a ≥20% increase in troponin concentration in a sample taken 6 hours after symptom onset or ECG changes [20]. Culprit artery reocclusion was defined as reinfarction with chest pain and new ST-segment elevation in the territory of the culprit artery. In this event, culprit artery reocclusion was defined as a stent thrombosis if a stent had been implanted. Definite and probable stent thromboses were defined according to the Academic Research Consortium definitions [20].

Statistical analysis

Categorical variables are expressed as frequencies and percentages and continuous variables as means and 95% Confidence Intervals (CIs). Student's t-test was used to compare continuous variables, and the chi-squared test or Fisher's exact test was used to compare categorical variables.

A propensity score was performed in the final regression adjustment to reduce bias between the two groups [21]. Each patient was assigned a propensity score using the logistic regression model. This score ranged from 0.0013 to 0.92 and reflected the probability that a patient would have DSI. The propensity score model yielded a c statistic of 0.85, and the corresponding Hosmer-Lemeshow goodness-of-fit chi-square was 12.4 (p=0.13).

ST-segment resolution was compared in the two groups using a multivariable logistic regression model designed with the propensity score and variables associated with ST regression that showed a significant difference in the univariate logistic regression analysis (p<0.02) and those in which a significant difference persisted after primary adjustment using the propensity score.

A paired-sample t-test was used to compare the difference in the means of thrombus burden score between the end of the first and the beginning of the second procedure in the DSI group.

Statistical significance was assumed at a 2-tailed **p**<0.05. All statistical analysis was performed with SPSS software (version 20.0; IBM Corp, NY, USA).

Results

Study population

The study cohort comprised 215 consecutive patients with STEMI (**Figure 1**). Thirty-six patients were excluded from the analysis, for the following reasons: 3 had non-interpretable ST-segment elevation on the ECG and 4 had LBBB or cardiac pacing, and 29 patients were not eligible for stenting. Therefore, 179 patients underwent PPCI with an indication for stent implantation and had paired, interpretable ECGs; 127 patients were treated with the ISI procedure and 52 with the DSI procedure.

Baseline characteristics are outlined in Table 1. The baseline characteristics in both groups were generally similar with the exception of hypertension and dyslipidemia which were more prevalent in patients assigned to delayed stening.

Angiographic and procedural characteristics

A TIMI 3 flow restoration after thrombus aspiration was obtained in 90.7% of patients assigned to DSI compared to 61.3% of patients assigned to ISI (p<0.001); This difference did not persist after adjusting for propensity score (p=0.84; **Table 2**). Glycoprotein IIb/IIIa antagonists were infrequently used overall with no statistically significant difference between the two groups. The only variable in which a difference persisted after primary adjustment using the propensity score was the delay from pain onset to hospital admission (p=0.04).

In the DSI group, 30 (57.7%) patients had thrombus burden score ≥3 and 22 (42.3%) with a score <3. **Figure 2** shows the decrease in the thrombus score between the first and the second procedure. The mean Gibson score was 2.67 (95% CI 2.43-2.90) at the end of the first procedure and 0.93 (95% CI 0.62-1.24) at the beginning of the second procedure; the mean decrease was 1.74 (95% CI 1.42-2.06; p<0.000).

Clinical outcomes

The primary outcome of ST-segment resolution ≥75% at 60-90 minutes was achieved more frequently in patients assigned to DSI (**Table 3**). The only variable associated with ST-segment resolution ≥ 75% was TIMI 3 flow versus TIMI <3 flow after thrombus aspiration in the univariate analysis (odds ratio [OR] 3.9, 95% CI 1.5-10.0, p=0.005). After adjustment in a multivariable regression model that included propensity score, TIMI 3 flow after thrombus aspiration, and pain-admission delay, the OR was 3.35 (95% CI 1.15-9.75, p=0.026).

TIMI 3 flow restoration was obtained in 92.1% of patients in the ISI group versus 96.2% in the DSI group at the end of the first procedure (OR 2.13, 95% CI 0.45-10.10, p=0.51; **Table 4**). By the end of the second procedure, 32.0% of DSI patients (16/50) had had a stent implantated compared with all 127 patients in the ISI group (p<0.0001; **Table 5**). In the DSI group, stent was not implantated in 50.0% (25/50) of patients because of inaugural stenosis had regressed to lesser than 50%; 7 patients (14.0%) could be treated by balloon angioplasty alone. There were no differences in the rates of documented infarct-related artery reocclusion (OR 0.21, 95% CI 0.02-2.14) or MACE (OR 5.3, 95% CI 0.67-42.0). The number of stents implanted per patient, the types of stent implanted, and the nature of the stents were also similar (**Table 5**).

Two patients assigned to delayed stenting ended up not getting a control angiogram either because of severe acute renal failure and or becauseof a major bleedling. One patient in the DSI group underwent an emergency procedure for reocclusion of the infarct artery.

Table 1: Patient baseline characteristics.

Variables	ISI group (n=127)	DSI group (n=52)	p	p*
Age, years (mean, 95% CI)	56.2 (54.1-58.3)	55.4 (52.6-58.2)	0.65	0.61
Men, n (%)	107 (84.3)	46 (88.5)	0.47	0.50
Cardiovascular history and risk factors, n (%)				
Body mass index, kg/m² (mean, 95% CI)	25,1 [24.1-26.1]	25.4 [24.4-26.4]	0.83	0.75
Tobacco smoking	60 (47.2)	25 (48.1)	0.92	0.54
Hypertension	45 (35.4)	26 (50.0)	0.07	0.18
Hypercholesterolemia	10 (7.9)	10 (19.2)	0.029	0.47
Diabetes mellitus	32 (25.2)	12 (23.1)	0.77	0.99
Prior myocardial infarction	2 (1.6)	1 (1.9)	0.87	-
Prior PCI	2 (1.6)	1 (1.9)	0.87	-
Prior stroke	0	0		-
Family history of premature CHD	4 (3.1)	1 (1.9)	0.65	-
Initial heart rate (beats/min) (mean, 95% CI)	81.3 (78.2-84.3)	82.2 (78.8-85.5)	0.74	0.91
Initial systolic blood pressure (mmHg) (mean, 95% CI)	130.4 (126.0-134.7)	138.3 (132.3-144.4)	0.039	0.24
Enrolment period			<0.001	0.08

Period 1 (Apr 2009 to Feb 2011)	84 (66.1)	7 (13.5)		
Period 2 (Mar 2011 to Dec 2012)	43 (33.9)	45 (86.5)		
Unstable angina in previous 48 hours, n (%)	23 (18.1)	7 (13.5)	0.45	0.98
Anterior myocardial infarction, n (%)	93 (73.2)	34 (65.4)	0.29	0.87
Cardiogenic shock, n (%)	1 (0.8)	0	-	-
LVEF at discharge (mean, 95% CI)	47.8 (46.0-49.5)	47.7 (45.0-50.4)	0.98	-

CHD: Coronary Heart Disease; CI: Confidence Interval; DSI: Delayed Stent Implantation; ISI: Immediate Stent Implantation; LVEF: Left Ventricular Ejection Fraction; PCI: Percutaneous Coronary Intervention.
*p adjusted on the propensity score.

Table 2: Angiographic and procedural characteristics.

Variables	ISI group (n=127)	DSI group (first procedure) (n=52)	p	p*
Delay from pain onset to hospital admission (minutes) (mean, 95% CI)	317.2 (288- 46.4)	303.9 (264-343.9)	0.60	0.04
Radial access, n (%)	5 (3.9)	1 (1.9)	0.67	-
Two- or three-vessel disease, n (%)	31 (24.4)	7 (13.5)	0.10	0.70
Initial TIMI 3, n (%)	8 (6.3)	10 (19.2)	0.009	0.44
Post-wire TIMI 3, n (%)	23 (18.1)	9/45 (20)	0.78	0.86
TIMI 3 after thrombus aspiration, n (%)	65/106 (61.3)	39/43 (90.7)	<0.001	0.84
Unfractionated heparin, n (%)	126 (99.2)	51 (98.1)	0.50	-
Glycoprotein IIb/IIIa inhibitor, n (%)	20 (15.7)	5 (9.6)	0.34	-
Thrombectomy (export), n (%)	99 (78.0)	39 (75.0)	0.62	-

CI: Confidence Interval; DSI: Delayed Stent Implantation; ISI: Immediate Stent Implantation; TIMI: Thrombolysis in Myocardial Infarction.
*p adjusted on the propensity score.

Table 3: ST-segment recovery at end of the first procedure.

ST-segment recovery	ISI group (n=127)	DSI group (n=52)	Odds ratio (95% CI)	p
≤50%, n (%)	42 (33.1)	15 (28.8)	0.8 (0.4-1.7)	0.63
51-74%, n (%)	68 (53.5)	18 (34.6)	0.4 (0.2-0.9)	0.02
≥75%, n (%)	17 (13.4)	19 (36.5)	3.7 (1.7-7.9)	0.001

CI: Confidence Interval; DSI: Delayed Stent Implantation; ISI: Immediate Stent Implantation.

Table 4: In-hospital clinical and angiographic outcomes.

Variables	ISI group (n=127)	DSI group (first procedure) (n=52)	p*
Angiographic endpoint, n (%)			
Final TIMI 3 coronary flow	117 (92.1)	50 (96.2)	0.51
Distal embolisation	4 (3.1)	2 (3.8)	0.999
No-reflow	4 (3.1)	0	0.58
Intraprocedural thrombotic events	13 (10.2)	3 (5.8)	0.40
Culprit artery reocclusion	7 (5.5)	1 (1.9)	0.44
Stent thrombosis	7 (5.5)	0	
Clinical outcome			
Length of stay (days) (mean, 95% CI)	7.46 (6.88-8.02)	8.31 (7.65-8.97)	0.057
Reinfarction, n (%)	7 (5.5)	1 (1.9)	0.44
All-cause death, n (%)	8 (6.3)	0	0.11
Cardiac death, n (%)	8 (6.3)	0	0.11
Stroke, n (%)	0	0	-
Major adverse cardiac event, n (%)	12 (9.4)	1 (1.9)	0.11

CI: Confidence Interval; DSI: Delayed Stent Implantation; ISI: Immediate Stent Implantation; TIMI: Thrombolysis in Myocardial Infarction.
*p adjusted on the propensity score.

Table 5: Comparison of implanted stent between immediate stenting group and second procedure of delayed stenting group.

Variables	Stent implantation		p
	ISI group (n=127)	DSI group (second procedure) (n=50)	
Patients stented, n (%)	127 (100)	16 (32.0)	<0.0001
Dilatation only with balloon, n (%)	0	7 (14.0)	-
Number of stents implanted per patient, n (%)			0.99
1	112 (88.2)	15/16 (93.7)	
2	11 (8.7)	1/16 (6.3)	
3	4 (3.1)	0	
Nature of stent, n (%) of stents implanted)			
Bare metal	111/127 (87)	11/16 (69)	0.06
Drug eluting	16/127 (13)	5/16 (31)	
Total length of stent (mm) (mean, 95% CI)	21.1 (19.2-23.0)	22.0 (11.8-32.2)	0.79
Minimal diameter (mm) (mean, 95% CI)	2.9 (2.9-3.0)	2.7 (2.2-3.3)	0.16
Minimal pressure (bars) (mean, 95% CI)	13.6 (13.0-14.2)	9.0 (3.8-14.2)	<0.0001

CI: Confidence Interval; DSI: Delayed Stent Implantation; ISI: Immediate Stent Implantation.

Discussion

On the basis of data from a single randomised trial and one meta-analysis [22,23], the use of stenting during PPCI is a class IA recommendation in guidelines from the European Society of Cardiology [2]. These two studies did not demonstrate any effect on mortality with the ISI approach, only a lower rate of revascularisations. It is therefore permissible not to systematically stent patients during PPCI.

Our comparative study showed a higher incidence of ST-segment resolution in patients treated with a DSI versus an ISI approach. Moreover, a DSI strategy allowed the avoidance of stenting in a high proportion of patients because of a non-significant residual lesion in the infarct-related artery.

The results of DSI in PPCI are consistent with retrospective observational studies. Cafri et al. reported a lower incidence of thrombus-related angiographic events in 24 patients treated with DSI versus 82 treated with ISI (4% vs. 26%, respectively, p=0.03) [12]. Meneveau et al. reported a higher rate of procedural success in infarct-related arteries, with spontaneous TIMI 3 flow in 39 patients treated with DSI versus 39 matched patients treated with ISI (95% vs. 77%, respectively, p=0.008) [3]. Tang et al. showed a significantly lower infarct size at 6 months in 40 patients treated with DSI performed 7 days later versus 47 patients treated with ISI [9]. Ké et al. reported a lower 6-month rate of major adverse events in 53 patients who underwent DSI (deferred for stenting for ≥7 days) versus 50 treated with ISI [10].

Furthermore, the low rate of stent implantation at the second procedure in patients treated with DSI in our study is consistent with findings from a recent study by Kelbaek et al [14]. In their study, 38% of 113 patients treated with DSI did not receive a stent at the second procedure because of <30% residual stenosis [14]. Escaned et al. Reported data from a cohort of 28 patients treated with only thrombus aspiration, without any stent implantation, with a low rate of major cardiac events at 40 months [13].

In our study we report one patient in the DSI group who developed an infarct-related artery reocclusion before the second procedure. However, in a recent meta-analysis of 6 studies published on the DSI strategy, none of the 283 subjects assigned to DSI experienced an acute coronary lesion in the interval between the initial reperfusion and stent implantation (average delay between procedures 3.7 days) [24].

ST-segment resolution was selected as the primary endpoint in the present study because it remains a reliable factor in myocardial perfusion during PPCI. The significantly higher rate of ST-segment resolution in patients treated with DSI versus ISI may be enhanced by 3 characteristics. First, antiplatelet treatment, with aspirin and clopidogrel, was started in the catheterisation laboratory. The lack of treatment started before the procedure may decrease the incidence of ST-segment resolution and increase that of reinfarction in the ISI group [25-27]. Second, our study registered a long delay between onset of pain and admission to hospital (303 minutes in the present study vs. 74 minutes in FAST MI [French registries of Acute ST-elevation and non-ST-elevation Myocardial Infarction] [28]). The relationship between long delays and poor reperfusion and prognosis has been reported [29], and such delays may make the DSI strategy more efficient. Third, this study included young patients (mean age 56 years vs. 63.7 years in FAST MI [28]) with a high proportion of smokers (48% vs. 40% in FAST MI [28]). Such patients are predisposed to thrombotic phenomena rather than stenotic lesions of atherosclerosis [30]. High thrombus burden is associated with a lower rate of ST-segment resolution.[30]

Under these conditions (i.e., lack of pretreatment with thienopyridines, long delays, high thrombus burden) complete removal of the thrombus in the infarct-related artery may be so hazardous that rupture of the residual clot and atherosclerotic plaque by subsequent stent implantation may result in distal coronary embolisation and may limit or even worsen myocardial reperfusion [31,32].

Comparisons of the DSI versus ISI strategies in PPCI had been lately reported in the Randomized Trial of Deferred Stenting versus Immediate Stenting to Prevent No or Slow Reflow in Acute ST-Elevation Myocardial Infarction (DEFER-STEMI). In this study, the rate of no/low reflow at angiogram was significantly reduced by 4-16 hours by deferred stenting. Moreover, 2 of 52

patients in the DSI group experienced an early infarct artery reocclusion, similar to the rate (1 in 52) in our study [33]. Other randomised studies are currently running, including the MIMI study (NCT01360242), with a primary endpoint of no-reflow assessed by cardiac magnetic resonance imaging 4-7 days after the first procedure, the Primary Reperfusion Secondary Stenting (PRIMACY) trial (NCT01542385) and the DANish Study of Optimal Acute Treatment of Patients With ST-elevation Myocardial Infarction (DANAMI-3) (NCT01435408), which had primary endpoints of MACEs.

Limitations

This study is subject to the usual limitations associated with non-randomised studies, leading to missing variables associated with ST-segment resolution; however, the use of a propensity score and multivariable analysis may help to overcome such limitations. Data on other relevant endpoints, such as adverse bleeding events, myocardial blush, and TIMI frame counts, were not collected, as the objective in our study was to determine ST-segment resolution.

Conclusions

The results of this study, which involved STEMI patients with a high thrombus burden, with no antiplatelet pretreatment, and with long delays to PPCI, suggest that DSI is safe, and is associated with a low rate of stent implantation and improved myocardial reperfusion. We also report a downward trend in the rate of infarct-related artery reocclusion in patients undergoing DSI. Large, randomised studies with longer follow-up are warranted to confirm the benefits of the DSI approach in these patients.

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