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Research Article

Deferred Versus Immediate Stenting for Treatment of Acute Myocardial Infarction: A Retrospective Matched Evaluation

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Abstract

Background: In myocardial infarction, despite successful treatment by primary percutaneous coronary intervention with stent implantation, unsuccessful reperfusion may occur. The aim of this study was to assess clinical outcomes of a deferred stenting strategy and to determine criteria benefitting most of this strategy.

Methods: This mono-centric retrospective study included all patients managed by deferred stenting for AMI between 2014 and 2020 (n = 80). This group was matched in 2:1 with patients treated by immediate stenting (n = 160). The primary endpoint was a composite of major adverse cardiac event at 1 and 2 years follow up. Secondary endpoints included angiographic and clinical parameters. Further patients were stratified according to conditions retained favorable to a deferred stenting strategy.

Results: The primary endpoint occurred in 26 (16%) patients in the IS group and in 21 (26%) in the DS group at 2 years follow-up. (OR 0.55 [0.28 – 1.05]; P = 0.07). No significant differences were found in intra-hospital outcome as well as LVEF at a median follow up of 36 months. A significant difference was observed in the subgroup of patients with lack of collaterals and with short ischemia time, favoring immediate stenting (6 [37.5%] vs 2 [6.2%] ; OR 0.11; P = 0.01).

Conclusion: In patients with AMI differate stent implantation does not reduce occurrence of MACE compared with conventional strategy up to 2 years follow-up. Stratified analysis suggests that deferred stenting should be avoided in absence of collaterals combined with an early AMI presentation.

Keywords: venous malformation; limb dysfunction; treatment status; sclerotherapy; surgical treatment; pharmacotherapy

Introduction

Acute myocardial infarction (AMI) is worldwide a significant cause of morbidity and mortality.(1) Despite advancements in medical therapy and reperfusion strategies, AMI continues to have negative effects on patient outcomes, such as reinfarction and heart failure and engendering an important socio-economic burden.(2) Further recent efforts to improve prognosis post-AMI through different revascularization strategies have not translated into clinical benefits.(3–5) Primary percutaneous intervention (PCI) with stent implantation, compared with balloon angioplasty alone, has been shown to prevent early reocclusion and reduce the need for subsequent revascularization of the target lesion. Although the mortality benefit of this strategy has not been well established, it is currently the standard treatment for patients with acute ST-segment elevation myocardial infarction (STEMI).(5,6) However, in some patients stenting in the presence of a significant thrombus burden at the culprit lesion can compromise coronary flow by distal embolization and obstruction of the microcirculation. Thus, despite obtaining a patent epicardial vessel, the impaired myocardial reperfusion is increasing the risk of myocardial injury, predisposing to heart failure and hampering prognosis.(7,8)

Various strategies for removing thrombus from the culprit lesion, such as thrombectomy or distal protection devices, have been evaluated in randomized trials with inconsistent results, while adjuvant

pharmacological treatment or pre-treatment seemed more promising.(9,10) Advances in dual antiplatelet therapy have significantly reduced the rates of subacute coronary re-occlusion after PTCA in STEMI patients.(11) Further pre-treatment using a combination of anti-thrombin agents and oral bi-anti-platelet therapy has also led to a reconsideration of immediate stenting and has opened the way of stenting after resolution of the acute thrombotic environment. This delayed stenting approach consists of a minimalistic strategy of immediate mechanical intervention - proposed for the first time by Isaaz et al.(12) - enabling coronary reperfusion with minimal damage to the coronary artery and minimizing the risk of distal embolization. The stent may be implanted when the thrombotic load has significantly regressed after a time-period of a combination therapy including an anti-thrombin agent and an oral dual antiplatelet therapy, with or without GPIIb/IIIa blockade, to minimize the occurrence of no-reflow after stenting.(8)

This strategy has been the subject of five randomized trials (3,13–16), without succeeding to demonstrate a clinical benefit in an unselected patient population presenting with acute MI, despite initially promising results of observational series evaluating myocardial perfusion, left systolic function as well as adverse cardiac events.(17–19) Taking into account the results of Souteyrand et al.(20) showing a regression of the thrombotic load within 7 days of myocardial infarction, as well as those of Sianos et al.(21) showing that improved myocardial reperfusion following primary PCI correlates with low thrombotic load on initial angiography, we hypothesize that a deferred stenting strategy would be mostly beneficial in a selected patient population with a high thrombotic burden, at high risk of micro-vascular obstruction, and following a coherent anti-thrombotic protocol.

Methods:

Patient population

In this monocentric retrospective study all patients hospitalized for acute myocardial infarction (AMI), treated by primary PCI without stent deployment and followed by a second coronary angiogram within 30 days between January 2014 and December 2020 were pre-selected from the institutional database. Prior inclusion all patients' histories and coronary angiographies were reviewed to confirm a two-stage treatment strategy of AMI. Patients were matched 1:2 with AMI patients who had undergone primary PCI with immediate stenting. The matching process included a two step-procedure a first matching according to gender, age, culprit vessel, coronary status, TIMI flow and a second matching according to ischemic time and Killip class (described in the appendix). Exclusion criteria for both groups were pre-hospital cardiac arrest, cardiogenic shock on admission, fibrinolytic therapy, an intra-stent event, a type C or greater dissection on initial presentation, a suspected embolic origin of acute coronary syndrome or indications for emergency cardiovascular surgery. AMI was defined as symptoms consistent with myocardial ischemia associated with at least one of the following criteria: 1 mm of ST elevation or depression in two contiguous leads, or a raised troponin T or I level on blood sample.(22)

Sub-group stratification

The study population was also stratified according to the criteria: (1) complete application of the anti-thrombotic protocol, and (2) most favorable angiographic and clinical conditions for a deferred stenting strategy.

The complete anti-thrombotic protocol was defined by a curative anticoagulation in association with a bi-antiplatelet therapy for at least 5 days prior to the second coronary angiography. Most favorable condition was definite as a complete antithrombotic protocol and angiographic collaterals of at least Rentrop $\geq$ 1 distal to the culprit lesion on the initial angiography combined with an ischemia time of > 6 h (sub-group 1). Sub-group 2 had a complete anti-thrombotic protocol, no collaterals or an ischemia time $\leq$6h, subgroup 3 consisted of an incomplete anti-thrombotic protocol, Rentrop collaterals $\geq$1 and ischemia time > 6h. Most unfavorable condition was defined as an incomplete anti-thrombotic protocol, no collaterals and an ischemia time <6h (subgroup 4).

The stratification according to these two criteria resulted in a 2 by 2 contingency table and thus 4 subgroups.

Endpoints

The primary endpoint was the composite of overall mortality, or recurrent myocardial infarction, target lesion revascularization, stroke or re-hospitalization for heart failure (MACCE) at 2 years after the index AMI. Secondary endpoints included: MACCE at 1 year, MACCE without stroke (MACE) at 1 and 2 years, intra-hospital clinical outcomes, angiographic results at the end of procedure (including TIMI flow grade, myocardial blush grade (MBG) (23) and distal embolization and procedural variables.

Intra-hospital clinical outcomes included biomarker-levels (CPK value measured on patient admission and at 24 hours), LVEF on admission, acute renal failure, hemorrhagic complications, stroke, need for urgent revascularization, recurrence of myocardial infarction and mortality during the intra-hospital period. Renal failure was defined as a grade 2 according to the KDIGO classification (24) and consisted of an increase in plasma creatinine of > 2 times its previous value or the appearance of oliguria (<0.5 ml/kg/h) lasting > 12 hours. Hemorrhagic complication was defined as TIMI major or minor bleeding that was unrelated to coronary-artery by- pass graft (CABG) surgery.(25) Angiographic analysis is described in the appendix.

Data collection and follow up

The clinical endpoints were collected via the computerized software (DxCare, Dedalus, France) of the University Hospital of Nancy, via the medical correspondence of peripheral hospitals. For each patient latest clinical history, LVEF, percentage of myocardial necrosis as obtained by functional ischemic test were collected. Baseline LVEF was performed within 24 months after inclusion. Re-hospitalization for follow-up coronary angiography and target lesion revascularization, for heart failure, re-infarction or stroke were monitored. Mortality was assessed by consulting two nationwide dedicated websites.

Statistical analysis

Data are represented as number and percentage for categorical variables, and mean ±standard deviation or median and interquartile range [IQR] for quantitative variables [25th percentile - 75th percentile]. The Kolmogorov-Smornov test was performed in order to evaluate variables distribution. Chi square test or Fisher's exact test were used to compare categorical variables, and Student t-test or Mann-Whitney U test to compare quantitative variables. Significant p value was set at 0.05. Statistical analysis was performed using SPSS ver. 25.0 (IBM, Chicago, IL, USA).

Results:

At the University Hospital of Nancy between January 2014 and December 2020 80 patients were treated for AMI with a deferred stenting strategy (DS-group) and all consecutive patients were included in this study. In the same time period a total of 2621 patients underwent primary PCI with immediate stenting. The flow-chart of the included 160 matched patients with immediate stenting (IS-group) is described in Figure 1.

		Deferred stenting (n = 80) N(%)	**Immediate stenting (n = 160) N(%)**	P
Male sex		58 (72)	116 (72)	1
Age, mean (standard deviation)		61.8 (14.2)	61.8 (13.8)	0.98
Body-mass index (kg/m2) Median [IQR]		26 [23.6 – 30.4]	26.5 [24.3 – 29.8]	0.56
Diabetes mellitus		11 (14)	22 (14)	1
Hypertension		40 (50)	81 (51)	0.93
Hypercholesterolemia		25 (32)	53 (33)	0.82
History of smoking		49 (61)	96 (60)	0.85
Current smoker		39 (49)	75 (47)	0.78
Premature coronary artery disease in first-degree relative		9 (11)	21 (13)	0.68
Previous myocardial infarction		4 (5)	11 (6.9)	0.57
Previous coronary revascularization		5 (6.2)	8 (5)	0.76
Previous stroke		0 (0)	2 (1.2)	0.55
Peripheral-artery disease		1 (1.2)	2 (1.2)	1
Chronic renal insufficiency		6 (7.5)	10 (6.2)	0.71
Creatinin clearance (ml/min) Median [IQR]		88 [73-100]	90 [79- 90]	0.57
Chronic obstructive bronchopathy		4 (5)	10 (6.2)	0.78
Hemoglobin (g/dl), mean (standard deviation)		13.9 (2.05)	14.5 (1.67)	**0.02**
STEMI		71 (89)	130 (81)	0.14
Killip class	1	74 (92)	153 (96)	0.42
	2	4 (5)	6 (3.8)	-
	3	2 (2.5)	1 (0.62)	-
Class of delay to treatment	< 6h	34 (42)	71 (44)	0.99
	6-11h	19 (24)	36 (22)	-
	12-24h	13 (16)	25 (16)	-
	> 24h	14 (18)	28 (18)	- -
Delay to treatment		9.00 [4.00 - 14.7]	7.00 [3.00 - 15.0]	0.58

There were no significant differences between the DS-group and IS-group in terms of baseline demographic characteristics and clinical presentation except for hemoglobin-levels on admission, which were higher in the IS-group (Table 1). Of the overall population, 72% were male and the average age was 61.8 years. On admission 84% presented a STEMI with a Killip class 1 in 94% of the cases. Median ischemic time was 8 hours and 57% of the patients were managed with an ischemia delay of more than 6 hours. The baseline angiographic data are summarized in Table 2 and were significatively different between the two groups: calcification and thrombotic burden were higher in the DS-group in which a thrombotic load was observed in 100% of the cases. TIMI thrombus grade 0 to 3 was seen in 1.2% in the DS-group vs 18% in the IS-group. Lesions were also longer on average, in the IS-group (median: 18mm versus 16mm). There were no significant differences in the initial TIMI flow or in the collateral vessels according to the Rentrop grade.

	Deferred stenting (n = 80) N (%)	**Immediate stenting (n = 160) N (%)**	OR[$CI_{95\%}$]	P
All cause death	2 (2.5)	4 (2.5)	1 [0.18 – 5.58]	1
Unplanned target lesion revascularization	7 (8.8)	5 (3.2)	0.34 [0.10 – 1.10]	0.11
Myocardial reinfarction	7 (8.8)	5 (3.2)	0.34 [0.10 – 1.10]	0.11
Stroke	1 (1.2)	1 (0.62)	0.50 [0.31 – 8.01]	1
Hemorrhage	5 (6.3)	7 (4.4)	0.68 [0.21 – 2.21]	0.54
Renal failure	4 (5.1)	11 (6.9)	1.38 [0.43 – 0.43]	0.78
CPK (U/L)	1772 [724; 2976]	1402 [552; 2569]		0.14
Admission LVEF, %	46.64 ± 8.52	48.62 ± 7.86		0.32
Length of stay (days)	8.00 [7.00; 11.0]	4.00 [3.00; 6.00]	0.73 [0.66 – 0.81]	**<0.001**

Table 1 appendix : **Intra-hospital outcomes**

		Deferred stenting(n = 80) N (%)	**Immediate stenting (n = 160) N (%)**	P
Vessel location (by lesion)				1
Left anterior descending		24 (30)	48 (30)	-
Left circumflex		14 (18)	28 (18)	-

Right coronary artery		42 (52)	84 (52)	-
Bifurcation		11 (14)	16 (10)	0.41
Coronary status				1
Mono-truncal		54 (67.5)	108 (67.5)	-
Bi-truncal		19 (23.75)	38 (23.75)	-
Tri-truncal		7 (8.8)	14 (8.8)	-
Calcification		12 (15)	9 (5.7)	**0.02**
Thrombus burden		80 (100)	145 (91)	**< 0.01**
TIMI Thrombus grade	0	0 (0)	5 (3.1)	**< 0.01**
	1	0 (0)	7 (4.4)	-
	2	0 (0)	3 (1.9)	-
	3	1 (1.2)	13 (8.1)	-
	4	21 (26)	21 (13)	-
	5	58 (72)	111 (69)	-
Vessel diameter (mm)		3.00 [2.75; 3.50]	3.00 [2.75; 3.50]	0.09
Lesion length (mm)		18.0 [16.0; 26.0]	16.0 [12.0; 22.0]	**< 0.01**
Collaterality (Rentrop)	0	34 (42)	59 (37)	0.51
	1	25 (31)	62 (38)	-
	2	21 (26)	39 (25)	-
	3	0 (0)	0 (0)	-
Initial TIMI flow grade	0	58 (72)	113 (71)	0.08
	1	8 (10)	6 (3.8)	-
	2	11 (14)	24 (15)	-
	3	3 (3.8)	17 (11)	-

Table 2: Angiographic and lesion characteristics

The acute procedural data did not differ significantly between the two groups, as shown in Table 3 except for the number of stents. Although not significant, there was a trend towards more frequent use of thrombo-aspiration in the DS-group (37% vs 25%, p = 0.07). The use of a GPI therapy (52% versus 33%, p = 0.01) of which 18% vs 5% (p < 0.01) included a post-procedural i.v. infusion for ≥ 12h was more frequent in the DS-group. There was no significant difference in the procedural use of anti-thrombin and anti-platelet therapy between the 2 groups.

	Deferred stenting* (n = 80) N (%)	**Immediate stenting (n = 160) N (%)**	P
Guidewiring	77 (95)	160 (100)	0.11
Thrombectomy	29 (37)	40 (25)	0.07
Use of balloon	54 (68)	91 (57)	0.13
Stent implanted (mean ±SD)	0 (0)	1.19 ± 0.47	-
Anti-thrombin	78 (98)	148 (93)	0.15
ASA	79 (99)	158 (99)	1
Ticagrelor	60 (75)	98 (62)	0.05
Prasugrel	9 (11)	20 (13)	0.11
Clopidogrel	4 (5)	12 (7.6)	0.57
Glycoprotein inhibitors	42 (52)	52 (33)	**0.01**
Pursuit anti-thrombin therapy	77 (96)	31 (19)	-
Length of antithrombin therapy (days), median	6.00 [4.00; 7.00]	1.00 [1.00; 2.00]	**< 0.01**
Pursuit GPI infusion for ≥12hours	14 (18)	8 (5)	**< 0.01**
Fluoroscopy time (min)*	9.45 [6.25; 17.0]	8.47 [6.34; 12.5]	0.33
Total PDS (cGy)*	5952 [3315; 11726]	5480 [3629; 9322]	0.43
Total contrast used (mL)*	150 (60.4)	164 (55.8)	0.58

*First procedure

Table 3: Initial procedural characteristics and anti-thrombotic management

Post-procedural anti-thrombotic regimen consisted of a curative antithrombin therapy with a median duration of 6 days in 96% of the patients in the DS-group. In the IS-group 19% of the patients benefited from a post-procedural curative antithrombin therapy for a median duration of 24hours. Angiographic outcomes after 2nd procedure (DS-group) and the initial procedure (IS-group) are summarized in Table 4.

		Deferred stenting (n = 80) N (%)	**Immediate stenting (n = 160) N (%)**	P
TIMI flow grade	0	0 (0)	0 (0)	**0.01**
	1	0 (0)	6 (3.8)	-
	2	4 (5.1)	24 (15)	-

	3	75 (95)	130 (81)	-
Myocardial blush grade	0	0 (0)	6 (3.8)	< **0.01**
	1	6 (7.6)	33 (21)	-
	2	25 (32)	53 (33)	-
	3	48 (61)	68 (42)	-
No reflow		7 (8.9)	42 (26)	< **0.01**
Distal embolization		3 (3.8)	28 (18)	< **0.01**
Final stent number, mean± SD		0.81 ± 0.72	1.19 ± 0.47	< **0.01**
Patients with stent implanted		57 (61)	160 (100)	**-**
Total contrast used (mL)		261 [204 ; 316]	152 [125 ; 189]	< **0.001**
Total PDS used (cGy)		10185 [5798; 17319]	5479 [3624; 9329]	< **0.001**

Table 4: Angiographic results after final procedure

Coronary flow evaluated by TIMI flow grade and myocardial perfusion estimated by myocardial blush grade (MBG) was significantly higher in the DS-group versus the IS-group. On the contrary no reflow (8.9% vs 26%; $p < 0.001$) or distal embolization (3.8% vs 18% ; $p < 0.001$) were significantly more frequent in the IS-group. The finally used number of stents was significantly lower in the DS-group versus the IS-group with 23 patients (29%) not requiring stent implantation in the DS-group. Totally used contrast amount and radiation was higher in the dual procedure DS-group.

Intra-hospital outcomes are recapitulated in Table 1 appendix. There was no statistically significant difference in intra-hospital event rates between the two groups. Hospital stay was significantly longer in the DS-group, with a median of 8 days versus 4 days in the DS-group ($p < 0.01$).

	Deferred stenting (n = 80)	**Immediate stenting (n = 160)**	p
LVEF within 24 months, mean (SD)	52.8 ± 8.1	51.9 ± 8.9	0.43
Median delay LVEF within 24 months	13.0 [10.0 ; 18.0]	14.0 [11.0; 19.0]	0.29
LVEF latest, mean (SD)	53.3 ± 7.9	52.3 ± 9.1	0.43
Median delay LVEF latest	37 [20.0 – 55.0]	35 [24.0 – 53.0]	0.95
Myocardial necrosis, mean % (SD)	15.2 ± 8.2	19.2 ± 12.6	0.23

Table 2 appendix: Left ventricular ejection fraction and myocardial necrosis

Table 2 appendix shows the evolution of left ventricular ejection fraction obtained in 216 (90%) patients at a median follow-up of 13.5 months. There was no statistically significant difference between the 2 groups. The size of the necrosis measured isotopically was recorded in 89 patients (37%), and showed no significant difference but a trend towards a smaller median necrotic area with 10% in the DS-group versus 15% in the IS-group.

	Deferred stenting (n = 80) N (%)	**Immediate stenting (n = 160) N (%)**	OR[$CI_{95\%}$]	p
At 1 year				
Composite primary outcome (MACCE)	16 (20)	20 (13)	0.57 [0.28 – 1.18]	0.13
Composite primary outcome (MACE)	14 (18)	19 (12)	0.64 [0.30 – 1.34]	0.23
All cause death	5 (6.2)	8 (5)	0.79 [0.25 – 2.50]	0.76
Myocardial reinfarction	8 (10)	7 (4.4)	0.41 [0.14 – 1.18]	0.09
Unplanned target lesion revascularization	10 (12)	8 (5)	0.37 [0.14 - 0.97]	**0.04**
Hospital admission for heart failure	2 (2.5)	3 (1.9)	0.74 [0.12 – 4.55]	1
Stroke	3 (3.8)	2 (1.2)	0.33 [0.05 – 1.98]	0.34
At 2 years				
Composite primary outcome (MACCE)	21 (26)	26 (16)	0.55 [0.28 – 1.05]	0.07
Composite primary outcome (MACE)	19 (24)	25 (16)	0.60 [0.31 – 1.16]	0.13
All cause death	10 (12)	8 (5)	0.52 [0.21 – 1.27]	0.15
Myocardial reinfarction	10 (12)	9 (5.6)	0.42 [0.16 – 1.07]	0.06
Unplanned target lesion revascularization	10 (12)	10 (6.2)	0.47 [0.19 – 1.17]	0.1
Hospital admission for heart failure	2 (2.5)	4 (2.5)	1 [0.18 – 5.58]	1
Stroke	3 (3.8)	4 (2.5)	0.66 [0.14 – 3.01]	0.69

Table 5: Clinical outcomes at 1 year and 2 years are summarized

Clinical outcomes at 1 year and 2 years are summarized in Table 5. The composite primary endpoint of all-cause mortality, recurrent infarction and unplanned revascularization of the target lesion, hospital admission for heart failure and stroke at 2 years were not significantly different (21 [26%] vs 26 [16%], OR 0.55 [0.28 – 1.05], $p = 0.07$) but with a trend in favor of the IS-group. Individual components of the composite endpoint were also non-significantly different, with a trend towards a higher myocardial reinfarction rate in the DS-group (10 [12%] vs 9 [5.6%], OR

0.42 [0.16 – 1.07], p = 0.06). Results were consistent with the one-year data, with the exception of a significant difference in the occurrence of an unplanned revascularization of the culprit lesion (10 [12%] vs 8 [5%], OR 0.37 [0.14 – 0.97], p = 0.04) at 1 year in the DS-group.

At 1 year	**Deferred stenting (n = 80) N (%)**	**Immediate stenting (n = 160) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)				
Sub-group 1 (n = 21 vs 42)	2 (9.5)	8 (19.0)	2.24 [0.43 – 11.62]	0.47
Sub-group 2 (n = 35 vs 70)	6 (17.1)	8 (11.4)	0.62 [0.20 – 1.97]	0.42
Sub-group 3 (n = 8 vs 16)	2 (25.0)	2 (12.5)	0.43 [0.05 – 3.79]	0.58
Sub-group 4 (n = 16 vs 32)	6 (37.5)	2 (12.5)	0.11 [0.02 – 0.64]	**0.01**
Composite primary outcome (MACE)				
Sub-group 1 (n = 21 vs 42)	1 (4.8)	8 (19.0)	4.7 [0.55 – 40.44]	0.25
Sub-group 2 (n = 35 vs 70)	5 (14.3)	7 (10.0)	0.67 [0.20 – 2.28]	0.52
Sub-group 3 (n = 8 vs 16)	2 (9.5)	2 (12.5)	0.43 [0.05 – 3.79]	0.58
Sub-group 4 (n = 16 vs 32)	6 (17.1)	2 (12.5)	0.11 [0.02 – 0.64]	**0.01**

At 2 years	**Deferred stenting (n = 80) N (%)**	**Immediate stenting (n = 160) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)				
Sub-group 1 (n = 21 vs 42)	6 (28.6)	11 (26.2)	0.89 [0.26 – 2.86]	0.84
Sub-group 2 (n = 35 vs 70)	7 20.0)	11 (15.7)	0.75 [0.26 – 2.13]	0.58
Sub-group 3 (n = 8 vs 16)	2 (25.0)	2 (12.5)	0.43 [0.05 – 3.79]	0.58
Sub-group 4 (n = 16 vs 32)	6 (37.5)	2 (12.5)	0.11 [0.02 – 0.64]	**0.01**
Composite primary outcome (MACE)				
Sub-group 1 (n = 21 vs 42)	5 (23.8)	11 (26.2)	1.14 [0.34 – 3.84]	0.84
Sub-group 2 (n = 35 vs 70)	6 (17.1)	10 (14.3)	0.81 [0.27 – 2.43]	0.70
Sub-group 3 (n = 8 vs 16)	2 (25.0)	2 (12.5)	0.43 [0.05 – 3.79]	0.58
Sub-group 4 (n = 16 vs 32)	6 (37.5)	2 (12.5)	0.11 [0.02 – 0.64]	**0.01**

Table 6: Sub-groups outcome

Table 6 shows the primary outcome in the 4 sub-groups, stratified according to the administration of an optimal anti-thrombotic protocol and according to angiographic and clinical conditions retained favorable to deferred stenting.

A total of 21 patients in the DS-group received 5-7 days of anti-thrombin therapy in combination with a dual anti-platelet therapy, independently of GPIIb/IIIa administration (defined as optimal antithrombotic protocol) and had a Rentrop collaterality grade $\geq$ 1 combined with an ischemia time of $\geq$ 6 h (sub-group 1). Sub-group 4 consisted of 16 patients who had not received an optimal anti-thrombotic protocol, had no collaterality and an ischemia time < 6h. Analysis revealed a significant difference in the sub-group 4 on the incidence of composite primary endpoint, studied at 2 years in favor of the IS-group (sub-group 4 ; 6 [37.5%] vs 2 [6.2%] ; OR 0.11 [0.02 - 0.64] ; P = 0.01). These results were also found at 1-year. There was an overall trend towards increased incidence of the primary composite endpoint in the DS-group across all the four sub-groups, with the exception of sub-group 1 in which the trend was reversed at one year. Table 3 appendix shows the primary endpoint and its individual components for the sub-groups 1 and 4.

Sub-group 1 At 1 year	**Deferred stenting (n = 21) N (%)**	**Immediate stenting (n = 42) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)	2 (9.5)	8 (19.0)	2.23 [0.43 – 11.62]	0.47
Composite primary outcome (MACE)	1 (4.8)	8 (19.0)	4.71 [0.55 – 40.44]	0.25
All cause death	0 (0)	3 (7.1)	3.81 [0.19 – 77.25]	0.54
Myocardial reinfarction	0 (0)	4 (9.5)	5.03 [0.26 – 97.95]	0.29
Unplanned target lesion revascularization	0 (0)	3 (7.1)	3.81 [0.19 – 77.25]	0.54
Hospital admission for heart failure	1 (4.8)	1 (2.4)	0.49 [0.03 – 8.21]	1.00
Stroke	1 (4.8)	1 (2.4)	0.49 [0.03 – 8.21]	1.00
Sub-group 1 At 2 years	**Differate stenting (n = 21) N (%)**	**Immediate stenting (n = 42) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)	6 (28.6)	11 (26.2)	0.89 [0.27 – 2.86]	1
Composite primary outcome (MACE)	5 (23.8)	11 (26.2)	1.13 [0.34 – 3.83]	1
All cause death	3 (14.3)	5 (11.9)	0.81 [0.17 – 3.77]	1
Myocardial reinfarction	1 (4.8)	5 (11.9)	2.70 [0.29 – 24.76]	0.65

Unplanned target lesion revascularization	0 (0)	4 (9.5)	5.03 [0.26 – 97.95]	0.29
Hospital admission for heart failure	1 (4.8)	2 (4.8)	1 [0.08 – 11.70]	1.00
Stroke	1 (4.8)	2 (4.8)	1 [0.08 – 11.70]	1.00
Sub-group 4 At 1 year	**Differate stenting (n = 16) N (%)**	**Immediate stenting (n = 32) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)	6 (37.5)	2 (6.25)	0.11 [0.02 – 0.64]	**0.01**
Composite primary outcome (MACE)	6 (37.5)	2 (6.25)	0.11 [0.02 – 0.64]	**0.01**
All cause death	2 (12.5)	1 (3.12)	0.23 [0.02 – 2.70]	0.25
Myocardial reinfarction	4 (25)	0 (0)	0.04 [0.01 – 0.80]	< **0.01**
Unplanned target lesion revascularization	5 (31.2)	1 (3.12)	0.07 [0.01 – 0.68]	**0.01**
Hospital admission for heart failure	0 (0%)	0 (0%)	-	-
Stroke	0 (0%)	0 (0%)	-	-
Sub-group 4 At 2 years	**Differate stenting (n = 16) N (%)**	**Immediate stenting (n = 32) N (%)**	OR[$CI_{95\%}$]	P
Composite primary outcome (MACCE)	6 (37.5)	2 (6.25)	0.11 [0.02 – 0.64]	**0.01**
Composite primary outcome (MACE)	6 (37.5)	2 (6.25)	0.11 [0.02 – 0.64]	**0.01**
All cause death	2(12.5)	1 (3.12)	0.23 [0.02 – 2.70]	0.25
Myocardial reinfarction	5 (31.25)	0 (0)	0.03 [0.01 – 0.59]	< **0.01**
Unplanned target lesion revascularization	5 (31.2)	1 (3.12)	0.07 [0.01 – 0.68]	**0.01**
Hospital admission for heart failure	0 (0)	0 (0)	-	-
Stroke	0 (0)	0 (0)	-	-

Table 3 appendix: Composite primary outcome in sub-groups 1 and 4

Discussion

The main findings of the current study comparing a deferred versus and immediate stenting strategy for the treatment of AMI suggest: (1) a rheological better acute end-of-procedure outcome with the deferred stenting strategy, (2) a numerically better LVEF with a smaller necrotic extension following the deferred stenting strategy (3) the overall absence of a clinical benefit from a deferred stenting strategy, with a trend towards an increased incidence of MACCE and MACE at 2 years and (4) a significantly unfavorable outcome of the deferred stenting strategy in the sub-group receiving an incomplete antithrombotic therapy, with a lack of collateral circulation distal to the culprit lesion combined with a short ischemia time (<6h). Acute angiographic results obtained at the end of the initial procedure suggested a superiority of a deferred stenting strategy versus standard primary PCI in terms of management of intra-coronary thrombus and its related events secondary to distal embolization (Table 4), confirming the findings of previous studies.(3–7) The incidence of no-reflow after stent implantation in the current study was 26% in the IS-group, which was higher than previously described in the literature (between 5% and 25%).(8) This may reflect a higher thrombus burden in the matched group of the current series (Table 2). Given the present results as well as data from the literature immediate stenting seems to confirm an impairment of initial per-procedural myocardial perfusion in the setting of AMI. In fact the clinical results of the current study, compared to a control population matched according to risk factors for thrombosis-related events and unfavorable prognostic factors for myocardial infarction, suggest the absence of benefit from a deferred stenting strategy, with a trend towards an increased incidence of MACCE. These results are consistent with those found in prospective randomized studies carried out in recent years, and differ from previous observational series, which found a benefit in terms of clinical events.(3,16–18,26)

The DANAMI3-DEFER study, the largest prospective randomized trial to date studying this therapeutic strategy, found no significant difference in clinical outcomes in an unselected STEMI population at 4 years follow-up.(3) A meta-analysis carried out by Qiao et al. in 2017 including almost all studies on delayed stenting strategy as well as the latter study found a trend towards a reduction in MACE in favor of the deferred stenting group, without however reaching significance.(27) In the current study, the incidence of MACE in the DS-group was largely led by revascularization of the culprit lesion and reinfarction with 70% of occurrence during the intra-hospital period between the two procedures. The incidence of reinfarction during the intra-hospital period was 8.8% in the DS-group (Table 5), which was higher than observed in the literature (reported range between 2% and 7% in randomized trials).(3,14,16) This may be explained by a low use of GPI in the DS-group (52%) among which solely 33% (n=14) benefited from a GPI infusion for at least 12h following the procedure. In the trial of Tang et al.(19), a GPI infusion was systematically administered for 72 to 96 hours, with no cases of re-occlusion reported. This was observed also in the DEFER-STEMI randomized trial(16), in which 98% of the patients in the delayed stenting group received a 12h post-procedural GPI infusion with only 2 cases experiencing a re-occlusion. Also in the current study, no cases of re-infarction were detected in between the two procedures in patients (n = 14) receiving a bolus followed by a post-procedural infusion of GPI for at least 12h. Of interest in patients (n = 28) receiving only a bolus of GPI, 4 (14%) experienced an occlusion, demonstrating the importance of a continuous infusion when the use of GPI inhibitors seemed procedurally indicated. A further explanation of the increased re-occlusion and MI rate in the DS-group could be an initially lower thrombus burden and TIMI thrombus grade associated with a numerically higher TIMI 3 flow in the IS-group (Table 2), which may have influenced also overall long-term prognosis. Lastly, the median time between procedures was 6 days in the current series, which is longer than in most previous trials and performed

wittingly following observational dissolution of coronary thrombus mostly following ≥5 days of antithrombotic therapy. This strategy proved also previously its feasibility in a retrospective trial by Ke et al. in which nearly complete thrombus dissolution was observed after at least 7 days of curative anticoagulation.(18)

The stratification in four sub-groups according to antithrombotic protocol, presence of collaterals and ischemia time (Table 6), revealed a significant increase in the incidence of MACCE at one and two years in the sub-group receiving an antithrombotic protocol for < 5 days, with insufficient collateral vessels distal to the culprit lesion and a short ischemia time (<6h) (subgroup 4). These results indicate the need to evaluate risk-benefit ratio for the clinical application of the deferred stenting strategy. According to the current findings patients with an important thrombus load seem not to benefit from a deferred stenting strategy in the absence of collaterals combined with a short (<6h) ischemia time. This constellation is particularly vulnerable to a deferred reperfusion strategy due to the risks inherent to reocclusion-induced ischemia secondary to the lack of collaterals.(28) Analysis of the single components of the primary endpoint in sub-group 4 confirmed that myocardial infarction and unplanned target lesion revascularization contributed significantly to the main primary endpoint with three of those occurring between the two procedures. In contrast sub-group 1 receiving the antithrombotic therapy for > 5 days, presenting late and with sufficient collaterals distal to the culprit lesion showed a numerical trend favoring a deferred stenting strategy at 1 year, which however faded away at 2 years follow-up. Further of interest the observed almost absence of unplanned lesion revascularization and myocardial infarction at 1 and 2 years.

Limitations: Firstly, this is a retrospective, nonrandomized, monocentric trial, and a potential selection bias of the included patients may have occurred. Even though the number of operators accustomed to manage AMI is small and potentially allowing the development of a Center related strategy to treat AMI, the final choice and criteria of a deferred stenting strategy remained operator dependent. The current potential selection bias may also been as an advantage as solely patients retained unsuitable for a direct stenting strategy were selected. In this real world clinical setting the selected AMI patient population was characterized by an important thrombus burden. In fact solely 3% (80/2621) of the AMI patients were not retained suitable for a direct stenting strategy in the period from 2014 to 2020. Secondly, even though carefully executed the matching process may have a bias. The currently used 1:2 matching process according to risk factor of thrombus-related event aimed however to improve reliability of the matched patient population and of the statistical analysis. Nevertheless thrombus burden and TIMI flow were lower in the control-group, setting a higher bar to the deferred stenting strategy to demonstrate a benefit. Thirdly, as with any retrospective trial, there is an information bias, with data that may be incomplete or missing.

Conclusion:

In conclusion, this study suggests that deferred stent implantation in AMI patients does not appear to reduce MACCE/MACE rates compared with standard immediate PCI and may be associated with an increased rate of target lesion revascularization and reinfarction. It further suggests that in certain subgroup deferred stenting should be avoided and that it may be attempted in the presence of an important thrombus burden and in the presence of collaterals as well as of late presentation.

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Appendix:

Angiographic analysis

Angiographic analysis was made by experienced operators to determine epicardial blood flow of the culprit vessel as assessed by TIMI flow grade and thrombus score of the culprit lesion as assessed by Gibson TIMI thrombus grade.(29) Myocardial perfusion was quantified by Myocardial Blush Grade (MBG) and TIMI myocardial perfusion grade(30) at the end of the procedure. No reflow was defined as TIMI flow < 3 at the end of the procedure or TIMI 3 flow associated with MBG grade 0 or 1.(31) Distal embolization was defined as convex filling defect, partially or completely obstructing a coronary vessel distal to the culprit lesion.(32) Collaterality was assessed by Rentrop grade.(33)

Matching process

The matching process was carried out in two stages: the first step allowed to stratify the patients according to the following criteria: (1) gender, (2) date of birth +/- 5 years, (3) culprit vessel, (4) coronary status (mono-, bi- or tri-truncal), (5) TIMI flow score on initial angiography (TIMI = 0 or TIMI > 0)(30)

Then the medical records of the patients initially eligible after the first step were examined, in order to obtain:

(6) ischemic time defined as the time between onset of symptoms and initial angiography, stratified into 4 classes (class 1 : < 6h, class 2 : 6h to <12h, class 3: 12h to 24h, Class 4: > 24h)

(7) Killip class on admission(34)

Following the first matching step, if no patient matched all the 5 predefined matching criteria, the patient's date-of-birth was extended stepwise by 1 year, up to 5 additional years. Following the second matching step if no patient matched the ischemic time, the ischemic class was stepwise expanded by 1 class. If no patient matched, the Killip grade was expanded stepwise by 1 grade. If at the end of the matching process more than two patients of the control group (IS group) were matching one patient of the DS group they were randomly allocated.

Matching table

Number of eligible patients per stage of matching	Eligible after first matching	Eligible after exclusion	Eligible after 2° matching	Eligible after expansion of criteria
Patient 1	51	43	3	
Patient 2	37	30	8	
Patient 3	9	5	5	
Patient 4	36	31	17	
Patient 5	6	4	3	
Patient 6	9	7	2	
Patient 7	7	6	2	
Patient 8	37	32	23	
Patient 9	51	44	28	
Patient 10	11	10	3	
Patient 11	26	21	10	
Patient 12	31	26	7	
Patient 13	21	17	0	4
Patient 14	35	30	2	
Patient 15	15	5	2	
Patient 16	3	1	0	3
Patient 17	35	27	14	
Patient 18	6	5	2	
Patient 19	18	16	2	
Patient 20	7	3	0	2
Patient 21	34	18	5	
Patient 22	10	8	8	
Patient 23	27	21	10	
Patient 24	2	2	0	2
Patient 25	25	15	3	
Patient 26	6	6	2	
Patient 27	20	12	6	
Patient 28	50	41	19	
Patient 29	9	7	2	
Patient 30	19	17	7	
Patient 31	0	0	0	2
Patient 32	9	7	5	
Patient 33	7	7	3	
Patient 34	26	15	4	
Patient 35	11	9	2	
Patient 36	4	4	4	
Patient 37	7	3	0	2
Patient 38	24	17	7	
Patient 39	39	25	9	
Patient 40	17	16	7	
Patient 41	28	16	0	3
Patient 42	38	21	0	8
Patient 43	21	18	7	
Patient 44	28	19	0	6
Patient 45	1	0	0	2
Patient 46	5	4	2	
Patient 47	53	46	13	
Patient 48	43	36	17	
Patient 49	15	11	6	
Patient 50	26	21	2	
Patient 51	8	3	2	

Patient 52	24	22	11	
Patient 53	55	46	17	
Patient 54	11	9	9	
Patient 55	3	3	3	
Patient 56	11	9	6	
Patient 57	32	22	6	
Patient 58	9	7	5	
Patient 59	7	5	3	
Patient 60	6	6	1	3
Patient 61	35	21	6	
Patient 62	26	22	10	
Patient 63	18	16	5	
Patient 64	40	27	5	
Patient 65	10	9	2	
Patient 66	11	9	5	
Patient 67	4	4	2	
Patient 68	10	9	2	
Patient 69	3	3	3	
Patient 70	38	19	6	
Patient 71	41	33	10	
Patient 72	14	10	3	
Patient 73	13	12	5	
Patient 74	32	22	16	
Patient 75	21	14	5	
Patient 76	6	6	1	2
Patient 77	9	7	3	
Patient 78	24	17	4	
Patient 79	19	18	6	
Patient 80	14	12	3	

To obtain at least two matches for each DS group patient, expansion of criteria was done for 12 patients.
5 patients had a difference of 7 to 8 years at inclusion with at least one of the two matched patients.
1 patient had a difference of 10 years.
3 patients had, with at least one of the two matched patients, a difference in ischemia delay class of 1 to 2 categories.
3 patients had, with at least one of the two matched patients, a difference in Killip grade at admission of 1 grade.

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