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Original Article

Immediate versus Deferred Stenting for Patients Undergoing Primary Percutaneous Coronary Intervention

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ABSTRACT

Background: Deferred stenting are proposed to be associated with better clinical outcome than early stenting. However, the evidence is consistent.

Aim of the work: This study aimed to identify the effectiveness, safety, and outcomes of immediate versus deferred stenting in patients undergoing primary percutaneous intervention [PCI].

Patients and Methods: This study included 400 adult patients scheduled for primary PCI. All were evaluated by full history taking, clinical, electrocardiography and echo-cardiography examination, on admission, and at 60 minutes' post PCI. Additionally, an electrocardiographic study was completed for all patients before and after PCI. Patients were categorized according to treatment protocol, 200 for immediate stenting, and 200 for stenting 12 to 24 hours later. Patients follow up was achieved during the procedure, immediately after their return to the CCU and till their discharge. The follow included clinical, laboratory, echocardiographic assessment, and adverse cardiac events.

Results: Both groups were comparable regarding patient demographics, pre-interventional comorbidities, or thrombolysis in myocardial infarction [TIMI] flow before PCI. The majority were males in their sixties. The commonest location of infarction was the anterior location [45.75%]. The femoral access was the main approach [among 96.0%]. The procedure related complications was reported among 1.75%, and transfusion was reported among 0.50%. TIMI flow was significantly better among differed than early stenting. After six and twelve months after PCI, there was significant increase of ejection fraction delayed than early stenting [55±4.9, 57±2.6 vs 53±3.1 and 55±3.7, respectively].

Conclusion: Results of the current work are in favor of delayed than early stenting in primary PCI. Especially, for clinical outcome at 6 and 12 months after primary PCI.

Keywords: Primary Percutaneous Intervention; Delayed; Early; Stenting; Coronary Artery Disease

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* Main subject and any subcategories have been classified according to the research topic

INTRODUCTION

Worldwide, coronary artery disease [CAD] is considered as the leading cause of morbidity and even mortality. It exerts a major burden on the healthcare system and imposes an economic burden on the different developed and developing countries. For example, in the United States, CAD causes 790,000 heart attacks each year, that costs $89 billion at 2016 [1]. The last decades witnessed an improvement in CAD-treatment modalities, with reduced its associated mortality and increasing survival after myocardial infarction [MI]. However, the incidence of CAD continued to increase, as a result of the increased percentages of aging population [2].

The introduction of percutaneous coronary intervention [PCI] was a great transformation in the CAD therapy. PCI remains in the focus of the research community and development [3]. PCI with balloon dilatation and stenting becomes the standard treatment modality for patients with ST-segment elevation MI [STEMI] [4]. However, PCI in some patients lead to decreased coronary blood flow irrespective of patent vessels. In addition, it may be associated with distal embolization with impaired prognosis [5, 6].

Removal of the thrombus is a main part of primary PCI, as most infract-related lesions have residual thrombus fragments, after wiring and dilatation [7]. However, previous randomized trials did not yield consistent results, regarding the role of pharmacological therapy and delayed primary PCI [8]. One study suggested that, delaying stenting after securing a stable blood flow in the infract-related artery, could improve coronary blood flow and decrease the subsequent embolization risk, and associated with improved clinical outcome [9].

Deferred or delayed stenting proposed to decrease thrombus burden and increase myocardial salvage in cases with STEMI [10].

On the other side, the risk of occlusion was increased when the infarct-related artery is left un-stented. Thus, it remains to be assessed whether the risk of infract-related artery occlusion is related to timing of stenting [early versus delayed] in primary PCI [8]. A previous systematic review showed that deferred stenting is associated with better angiographic outcome than immediate stenting. However, the reduction of major adverse events had not been reduced [11]. Otherwise, a randomized clinical trial showed that deferred stenting is not associated with improved clinical prognosis or angiographic cardiovascular outcome [10].

Also it is unknown if deferred stenting was associated with a risk reduction of subsequent left ventricle functional impairment and subsequent heart failure development. Additionally, the value of delayed stenting is largely unknown. Therefore, the current study designed to evaluate whether deferred stenting will be associated with an improvement in the angiographic and clinical outcomes.

AIM OF THE WORK

This study aimed to detect the efficacy, safety, and clinical outcomes of immediate versus deferred stenting in patients undergoing primary PCI.

PATIENTS AND METHODS

This randomized controlled study included 400 adults aged above 18 years, with acute MI within 12 hours of chest pain. They were admitted to the coronary [cardiac] care unit [CCU] and they were candidates for primary PCI. All were selected from the Department of Cardiology [Al-Azhar University Hospital, New Damietta], from May 2019 to December 2020. The inclusion criteria were: Patients with STEMI; 18 years or older, from both sexes. On the extreme side, the exclusion criteria were: patients with chronic stable angina; patients allergic to contrast; post- coronary artery bypass graft [CABG]; patient refusal; rescue PCI; prolonged ischemic time [> 12 hours]; previous MI; Killip class IV; transient ST segment elevation [prinzmetal angina]; and patients scheduled for CABG.

During preparation of the Cath lab, all patients were subjected to full history taking [evaluation of the patients' complaint focused on chest discomfort and associated symptoms or risk factors], clinical examination and all were categorized according to Killip classification [12].

All patients submitted to a 12-lead electrocardiogram [ECG] on admission, and at 60 minutes' post PCI to follow ST segment resolution. Different methods have been used to measure ST-segment elevation resolution [STR]. Lack of STR <50% or 70% is used as a well-known indicator of no-reflow, as its predictive value was verified at the beginning of the pharmacological and mechanical reperfusion era [13]. Particularly, about one-third of cases with thrombolysis in myocardial infarction [TIMI] III flow and myocardial blush grade [MBG] 2 to 3 do not exhibit STR [14].

We used TIMI flow grade, MBG, and STR as they are inexpensive, and confer valuable prognostic information. Previous work reported a good outcome in patients with

an MBG grades 2 to 3 and STR >70%. At the same time, very poor outcome was associated with MBG 0 to 1 and STR<70% [15].

The electrocardiographic additional outcomes included the occurrence of complete [> 70%], partial [30 to 70%], or absent [< 30%] STR on the ECG evaluated 60 minutes after reperfusion compared with the baseline ECG before reperfusion. The measurement of STR was calculated as the sum of ST elevations in all leads with ST segment elevation before the procedure minus the sum of ST elevations after PCI divided by the sum of ST elevation before PCI [16]. A venous blood sample was drawn from each patient to assess cardiac enzymes [e.g., troponin and total creatine kinase [CK]-MB].

The intervention

Each patient had been submitted to percutaneous transfemoral or transradial coronary angio-graphy. The thrombus was assessed by the classification of thrombus burden as described by Sianos *et al*. [17]. In patients with TIMI flow of 0–1 in the infarct-related artery on arrival to the emergency department [ED], the lesion was wired, thrombectomy and balloon dilatation were done if indicated [with a balloon diameter substantially smaller than the reference size of the vessel] to restore and stabilize TIMI 2–3 flow using as little manipulation of the lesion as possible. The TIMI flow was categorized from 0 to 3, as described by Chalikias and Tziakas [18].

The proper visualization of the affected vessel to rule out coronary dissection, the presence of thrombus or residual stenosis and rule out coronary spasm, was performed by intra-coronary flush with heparinized saline, intra-coronary nitroglycerin injection only after achievement of TIMI III flow.

According to treatment protocol, 200 patients underwent immediate stent placement, and 200 patients underwent intense antiplatelet with GPIIb/IIIa inhibitors and stenting 12 to 24 hours later, provided that, no complications occurred. Patients follow up was achieved during the procedure, immediately after their return to the CCU and till their discharge. The follow up included:

- The use of adjunctive medical therapy [e.g., oral aspirin, oral clopidogrel, enoxaparin, Intravenous Glycoprotein IIb/IIIa antagonist, namely tirofiban, oral beta-blockers, oral angiotensin converting enzyme [ACE] inhibitors, oral statins and nitrates were used either sublingual initially as needed for chest pain or discomfort, or intravenous infusion then continued in the oral form].
- Hemodynamic monitoring [rhythm, blood pressure] and the need of any vasopressor or positive inotropes was documented.
- Clinical evaluation for heart failure or new ischemic events was also conducted.
- Electrocardiogram: Serial ECGs were done for assessment of heart rate, rhythm and exclude any new ischemic events.
- Transthoracic echocardiography: we stressed on the examination of the function of left ventricle, the presence & severity of mitral or tricuspid regurgitation, the presence or absence of segmental wall motion abnormalities [16 segments according to the American Society of Echocardiography]. The measurements were calculated from at least three cardiac cycles for each parameter. The average results were included in analysis.
- Laboratory investigations: cardiac markers, and renal function indicators [serum creatinine and blood urea].
- MACE [main adverse cardiac events] during in hospital stay [e.g., sudden cardiac death, reinfarction, major bleeding, and stroke].

Randomization: Patients were randomly divided into two group [1:1]. Group D received deferred stent and Group C received Conventional PCI. Patients, investigators, and treating clinicians were not masked to treatment allocation.

Ethical considerations: The protocol of this trail was approved by the institutional research and ethics review board, Damietta Faculty of Medicine, Al-Azhar University, Egypt [IRB00012367-20-02-011].

Statistical analysis: Analyses were completed by the software computer package termed SPSS version 23 [IBM Inc., USA]. A descriptive analysis was used to express the demographic data. Mean as a measure of central tendency and standard deviation as a measure of dispersion, were used to represent normal distributed quantitative variables. But, frequencies and relative percentages were used to represent categorical variables. The student's t test for unpaired samples or Mann–Whitney's tests were used to compare between two means, and Chi Square [χ^2] or Fisher's exact tests were used to test differences between proportions. The marginal significance was set at 0.05 and values < 0.05 indicated significant difference.

RESULTS

Group C included 200 patients; 170 [85%] of them were males and 30 [15%] were females. On the other hand, group D included 200 patients; 177 [88.5%] of them were males and 23 [11.5%] were females. The age ranged between 49 and 75 years in group C, and ranged between 47 and 75 years in group D [the mean age was 60 ± 3.1 and 62 ± 2.2 years, in C and D groups, respectively]. There was no significant difference between groups. In addition, there was no significant difference between groups C and D regarding medical history [diabetes mellitus, hypertension, previous myocardial infarction [MI] and smoking] [Table 1].

The commonest location of infarction was the anterior location [45.75%], followed by inferior location [24.5%]. The least was left bundle branch clock [0.75%]. Regarding Thrombolysis in myocardial infarction [TIMI] flow before Percutaneous coronary intervention [PCI], there was no significant difference between groups C and D. The commonest grade was grade 1 [45.5%], followed by grade 2 [20.8%] and finally grade 3 [2.0%] [Table 2].

Regarding PCI data, the femoral access was the main access [among 96.0%]. The adjuvant glycoprotein therapy was used among 98.8%, while thrombus aspiration was reported among 4.0%. The TIMI flow after PCI was mainly of grade 3 [95.0%], followed by grade 2 [5.0%]. The procedure related complications was reported among 1.75%, and transfusion was reported among 0.50%. there was no stroke or contrast-induced nephropathy. There was no significant difference between groups C and D was reported regarding access, adjuvant therapy, ejection fraction at discharge, procedure related complications, or transfusion. However, TIMI flow was significantly better among group D than group C [Table 3].

Regarding outcome, there was no significant difference between two groups for all variables [all-cause mortality, heart failure, non-fetal myocardial reinfarction, cardiac death, target vessel revascularization by PCI or CABG] [Table 4].

After six and twelve months after PCI, there was significant increase of ejection fraction in group D than group C [55±4.9, 57±2.6 vs 53±3.1 and 55±3.7, respectively] [Table 5].

Table [1]: Comparison between groups C and D, regarding patient age, sex and medical history

Variable		Group C	Group D	P value
Age [years] [mean±SD; Min.-Max.]		60.0±3.1; 49- 75	62.0±2.2; 47-75	0.65
Sex [n,%]	Male	170 [85.0%]	177 [88.5%]	0.70
	Female	30 [15.0%]	23 [11.5%]	
Medical history [n,%]	Diabetes mellitus	150 [75.0%]	152 [76.0%]	0.90
	Hypertension	121 [60.5%]	116 [58.0%]	0.68
	Previous MI	5 [2.5%]	3 [1.5%]	0.72
	Smoking	98 [49.0%]	112 [56.0%]	0.19

Table [2]: Comparison between groups C and D, regarding location of infarction and TIMI flow before intervention

		Group C		Group D		Total		P – Value
		n.	%	n.	%	n.	%	
Location of infarction	Anterior	94	47%	89	44.5%	183	45.75%	0.14
	Anterolateral	36	18%	34	17%	70	17.5%	
	Inferolateral	24	12%	22	11%	46	11.5%	
	Inferior	46	23%	52	26%	98	24.5%	
	LBBB	0	00%	3	1.5%	3	0.75%	
TIMI flow before PCI	0	62	31.0%	65	32.5%	127	31.8%	0.94
	1	94	47.0%	88	44.0%	182	45.5%	
	2	40	20.0%	43	21.5%	83	20.8%	
	3	4	2.0%	4	2.0%	8	2.0%	

Table [3]: Comparison between groups C and D, regarding PCI data

		Group C		Group D		Total		P – Value
		n.	%	n.	%	n.	%	
Access	Femoral	194	97.0%	190	95.0%	384	96.0%	0.44
	Radial	6	3.0%	10	5.0%	16	4.0%	
Adjuvant therapy	Glycoprotein	195	97.5%	200	100.0%	395	98.8%	0.06
	Thrombus aspiration	6	3.0%	10	5.0%	16	4.0%	0.7
TIMI flow after PCI	0	0	0.0%	0	0.0%	0	0.0%	***<0.001****
	1	0	0.0%	0	0.0%	0	0.0%	
	2	20	10%	0	0.0%	20	5.0%	
	3	180	90%	200	100%	380	95.0%	
EF% at discharge		49± 1.7; 40-55		50± 1.3; 40-55				0.30
Procedure related complications		2	1.0%	5	2.5%	7	1.75%	0.25
Transfusion		0	0.0%	2	1.0%	2	0.50%	0.15
Stroke		0	0.0%	0.0%	0.0%	0.0%	0.0%	-
Contrast-induced nephropathy		0	0.0%	0.0%	0.0%	0.0%	0.0%	-

Table [4]: Comparison between groups regarding outcome

	C		D		P – Value
	n.	%	n.	%	
All-cause death	4	2.0%	3	1.5%	0.7
Heart failure	4	2.0%	4	2.0%	1.0
Non-fatal myocardial reinfarction	2	1.0%	1	0.5%	0.56
Cardiac death	3	1.5%	3	1.5%	1.0
Target vessel revascularization by PCI	1	0.5%	1	0.5%	1.0
Target vessel revascularization by CABG	0	0.0%	2	1.0%	0.15

Table [5]: Comparison between groups regarding follow up EF after 6 and 12 months

	Group C		Group D		P – Value
	Mean± SD	Range	Mean± SD	Range	
EF at 6 months	53±3.1	50 - 60	55±4.9	50 - 60	0.039*
EF at 12 months	55±3.7	50 – 60	57±2.6	52 - 60	0.043*

DISCUSSION

Deferred stenting in the primary PCI remains a controversial issue [19] Thus, we designed the study to compare between immediate and deferred stenting in primary PCI. It included 400 patients [200 for immediate and 200 for deferred stent]. The results of the study revealed that, the deferred stenting was associated with better TIMI flow after PCI and ejection fraction was significantly better after 6 and 12 months in the deferent than immediate group. Otherwise, no significant differences were reported for other outcome variables [e.g., complications and all-cause mortality].

A recent meta-analysis by Li W *et al.* [20] indicated that, both deferred and immediate stenting provide comparable results. No modality is superior than the other. Specifically, no significant differences were reported regarding major adverse cardiovascular events [MACEs], post-PCI MI] all-cause related deaths, and target vessel revascularization [TVR], regardless the ST segment elevation. However, the current study revealed significant improvement in TIMI flow after PCI; the fact which could not be confirmed in such meta-analysis.

The improved TIMI flow after deferred stenting could be explained as the following: first delayed stenting permits for a better sizing of the lesion and artery, that lead to optimized stent selection [21]; Second: delayed stenting PCI need better assessments of the revascularization strategy, which could escape unnecessary stenting for insignificant residual stenosis [22]; and third delayed PCI always includes repeated angiograms, which could detect non-culprit arteries in cases with multivessel lesions [23].

Desch *et al.* [24] conducted another meta-analysis and found that immediate PCI had a significant reduction in all-cause mortality risk; but stroke or major bleeding risk showed no significant difference.

Freixa *et al.* [25] in another meta-analysis found that

deferred stenting is associated with favorable angiographic outcomes in cases with acute MI.

Liu *et al*. [26] included 16 trials in a meta-analysis and found that early PCI, as compared to primary PCI alone with fibrinolysis showed similar results, and both are better than deferred stenting.

On the other side, Lee *et al*. [27] concluded that, deferred stenting provided favorable outcomes than early stenting after STEMI. However, they included only three trials in their meta-analysis. In addition, Qiao *et al*. [28] conducted another meta-analysis and reported that deferred stenting was linked to an improvement of the left ventricular function; however, clinical end point showed non-significant differences. Mahmoud *et al*. [29] in a more-recent meta-analysis advocated the deferred over early stenting, as it was associated with no slow reflow and improved myocardial blush grade 3 [MBG3]. However, the clinical endpoints did not differ significantly between early and delayed stenting.

In favor for delayed stenting, it was reported that, the reduction of the intraprocedural flow in connection with primary PCI was reported in previous studies, and has been considered as a strong predictor of long-term mortality [30].

Thus, residual thrombus might best be left to dissolve during subsequent intensive antiplatelet therapy before stent implantation takes place. Kelbæk *et al*. [31] tested this concept, and showed that deferred stenting can be done safely, with considerable reduction of thrombus burden after 48h, and stent implantation can be evaded in some cases. In line with the current results, Carrick *et al*. [32] reported an outcome improvement with delayed stenting after deferral of stent for 4 – 16 hours.

The most recent meta-analysis conducted Yang et al. [33] investigated the link between the timing of stenting the clinical outcomes. Results revealed that patients with early stenting had worse clinical outcomes than patients with late or very late stenting in both short- and long-term outcome after PCI. The worse clinical outcome with early stenting was ascribed to the increased baseline comorbid disease such as diabetes, bifurcation lesions and multi-vessel disease [34]. Finally, the high adverse events early stenting may be related partly to damage of coronary collaterals. Indeed, collaterals can minimize myocardial injury at the time of the event and results in better outcomes [35, 36]. On the other hand, in late and very late stenting, the thrombus formation was more like an advanced evolution, permitting enough time for development of collateral circulation. However, in early stenting, the capability to establish coronary collateral circulation may be reduced by the rapid onset of stent thrombosis due to the higher on-treatment platelet reactivity, which may lead to a larger infract size of the myocardium and higher rates of adverse events [33].

CONCLUSION

In short, results of the current work are in favor of delayed stenting than early stenting in primary percutaneous PCI.

Financial and Non-financial Relationships and Activities of Interest

None

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