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ORIGINAL ARTICLE

Outcome of Immediate versus Delayed Stenting in ST-segment Elevation Myocardial Infarction Patients with High Thrombus Burden

Kamel H.A. Ghazal [1], Ekhlas. E. Hussein[1], Mohammad G. Mohammad[1], Wesam R.M. Hozien [2*]
[1] Cardiology Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt
[2] Cardiology Department, National Heart Institute, Cairo, Egypt.

Corresponding author
Wesam Rabieh Mahmoud Mosa Hozien*
Cardiology Department, National Heart Institute, Cairo, Egypt.

E-mail:
wesam.hozien@gmail.com

ABSTRACT

Background: The safety of deferred stenting as a technique in patients with ST segment elevation myocardial infarction (STEMI) is debatable by guidelines. This study aims to see how effective immediate stenting versus delayed stenting in lowering angiographic outcomes (no/slow reflow, distal embolization, and improved myocardial blush grade MBG) in STEMI patients.

Methods: Multi centers prospective clinical trial included 108 patients with STEMI with heavy thrombus burden. Patients were divided equally into two groups: Group (1): which included 54 patients who underwent immediate stenting and Group (2) which involved 54 patients who underwent deferred stenting. Procedural angiographic events were the primary endpoints, while the secondary endpoints were the presence of Major Adverse Cardiac Events (MACE) and bleeding complications with follow up duration for 6 months.

Results: Deferred stenting patients had a statistically significant decrease in slow flow and no reflow (P = 0.03). In addition, the defer group showed a greater increase in myocardial blush grade (MBG) than immediate stenting group (P value 0.04). Distal embolization, on the other hand, showed no statistical difference (P value 0.1), and there was no statistically significant difference between the two groups in terms of bleeding complications (P value 0.7), however there was no statistically meaningful improvement in the deferred stenting group (P value = 0.3) regarding the composite of MACEs between the two groups.

Conclusions: Deferred stenting was associated with improved immediate myocardial perfusion, less no/slow reflow, but not with a substantial decrease in MACEs at six months, as a result, direct stenting is a standard treatment option for STEMI patients.

Keywords: No reflow, Microvascular obstruction, STEMI, Delayed stenting.

INTRODUCTION

Even in patients with normal epicardial flow, reduced flow to the vascular bed of the infarct-related artery (IRA) is observed in a significant number of patients treated with Primary Percutaneous coronary Intervention (PCI), particularly after stent implantation **[1].** Stent implantation that is postponed (deferred strategy) can help to reduce the risk of distal coronary embolization and improve the prognosis**[2]**. Previous research has shown that deferred stenting reduces the rate of angiographic events (distal emboli, no-reflow) and the infarct size**[3],** in addition to significant reduction in congestive heart failure, re infarction and cardiac mortality**[4].** Other randomized trials, on the other side, found that deferring stent implantation has unintended risks, including the risk of acute coronary re-occlusion in the period between index reperfusion and final stent implantation, as well as a longer hospital stay and higher immediate costs **[5].**The goal of this study is to see if a postponed stenting approach in primary PCI reduces angiographic and clinical major adverse cardiac events (MACE) as compared to an immediate stenting in STEMI patients with high thrombus burden.

METHODS

Study population: Our study was multi centers prospective clinical trial that targeted patients who presented with ST-segment elevation myocardial infarction (STEMI) and treated with primary PCI in Zagazig University Hospital and National Heart Institute in Cairo.

The study included the patients presented with ST-segment elevation myocardial infarction (STEMI) or new left bundle branch block undergoing primary PCI in the presence of a heavy thrombus burden in the infarcted related artery (IRA) (thrombus burden score, TBS ≥ 3) **[6]** and gained at least TIMI flow II or III either spontaneously or after manual inspiration or balloon dilatation

Study protocol: 108 patients were subjected either to immediate or deferred stenting strategies according to discretion of the operator. They were divided into two main groups based on the strategy of management. Group (1): included 54 patients who were treated with conventional immediate stenting. Group (2): included 54 patients who were treated with deferred stenting,

Ethical approval: Written informed consent was obtained from all patients. The study was approved by the research ethical committee of faculty of medicine, Zagazig University and National Heart Institute. This study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Full medical history taking, Clinical examination and ECG: The medical history included age, gender, and the risk factors (diabetes, hypertension, smoking, positive family history). Hypertension was diagnosed if Values of ≥ 140 mmHg SBP and /or ≥ 90 mmHg DBP or current anti-hypertensive treatment. While DM conditions defined by an elevated level of blood glucose ≥126 mmHg or HBA1c **≥ 6.5** or current anti diabetic drugs**[7].** Detailed clinical examination was performed on admission with special emphasis on BP, HR and Killip class and standard twelve lead ECG**[8].**

Laboratory investigation: Kidney function tests, complete blood count, prothrombin time concentration and international normalized ratio (INR) and cardiac enzymes (CK-MB and cardiac troponin) were performed on admission and after intervention.

Echocardiography assessment: Using the Philips i.e.,33 machines, we had measured LV end diastolic and end systolic dimensions before and soon after percutaneous coronary intervention, throughout hospital stay and 6 months afterwards. Also, we had measured left ventricular ejection fraction percent by Simpson technique and Stroke volume index (SVI)**[9].**

Percutaneous coronary intervention: Coronaries were accessed through femoral or radial artery, according to the operator decision, using modified Seldinger technique. A variety of supporting guiding catheters and flobby wires were used according to the feasibility, suspected culprit vessel and sometimes to the operator decision. The patients who had intracoronary thrombi with TIMI flow II or less subjected to wire introduction, thrombus aspiration using suction device and/or dilation of the lesion with an undersized balloon (1.5 or 2.0 mm in diameter) to achieves at least TIMI flow II.

Study endpoints: The primary endpoints were the periprocedural angiographic events. We assessed the periprocedural angiographic events as distal embolization and TIMI flow grades (0, 1, 2, 3). Distal embolization was defined as filling defect with an abrupt cutoff in one of the peripheral coronary artery branches of the infarct-related vessel, distal to the site of angioplasty **[10].** Slow flow was defined as TIMI grade 2 flow at the end of the procedure. No reflow was defined as TIMI grade 1 or 0 flow in the distal infarct-related artery in the absence of an occlusion at the treatment site or evidence of distal embolization**[11].** The secondary endpoints were the presence of major adverse cardiovascular events (MACE) and the bleeding complications. MACE was defined as the composite endpoint of all-cause mortality (cardiovascular and non-cardiovascular), non-fatal myocardial infarction defined as ST elevation MI and non-ST elevation MI) and target vessel revascularization (PCI or CABG for the target site, adjacent site and/or other new segments of the treated vessel)**[12].** Bleeding complications were defined according to Global Utilization of Streptokinase and Tissue-Plasminogen Activator for Occluded Coronary Arteries (GUSTO) score into: Severe or life-threatening, moderate or mild bleeding **[13].** Hemodynamic instability as cardiogenic shock or pulmonary edema was considered. Urgent revascularization in the form of PCI to infarct related artery (IRA) was assessed post discharge and left ventricular ejection fraction and MACE was assessed till 6 months**[1].**

STATISTICAL ANALYSIS

The association between variables and treatment groups was investigated by Mann Whitney U and Chi-square tests. A p value less than 0.05 was considered significant (2-sided). All analyses were carried out using Stata 12 software (Stata Corp LP, College Station, Texas).

RESULTS

Demographic, clinical and echo cardio graphic data Male gender represented (83%) of the study populations with mean age of 56 years. The baseline

demographic, clinical and echocardiographic characteristics were matched with statistical non-significant differences between both groups. All data were demonstrated in table 1. Angiographic data**:** Femoral approach was the common access for coronary angiography; radial approach is achieved in (0 % and 2 %) in group 1 and group 2 respectively. LAD represented as the IRA in group 1 and group 2 (50 % and 48 %) respectively, followed by RCA in (22 % and 24 %) then LCX in (5 % and 4 %). Culprit lesions were done as apart of complete revascularization as recommended by ESC guidelines for coronary revascularization in 2018 **[14].** Initial TIMI flow (at initial angiography) was comparable in both groups; (P value = 0.09), the same as thrombus burden score that was nearly equal in both groups; (P value = 0.1) (Table 3).Culprit residual lesion length and culprit residual stenosis was comparable after initial thrombectomy procedure (P value = 0.06 & 0.1) (Table 2). Tirofiban or eptifibatide (180 µg/kg bolus, infusion 2 µg/kg/min) was administered intravenously immediately after initial PCI in all patients with deferred stenting and maintained for 20-48 hours. Only patients with major thrombotic complications (no slow flow or significant distal embolization) in the immediate stenting group received GP IIb IIIa inhibitors (17 patients; 33 % for a mean duration of 24 h). Coronary angiography in the delayed stenting group was performed 48 to 72 after initial angiography with mean duration of 36h. Stenting was needed less frequently in the deferred stenting group. 22 patients (40.7) had no longer significant coronary stenosis at the time of the delayed procedure, and this was statistically significant (P value < 0.001) as shown in figure 1.

Primary endpoints (angiographic outcomes): Among patients of deferred stenting group 3 cases (5.5%) of no reflow recorded, while 6 cases occurred in immediate stenting group (11%) (= 0.02). Among patients of immediate stenting group, TIMI III flow was achieved in 34 patients (63.5%) as shown in figure 2, while composite of slow flow and no re flow occurred in 20 cases (37%) (Table 3). The rate of patients achieving TIMI grade III flow at the end of PCI procedure was higher in the deferred stenting group compared with immediate stenting group figure 3 and this was statistically significant (81.5% and 63.0%) (P value = 0.03) (Table 3). Distal embolization occurred more in immediate stenting group, 6 patients (14%) (4 had small distal filling defect and two had abrupt cut off distally) versus 4 patients (10%) in the deferred stenting group (four had just small filling defect distally in the infarct related vessel,) (P value = 0.1) (Table 3).

Secondary endpoints (clinical outcome): Major adverse cardiac events were observed in the two groups during the initial hospital stay and post discharge The composite of MACEs was statistically not significant in the deferred stenting group (3.8%) versus only (3.8%) in the immediate stenting group (P value = 0.37) (Table 4). As regard to LV ejection fraction among the studied two groups there was statistically significant difference (P <0.05) between them regarding LVEF after 6 months as it was higher in group B than group A (49.67±5.75 % and 45.57±6.53% respectively) (p <0.05). And there was statistically significant difference (P = 0.03) between them regarding SVI after 6 months of discharge.

Regarding cardiac mortality, one patient died in immediate stenting group secondary to cardiogenic shock while no patients died in deferred stenting group, this was statistically non-significant (P value = 0.3) (Table 4). Due to recurrence of symptoms within 48 hours after the procedure, target vessel revascularization (TVR) was needed for only one patient in the immediate stenting group while was needed for 2 patients in deferred stenting group (P value = 0.3) (Table 4). Enhanced antithrombotic therapies showed no increase in major or moderate bleeding in the deferred stenting group compared with the immediate stenting group, Minor hemorrhagic complications were observed in 5 patients (9.3%) in deferred stenting group versus 4 patients (7.4 %) in immediate stenting group (P value = 0.7) (Table 4).

Table 1: Comparison between two groups regarding demographic, clinical and echocardiographic data.

Demographic data	Group1	Group 2	Test	P-value
Age Mean ± SD	56±9.6	52.4±10	1.8•	0.6
(Range)	34-75	23-72		
Male	45	49	1.3‡	0.2
Female	9	5		
Hypertension	26	29	0.3‡	0.5
Diabetes	25	27	0.1‡	0.7
Smoking	23	25	0.15‡	0.6
Prior angina	16	15	0.05‡	0.8

Demographic data	Group1	Group 2	Test	P-value
Killip class I	18	17	0.84‡	0.8
Class II	30	30		
Class III	4	6		
Class IV	2	1		
Total ischemic time (h) Mean ± SD	5.87±2.38 2-11	6.27±2.37 2-12	0.8•	0.37 NS
LVEF % Mean ± SD	43.29±5.7 25-53	45.38±5.64 33-55	3.08•	0.06 NS

•Mann Whitney U test. ‡ Chi-square test.

Table 2: Comparison between the studied groups regarding the initial angiographic data.

Initial angiographic data	Group I	Group 2	Test	P-value
Femoral approach	54	53		
Radial approach	0	1	0.07‡	P value >0.05
Infarct related artery				
LAD	27	26	0.2‡	0.8 NS
Lcx	5	4		
RCA	22	24		NS
Initial TIMI flow				
TIMI 0	47	39		
TIMI I	4	6		
TIMI II	3	4		
TIMI III	0	5	6.2‡	0.09
Thrombus burden score Mean ± SD	4-5 4.62±0.48	3-5 4.46±0.57	MW	0.7NS
Culprit lesion length (mm) Mean ± SD	22.46±6.3 12-38	24.9±7.4 12-40	1.9•	0.06 NS
Culprit lesion stenosis (%) Mean± SD	83.5±11.35 60-95	79.4±14.17 40-99	1.6•	0.1NS

•Mann Whitney U test. ‡ Chi-square test.

Table 3: Comparison between the studied groups regarding the angiographic outcome

Angiographic outcome	Group1	Group2	Test	p-value
TIMI 0-I **TIMI II** **TIMI III**	6 14 34	3 7 44	4.6	0.03
Normal flow	34	44	7.7 ‡	0.02
Slow flow	14	7		
No reflow	6	3		
Distal embolization	6	4	**Fisher's** 4.5	0.1 NS
Myocardial blush grade (MBG) post PCI: **MBG ≤II** **MBG III(good flow)**	 25 29	 15 39	3.9 ‡	0.04

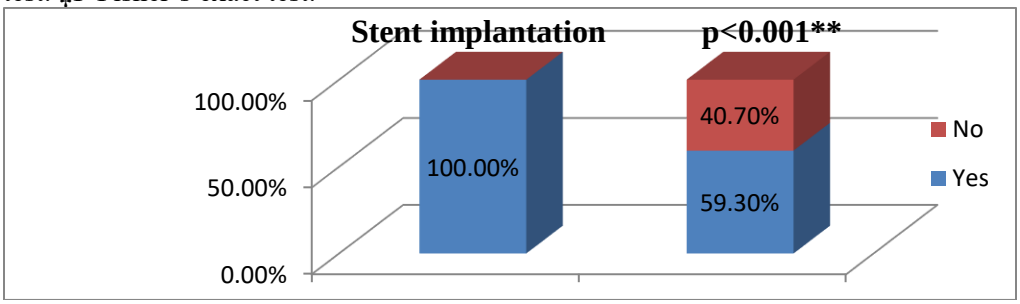
‡ Chi-square test.

Table 4: Comparison between the studied groups regarding the clinical outcomes.

Clinical outcomes	Group 1	Group 2	t-test	P-value
LVEF after 6 months	45.57±6.53%	49.67±5.75%	3.08	0.06
SVI after 6 months	23.26±8.4	26.4±6.88	2.1	0.03
Composite of MACEs	2	2	4.3‡	0.3
TVR	1	2	1‡	0.33
Death	1	0	1	0.3

Clinical outcomes	Group 1	Group 2	t-test	P-value
major bleeding	0	0	0.1‡F	0.7
Minor bleeding	4	5		

‡ Chi-square test. ‡F Fisher's exact test.



**high statistically significant difference

Figure 1: Bar chart of frequency distribution of the studied patients' groups regarding stent implantation (n=108).

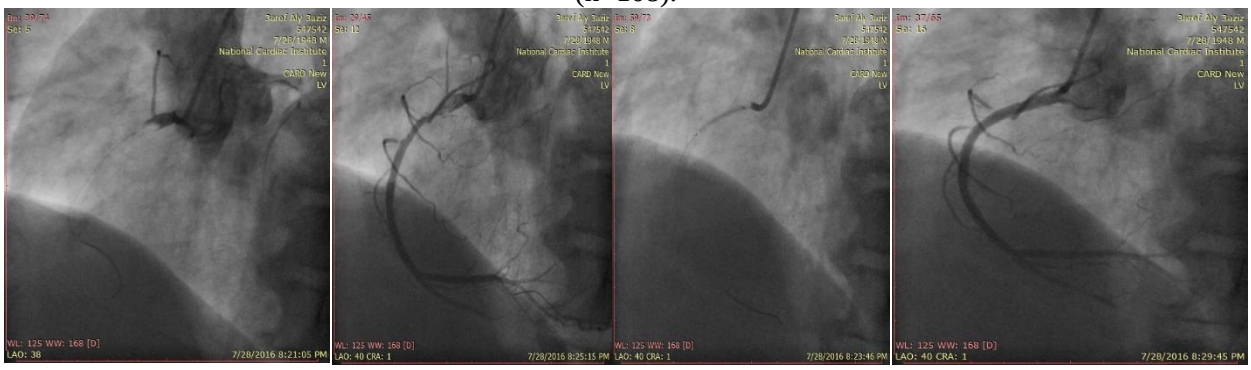


Figure 2: Patient from group 1 (Immediate stenting group) was presented with Inferior STEMI with heavy thrombus burden. Primary percutaneous coronary intervention to RCA was done using drug eluting stent with successful result and TIMI III flow

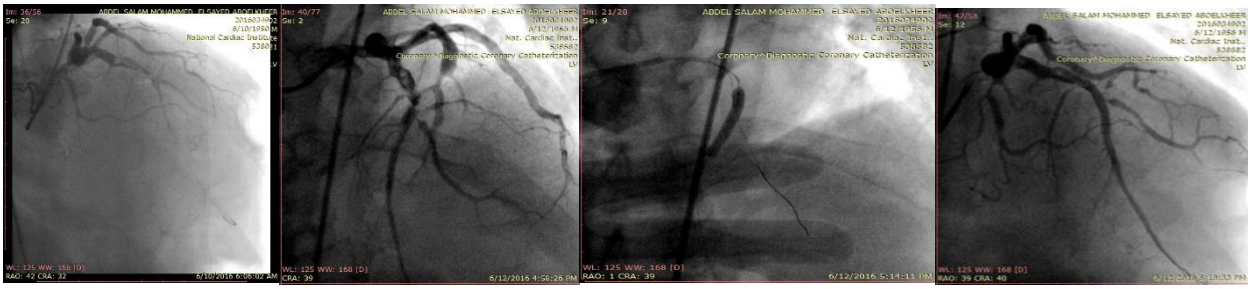


Figure 3: Patient of group 2 (Deferred stenting group) had presented with anterior STEMI. Primary PCI to LAD Showed total LAD occlusion, wire was crossed to LAD, TIMI III flow with heavy thrombus burden in the infarcted artery was occurred then patient was admitted to CCU and GP IIb-IIIa Inhibitor was given for 36 hours then second look and percutaneous coronary intervention with Drug Eluting Stent was performed. Finally, we had TIMI III flow.

DISCUSSION

For re-establishing effective flow in occluded IRAs in patients with STEMI, percutaneous coronary intervention (PCI) has been the therapy of choice. **[15]**. Even though early PCI is frequently the best option in this situation, distal embolization occurs in a considerable proportion of patients following primary PCI and is connected to poor ST segment resolution, greater necrosis volume, and a poor result with a higher 5-year death rate**[16].** Deferred stenting in primary PCI was investigated in two small trials as a strategy to reduce microvascular blockage and maintain microcirculatory function, with mixed results. **[5].** In current study, TIMI III flow was achieved in majority of deferred stenting group (81%) versus only (63%) in immediate stenting group (P value = 0.03) (Table 3). The thrombus related angiographic complications as no

reflow were nearly low in deferred stenting group only 3 patients (5.6%) while detected in six patients of immediate stent group (11%) (P value = 0.02) (Table 3). Distal embolization was occurred less frequently in deferred stenting group (7% versus 11.1%) (P value = 0.1) (Table 3) in agreement with Liu et al in 2019showed that stent implantation appears to further increase the risk of no reflow in patients undergoing primary PCI **,** The TIMI 3 flow grade (86.8%) in immediate stent group was significantly less than that (97.6%) in deferred stent group (P < 0.05**[17].** On the other hand, in Belle et al 2016as regard TIMI 3 grade flow, no significant difference was found between 2 groups where in IS group 66 patient (94%) VS in DS group 63 patients (96.7 %), as regard TIMI ≤ 2, no significant difference was found between 2 groups where in IS group 7 patients (6%) VS 4 patient in DS group (3.2%) (p value>0.05) this may be attributed to that patients in immediate stenting group in MIMI study was younger and selected patients included in the study are all patients with STEMI with all thrombus grades, and Patients with a large thrombus (4× longer than the width of the coronary artery) were excluded because investigators were reluctant to implant a stent immediately in these individuals due to their high risk of no-reflow**[5].** Regarding myocardial blush grade (MBG) in the current study, MBG 3 was 29 patients in IS group (53%) VS 39 patients in DS group (72%) with presence of significant difference between two groups (P value = 0.04).This is in agreement with Liu et al 2019 where the myocardial perfusion level of MBG 3 grade (84.5%) in immediate group was also significantly lower than that (97.6 %) in the defer group (P < 0.05) **[5].** Tang et al. in 2011also reported that MBG 3 at the end of the PCI procedure was obtained in the IS group 34 (73.9 %) VS in DS group 37 (94.9%) (P value= 0.017), also MBG 0–1 was observed more often in the IS group (9 (19.6%) VS in DS group 0 (0%) **(**P value= 0.003)**[18].** During acute phase of STEMI, the release of vasoconstrictive substances from platelets may explain the reduction in TIMI flow during stent deployment at high pressure balloon inflation so postponed stenting allows both spontaneous structural modifications and pharmacological treatment to act with time on the platelet thrombus and fibrin rich clot, resulting in enhancement of clot lysis and dissolution of thrombus and so less distal embolization. In addition, the deferred stenting approach may avoid unnecessary stent implantation. In current study, stenting was less frequently needed in the deferred stenting group. 22 patients had no longer significant coronary stenosis at the time of the delayed procedure, and this was statistically significant: (P value <0.001). In correlation with current study, Pascal et al in 2016 concluded that stent implantation is avoided in (28.5%) patients underwent delayed PCI**[19].** Also, in Mester et al study where a stent was implanted in 97 patients (62.6%); the residual lesion was considered non-significant in 56 patients (36.1%)**[20].** As regard stent length and stent diameter in current study, all patients subjected to stent implantation in group I had mean stent diameter 3.2±0.37 mm and mean stent length 29.±7.4 mm while patients subjected to stent implantation in group II (59.3%of them) had mean stent diameter 3.3±0.39 mm and mean stent length 27±6.9 mm with no significant difference between the two groups p value (P=0.16&0.1 respectively) (P>0.05). This is in agreement with Liu et al**,** where the average of stent diameter was in group I 3.10±0.47 mm VS in group II 3.12±0.42mm (P value = 0.759), and stent length (mm) 21.61±5.15 in group I VS 18.00±4.30 in group II (P value = 0.00)**[17].**

As regards to left ventricular ejection fraction in our results there were significant differences (P <0.05) between the two groups after 6 months as it was higher in DS group than IS group A (49.67±5.75 % vs 45.57±6.53% respectively) (P<0.05). Also, there were significant differences (P<0.05) between them regarding SVI after 6 months. The same results were reported in Jolicoeur et al. 2020 that showed improvement of left ventricular ejection fraction in the defer group more than immediate group the p value <0.05**[21]**, Keelback et al. in 2016Echocardiography was done in 775 (64%) patients a median of 18 months after the index PCI. Left ventricular ejection fraction was higher in patients who received deferred stent implantation than in those who received conventional PCI (p=0.043)**[22].** As the results of angiographic outcomes, it was believed that deferred stenting would provide some clinical potential advantages that could reduce MACEs in comparison to immediate stenting. The above-mentioned angiographic advantages were not translated into significant clinical benefit in current study. MACEs were observed in the two groups, Composite of cardiac mortality, TVR and reinfarction showed statistically no significant difference in between 2 groups (3.8% versus 3.8%) (P value = 0.3) (Table 4), Liu et al. in 2019 reported also that the incidence of Major adverse cardiac events was 4.5% in immediate

stent group and 0% in deferred stent group**[17]**, also. Keelback et al in 2016, the results of DANAMI 3-DEFER showed MACE (including all-cause mortality, rate of re-hospitalization because of heart failure, non-fatal myocardial infarction, target vessel revascularization) between the immediate stent group and deferred stent group had no significant difference (P > 0.05) in mean follow-up 42 months **[22].** There was no difference in significant or moderate bleeding in the postponed stenting group compared to the immediate stenting group in terms of bleeding consequences. Minor hemorrhagic complications were observed in (9.3%) of deferred stenting group versus (7.4%) in immediate stenting group (P value =0.70) (Table 4). In agreement, there was no more major bleeding complication noted in the study reported by Kelbæk et al**.** in 2016, cases requiring blood transfusion or surgery in IS group were 7 cases (1%) VS in DS group 11 case (2%), with no significant difference (P value= 0.33) between the 2 groups**[20].**Pascal et al.2016 also reported that there was no significant difference in hemorrhagic complications between the 2 groups**[19].**so our observations provide supporting evidence of the safety of this therapeutic strategy.

CONCLUSIONS

When compared to immediate stenting, postponed stenting improves angiographic results but not short-term clinical outcomes in patients with STEMI, particularly those with a high thrombotic burden. Deferred stenting should not be performed as a regular procedure in STEMI patients.

Conflict of Interest: none.

Financial Disclosures: none.

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