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ORIGINAL ARTICLE

Impact of Deferred Stent Insertion on Elevated St-segment Myocardial Infarction Patients with a Big Thrombus Load

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Abstract

Background: **No clear recommendations as regard deferred stenting in ST-segment elevation myocardial infarction (STEMI) patients with big thrombus load.**

Aim of the study: **Our study might answer the question that deferred stenting might reduce no reflow and in-hospital major adverse cardiac events (MACE) compared to immediate stenting in primary percutaneous coronary intervention (PCI) for STEMI patients with high thrombus burden.**

Patients and methods: **A prospective double blinded control non-randomized study which included fifty Patients presented by STEMI with high thrombus load and undergoing primary PCI, 25 patients (group number 1) managed with deferred stenting, and 25 patients (group number 2) managed with immediate stenting. All patients follow-up for MACE during hospital stay and follow-up echocardiography was done on admission and after 6 months. Result: Stenting was avoided in 36 % of patients in group number 1; $P = 0.001$. As regard, Left Ventricular Ejection Fraction (LVEF), deferred stenting showed improvement of EF on 6 months follow-up when compared to the direct conventional stenting (47.28 ± 6.43 vs. 41.33 ± 9.10); $P = 0.011$. Deferred stenting did not show any decrease in no reflow or in hospital MACE when compared to direct conventional stenting.**

Conclusion: **Deferred stenting specific category of patients presenting with STEMI and big thrombus burden undergoing primary PCI, may improve LEVF, and avoid unneeded stenting with its potential complication when compared to conventional direct stenting, but it is not improving clinical outcome or decreasing incidence of no reflow nor MACE during the hospital stay.**

Keywords: Deferred, Thrombus, STEMI, PCI

1. Introduction

Primary percutaneous coronary intervention (pPCI) is recommended by recent studies as the best way of management strategies for ST-segment elevation myocardial infarction (STEMI) patients in a window.[1] However, the distal embolization risk due to mechanical intervention which is manifested by low/no reflow, accompanied with increased the infarcted area, reduced ventricular recovery, and even high mortality rate.[2] Stent inflation can result in no reflow phenomenon, particularly in cases with high thrombus load in the infarct related artery (IRA).[3] Deferred stent placement may offer an opportunity to reduce coronary thrombus load and restoration of microvascular function, which would decrease the probability of no reflow. No reflow was detected in 10 % of patients with primary PCI, and is complicated by up to a sevenfold increase in the rate of periprocedural MI.[4]

2. Patients and methods

Fifty patients with STEMI and high thrombus load and planned for primary PCI, were admitted to the CCU of National Heart Institute.

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They were categorized into 2 groups according to the strategy of management: either immediate or deferred stenting.

Group number 1: patients that were managed with deferred stenting (DS group).

Group number 2: patients that were managed with conventional immediate stenting (IS group).

Inclusion criteria: All patients with STEMI or new left bundle branch block undergoing primary PCI in the presence of a heavy thrombus load in the IRA (thrombus burden score, TBS $\geq$3). Patients presented with new left bundle branch block or acute STEMI by having at least two of these criteria continuous chest pain as presenting symptom not responded to nitrates and lasting more than 30 min, ST-segment elevation more than 2 mm in more than 2 contiguous precordial leads, or more than 1 mm in more than 2 contiguous limb leads and having elevated cardiac enzymes.[5]

3. Methods

Full history to all patients was taken and data were recorded covering demographic data like (age, sex) risk factors as smoking, hypertension, diabetes, dyslipidemia, positive family history for premature coronary artery disease, and/or prior angina, PCI, and CABG.

Every patient had gone through physical examination, which included taking their vital signs (such as their heart rate and blood pressure), as well as a thorough physical examination overall and a local cardiac assessment.

As a routine examination, ECG was done, for detecting arrhythmias and electrocardiographic signs of STEMI. Serum creatinine and cardiac enzyme levels were checked as part of the admissions process. CBC, electrolytes, blood gases, and other customary normal laboratory tests are also performed. A VIVID S5 GE machine was used to do an echocardiogram on the first day of hospitalization and six months later, with a focus on mechanical problems and Left Ventricular Ejection Fraction (LVEF). Discrepancies in outcomes of the two investigations were compared.

3.1. Percutaneous primary intervention

All patients loaded with 300 mg of aspirin, and 600 mg of clopidogrel prior to coronary angiography. Patients assigned to either the IS group ($n = 25$) or the DS group ($n = 25$). The IS group managed with stent placement as needed on the spot after angiography and initial coronary interventions, however the DS group was deferred for stent implantation for 24–72 h.

While, at the first level of the DS group, primary interventions were conducted on the spot after angiography to achieve at least Thrombolysis In Myocardial Infarction (TIMI) II flow, followed by aggressive antithrombotic therapy using (25 μg/kg bolus dose of Tirofiban then 0.15 μg/kg/min as maintenance) or ((25 μg/kg bolus dose of eptifibatide then 2 μg/kg/min as maintenance) was given intravenously after initial PCI in a patients with deferred stenting and maintained for 20–48 h, with precaution of using adjusted doses according to the renal profile in patients with renal impairment.

The second stage, repeated angiography was performed 24–72 h later and managed with stenting based on residual stenosis in IRA according to the operator decision. The primary interventions like manual thrombus aspiration or balloon pre-dilation were performed for both groups. Primary PCI and pharmacological agents during and after primary intervention was controlled by the interventional and coronary care unit cardiologists based on best standards of care.

IRA was stratified dependent on TIMI classification 0, 1, 2, 3, then thrombus burden score (TBS) grades 1,2,3,4,5.[6]

TBS is graded as:

TBS 0: No cine-angiographic characteristics of thrombus present.

TBS 1: Possible thrombus present. Angiography shows characteristics such as reduced contrast density, haziness, irregular lesion contour, or a smooth convex meniscus at the site of total occlusion suggestive but not diagnostic of thrombus.

TBS 2: Thrombus present, small size: definite thrombus with greatest dimensions less than or equal to half vessel diameter.

TBS 3: Thrombus present, moderate size: definite thrombus but with greatest linear dimension greater than half but less than 2 vessel diameters.

TBS: 4: Thrombus present, large size: as in grade 3 but with the largest dimension greater than or equal to 2 vessel diameters.

TBS 5: Total occlusion.[7]

3.2. Follow-up

Follow-up was done in-hospital period for major adverse cardiac events (MACE), that was described by in stent thrombosis, non-fatal myocardial infarction, acute heart failure, and death. Correlation between management strategy either deferred or direct stenting and incidence of MACE during hospital stay was observed and reported.

3.3. Endpoints definitions

The main goal was to determine frequency of 'no reflow,' which was determined by the angiographically visible disappearance of flow (TIMI flow 0), while incomplete filling (TIMI flow I), and complete filling with slow flow (TIMI flow II), of the 'infarct related artery' at intervention conclusion. The following endpoint consisted of MACE, echocardiographic parameters, and angiographic parameters (such as TBS and TIMI scores).

3.4. Statistical analysis

SPSS version 17 was used for statistical analysis of collected data. Qualitative data were summarized by frequency and percentages. All data were expressed as Mean ± SD for quantitative variable number. Standard T test, Chi-square correlation, coefficient were used. Statistically significant results were the results with $P < 0.05$.

4. Results

50 patients are involved in our study with mean age 53.04 ± 10.33 years with maximal age of 75 years and minimal age of 29 years; males represented 96.0 %.

The results of the risk factor analysis show that none of the patients in the study sample had a family history of early CAD. Instead, 48%f of patients were smokers and 44 % are dyslipidemic, while approximately 30 % were diabetic, and about 30 % are hypertensive. According to Table 1 is showing the distribution of STEMI according ECG findings.

The basic characteristics (age, sex, risk factors), as well as the basic echocardiographic data (EF) ($P > 0.05$), shows that no statistically significant difference is found between the analyzed groups (Table 2).

Comparison between the groups regarding angiographic and 1st procedural data shows that there was statistically significant difference as regard thrombus burden score (TBS) between the two groups where 11 patients had TBS III in group I (44.0 %) vs 4 patients in group II (16.0 %), and angiography of 10 patients of group I shows TBS IV (40.0 %) vs 7 patients in group II (28.0 %), while only 4 patients in group I have TBS V (16.0 %) vs 14 patients in group II (56.0 %) who has TBS V ($P = 0.009$) but, it does not shows statistically significant difference is found as regard baseline TIMI flow as shown in Table 3.

As regards the angiographic data of the 2nd procedure; comparison between two groups reveals that the number of patients that needed stenting is statically significant between the 2 studied groups with p value < 0.001, while other post-intervention parameters including TIMI flow, TBS grades, culprit lesion length, stent length and no reflow, there is no statistically significant difference found with p value > 0.05 as shown in Table 4.

As shown in Table 5, no statistically significant difference is found between the two groups in terms of overall MACE based on comparisons between the compared groups regarding the 'in-hospital' outcome.

As regard ejection fraction, we found initially the mean ejection fraction 41.76 ± 6.39 % in group I, with a minimum of 30 % and maximum of 52 %; whereas the mean ejection fraction 41.56 ± 8.66 % in group II, with a minimum of 30 % and maximum of 60 %. The comparative study between the two groups shows no statistically significant difference ($P > 0.05$) Table 6 and Fig. 1.

On the other hand, follow-up echocardiography after 6 months, shows that, the is statistically

Table 1. Basic data of the study population.

Baseline data	All patients ($N = 50$)
Age	53.04 ± 10.33
Male sex	48 (96.0 %)
Risk factors	
DM	19 (38.0 %)
HTN	19 (38.0 %)
DLP	22 (44.0 %)
Smoking	24 (48.0 %)
Premature CAD	0 (0.0 %)
Diagnosis	
Anterior STEMI	26 (52.0 %)
Inferior STEMI	22 (44.0 %)
Lateral STEMI	2 (4.0 %)

CAD, (Coronary Artery Disease); DLP, (Dyslipidemia); DM, (Diabetes Miletus); HTN, (Hypertension); N, (Number); STEMI, (ST Elevation Myocardial Infarction).

Table 2. Comparison between the compared groups regarding the general data.

	Deferred group ($N = 25$)	Direct group ($N = 25$)	Test value[a]	P value
DM	11 (44.0 %)	8 (32.0 %)	0.764	0.382
HTN	12 (48.0 %)	7 (28.0 %)	2.122	0.145
Dyslipidemia	11 (44.0 %)	11 (44.0 %)	0.000	1.000
Smoking	14 (56.0 %)	10 (40.0 %)	1.282	0.258
Family history	0 (0.0 %)	0 (0.0 %)	NA	NA
Baseline EF (%)	41.76 (30–52)	41.56 (30–60)	0.093	0.926

DM, (Diabetes Miletus); EF, (Ejection Fraction); highly significant, (HS); HTN, (Hypertension); N, (Number); P value > 0.05; Non significant, (NS); P value < 0.05; Significant, (S); P value < 0.01.
[a] : Independent t-test.

Table 3. Comparison between the compared groups regarding the baseline TBS grades and TIMI flow grades.

	Deferred group Number (%)	Direct group Number (%)	Test value[a]	*P* value	Sig.
TBS					
TBS III	11 (44.0 %)	4 (16.0 %)			
TBS IV	10 (40.0 %)	7 (28.0 %)	9.352	0.009	HS
TBS V	4 (16.0 %)	14 (56.0 %)			
TIMI before					
TIMI 0	4 (16.0 %)	9 (36.0 %)			
TIMI I	1 (4.0 %)	3 (12.0 %)			
TIMI II	9 (36.0 %)	7 (28.0 %)	4.644	0.200	NS
TIMI III	11 (44.0 %)	6 (24.0 %)			

Highly significant, (HS); No, (Number); *P* value > 0.05; Non significant, (NS); *P* value < 0.05; Significant, (S); *P* value < 0.01; TBS, (Thrombus Burden Score); TIMI, (Thrombolysis In Myocardial Infarction).
[a] : Independent *t*-test.

Table 4. Comparing between the compared groups regarding the angiographic data of the 2nd procedure.

PCI (dilation) procedure (after GPIIb IIIa inhibitor)	Deferred group Number = 25	Direct group Number = 25	Test value[a]	*P* value	Sig.
Culprit lesion length					
Mean ± SD	21.72 ± 7.33	21.24 ± 5.92	0.255•	0.800	NS
Range	10–38	12–35			
TIMI post					
TIMI 0	0 (0.0 %)	2 (8.0 %)			
TIMI I	2 (8.0 %)	1 (4.0 %)	2.357*	0.502	NS
TIMI II	1 (4.0 %)	1 (4.0 %)			
TIMI III	22 (88.0 %)	21 (84.0 %)			
Thrombus score					
Median (IQR)	2 (1–3)	–			
Range	0–3	–	–	–	–
Stent					
No	9 (36.0 %)	0 (0.0 %)	10.976*	0.001	HS
Yes	16 (64.0 %)	25 (100.0 %)			
Stent length					
Mean ± SD	26.38 ± 8.85	24.28 ± 5.44	0.941•	0.353	NS
Range	12–40	15–38			
No reflow					
No	24 (96.0 %)	22 (88.0 %)	1.087*	0.297	NS
Yes	1 (4.0 %)	3 (12.0 %)			

GPIIb IIIa, (Glyco-Protein IIb IIIa); highly significant, (HS); No, (Number); *P* value < 0.01; Non significant, (NS); *P* value < 0.05; PCI, (Percutaneous Coronary Intervention); Significant (S); TIMI, (Thrombolysis In Myocardial Infarction); *P* value > 0.05.
[a] : Independent *t*-test.

significant difference was found between the two groups, as EF is ranging from 35 to 58 % in the deferred stenting group with Mean ± SD (47.28 ± 6.43) vs EF 20–59 % in the direct stenting group with Mean ± SD (41.33 ± 9.10) ($P = 0.011$) as shown in Table 6 and Fig. 1.

5. Discussion

Recent studies on patients undergoing PCI, only a small number of trials have demonstrated the positive effects of delaying stent placement in acute myocardial infarction.[8]

Our study was directed to determine either postponed stenting, as opposed to immediate stenting, could reduce 'no reflow' and in-hospital 'major adverse cardiac' events (MACE) in ST-segment elevation myocardial infarction (STEMI) patients with significant thrombus loads.

Results of the study revealed that 9 (36 %) of the 25 patients in group I did not require stenting, as opposed to group II, where all patients necessitate stenting using a direct stenting method. The comparative assessment of the two groups reveals a highly significant difference ($P = 0.001$), which may be explained by the resolution of the thrombus upon deferral and the subsequent relief of the vasospasm that may have resulted from the substantial thrombus load.

Three patients representing 6 % of the deferral group in the 'DEFER-STEMI' trial[2] and 15 % of the

Table 5. Clinical outcome results between the examined groups.

Post procedural follow-up (MACE)	Deferred group Number (%)	Direct group Number (%)	Test value[a]	*P* value	Sig.
Bleeding					
No	20 (80.0 %)	24 (96.0 %)	3.030	0.082	NS
Yes	5 (20.0 %)	1 (4.0 %)			
IST					
No	25 (100.0 %)	25 (100.0 %)	NA	NA	NA
MI					
No	25 (100.0 %)	24 (96.0 %)	1.020	0.312	NS
Yes	0 (0.0 %)	1 (4.0 %)			
HF					
No	23 (92.0 %)	23 (92.0 %)	0.000	1.000	NS
Yes	2 (8.0 %)	2 (8.0 %)			
Death					
No	25 (100.0 %)	24 (96.0 %)	1.020	0.312	NS
Yes	0 (0.0 %)	1 (4.0 %)			

HF, (Heart Failure); *P* value > 0.05; highly significant, (HS); IST, (In-Stent Thrombosis); MACE, (Major Adverse Cardiovascular Events); MI, (Myocardial Infarction); No, (Number); *P* value < 0.01; Non significant, (NS); *P* value < 0.05; Significant, (S).
[a] : Independent *t*-test.

Table 6. Comparison between the studied groups systolic function at presentation and after 6 months follow-up.

LVEF	Deferred group Number = 25	Direct group Number = 25	Test value[a]	*P* value	Sig.
At presentation					
Mean ± SD	41.76 ± 6.39	41.56 ± 8.66	0.093	0.926	NS
Range	30–52	30–60			
After 6 months					
Mean ± SD	47.28 ± 6.43	41.33 ± 9.10	2.650	0.011	S
Range	35–58	20–59			

Highly significant, (HS); LVEF, (Left Ventricular Ejection Fraction); *P* value > 0.05; No, (Number); *P* value < 0.05; Non significant, (NS); Significant, (S); *P* value < 0.01.
[a] : Independent *t*-test.

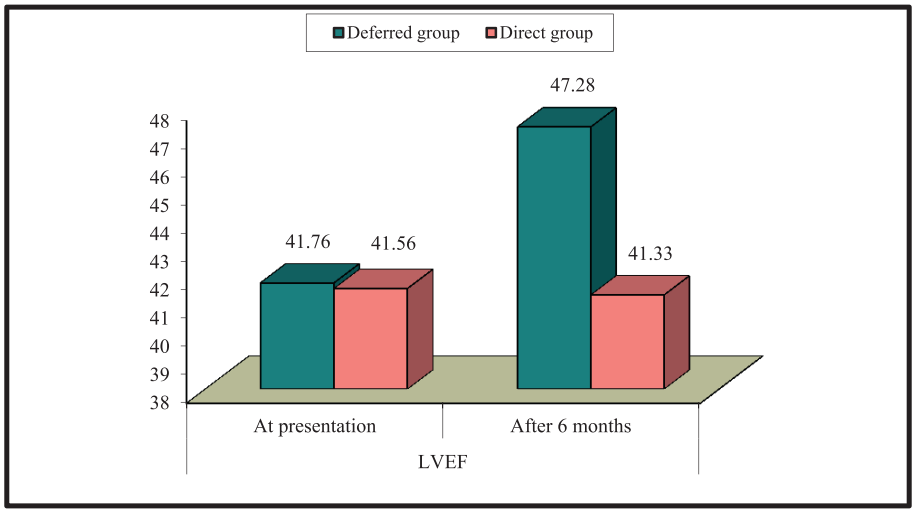

Fig. 1. Comparison between the studied groups LV systolic function at presentation and after 6 months of follow-up).

deferral group in the 'DANAMI-3-DEFER' trial,[8] both of which did not suggest routinely deferring stenting, respectively, were found to have no need for stenting, as there is no residual lesion was found after second angiography. In a 2004 study, Cafri *et al.*[9] examined the effectiveness of percutaneous coronary intervention (PCI) in treating coronary thrombotic lesions in 82 patients who treated by

immediate PCI (IPCI) and 24 patients who underwent deferred stenting. They came to the conclusion that 22.6 % of patients who underwent delayed PCI did not require stent implantation.

While Kim *et al.*[10] reported that no statistically significant difference was found as regard the need for stent implantation between both groups (92.9 % in deferred stenting group vs. 100 % in the direct stenting group *P* value 0.118).

In our study we found that baseline TBS was higher significantly in the group of deferred stenting, out of the 25 patients in group I, 11 (44.0 %) had TBS III, 10 (40.0 %) had TBS IV, and 4 (16.0 %) had TBS V; whereas out of the 25 patients in group II, 4 (16.0 %) had TBS III, 7 (28.0 %) had TBS IV, and 14 (56.0 %) had TBS V. The comparative study between the two groups shows that there is a highly statistically significant difference regarding the TBS ($P = 0.009$).While, Kim *et al.*[10] reported no statistically significant difference between both groups regarding initial TBS in the studied groups (4.7 %, and 95.3 % showed TBS 4, and 5, respectively for deferred stenting group vs 4.3 %, 11.4 %, and 84.3 % showed TBS 3, 4, and 5 respectively for immediate stenting group *P* value 0.08). Furthermore, Belle *et al.*[10] also reported that no statistically significant difference was found as regard initial TBS between the two groups (8.8 %, 15.8, and 71.9 % showed TBS 3, 4, and 5, respectively for deferred stenting group vs 8.8 %, 10.5 %, and 77.2 % showed TBS 3, 4, and 5, respectively for immediate stenting group *P* value 0.675).

As regard no reflow, we found that only one patient (4.0 %) out of 25 patients in group I had no reflow, whereas 3 (12.0 %) patients out of 25 patients in group 2 had no reflow. The comparative study between the two groups shows no statistically significant difference ($P > 0.05$). Kim *et al.*[10] also reported that no statistically significant difference was found regarding no reflow in the two groups (22.8 % had no reflow in deferred stenting group vs. 35.1 had no reflow for immediate stenting group *P* value 0.139). Furthermore, Belle *et al.*[11] found that there was no statistically significant difference as regard no reflow between the two groups (6.0 % had no reflow in deferred stenting group vs. 10.0 had no reflow for immediate stenting group *P* value 0.43). While Tang L *et al.*[12] who reported that statistically significant difference was found between both groups as regard no reflow in the studied groups (No patients in deferred stenting group had no reflow vs. 14.9 % *P* value 0.014).

All our patients had initial echocardiography on presentation during admission, and follow-up echocardiography for assessment of LVEF at presentation, and after 6 months to assess the impact of deferred stenting strategy vs the immediate stenting strategy on the grade of LVEF, and we reported that there was no statistically significant difference between both groups on presentation (initial mean ejection fraction 41.76 ± 6.39 % in group I, with a minimum of 30 % and maximum of 52 %; whereas the mean ejection fraction 41.56 ± 8.66 % in group II, with a minimum of 30 % and maximum of 60 %). On the other hand, statistically significant difference was found regarding improvement of EF after follow-up of 6 months in the deferred stenting group in comparison to the direct conventional stenting (47.28 ± 6.43 in group I, with a minimum of 35 and maximum of 58; whereas the mean ejection fraction 41.33 ± 9.10 in group II, with a minimum of 20 and maximum of 59. The comparative study between the groups shows a ($P = 0.011$).

Also, Tang *et al.*[12] reported that statistically significant difference was found between both groups in the improvement of LVEF in the deferred stenting group in comparison to immediate stenting group with *P* value < 0.05). Whereas Kelbæk *et al.*[13] reported that no statistically significant difference was found between the both groups as regard follow-up of LVEF in the studied groups (the mean ejection fraction 55 ± 5 % in deferred stenting group, whereas the mean ejection fraction 57 ± 3 % in immediate stenting group *P* value 0.420). Furthermore, Belle *et al.*[11] reported that no statistically significant difference was found as regard initial LVEF between the two groups (the mean ejection fraction 53 ± 7 % in deferred stenting group, whereas the mean ejection fraction 53 ± 5 % in immediate stenting group *P* value 0.70).

Major adverse cardiac events (MACE) were recorded in the observed groups during their hospital stay, we found major bleeding was more in deferred stenting group, 5 (20.0 %) patients out 25 versus only one patient (4.0 %) in direct stenting group. This can be explained by the longer duration of antithrombotic agents for all patients in group 1 in comparison to only few selected patients in group 2 who had slow or no reflow. This reported difference had no statistically significant difference. In the same line, no additional significant bleeding complication was identified in the Tang *et al.* study.[12]

Although the postponed stenting group avoided stenting at a statistically significant rate, no difference was reported between both groups in as regard of MACE during the hospital stay ($P > 0.5$). Meneveau *et al.*[14] also discovered in 2009 that there were no statistically significant variations in MACEs comparing techniques for both groups (*P* value = 0.64). While in 2016, Kelbaek *et al.*[13] revealed

that 109 (18 %) patients who underwent traditional 'PCI' and 105 (17 %) patients who delayed stent insertion experienced events that made up the primary outcome. With no reported statistically significant differences between the examined groups, procedure-related 'myocardial infarction', bleeding necessitating transfusion, or surgery occurred in 28 (5 %) patients in the conventional PCI group versus 27 (4 %) patients in the postponed stent placement group. However, Carrick *et al.*[2] showed a 'statistically significant difference' between the two groups in terms of the post-stenting 'TIMI flow' grade (98.0 % of the deferred stenting group demonstrated TIMI 3 flow compared to 79.6 % of the immediate stenting group; *P* value 0.018). Additionally, Tang *et al.*[12] reported that there was a statistically significant difference between the two groups for the post-stenting TIMI flow grade in the investigated groups (97.5 % of the deferred stenting group showed TIMI 3 flow vs. 80.95 % TIMI 3 flow for the immediate stenting group, respectively; *P* value 0.018).

5.1. Conclusion

According to the results of our study, we concluded that deferred stenting in specific category of patients presenting with 'STEMI' and big thrombus burden treated with primary PCI may improve LEVF and avoid unneeded stenting with its potential complication when compared to conventional direct stenting, but it is not improving clinical outcome or decreasing incidence of no reflow nor MACE during the hospital stay.

Conflicts of interest

There is no any conflict of interest.

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