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Aspiration thrombectomy and intracoronary tirofiban in ST-segment elevation myocardial infarction

Combination treatment for patients undergoing primary percutaneous coronary intervention

The key to treating ST-segment elevation myocardial infarction (STEMI) is opening the infarct-related artery as quickly as possible [1]. Primary percutaneous coronary intervention (PCI) is commonly accepted as the most effective means for treating patients with STEMI [2, 3]. However, many patients who have a high thrombus burden lesion often experience the slow-flow or no-reflow phenomenon during primary PCI. This occurs because of the coronary microcirculation, distal embolization, microvascular spasms, endothelial dysfunction, etc. [4–6]. Aspiration thrombectomy and intracoronary platelet glycoprotein (GP) IIb/IIIa receptor antagonists are widely used to reduce distal embolization [7–11]. GP IIb/IIIa receptor antagonists can reduce thrombus burden and secondary distal embolization microcirculation [12]. Some studies suggest that the intracoronary application of platelet membrane GP IIb/IIIa receptor antagonists improves myocardial perfusion; however, such studies are currently few in number, and their results are controversial [13–15]. Most of these studies used abciximab as their GP IIb/IIIa receptor antagonist, and tirofiban was rarely used. The present study investigated whether aspiration thrombectomy in combination with intracoronary tirofiban treatment could result in smaller infarcts and better clinical prognosis for patients with STEMI undergoing primary PCI than aspiration thrombectomy alone.

Patients and methods

Patient selection

Patients with STEMI who received treatment between November 2011 and November 2013 were selected for the present study. The study was performed in compliance with guidelines on human studies and approved by the ethical review board. The inclusion criteria were: (1) typical chest discomfort lasting ≥ 30 min; (2) leads of ST-segment elevation ≥ 2 in V_1–V_4; (3) new left bundle-branch block; (4) time of symptom presentation to hospital arrival of 12 h or less; (5) patients underwent primary PCI, and outcome determined by coronary angiography was according to the proximal or mid-left anterior descending artery (LAD); and (6) coronary angiography indicated a large angiographic thrombus burden [16, 17]. The exclusion criteria were: (1) prior myocardial infarction (MI); (2) prior coronary artery bypass graft (CABG) or LAD stenting; (3) recent major bleeding or bleeding diathesis; (4) cardiogenic shock; (5) severe liver disease, kidney disease, or cerebral vascular disease; and (6) hematologic diseases.

Among 156 patients initially selected for the study, six were excluded because it was difficult to follow their progress after admission to the hospital. The data of the remaining 150 patients (83 men and 67 women; mean age, 52.8 ± 7.8 years) were analyzed. The enrolled patients were divided into two groups based on a random-number table: group A received primary PCI with aspiration thrombectomy; group B received primary PCI with aspiration thrombectomy and intracoronary tirofiban (**Fig. 1**).

Treatment methods

After hospital admission, the patients were immediately administered 300 mg of aspirin and 300 mg of clopidogrel [18]. Then, emergent coronary arteriography was performed. Prior to PCI, all the patients received heparin (60–100 U/kg) anticoagulation therapy, and none of them were routinely given GP IIb/IIIa receptor antagonists.

Primary PCI

A 6-Fr sheath was inserted into the right radial artery. After the guide wire

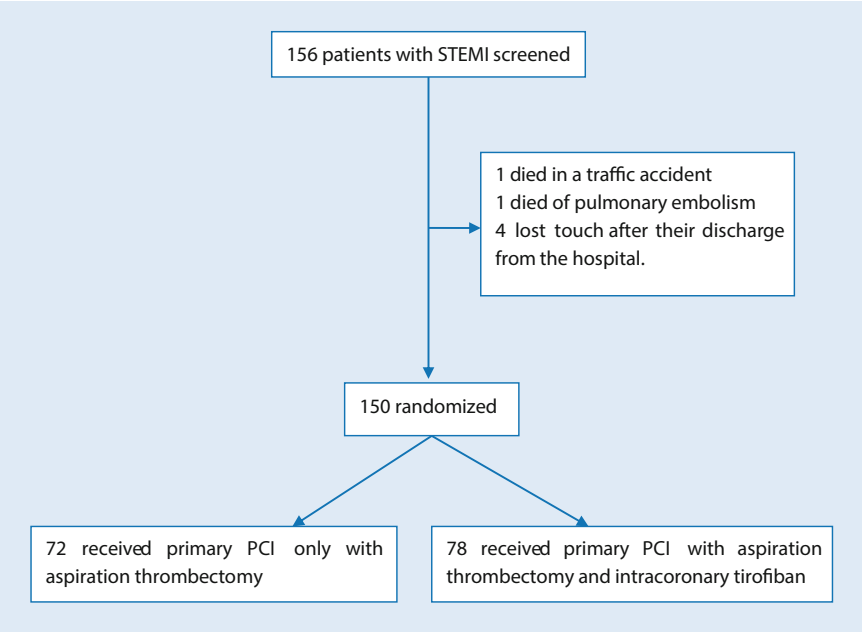

Fig. 1 ▲ The number of patients screened, excluded, and those who completed follow-up. *PCI* percutaneous coronary intervention, *STEMI* ST-segment elevation myocardial infarction

was passed through the lesion, manual thrombus aspiration was performed with a 6-Fr Export catheter (Rebirth, Meito-kuNagoya-sh, Aichi, Japan). Aspiration was started with the tip of the catheter crossing the lesion. The catheter was then flushed with heparinized saline repeatedly (more than two times) until no further thrombus or debris could be retrieved. After rinsing the catheter with heparinized saline again, it was passed across the lesion along the guide wire and tirofiban was injected through the thrombus aspiration catheter (25 μg/kg). To avoid predilation and postdilatation, PCI was performed using the standard technique with a drug-eluting stent.

After PCI, the patients were prescribed 100 mg of aspirin and 75 mg of clopidogrel for at least 1 year. Additionally, while in the hospital, they were given low-molecular-weight heparin subcutaneously and angiotensin-converting enzyme inhibitors, beta-blockers, and other expanding coronary drugs, according to the patient's condition. Cardiac magnetic resonance imaging (CMRI) was performed on the patients during hospitalization (median, 12 days; range, 10–15). Echocardiography was regularly scheduled for all patients at 7 days, 30 days, and 6 months.

Data collection

After admission to the hospital, the patients were followed up for 6 months. Outcome measures included the following: (1) thrombolysis in myocardial infarction (TIMI) flow grade; (2) TIMI myocardial perfusion grade (TMP); (3) 12-lead electrocardiography at 2 h after PCI, with ST-segment recovery <50 %, indicating that ST-segment went bad: After 2 hours of primary PCI, the ST-segment usually fell more than 50 %. While the ST-segment fell less than 50 %, it suggested that it fell poor; (4) hospital bleeding rate; (5) echocardiography results, especially left ventricular ejection fraction (LVEF); (6) CMRI results, including infarct size, left ventricular myocardial mass, and LVEF; and (7) perioperative complications, nonfatal myocardial re-infarctions, and cardiovascular mortality. The patients were followed up for 6 months using telephone interviews and out-patient review, and the occurrence of the following major adverse cardiac events (MACE) was noted: cardiovascular mortality, nonfatal myocardial infarction, and target vascular revascularization (including re-PCI and CABG).

Statistical analysis

Continuous data are expressed as means ± SD, and categorical data are expressed as percentages. Testing for normality was performed with use of the Shapiro–Wilk test. Continuous data were analyzed using a *t* test. Categorical data were analyzed using a chi-square test. Event rates were analyzed using the Kaplan–Meier method and the log-rank test. The statistical software of Statistical Product and Service Solutions (SPSS 13.0) was used to analyze all the data, and statistical significance was set at $p < 0.05$.

Results

Clinical characteristics

The baseline characteristics of the groups are presented in **Tab. 1**. The frequencies of the general clinical characteristics, such as age, sex, diabetes mellitus history, hypertension, hyperlipidemia, current smoking status, and body mass index, were not significantly different between the groups. The time from symptom presentation to hospital arrival was also not significantly different between the two groups ($p = 0.093$). The outcome measure regarding ST-segment resolution of <50 % was similar between the two groups (5.6 vs. 2.6 %, $p = 0.482$).

PCI and myocardial perfusion

The characteristics of PCI and myocardial perfusion are presented in **Tab. 2**. The door-to-balloon time was not significantly different between the groups ($p = 0.372$). There were 88 patients with a proximal LAD lesion (58.3 vs. 59.0 %, $p = 0.937$) and 62 patients with a mid-LAD lesion (41.7 vs. 41.0 %, $p = 0.937$). No significant differences were observed in the TIMI flow rates before or after PCI between the groups ($p > 0.05$); however, the patients who underwent aspiration thrombectomy with intracoronary tirofiban had a better TIMI grade than the patients who underwent aspiration thrombectomy alone (TIMI 3; 100 vs. 97.2 %). A higher number of patients who underwent aspiration thrombectomy with intracoronary tirofiban had

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Abstract

Aim. Primary percutaneous coronary intervention is the most effective treatment for patients with ST-segment elevation myocardial infarction (STEMI). This study aimed to investigate whether the combination of aspiration thrombectomy with intracoronary tirofiban treatment can result in smaller infarcts and better patient prognosis compared with aspiration thrombectomy alone.

Patients and methods. In all, 150 patients with STEMI underwent primary percutaneous coronary intervention. Group A received aspiration thrombectomy and group B received a combination treatment of aspiration thrombectomy with intracoronary tirofiban. The endpoint was major adverse cardiovascular events, including myocardial (re)infarction, cardiovascular death, and target vessel revascularization.

Results. The clinical characteristics of the groups were not significantly different ($p > 0.05$). The percentage of patients whose thrombolysis in myocardial infarction (TIMI) myocardial perfusion grades were less than 3 was significantly higher for group B than for group A (13.9 vs. 3.8 %, $p = 0.029$). The infarct size on cardiac magnetic resonance imaging was significantly different between groups ($p = 0.036$). At 6 months after the operation, the echocardiography results were better for patients in group B than for those in group A ($p = 0.024$ and $p = 0.016$, respectively). The frequency of bleeding complications and major adverse cardiac events of the groups were not significantly different ($p > 0.05$).

Conclusion. Aspiration thrombectomy with intracoronary tirofiban in patients with STEMI is safe and effective. For cases with a large angiographic thrombus burden, tirofiban did not increase the rate of bleeding complications or major adverse cardiovascular events.

Keywords

Aspiration thrombectomy · Intracoronary tirofiban · Myocardial infarction · Platelet glycoprotein IIb/IIIa receptor antagonist · Percutaneous coronary intervention

Aspirationsthrombektomie und intrakoronare Tirofibangabe bei ST-Hebungs-Infarkt. Kombinationstherapie bei Patienten mit primärer perkutaner Koronarintervention

Zusammenfassung

Ziel. Die primäre perkutane Koronarintervention ist die wirksamste Behandlung für Patienten mit ST-Hebungs-Infarkt (STEMI). Ziel der vorliegenden Studie war zu untersuchen, ob die Kombination der Aspirationsthrombektomie mit intrakoronarer Tirofibantherapie zu kleineren Infarkten und einer besseren Prognose für den Patienten als die alleinige Aspirationsthrombektomie führen kann.

Patienten und Methoden. Insgesamt 150 Patienten mit STEMI wurden mit primärer perkutaner Koronarintervention behandelt. Bei Gruppe A erfolgte eine Aspirationsthrombektomie und bei Gruppe B eine Kombinationsbehandlung aus Aspirationsthrombektomie und intrakoronarer Tirofibangabe. Der Endpunkt bestand aus schweren unerwünschten kardiovaskulären Ereignissen einschließlich Myokard(re)infarkt, Tod aus kardiovaskulärer Ursache und Zielgefäßrevaskularisierung.

Ergebnisse. Bei den klinischen Kennzeichen der Gruppen gab es keine signifikanten Unterschiede ($p > 0,05$). Der Anteil an Patienten, deren Myokardperfusionsgrad nach TIMI („thrombolysis in myocardial infarction") unter 3 lag, war in Gruppe B signifikant höher als in Gruppe A (13,9 vs. 3,8 %; $p = 0,029$). Die Infarktgröße der beiden Gruppen in der kardialen Magnetresonanztomographie unterschied sich in signifikanter Weise ($p = 0,036$). In der Echokardiographie waren 6 Monate nach der Operation die Befunde bei den Patienten der Gruppe B besser als bei denen der Gruppe A ($p = 0,024$ bzw. $p = 0,016$). Die Häufigkeit von Blutungskomplikationen und schweren unerwünschten kardialen Ereignissen unterschied sich in den Gruppen nicht signifikant ($p > 0,05$).

Schlussfolgerung. Die Aspirationsthrombektomie mit intrakoronarer Tirofibangabe stellt bei Patienten mit STEMi eine sichere und wirksame Therapie dar. In Fällen mit einer hohen angiographischen Thrombuslast erhöhte sich durch Tirofiban die Rate an Blutungskomplikationen oder schweren unerwünschten kardiovaskulären Ereignissen nicht.

Schlüsselwörter

Aspirationsthrombektomie · Intrakoronare Tirofibangabe · Myokardinfarkt · Plättchen-Glykoprotein-IIb/IIIa-Rezeptor-Antagonist · Perkutane Koronarintervention

a TMP grade of <3 than the patients who underwent aspiration thrombectomy alone ($p = 0.029$).

Echocardiography

The echocardiography results of the two groups are presented in **Tab. 3**. The echocardiography results at 7 days and 30 days after the operation were not significantly different between the two groups ($p > 0.05$). However, at 6 months after the operation, the echocardiography results were better for the patients who underwent aspiration thrombectomy with intracoronary tirofiban than for those who underwent aspiration thrombectomy alone ($p = 0.024$ and $p = 0.016$, respectively).

Cardiac MRI

The CMRI results of the two groups are presented in **Tab. 4**. A total of 119 patients (79.3 %) accepted to undergo CMRI during hospitalization. One patient died in the course of treatment, and the others refused to have the examination because of the costs of the procedure. The infarct size was significantly different

Tab. 1 Clinical characteristics of the study groups

	Group A ($n = 72$)	Group B ($n = 78$)	p
Age (years)	59.7 ± 7.1	58.4 ± 5.8	0.215
Men (%)	40 (55.6)	43 (55.1)	0.958
Diabetes mellitus (%)	8 (11.1)	6 (76.9)	0.472
Hypertension (%)	45 (62.5)	42 (53.8)	0.283
Hyperlipidemia (%)	10 (13.9)	16 (20.5)	0.284
Previous myocardial infarction (%)	2 (2.8)	1 (1.3)	0.608
Currently smoking (%)	22 (30.6)	31 (39.7)	0.240
cTNI (ng/ml)	11.6 ± 5.1	12.7 ± 7.8	0.463
Killip class			0.955
I (%)	71 (98.6)	77 (98.7)	
II (%)	1 (1.4)	1 (1.3)	
Symptom to hospital (h)	1.2 ± 1.8	1.1 ± 1.6	0.093
ST-segment resolution <50 % (%)	4 (5.6)	2 (2.6)	0.428

cTNI cardiac troponin I (normal value is <0.4 ng/ml)
Data are presented as means ± SD or numbers of patients (percentages); p <0.05 was considered statistically significant.

Tab. 2 Procedural outcomes and reperfusion indices

	Group A ($n = 72$)	Group B ($n = 78$)	p
PCI			
Door-to-balloon time (min)	17.8 ± 9.1	19.2 ± 8.3	0.372
Intra-aortic balloon pump	0	0	
Proximal LAD (%)	42 (58.3)	46 (59.0)	0.937
Mid-LAD (%)	30 (41.7)	32 (41.0)	0.937
TIMI flow before PCI			1.000
0/1 (%)	70 (97.2)	75 (96.2)	
2 (%)	2 (2.8)	3 (3.8)	
TIMI flow after PCI			
0/1	0	0	
2 (%)	2 (2.8)	0	0.229
3 (%)	70 (97.2)	78 (100)	0.229
TMP < 3 (%)	10 (13.9)	3 (3.8)	0.029

PCI percutaneous coronary intervention, *LAD* left anterior descending artery, *TIMI* thrombolysis in myocardial infarction, *TMP* TIMI myocardial perfusion grade
Data are presented as means ± SD or numbers of patients (percentages); p < 0.05 was considered statistically significant.

between the two groups ($p = 0.036$). Left ventricular myocardial mass and LVEF were not different between the groups.

MACE and bleeding in and out of hospital

The occurrences of MACE and bleeding in the two groups are presented in **Tab. 5**, and the results of Kaplan–Meier analysis are shown in **Fig. 2**. Two patients undergoing aspiration thrombectomy alone experienced mild bleeding: one case was bleeding gums and the other was epistaxis. Two patients undergoing aspiration thrombectomy with intracoronary tirofiban experienced mild bleeding: one case was microscopic hematuria and the other was epistaxis. During hospitalization, the rates of myocardial re-infarction, cardiac death, re-PCI, and CABG were not significantly different between the two groups. During the 6-month follow-up period, no significant differences were observed in the rates of myocardial re-infarction, cardiac death, re-PCI, or CABG between the groups. The rate of MACE in the two groups in the log-rank test was not significantly different ($p = 0.172$).

Discussion

The principal results of this study were: (1) The combination of aspiration thrombectomy and intracoronary tirofiban is better than using aspiration thrombectomy alone to enhance myocardial perfusion. (2) The combination of aspiration thrombectomy and intracoronary tirofiban demonstrated a better level of left ventricular reconstruction and infarction size compared with aspiration thrombectomy alone and did not increase the occurrence of bleeding complications. (3) The rate of MACE in the two groups was not significantly different, but the combined-treatment group had lower rates compared with the single-treatment one. Because left ventricular reconstruction is a slow process, the LVEF and left ventricular diastolic diameter (LVDD) improved only at 6 months. All the patients in the present study had a large angiographic thrombus burden; thus, the control group without aspiration thrombectomy and intracoronary tirofiban was not included in the study design. The anterior MI location and abnormal TIMI flow are the strongest baseline determinants of infarct size [19]. Therefore, the patients with proximal or mid-LAD occlusion were conditionally chosen in this study. Owing to the lack of a dedicated intracoronary catheter, heparinized saline was used to rinse the aspiration catheter repeatedly (more than twice), and tirofiban was administered through the aspiration catheter.

Because the infarct-related artery in acute MI tends to have a higher thrombus burden and more atherosclerotic plaque debris, which can result in the occurrence of no-reflow or a slow-reflow phenomenon, drug treatment has certain limitations in these areas. Although TIMI 3 epicardial flow is restored by primary PCI, the patients may have a lower level of myocardial perfusion [20]. Thus, these patients may have a higher rate of mortality. Clinical manifestations are a progressive

Tab. 3 Echocardiography at 7 days, 30 days, and 6 months

	Group A ($n = 72$)	Group B ($n = 78$)	p
At 7 days			
LVDD	48.7 ± 7.3	48.3 ± 8.6	0.793
LVEF (%)	52.3 ± 6.8	50.7 ± 4.3	0.087
At 30 days			
LVDD	50.6 ± 6.7	49.2 ± 9.1	0.361
LVEF (%)	50.9 ± 7.6	50.2 ± 6.9	0.683
At 6 months			
LVDD	51.9 ± 5.9	49.3 ± 7.3	0.024
LVEF (%)	46.7 ± 8.4	49.8 ± 6.8	0.016

LVDD left ventricular diastolic diameter, *LVEF* left ventricular ejection fraction
Data are presented as means ± SD or numbers of patients (percentages); $p < 0.05$ was considered statistically significant.

Tab. 4 Cardiac magnetic resonance imaging results

	Group A ($n = 57$)	Group B ($n = 62$)	p
Infarct size	18.1 ± 8.5	15.2 ± 7.6	0.036
LV myocardial mass	130.2 ± 25.5	129.3 ± 24.2	0.785
LVEF (%)	51.3 ± 6.2	50.6 ± 6.9	0.089
Transmurality ≥ 75 %	34 (59.6)	28 (15.2)	0.261

LV left ventricular, *LVEF* left ventricular ejection fraction
Data are presented as means ± SD or numbers of patients (percentages); $p < 0.05$ was considered statistically significant.

Tab. 5 Clinical endpoints

	Group A ($n = 72$)	Group B ($n = 78$)	p
During hospitalization			
Myocardial re-infarction (%)	1 (1.4)	0	0.480
CHD death (%)	1 (1.4)	0	0.480
Re-PCI	0	0	
CABG	0	0	
Any of the above (%)	2 (2.8)	0	0.229
Bleeding complication (%)	2 (2.8)	2 (2.6)	1.000
At the 6-month follow-up			
Myocardial re-infarction (%)	3 (4.2)	1 (1.4)	0.351
Cardiac mortality (%)	2 (2.8)	1 (1.4)	0.608
Re-PCI	0	0	
CABG	0	0	
Any of the above	5 (6.9)	2 (2.6)	0.261

CHD coronary heart disease, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass graft
Data are presented as means ± SD or numbers of patients (percentages); $p < 0.05$ was considered statistically significant.

deterioration of heart function or recurrent ischemic cardiovascular events [21]. Thrombus aspiration is primarily used in large thrombus burden lesions, in stent thrombosis, and in patients who exhibit no-reflow phenomenon. Moreover, this approach can result in blood clots and lead to embolize the distal microvascular bed [22].

Cardiac death and re-infarction after 1 year, according to the Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study (TAPAS trial) [23, 24], have the most far-reaching effects, which demonstrates that manual thrombectomy is superior to simple primary PCI based on the improvement in myocardial blush grade and can reduce the incidence of MI and cardiac death in the first year after the procedure. The EXPIRA trial (Impact of Thrombectomy with Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention on Cardiac Death) includes 175 cases with STEMI [25]. The results of the trial can be summarized as: (1) Thrombectomy can improve short-term prognosis; (2) the cardiac mortality of the thrombus aspiration group was lower than that of the PCI-only group at 9 and 12 months; (3) at 2 years, PCI and thrombectomy were independent risk factors for cardiac mortality. Burzotta et al. analyzed the pooled results of 11 trials, which indicated that for STEMI patients, manual thrombectomy was better than PCI alone [26]. Thus, the guidelines of the American College of Cardiology Foundation and American Heart Association (ACCF/AHA, 2013) on the treatment of STEMI suggested that manual aspiration thrombectomy could be used in primary PCI (IIa, B).

Platelets play a key role in the early formation of microthrombi. Theoretically, a GP IIb/IIIa receptor antagonist can reduce the formation of microthrombi and subsequent effects on the destruction of microcirculation, thereby increasing the level of myocardial reperfusion. Therefore, the routine use of a Gp IIb/IIIa receptor antagonist is recommended [27–29]. The study of Zhu et al. included 453 cases with acute MI [30]. The results indicated that intracoronary tirofiban after intravenous treatment could reduce coronary circulatory platelet activation and significantly improve left ventricular function and myocardial reperfusion in the subsequent 6 months. But according to the current guidelines, it is not considered to be a class I indication [31, 32]. This indication may be due to the potential increase in bleeding complications. An intracoronary injection of the GP IIb/IIIa receptor antagonist was proposed to decrease bleeding complications while maintaining anti-ischemic efficacy [33]. Moreover, intracoronary

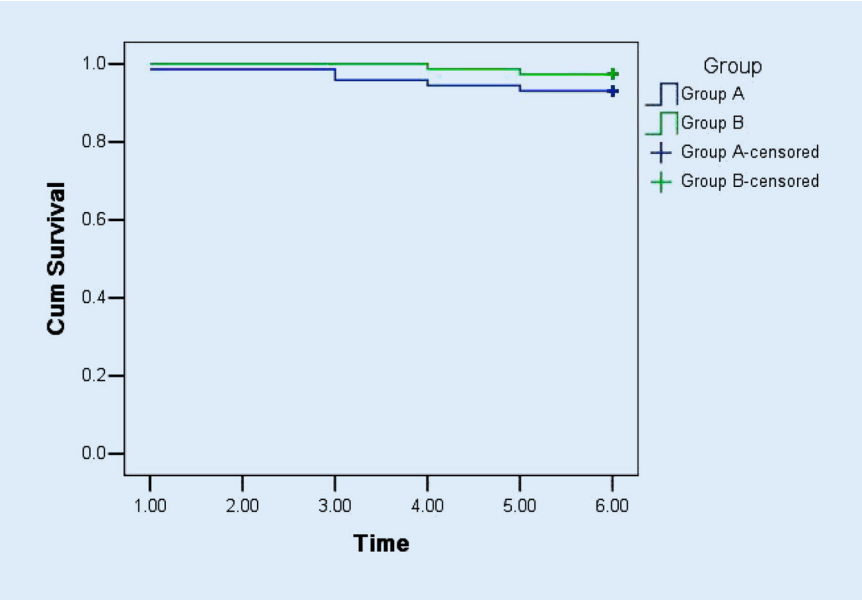

Fig. 2 ▲ Kaplan–Meier plot of the major adverse cardiovascular events during the 6-month follow-up ($p = 0.172$); $p < 0.05$ was considered statistically significant. *Cum* cumulative

abciximab was also better than the intravenous approach in improving myocardial perfusion [34–37].

GP IIb/IIIa receptor antagonists include tirofiban, abciximab, and integrilin, among other drugs. Kandzari et al. analyzed the pooled results of previous studies [37], and found that primary PCI combined with abciximab could significantly reduce the rate of re-infarction and cardiac death and target vessel revascularization in the following 30 days (odds ratio: 0.54). Urgent target vessel revascularization was the most significant effect (odds ratio: 0.46), and the benefits of combined treatment with abciximab persisted after 6 months (odds ratio: 0.80).

Findings from the INFUSE-AMI randomized trial (Intracoronary Abciximab and Aspiration Thrombectomy in Patients with Large Anterior Myocardial Infarction) suggest that the most efficient treatment for decreasing infarct size and mortality is the combination of abciximab administration and manual thrombectomy rather than each treatment alone [38]. A recent analysis came to a similar conclusion, in which the combination of aspiration thrombectomy and intracoronary abciximab may be conducive to myocardial perfusion in patients with STEMI [39].

Previous studies of the GP IIb/IIIa receptor antagonist focused almost exclusively on abciximab than on tirofiban [37–42]. Abciximab is expensive; therefore, the application of tirofiban requires further study. In the present study, tirofiban was applied for intracoronary injection. The study found that the combined treatment with aspiration thrombectomy and intracoronary tirofiban was more effective than treatment with aspiration thrombectomy alone. While aspiration thrombectomy retrieves most thrombotic materials in patients with STEMI, intracoronary tirofiban could further dissolve residual thrombus and microemboli in the microvasculature. Thus, only using intracoronary tirofiban without aspiration thrombectomy may have a limited value, while the lesion has a heavy thrombotic burden.

The present study had some limitations. First, the trial was a single-center study, and the number of cases was not sufficient. Thus, we could not conclusively demonstrate the safety and effectiveness of the combination treatment. Second, the follow-up evaluation period was short, and hence it was difficult to completely describe the long-term prognosis. Third, the intracoronary infusion catheter used to deliver tirofiban was not specialized. Thus, although professional tools were used during the study, further research is still warranted.

Conclusion

In conclusion, the strategy for primary PCI is to aim for multiple removal of thrombus and less stent implantation. Combined treatment with aspiration thrombectomy and intracoronary tirofiban in patients with STEMI is safe and effective, and does not increase the rate of bleeding complications, particularly in the case of a large angiographic thrombus burden. Moreover, this treatment may be an efficient method for improving myocardial perfusion.

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Compliance with ethical guidelines

Conflict of interest. T. Geng, J.-G. Zhang, Z.-Y. Song, S.-P. Dai, Y. Luo, and Z.-S. Xu state that there are no conflicts of interest.

All studies on humans described in the present manuscript were carried out with the approval of the responsible ethics committee and in accordance with national law and the Helsinki Declaration of 1975 (in its current, revised form). Informed consent was obtained from all patients included in studies.

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