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Research article

Low-dose intravenous tirofiban infusion after endovascular recanalization for non-acute middle cerebral artery occlusion

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ABSTRACT

Background and purpose: Endovascular recanalization for patients with symptomatic non-acute middle cerebral artery occlusion still remines challenging. Postoperative treatment is still controversial. This study aims to investigate the safety and effectiveness of tirofiban after elective angioplasty in patients with non-acute middle cerebral artery occlusion related ischemic stroke.

Methods: Our study is a retrospective case series study of 48 stroke patients who received elective endovascular recanalization for middle cerebral artery occlusion. Patients who received EVT without hemorrhage were divided into 2 groups: those who did not receive intravenous tirofiban treatment (control group, n = 25); those who received continuous intravenous infusion of 0.2–0.3 mg/h tirofiban for 48 h after endovascular recanalization (intravenous tirofiban group, n = 23). Early reocclusion of treated arteries, symptomatic hemorrhage, and 90-day functional outcome of the 2 groups were compared.

Results: The 90-day mRS score and NIHSS score after endovascular recanalization showed no significantly different between the two groups. However, the rate of mRS score reverse (≥1) was significantly higher in the intravenous tirofiban group than the control (73.9% versus 24.0%, P = 0.001), and the rate of NIHSS score reverse (≥3) in the intravenous tirofiban group was also higher (43.5% verse 16.0%, P = 0.037). The rate of early reocclusion, symptomatic hemorrhage (4.3% versw 4%, P = 0.734), showed no difference between the two groups.

Conclusions: Low-dose intravenous tirofiban infusion (0.2–0.3 mg/h for 48 h) after endovascular treatment seems to be safe and potentially effective for non-acute middle cerebral artery occlusion patients.

1. Introduction

Non-acute intracranial atherosclerotic occlusion (NAICAO) was closely related to the occurrence of cerebral ischemic events. Nearly 10% of ischemic stroke is caused by NAICAO [1]. The risk of stroke in patients with NAICAO is 3.6%–22.0% [1]. For patients with hemodynamic disorders, the risk is significantly increased. 23.4% patients presented stroke recurrence even given the best drug treatment [2, 3]. Epidemiological investigation found that 33–50% ischemic stroke and 50% transient ischemic attack (TIA) patients in China showed intracranial artery stenosis/occlusion, which is an extremely large patient group [4].

For patients with symptomatic non-acute middle cerebral artery occlusion (NAMCAO), drug therapy is in the dominant position, and endovascular treatment (EVT) is still in its infancy [5]. The efficacy of extracranial intracranial artery bypass grafting has not been finally proved in large studies [6]. Many stroke centers have tried endovascular treatment in these patients, but the perioperative complications, including stent thrombosis and symptomatic hemorrhage, and the 90-day outcome of endovascular recanalization still remain controversial [7, 8]. Only a few case reports have revealed that EVT seems to prevent stroke recurrence for NAMCAO patients [9, 10, 11]. Clinical studies with a large sample size is need.

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Postoperative treatment for NAMCAO patients received endovascular treatment is still controversial. Similar chronic coronary occlusion patients, Aspirin (100 mg/d) and clopidogrel (75 mg/d) were given for at least 90 days after EVT [12, 13]. How to decrease the rate of stent thrombosis and improve the 90-day outcome of NAMCAO patients with EVT are particularly important. Tirofiban has been proved effective in acute ischemic stroke patiens with EVT, and could improve the rate of good outcome [14, 15]. Does it have the same effect in NAMCAO patients with EVT?

Tirofiban is a reversible glycoprotein (GP) IIB/IIIa receptor antagonist with high efficiency, which has been proved safe and effective in patients with acute stroke who received thrombectomy [14, 15]. However, whether intravenous infusion of tirofiban could increase the risk of symptomatic hemorrhage or improve outcome after endovascular recanalization in NAMCAO patients are still uncertain.

Therefore, in our study, we concentrated on the safety and effectiveness of intravenous treatment of tirofiban for 48 h after endovascular treatment in NAMCAO patients.

2. Methods

The corresponding author could provide all data that support the findings of our study upon reasonable request. The institutional review board approved this study and IRB (Ethics Committee of Nanjing Drum Tower Hospital) number: 2021-399-02.

2.1. Patients

A total of 56 stroke patients who presented with non-acute middle cerebral artery occlusion were treated with endovascular recanalization at our regional comprehensive stroke center from August 2017 to April 2021. Patients without contrast extravasation and hemorrhage at Dyna CT after EVT were divided into 2 groups: Intravenous Tirofiban infusion group, control group, 48 patients were enrolled.

The selection criteria of patient for endovascular recanalization were as follows: 1) MCA occlusion confirmed by digital subtraction angiography (DSA); 2) presenting with occluded artery related stroke; 3) occlusion time exceeds 1 month and less than 3 months; 4) occlusion length less than 2 cm (measured by high-resolution vessel wall); 5) decreased perfusion in occluded arterial supply area (measured by magnetic resonance perfusion); 6) ASITN/SIR $\geq$3 (measured by DSA); 7) a preoperative mRS score $\leq$3; 8) patient refusal to undergo bypass surgery. The exclusion criteria were as follows: 1) clinical, laboratory, or imaging findings not suspicious for atherosclerotic lesions, such as vasculitis, Moyamoya syndrome, arterial dissection; 2) a coexisting cardioembolic source (eg, atrial fibrillation, mitral stenosis, prosthetic valve, Myocardial infarction within 6 weeks, intracar-diac clot, ventricular aneurysm, and bacterial endocarditis); 3) a concomitant intracranial aneurysm or any bleeding disorder; 4) large infarct core, defined as an ASPECTS of $<$6 points.

The following data were analyzed: age, sex, risk factors, such as hypertension, diabetes, dyslipidemia, smoking, previous stroke or TIA, baseline NIHSS and mRS score. 90-day modified Rankin Scale. Perioperative complications including stent thrombosis and symptomatic intracerebral hemorrhage were observed. 90-day mRS decrease and 90-day NIHSS decrease were taken as prognostic indicators.

2.2. Endovascular therapy

Endovascular recanalization for NAMCAO were performed under general anesthesia. The details of the techniques for endovascular recanalization: in all cases, the Sino balloon catheter (Sinomed, China) and the Enterprise stent system (JNJ, the USA) were used to perform balloon angioplasty and stenting respectively.

2.3. Postprocedural antiplatelet therapy

NAMCAO patients received a 48-hours intravenous infusion of tirofiban at a rate of 0.2–0.3 mg/h after the completion of endovascular therapy. Clopidogrel (75 mg/d) and aspirin (100 mg/d) were taken 4 h before the end of tirofiban treatment. This antiplatelet therapy was continued for at least 90 days after endovascular recanalization. Patients were divided into two groups: intravenous tirofiban infusion group (n = 23) and control group (n = 25) according to the postprocedural antiplatelet therapy.

2.4. Tirofiban treatment

Dyna CT was performed once EVT completed, patients without contrast extravasation and hemorrhage were given intravenous tirofiban infusion according to the choice of the operator. Intravenous infusion of tirofiban was given at a rate of 0.2–0.3 mg/h. The follow-up head CT was taken to measure hemorrhage within 4 h–7 days after EVT. Once hemorrhage was found, the intravenous tirofiban was stopped immediately.

2.5. Outcome measures

Reperfusion status was assessed by DSA according to the modified Thrombolysis in Cerebral Ischemia scale (mTICI), and mTICI score of 2b or 3 was considered as successful recanalization. All patients underwent follow-up brain CTA or MRA within 4 h–7 days after EVT to evaluate the cerebral hemorrhage and the patency of the target vessel. The discrete discontinuation of the arterial contrast column within the treated artery on follow-up CTA or MRA was defined as early reocclusion. Hemorrhage associated with neurological deterioration ($>$3 points increase in NIHSS) was defined as symptomatic hemorrhage. Clinical outcomes were evaluated by using mRS score reverse and NIHSS score reverse during the outpatient visit 3 months after endovascular recanalization. A good clinical outcome was defined as mRS score reverse $\geq$1 or NIHSS score reverse $\geq$3.

2.6. Statistical analysis

Median and interquartile range were used to describe continuous variables. The count (n) and percentage (%) were used to describe categorical variables. Baseline and procedural characteristics and treatment outcomes of intravenous tirofiban group and control group were compared. The categorical and binary variables were analyzed by $\chi 2$ test, and continuous variables were analyzed by Mann-Whitney U test. All data was analyzed by SPSS software (version 25.0; IBM SPSS, Chicago, IL), and statistical differences was defined P value $<$ 0.05.

3. Results

Our study included 48 patients (79.2% male; median age 57). Of these, 23 patients received intravenous treatment of tirofiban for 48 h Table 1 showed the baseline and procedural characteristics of patients. 64.5% (31/48) of patients had hypertension, 37.5% (18/48) had diabetes, 41.7% (20/48) had a smoking history, 12.5% (6/48) had hyperlipidemia, 27.1% (13/48) had a history of prior ischemic stroke. The baseline mRS and NIHSS score showed no difference between the 2 group.

Treatment outcomes are presented in Table 2. Overall, 46 patients (95.8%) achieved successful reperfusion after endovascular therapy. Two patient occurred symptomatic hemorrhage, one in control group (4%), and one in tirofiban group (4.3%). No fatalities occurred. All patients received oral antiplatelet medication after endovascular recanalization. The rates of successful reperfusion, symptomatic hemorrhage showed no significant differences between the 2 groups.

Table 1. Comparison of baseline and procedural characteristics between patients who received 48-hour IV tirofiban and control.

	All patients (n = 48)	No IV tirofiban (n = 25)	48-h IV tirofiban (n = 23)	P value
Age, y	57 (50–68.5)	58 (51.5–69.5)	57 (49–67)	0.686
Sex, male	38 (79.2)	19 (76.0)	19 (82.6)	0.727
Risk factors				
Hypertension	31 (64.5)	16 (64.0)	15 (65.2)	1.000
Diabetes	18 (37.5)	10 (40.0)	8 (34.8)	0.771
Smoking	20 (41.7)	11 (44.0)	9 (39.1)	0.777
Dyslipidemia	6 (12.5)	3 (12.0)	3 (13.0)	0.625
Stroke frequency ≥2	13 (27.1)	7 (28.0)	6 (26.1)	0.570
Baseline NIHSS score	4 (2–7)	3 (1.5-8)	5 (2–6)	0.762
Baseline mRS score	2 (1–3)	2 (1–3)	2 (1–3)	0.522
Postprocedural oral antiplatelet medication	45 (93.8)	23 (92.0)	22 (95.7)	0.532

Table 2. Comparison of treatment outcomes between patients who received 48-hour IV tirofiban and control.

	All patients (n = 48)	No IV tirofiban (n = 25)	48-h IV tirofiban (n = 23)	*P* value
Successful reperfusion	46 (95.8)	23 (92.0)	23 (100.0)	1.000
Early reocclusion	2 (4.2)	2 (8.0)	0 (0)	0.490
Postoperative contrast medium exudation (4 h)	3 (6.3)	2 (8.0)	1 (4.3)	0.601
Asymptomatic hemorrhage	2 (4.2)	1 (4.0)	1 (4.3)	0.734
Symptomatic hemorrhage	2 (4.2)	1 (4.0)	1 (4.3)	0.734
Hyperperfusion	2 (4.2)	1 (4.0)	1 (4.3)	0.734
90-day mRS score	1 (1–2)	1 (1–2)	1 (1–2)	0.259
90-day NIHSS score	2 (1–5.75)	2 (1–7)	2 (1–5)	0.198
90-day mRS score <3	43 (89.6)	21 (84.0)	22 (95.7)	0.350
mRS score reverse ≥1	23 (47.9)	6 (24.0)	17 (73.9)	0.001
NIHSS score reverse ≥3	14 (29.2)	4 (16)	10 (43.5)	0.037

Early reocclusion of the treated artery occurred in 2 patients (4.2%) on follow-up computed tomography angiography, and both in control group (8%). No early reocclusion occurred in intravenous tirofiban infusion group, but there were no significant differences of the rate of early reocclusion between the 2 groups (P = 0.490).

The follow-up head CT 4h to 7 days after EVT showed that, 3 patients (6.3%) showed contrast agent exudation, 1 patient in control group, 2 patients in tirofiban group (8.0% vs 4.3%, P = 0.601). 2 patients (4.2%) showed asymptomatic hemorrhage, 1 patient in control group and 1 patient in tirofiban group (4.0% vs 4.3%, P = 0.734), and the hemorrhage was absorbed in 7 days, with no symptoms left. 2 patients showed hyper-perfusion after EVT, 1 patient in control group and 1 patient in tirofiban group (4.0% vs 4.3%, P = 0.734).

There were 43 (89.6%) patients showed good outcome (90-day mRS score<3). 23 patients (47.9%) mRS score reverse ≥1, 17 (73.9%) in intravenous tirofiban infusion group, 6 in control group (24%). The rate was higher in intravenous tirofiban infusion group (p = 0.001, Figure 1A and B). There were 14 patients (29.2%) achieved NIHSS score reverse ≥3, and 10 (43.5%) in intravenous tirofiban infusion group, 4 in control group (16%). The rate was also higher in intravenous tirofiban infusion group (p = 0.037, Figure 2A and B).

4. Discussion

We found that intravenous tirofiban infusion (0.2–0.3 mg/h for 48 h) after endovascular treatment in NAMCAO patients seemed to be effective and safe, which did not increase the risk of symptomatic hemorrhage or asymptomatic hemorrhage, and could improve 90-days outcome.

Early occlusion was a common complication after EVT, especially within 24 h after operation [16]. Early occlusion is the most common cause of ischemic stroke after EVT, which could lead to severe neurological impairment and even death [17, 18]. In our study, no early occlusion occurred in intravenous tirofiban infusion group, 2 patients showed stent thrombosis and early occlusion happened in control group. But due to the insufficient sample size, there was no significant difference between the two groups. DSA images of the 2 patients were replayed after operation. Patient 1: we suspected that the stent was released in the vascular dissection. Patient 2: the DSA image showed left anterior cerebral artery occlusion after left MCA recanalization, we thought plaques in the left middle cerebral artery were squeezed into the anterior cerebral artery after balloon dilatation.

In research of acute ischemic stroke, good out come was defined as 90-day mRS ≤2 [19]. Since the baseline mRS of all patients received EVT was between 0 to 3, the 90-days mRS and NIHSS score showed no difference between the two groups. The increase of mRS score >1 point was defined as neurological function deterioration. So we defined a 1-point decrease in mRS score or 3-point decrease in NIHSS score as a good outcome. The rate of good prognosis in intravenous tirofiban infusion group was significantly higher than control.

In China, the annual risk of stroke in patients with symptomatic chronic intracranial artery occlusion is as high as 23.4%, prognosis of these patients is poor [20, 21]. Especially, the rate of 90-days poor outcome (mRS>2) in NAMCAO patients is 47–87% [22], the mortality is 3%–10% [17]. It is extremely important to maintain the blood perfusion of occluded vessels to decrease the rate of stroke recurrence and

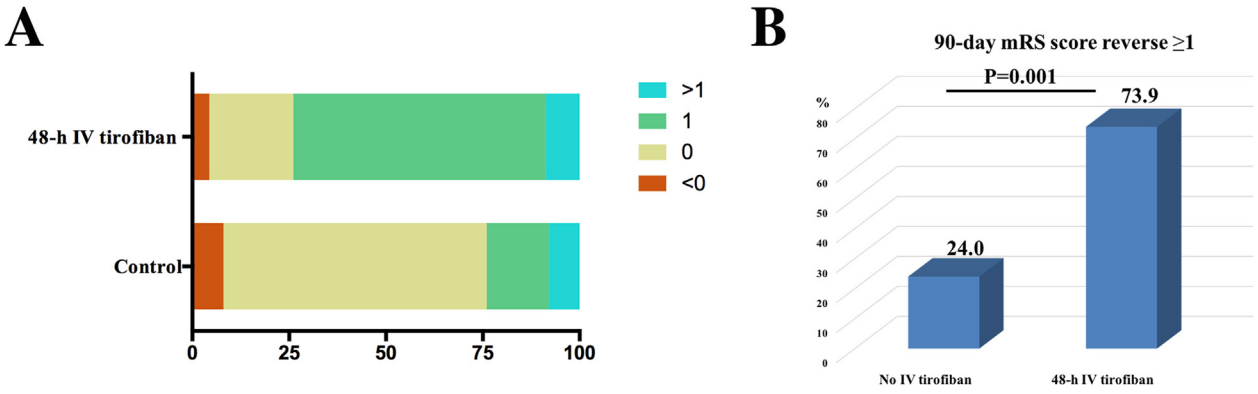

Figure 1. Comparison of mRS reverse between the intravenous tirofiban group and the control group. A 90-d mRS reverse between the intravenous tirofiban group and the control group. B Proportion of 90-d mRS reverse ≥1 of intravenous tirofiban group and the control group (P = 0.001).

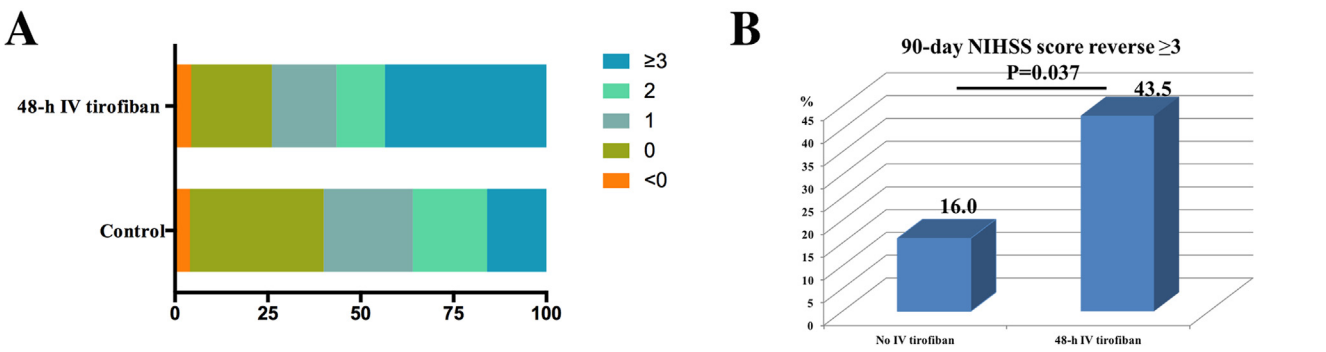

Figure 2. Comparison of NIHSS reverse between the intravenous tirofiban group and the control group. A 90-d NIHSS reverse between the intravenous tirofiban group and the control group. B Proportion of 90-d NIHSS reverse ≥3 of intravenous tirofiban group and the control group (P = 0.037).

mortality. Extracranial and extracranial artery bypass grafting was first used to treat intracranial large artery occlusion, but it has no advantage over the drug treatment group in preventing stroke recurrence [23, 24, 25, 26]. A few case reports showed that EVT seemed to be effective to treat NAMACO, but the perioperative complications and outcomes of patients need further confirmation in large sample size studies [27, 28]. Our study showed that intravenous tirofiban infusion could improve the outcomes in NAMCAO patients who received EVT.

Symptomatic hemorrhage is a terrible complication of endovascular treatment, usually lead to severe neurological dysfunction, even death. Tirofiban is a reversible glycoprotein (GP) IIB/IIIa receptor antagonist with high efficiency [29, 30], which has been proved could reduce the risk of stent restenosis and improve cardiac function in cardiovascular field [31, 32]. The research of tirofiban in ischemic stroke is still in a fledgling phase. Intraarterial bolus injection provides a direct contact of tirofiban to the thrombus with a dramatic increase in the local drug concentration, but increased the risk of cerebral hemorrhage [29]. Yang J et al found that intravenous tirofiban is associated with high recanalization rate and good outcome [33]. Zhao W et al found that in patients with AIS undergoing ET, tirofiban is not associated with higher sICH, it seems to lead to lower odds of deaths and better odds of long-term functional independence [30]. Despite the function of inhibits fibrinogen-dependent platelet aggregation, tirofiban could also reduce the inflammatory reaction and accelerate repair of epithelial cells, which could reduce the blood brain barrier dysfunction [34]. The endothelial injury of occluded artery is more serious than narrowed artery. Once the stent is placed, the risk of occlusion is much more high. And the patients who received EVT have already taken aspirin (100 mg/d) and clopidogrel (75 mg/d) for a period of time, high-dose tirofiban could increase the risk of hemorrhage. Considering the above factors, we chose a low-dose intravenous tirofiban infusion (0.2–0.3 mg/h for 48 h) after endovascular treatment in NAMCAO patients [35]. The use of intravenous tirofiban is cautious for patients with intracerebral hemorrhage and contrast medium exudation in dyna-CT. Also, follow-up head CT from 4 h to 7days after EVT was taken to assess hemorrhage, once hemorrhage was found, the tirofiban was stopped immediately. Fortunately, tirofiban did not increase the risk of hemorrhage after EVT. We therefore believe that low-dose intravenous tirofiban seems to be safe for NAMCAO patients received EVT.

Still, there are several limitations of our study. This study is a single center retrospective study. Due to the limitation of sample size, we did not get positive results in preventing early occlusion by intravenous tirofiban infusion. The measurement methods of good outcome are relatively simple, only 90-days mRS reverse and 90-days NIHSS reverse were considered. The perfusion of hypoperfusion brain tissue after endovascular treatment were not measured. The cognitive function of patients was lacked. In the future, multiple-center randomized controlled trials are needed to investigate whether endovascular treatment is effective and safe for NAMCAO patients, and the function of tirofiban in preventing early occlusion and improving outcomes.

5. Conclusion

Low-dose intravenous tirofiban infusion (0.2–0.3 mg/h for 48 h) after endovascular treatment seems to be safe and potentially effective for NAMCAO patients.

Declarations

Author contribution statement

Zhang Xi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

Chen Zhibin, Luo Yun, Xu Yun: Performed the experiments; Analyzed and interpreted the data.

Duan Guangxin, Zhang He: Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data.

Li Jingwei: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

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Data availability statement

Data included in article/supp. material/referenced in article.

Declaration of interest's statement

The authors declare no competing interests.

Additional information

No additional information is available for this paper.

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