·临床研究·

替罗非班在老年急性前循环大动脉闭塞性脑梗死机械取栓中的应用价值及患者短期预后

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【摘 要】 目的 探讨老年急性前循环大动脉闭塞性脑梗死患者替罗非班联合机械取栓治疗后血管再通率及安全性,并分析影响患者短期预后的相关因素。**方法** 选择邢台市中心医院2022年12月至2024年3月收治的120例老年急性前循环大动脉闭塞性脑梗死患者为研究对象,根据患者是否应用替罗非班将其分为替罗非班组(替罗非班+机械取栓,$n=67$)和对照组(机械取栓,$n=53$),比较两组患者血管再通率、症状性颅内出血、治疗安全性及治疗后神经功能。术后随访90 d,采用Rankin修订量表(mRS)评分评价两组患者预后情况(mRS≤2分为预后良好)。采用SPSS 26.0统计软件进行数据分析,根据数据类型组间比较分别行t检验或χ^2检验。采用二元logistic回归模型分析影响患者预后的相关因素。**结果** 替罗非班组患者血管再通率高于对照组[85.07%(57/67)和67.92%(36/53)];术后90 d mRS量表得分≤2分(预后状况良好)者占比高于对照组[80.60%(54/67)和(58.49%31/53)];治疗后7 d美国国立卫生研究院卒中量表(NIHSS)评分低于对照组,差异均有统计学意义($P<0.05$)。两组患者症状性颅内出血、再闭塞及住院期间死亡率比较,差异无统计学意义($P>0.05$)。以患者术后90 d预后状态作为因变量,行二元logistic回归分析提示,合并2型糖尿病($OR=2.109$,95%CI 1.442~3.084)及基线NIHSS评分($OR=2.408$,95%CI 1.713~3.387)是患者预后不良的危险因素($P<0.05$);侧支循环分级3~4级($OR=0.359$,95%CI 0.159~0.810)、联合替罗非班($OR=0.482$,95%CI 0.296~0.786)及血管再通($OR=4.100$,95%CI 2.069~8.126)是患者预后不良的保护因素($P<0.05$)。**结论** 机械取栓联合替罗非班能有效提高老年急性前循环大动脉闭塞性脑梗死患者闭塞血管再通率,改善神经功能及预后,且不增加出血风险,联合替罗非班是患者术后短期预后不良的保护性因素。

【关键词】 老年人;急性前循环大动脉闭塞性脑梗死;替罗非班;血管再通;安全性
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Application value of tirofiban during mechanical thrombectomy and its effect on short-term prognosis in elderly patients with anterior circulation large artery occlusion-related acute cerebral infarction

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【Abstract】 Objective To explore the vascular recanalization rate and safety of tirofiban combined with mechanical thrombectomy in elderly patients with acute cerebral infarction due to anterior circulation large artery occlusion (AC-LAO), and analyze the related factors affecting the short-term prognosis of patients. **Methods** A total of 120 elderly eligible patients admitted to our hospital from December 2022 to March 2024 were enrolled, and according to whether tirofiban was used or not, they were divided into tirofiban group (tirofiban+mechanical thrombectomy, $n=67$) and control group (mechanical thrombectomy, $n=53$). The vascular recanalization rate, symptomatic intracranial hemorrhage, treatment safety and neurological function after treatment were compared between the two groups. In 90 d after follow-up, modified Rankin scale (mRS) was applied to assess the prognosis of patients (mRS score ≤2 points as good prognosis). Data analysis was performed by using SPSS statistics 26.0, and t test or Chi-square test was performed depending on data type. Binary logistic regression model was used to analyze the related factors affecting the prognosis. **Results** The tirofiban group had significantly higher vascular recanalization rate [85.07% (57/67) *vs* 67.92% (36/53)], larger proportion of mRS score ≤2 points (good prognosis status) at 90 d after surgery [80.60% (54/67) *vs* 58.49% (31/53)], and lower National Institutes of Health stroke scale (NIHSS) score at 7 d after treatment when compared with the control group ($P<0.05$). There were no statistical differences between the two groups in incidence of symptomatic intracranial hemorrhage, re-occlusion occurrence and mortality rate during hospitalization ($P>0.05$).

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Taking the prognostic status at 90 d after surgery as a dependent variable, binary logistic regression analysis indicated that concurrent type 2 diabetes mellitus (*OR*=2.109, 95%*CI* 1.442-3.084) and baseline NIHSS score (*OR*=2.408, 95%*CI* 1.713-3.387) were risk factors for poor prognosis, and collateral circulation grade 3-4 (*OR*=0.359, 95%*CI* 0.159-0.810), combination of tirofiban (*OR*=0.482, 95%*CI* 0.296-0.786) and vascular recanalization (*OR*=4.100, 95%*CI* 2.069-8.126) were protective factors for poor prognosis (*P*<0.05). **Conclusion** Mechanical thrombectomy combined with tirofiban can effectively enhance the vascular recanalization rate and improve the neurological function and prognosis in the elderly patients with acute cerebral infarction due to AC-LAO, and it does not increase the risk of hemorrhage. Combination of tirofiban is a protective factor for poor postoperative short-term prognosis.

【Key words】 aged; anterior circulation large artery occlusion-related acute cerebral infarction; tirofiban; vascular recanalization; safety

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前循环大动脉主要负责保证大脑前部区域血流供应,急性前循环大动脉闭塞性脑梗死是最危险的脑梗死类型之一,该类型的脑梗死静脉溶栓再通率仅在 20%左右,通常需尽快进行机械取栓[1,2]。随着导管技术及血管内皮设备的不断更新,机械取栓的安全性及血管再灌注率较以往明显上升,但仍然有部分患者存在血管再闭塞问题[3]。如何提高急性前循环大动脉闭塞性脑梗死患者治疗效果是当前研究的热点。替罗非班是一种抗血小板药物,具有溶栓及抗血栓生成功效,目前已广泛应用于急性冠脉综合征等心血管疾病的治疗[4],但其在急性前循环大动脉闭塞性脑梗死中的应用报道不多且存在争议。本研究对替罗非班联合机械取栓在急性前循环大动脉闭塞性脑梗死患者中的应用价值与安全性进行探讨,并对影响患者预后的相关因素进行分析,为临床治疗提供参考。

1 对象与方法

1.1 研究对象

选择邢台市中心医院 2022 年 12 月至 2024 年 3 月收治的 120 例老年急性前循环大动脉闭塞性脑梗死患者为研究对象,根据患者是否应用替罗非班将其分为替罗非班组(替罗非班+机械取栓,$n=67$)和对照组(机械取栓,$n=53$)。纳入标准:年龄≥60 岁;符合《中国急性缺血性脑卒中诊治指南》[5]中相关诊断标准,并经血管造影术确诊,闭塞部位位于前循环大血管处;发病 6 h 内入院;接受机械取栓手术;发病前 Rankin 修订量表评分(modified Rankin scale,mRS)评分 0~1 分。排除标准:合并心肝肾等重要器官损伤;受试药物过敏;术前接受过肝素抗凝治疗;有出凝血功能障碍;其他原因引起的血管闭塞;合并精神障碍。本研究经医院医学伦理委员会批准(2022-KY-22),患者及其家属对研究内容知情并签署知情同意书。

1.2 方法

1.2.1 手术方法 对照组患者进行机械取栓。机械取栓:先行头颅 CT 排除颅内出血,对于时间窗内符合静脉溶栓条件者给予静脉注射重组人体组织型纤维蛋白溶酶原激活剂(recombinant tissue-type plasminogen activator,rt-PA)治疗。指导患者取平卧位,局部或全身麻醉,经皮穿刺导丝引导法穿刺股动脉置入 6~8F 导管鞘后行脑数字减影血管造影(digital subtraction angiography,DSA),明确患者闭塞血管及血栓位置,同时基于 DSA 的美国介入和治疗神经放射学学会/介入放射学学会(American Society of Intervention and Therapeutic Neuroradiology/Society of Interventional Radiology, ASITN/SIR)[6]标准评估患者侧支循环状态。将6~8F指导管置于颈总动脉,将 Rebar-18/27 微导管推送至闭塞段远端,行微导丝造影观察远端血流,置入并释放 Solitaire AB 或 FR 型支架,原位保持至少 5 min 后缓慢回收支架,观察血管开通情况。

替罗非班组患者在机械取栓基础上动脉注射替罗非班(四川美大康佳乐药业有限公司,国药准字:H201835175),速度 1 ml/min,总用量≤0.5 mg。术后即刻行头颅 CT 检查,观察有无颅内出血,24 h 后复查头颅 CT 并根据复查结果决定后续治疗方案。

1.2.2 观察指标 (1)血管再通率。根据术后即刻头颅 CT 资料,参照改良脑梗死溶栓后血流分级(modified thrombolysis in cerebral ischemia,mTICI)[7]评价血管再通情况,mTICI 分级≥2b 级为血管再通,mTICI 分级0、1、2a 级为无再通。(2)治疗安全性。统计患者症状性颅内出血、血管再闭塞及住院期间死亡病例。症状性颅内出血:参照欧洲协作急性卒中研究Ⅲ(European Cooperative Acute Stroke Study Ⅲ,ECASS-Ⅲ)制定的相关标准[8]。血管再闭塞:患者术后即刻 CT 血管造影(computer tomography angiography,CTA)提示血管再通,但后续复查发现血管再闭塞。(3)神经功能恢复情况。分别在治疗前及治疗 7 d 后采用美国国立卫生研究院卒中量表(National Institutes of Health stroke scale,NIHSS)[9]评估患者神经功能。(4)预后。统计两组患者术后 90 d 预后,根据 mRS 量表[10]评估,将 mRS≤2 分定义为预后良好。

1.3 统计学处理

采用SPSS 26.0统计软件进行数据分析。计量资料以均数±标准差($\bar{x}\pm s$)表示,组间比较采用t检验。计数资料以例数(百分率)表示,组间比较采用χ^2检验。采用二元logistic回归模型分析影响老年急性前循环大动脉闭塞性脑梗死患者术后90 d预后状态的相关因素。$P<0.05$为差异有统计学意义。

2 结 果

2.1 两组患者基线资料

两组患者性别、年龄、体质量指数(body mass index,BMI)、高血压、2型糖尿病(type 2 diabetes mellitus,T2DM)、高脂血症、心房颤动、吸烟史、饮酒史、rt-PA静脉溶栓、发病至入院时间等基线资料比较,差异无统计学意义($P>0.05$;表1)。

2.2 两组患者血管再通率、治疗前后NIHSS评分及治疗安全性情况

替罗非班组患者血管再通率高于对照组,差异有统计学意义($P<0.05$);两组患者治疗前NIHSS评分比较,差异无统计学意义($P>0.05$),治疗7 d后NIHSS评分均较同组治疗前下降,且替罗非班组患者治疗后7 d NIHSS评分低于对照组,差异有统计学意义($P<0.05$);两组患者症状性颅内出血、再闭塞及住院期间死亡率比较,差异无统计学意义($P>0.05$;表2)。

2.3 影响患者90 d预后的单因素分析

替罗非班组患者90 d预后良好率为80.60%(54/67),对照组为58.49%(31/53),替罗非班组高于对照组,差异有统计学意义($\chi^2=7.000$,$P=0.008$)。

根据患者术后90 d预后状态,将患者分为预后良好组($n=85$)和预后不良组($n=35$),结合临床经验及相关文献资料[11,12]将可能影响患者预后的相关因素纳入研究。结果提示,预后不良组中合并T2DM者占比、基线NIHSS评分高于预后良好组;侧支循环分级3~4级、联合替罗非班治疗及血管再通成功者占比低于预后良好组,差异均有统计学意义($P<0.05$)。两组患者年龄、性别、高血压等资料比较,差异无统计学意义($P>0.05$;表3)。

2.4 影响患者预后的二元logistic回归分析

以老年急性前循环大动脉闭塞性脑梗死患者术后90 d预后状态作为因变量,单因素分析中有意义的指标作为自变量,行二元logistic回归分析提示,合并T2DM及基线NIHSS评分是患者预后不良的危险因素;侧支循环分级3~4级、联合替罗非班及血管再通是患者预后不良的保护因素($P<0.05$;表4)。

表1 两组患者基线资料比较

Table 1 Comparison of baseline data between two groups

Item	Tirofiban group($n=67$)	Control group($n=53$)	χ^2/t	P value
Gender[n(%)]			0.073	0.787
Male	35(52.24)	29(54.72)		
Female	32(47.76)	24(45.28)		
Age(years, $\bar{x}\pm s$)	67.49±4.13	68.04±4.49	0.697	0.487
BMI(kg/m^2, $\bar{x}\pm s$)	23.15±2.03	23.09±2.14	0.167	0.876
Hypertension[n(%)]	33(49.25)	29(54.72)	0.354	0.552
T2DM[n(%)]	10(14.93)	9(16.98)	0.094	0.759
Hyperlipidemia[n(%)]	11(16.42)	8(15.09)	0.039	0.844
Atrial fibrillation[n(%)]	8(11.94)	6(11.32)	0.011	0.916
Smoking[n(%)]	30(44.78)	23(43.40)	0.023	0.880
Alcohol drinking[n(%)]	17(25.37)	13(24.53)	0.011	0.915
rt-PA intravenous thrombolysis[n(%)]	23(34.33)	20(37.74)	0.149	0.699
Time from onset to admission(h, $\bar{x}\pm s$)	3.64±0.46	3.71±0.51	0.789	0.432

BMI: body mass index; T2DM: type 2 diabetes mellitus; rt-PA: recombinant tissue-type plasminogen activator.

表2 两组患者血管再通率、治疗前后NIHSS评分及治疗安全性情况比较

Table 2 Comparison of vascular recanalization rates, NIHSS scores before and after treatment, and treatment safety between two groups

Group	n	Vascular recanalization[n(%)]	NIHSS score(points, $\bar{x}\pm s$)		Symptomatic intracranial hemorrhage[n(%)]	Re-occlusion[n(%)]	Mortality during hospitalization[n(%)]
			Before treatment	7 d after treatment			
Tirofiban	67	57(85.07)	16.15±2.73	3.78±0.84$^{\#}$	1(1.49)	0(0.00)	1(1.49)
Control	53	36(67.92)	15.94±2.49	5.11±1.03$^{\#}$	2(3.77)	1(1.89)	2(3.77)
χ^2/t		4.991	0.435	7.792	*	*	*
P value		0.025	0.665	<0.001	0.837	0.906	0.837

NIHSS: National Institutes of Health stroke scale. Compared with before treatment, $^{\#}P<0.05$. *: Fisher's exact probability test.

表 3 影响患者术后 90 d 预后的单因素分析

Table 3 Univariate analysis of factors influencing postoperative 90 d prognosis

Item	Good prognosis group(n=85)	Poor prognosis group(n=35)	χ^2/t	P value
Age[n(%)]			2.416	0.120
60-80 years	61(71.76)	20(57.14)		
≥80 years	24(28.24)	15(42.86)		
Gender[n(%)]			3.529	0.060
Male	50(58.82)	14(40.00)		
Female	35(41.18)	21(60.00)		
Hypertension[n(%)]	40(47.06)	22(62.86)	2.478	0.115
T2DM[n(%)]	8(9.41)	11(31.43)	9.108	0.003
Atrial fibrillation[n(%)]	9(10.59)	5(14.29)	0.329	0.566
Baseline ASPECT score(points, $\bar{x}\pm s$)	9.46±1.85	8.88±1.77	1.580	0.117
Baseline NIHSS score(points, $\bar{x}\pm s$)	15.25±2.16	18.03±2.43	6.176	<0.001
Time from onset to vascular recanalization(min, $\bar{x}\pm s$)	351.03±46.15	348.84±41.39	0.243	0.808
Vascular occlusion site[n(%)]			0.585	0.747
Middle cerebral artery M1 segment	60(70.59)	25(71.42)		
Middle cerebral artery M2 segment and distal end	9(10.59)	5(14.29)		
Internal carotid artery	16(18.82)	5(14.29)		
Intravenous thrombolysis[n(%)]	29(34.12)	14(40.00)	0.373	0.541
DSA-based ASITN/SIR collateral circulation grading[n(%)]			7.618	0.006
0-2	45(52.94)	28(80.00)		
3-4	40(47.06)	7(20.00)		
Combined tirofiban[n(%)]	54(63.53)	13(37.14)	7.000	0.008
Successful vascular recanalization[n(%)]	70(82.35)	23(65.71)	3.936	0.047

T2DM: type 2 diabetes mellitus; ASPECT: the Alberta Stroke Program Early CT Score; NIHSS: National Institutes of Health stroke scale; DSA: digital subtraction angiography; ASITN: American Society of Intervention and Therapeutic Neuroradiology; SIR: Society of Interventional Radiology.

表 4 影响患者预后的二元 logistic 回归分析

Table 4 Binary logistic regression analysis of factors influencing prognosis of patients

Factor	β	SE	$Wald\ \chi^2$	OR	95%CI	P value
T2DM	0.746	0.194	14.787	2.109	1.442-3.084	<0.001
Baseline NIHSS score	0.879	0.174	25.520	2.408	1.713-3.387	<0.001
Collateral circulation grading(grade 3-4 *vs* grade 0-2)	-1.024	0.415	6.088	0.359	0.159-0.810	0.014
Combined tirofiban	-0.729	0.249	8.571	0.482	0.296-0.786	0.004
Vascular recanalization	-1.411	0.349	16.346	4.100	2.069-8.126	<0.001

T2DM: type 2 diabetes mellitus; NIHSS: National Institutes of Health stroke scale.

3 讨 论

在时间窗内通过机械取栓及时开通闭塞血管，是保障急性前循环脑梗死患者预后的关键，但在实际临床中，大部分患者病情复杂，需多次取栓才能实现血管再通，加上老年人多合并各种基础性疾病，出凝血障碍风险高，机械取栓效果有限，即使术后即刻实现血管再通，术后也可能发生血管再闭塞[13]。其中颅内动脉硬化相关急性闭塞血栓中富含血小板，因此有研究指出，抗血小板聚集在预防血栓形成，保障急性前循环脑梗死患者血管再灌中具有重要意义[14]。替罗非班是一种糖蛋白 Ⅱb/Ⅲa 抑制剂，其可通过占据血小板糖蛋白 Ⅱb/Ⅲa 受体交联位点阻断血小板聚集，抑制血栓形成。目前替罗非班已广泛应用于急性冠脉综合征等心血管疾病的治疗，但其在辅助血管内机械取栓中价值尚存在争议。Wu 等[15]研究发现，加用替罗非班将增加患者脑出血风险（OR = 2.9，95%CI 1.1～7.5）。但 Zhang 等[16]研究表示，替罗非班可改善脑卒中患者神经功能，抑制卒中后血小板聚集及纤维蛋白原形成，且并不增加出血风险。Li 等[17]通过荟萃分析发现，在脑卒中静脉溶栓及机械取栓术中应用替罗非班并不会增加患者症状性脑卒中及颅内出血风险，且可降低术后血管再闭塞及患者病死率。

本研究结果显示，联合替罗非班可增加急性前循环脑梗死患者机械取栓血管再通率，且不增加患者颅内症状性出血及死亡风险，与 Zhang[16] 和 Li 等[17]研究结论一致，这可能与替罗非班的性质相关。替罗非班是一种高特异性的抗血小板聚集药物，能有效抑制血小板聚集，防止血栓形成，因此机

械取栓联合替罗非班能有效提高血管再通率。此外,还有研究表示,替罗非班可刺激内皮细胞迁移与增殖,而在机械取栓过程中会导致血管内皮受损,因此推测替罗非班还可通过促进患者血管内皮修复增加血管再通率[18]。此外,替罗非班不增加患者出血风险的原因可能与替罗非班失活快速、诱发出血的风险较小有关[19]。

为进一步探讨联合替罗非班在老年急性前循环脑梗死患者中的应用价值,本研究对患者进行90 d随访,统计其短期预后,结果显示联合替罗非班能有效改善老年急性前循环脑梗死患者术后90 d预后状况,且二元logistic回归分析提示,联合替罗非班是老年急性前循环大动脉闭塞性脑梗死患者机械取栓术后预后不良的保护因素,提示替罗非班在急性前循环脑梗死中具有良好的应用价值。这可能与替罗非班能有效提高患者血管再通率,减少患者神经功能受损程度,改善患者预后有关。

综上所述,联合替罗非班能有效提高老年急性前循环脑梗死患者机械取栓效果,且不增加症状性颅内出血风险,还是患者预后不良的保护因素。但本研究也存在一些不足,如病例样本量不高,所得结论可能存在偏倚,后续可针对以上不足调整实验方案,开展更为完善的研究,以验证替罗非班在急性前循环脑梗死机械取栓中的应用价值。

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