

论著·临床研究

急性大血管闭塞性轻型卒中血管内治疗的早期有效性和安全性分析

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[摘要] 目的·探讨急性大血管闭塞性轻型卒中 (acute mild ischemic stroke with large vessel occlusion, LVO-MIS) 血管内治疗 (endovascular therapy, EVT) 的早期有效性和安全性。方法·回顾性连续纳入2016年6月—2022年10月在上海交通大学医学院附属第六人民医院脑卒中绿色通道收治的急诊EVT辅助标准内科治疗的31例LVO-MIS患者 (EVT组), 以及同期仅采用标准内科治疗的32例LVO-MIS患者 (对照组)。收集2组患者的一般临床资料和血管内治疗相关资料。其中, 主要结局为早期有效, 即治疗后第7日美国国立卫生研究院卒中量表 (National Institute of Health Stroke Scale, NIHSS) 评分 (NIHSS at seventh day after treatment, d7NIHSS) 较基线NIHSS评分下降≥3分或直接下降到0分; 次要结局包括血管成功再通、早期神经功能恶化; 安全性评价包括症状性颅内出血、死亡。对2组患者的主要结局、次要结局进行分析, 以评估EVT早期有效性。对2组患者的安全性评价指标进行分析, 以评估EVT的安全性。采用Kruskal-Wallis H检验对EVT组中24例实际行EVT的患者治疗前后的NIHSS评分进行分析。结果·2组患者的一般临床资料以及闭塞部位、发病至入院时间等血管内治疗相关资料间差异均无统计学意义。EVT组患者的基线NIHSS评分 [5.0 (3.0, 5.0) 分] 高于对照组 [3.5 (2.0, 5.0) 分] ($P=0.001$), 其d7NIHSS评分 [1.0 (0, 3.0) 分] 低于对照组 [2.0 (1.0, 5.8) 分] ($P=0.040$)。2组患者中共有24例 (38.1%) 患者达早期有效, 其中EVT组16例、对照组8例; 且EVT组的有效率较对照组更高 ($\chi^2=4.729$, $P=0.030$)。EVT组患者的早期神经功能恶化率较对照组更低 ($\chi^2=6.097$, $P=0.014$), 且EVT组中血管成功再通为29例 (93.5%)。2组患者在症状性颅内出血率、死亡率间差异无统计学意义。EVT组中, 24例患者基线NIHSS评分 [5.0 (3.0, 5.0) 分]、术后24 h的NIHSS评分 [2.0 (0.3, 3.8) 分]、d7NIHSS评分 [1.0 (0, 2.8) 分] 间差异具有统计学意义 ($H=16.997$, $P=0.000$)。结论·血管内治疗LVO-MIS是安全有效的; 该疗法的早期效果优于标准内科治疗, 早期神经功能恶化率更低且不增加症状性颅内出血的风险。

[关键词] 轻型卒中; 大血管闭塞; 血管内治疗; 早期神经功能恶化

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Analysis of early efficacy and safety of endovascular therapy for acute mild ischemic stroke with large vessel occlusion

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[Abstract] Objective·To investigate the early efficiency and safety of endovascular therapy (EVT) for patients with acute mild ischemic stroke with large vessel occlusion (LVO-MIS). Methods·A total of 31 patients with LVO-MIS who received emergency EVT-assisted standard medical treatment at the Green Channel of Stroke in Shanghai Sixth People's Hospital, Shanghai Jiao Tong University School of Medicine from June 2016 to October 2022 were retrospectively included as endovascular therapy group (EVT group), and 32 LVO-MIS patients who only received standard medical treatment in the same period were selected as the control group. General clinical data and parameters related to EVT of the two groups were collected. The primary outcome was early efficacy, that is, the NIHSS at seventh day after treatment (d7NIHSS) score decreased by ≥3 points or directly to 0 points from baseline NIHSS score. Secondary outcomes included successful revascularization of blood vessels and early neurological deterioration (END), and safety outcomes included symptomatic intracranial hemorrhage (sICH) and mortality. The primary and

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secondary outcomes of the two groups of patients were analyzed to evaluate the early efficiency of EVT, and the safety evaluation indicators of the two groups of patients were analyzed to evaluate the safety of EVT. Kruskal-Wallis H test was used to analyze the NIHSS scores of 24 patients in the EVT group who underwent EVT before and after treatment. **Results**· There was no statistically significant difference in the general clinical data between the two groups, as well as parameters related to EVT such as occlusion site, and onset-to-admission time. The baseline NIHSS score of the EVT group [5.0 (3.0, 5.0) points] was higher than that of the control group [3.5 (2.0, 5.0) points] ($P=0.001$), and their d7NIHSS score [1.0 (0, 3.0) points] was lower than that of the control group [2.0 (1.0, 5.8) points] ($P=0.040$). A total of 24 patients (38.1%) in the two groups achieved early efficacy, including 16 cases in the EVT group and 8 cases in the control group; and the early efficacy rate of the EVT group was higher than that of the control group ($\chi^2=4.729$, $P=0.030$). The END rate in the EVT group was lower than that in the control group ($\chi^2=6.097$, $P=0.014$), and there were 29 cases (93.5%) in the EVT group of patients whose blood vessels were successfully reopened. There was no statistically significant difference in sICH rate and mortality rate between the two groups. In the EVT group, there was a statistically significant difference ($H=16.997$, $P=0.000$) among the baseline NIHSS scores [5.0 (3.0, 5.0) points] of 24 patients, postoperative 24hNIHSS score [2.0 (0.3, 3.8) points] and d7NIHSS scores [1.0 (0, 2.8) points]. **Conclusion**· EVT is safe and effective in treating LVO-MIS, and the early efficacy rate of EVT is superior to standard medicine treatment, with a lower rate of END and no increased risk of sICH.

[Key words] mild ischemic stroke; large vessel occlusion (LVO); endovascular therapy (EVT); early neurological deterioration (END)

据报道,急性大血管闭塞性轻型卒中(acute mild ischemic stroke with large vessel occlusion, LVO-MIS)的神经功能缺损症状表现较轻,但神经功能恶化风险较高^[1-2]。目前,国内外相关指南^[3-4]均推荐对于美国国立卫生研究院卒中量表(National Institute of Health Stroke Scale, NIHSS)评分≥6分的急性大血管闭塞性卒中(acute ischemic stroke with large vessel occlusion, LVO-AIS)行血管内治疗(endovascular therapy, EVT),而对NIHSS<6分(即LVO-MIS)没有明确的指导建议。国外一项多中心回顾性研究^[5]显示,对LVO-MIS患者行EVT的良好预后并不优于标准内科治疗,且出血风险更高。个别研究^[6-7]报道,对行EVT的LVO-MIS患者进行随访观察后发现,其3个月时的独立生活能力与行标准内科治疗的该类患者的结果相似。也有研究^[2,8]显示,行EVT的LVO-MIS患者在出院时、长期随访中均具有较强的独立生活能力。且国内有少量病例报道显示,对LVO-MIS行EVT是安全有效的^[9]。由于国内关于EVT与标准内科治疗在LVO-MIS早期有效性和安全性方面的研究较少,本研究以LVO-MIS患者为研究对象,针对NIHSS评分变化、早期神经功能恶化(early neurological deterioration, END)、症状性颅内出血(symptomatic intracerebral hemorrhage, sICH)等指标进行回顾性分析,以期为LVO-MIS治疗提供参考。

1 对象与方法

1.1 研究对象

连续纳入2016年6月—2022年10月于上海交通

大学医学院附属第六人民医院脑卒中绿色通道收治的LVO-MIS患者72例。纳入标准:①年龄≥18岁。②影像学检查证实为大血管闭塞,即颈内动脉、大脑中动脉M₁~M₂段、椎/基底动脉。③基线NIHSS评分<6分。④基线改良Rankin量表(modified Rankin Scale, mRS)评分≤2分。⑤参考DEFUSE3研究^[10],发病时间>6 h,同时影像学检查为低灌注体积/核心梗死体积>1.8且核心梗死体积≤70 mL。排除标准:①既往有活动性出血、出血性脑血管病史,或存在凝血功能异常。②合并严重心、肝、肾等脏器功能不全。③影像学提示,存在颅内出血、颅脑创伤或其他颅内疾病。④有昏迷、癫痫、中枢神经损伤等病史。⑤入院前1个月内有重大手术或外伤病史。⑥数据资料不全。⑦拒绝住院治疗。

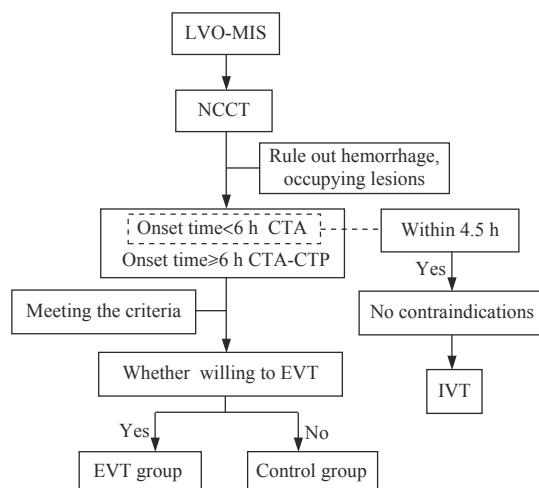
1.2 研究方法

1.2.1 入院评估、患者分组及其资料收集 所有患者均经卒中绿色通道完成头颅CT平扫,实验室检查及心电图等常规检查。根据患者的发病至入院时间,采用计算机体层血管成像(computed tomography angiography, CTA)-计算机体层灌注(computed tomography perfusion, CTP)对LVO-MIS患者开展影像学评估:①发病时长<6 h者,需行头颈CTA检查,明确责任血管并评估侧支代偿情况;如在溶栓时间窗内,需排除静脉溶栓禁忌,在患方知情同意后立即行静脉溶栓治疗。②发病时长≥6 h者,需行CTA、CTP检查。

在初步影像学评估后,需向患者及家属详细解释



患者病情、EVT 及标准内科治疗可能的获益和风险，而后根据患者及家属是否愿意进一步行血管内治疗，将其分为 EVT 组和对照组；前者采用 EVT 辅助标准内科治疗，后者仅采用标准内科治疗。入院评估及分组的流程见图 1。



Note: NCCT—non-contrast computed tomography; IVT—intravenous thrombolysis.

图 1 患者入院评估及分组的流程图

Fig 1 Flow chart for patient admission assessment and grouping

最终，本研究共计纳入 LVO-MIS 患者 63 例（超溶栓时间窗患者 21 例），其中 EVT 组 31 例（造影显示血管成功再通者 7 例）、对照组 32 例。收集 2 组患者的一般临床资料，包括年龄、性别、吸烟史、饮酒史、既往史 [高血压、糖尿病、房颤、卒中或短暂性脑缺血发作 (transient ischemic attack, TIA)、冠心病]，以及血管内治疗相关资料，包括发病至入院时间、NIHSS 评分（基线、治疗后 24 h、治疗后第 7 日）、闭塞部位，以及早期有效、血管成功再通、END、sICH 和死亡等情况。

1.2.2 治疗方案

(1) 标准内科治疗。根据《中国急性缺血性脑卒中诊治指南 2018》^[11] 中推荐的标准内科治疗方案对 2 组 LVO-MIS 患者开展相关治疗：①未接受静脉溶栓治疗的患者，需立即启动阿司匹林和氯吡格雷的双重抗血小板聚集治疗。②接受静脉溶栓治疗的患者，在静脉溶栓后 24 h 复查头颅 CT，根据 CT 结果启动抗血小板聚集治疗。

(2) 血管内治疗。EVT 组患者需先行脑血管造影检查，根据其造影情况再决定进一步的治疗方案，包括支架取栓、负压抽吸、球囊扩张、支架置入等。术后 24 h 后复查头颅 CT，根据 CT 结果决定是否启

动抗血小板聚集治疗。

1.3 早期有效性和安全性评价

早期有效性评价需通过对 2 组患者的主要结局和次要结局指标进行分析，安全性评价需通过 sICH、死亡等指标进行分析。

1.3.1 主要结局指标 本研究的主要结局指标为早期有效，即患者治疗后第 7 日 NIHSS 评分 (NIHSS at seventh day after treatment, d7NIHSS) 较基线 NIHSS 评分下降≥3 分或直接下降到 0 分。

1.3.2 次要结局指标 本研究的次要结局指标为血管成功再通、END。采用改良脑梗死溶栓分级 (modified Thrombolysis in Cerebral Infarction Score, mTICI) 评估责任血管的再通情况，其中 mTICI 2b~3 级定义为血管成功再通^[12]。将患者入院 72 h 内 NIHSS 评分比基线评分增加≥4 分^[13-14] 定义为 END。

1.3.3 安全性评价 安全性评价指标为 sICH、死亡。参照欧洲协作组急性卒中研究Ⅲ (European Cooperative Acute Stroke Study Ⅲ, ECASS Ⅲ)^[15] 的试验标准，将术后 24 h 复查影像存在颅内出血的证据，且颅内出血导致 NIHSS 评分增加≥4 分或导致死亡定义为 sICH。

1.4 统计学方法

采用 SPSS 22.0 对数据进行处理。符合正态分布的定量资料以 $\bar{x} \pm s$ 表示，采用独立样本 *t* 检验进行比较；不符合正态分布的定量资料以 $M(Q_1, Q_3)$ 表示，采用 Mann-Whitney *U* 检验进行比较。定性资料以频数（百分率）表示，采用 χ^2 检验进行比较。采用 Kruskal-Wallis *H* 检验比较 EVT 组患者血管内治疗前、后的 NIHSS 评分。 $P<0.05$ 表示差异具有统计学意义。

2 结果

2.1 患者一般临床资料及血管内治疗相关资料的基线数据比较

对 2 组患者的一般临床资料和血管内治疗相关资料的基线数据（闭塞部位、基线 NIHSS 评分、发病至入院时间）进行比较，结果（表 1）显示，EVT 组患者的基线 NIHSS 评分高于对照组 ($P=0.001$)，其余指标间差异均无统计学意义。

表 1 2组患者的一般临床资料及血管内治疗相关资料的基线数据比较

Tab 1 Comparison of general clinical data and baseline characteristics related to EVT between the two groups of patients

Item	EVT group (n=31)	Control group (n=32)	P value
Age/year	67.8±14.3	66.6±14.7	0.483
Male/n(%)	24 (77.4)	28 (87.5)	0.292
Smoking ^a /n(%)	10 (32.3)	10 (31.3)	0.932
Drinking ^a /n(%)	8 (25.8)	8 (25.0)	0.941
Medical history ^b /n(%)			
Hypertension	19 (61.3)	25 (78.1)	0.146
Diabetes	8 (25.8)	8 (25.0)	0.941
Atrial fibrillation	12 (38.7)	7 (21.9)	0.146
Ischemic stroke or TIA	5 (16.1)	10 (31.3)	0.159
Coronary heart disease	1 (3.2)	4 (12.5)	0.173
Occlusion site/n(%)			
ICA	5 (16.1)	7 (21.9)	0.561
MCA (M1)	21 (67.7)	16 (50.0)	0.153
MCA (M2)	2 (6.5)	2 (6.3)	0.974
VB/BA	3 (9.7)	7 (21.9)	0.185
Baseline NIHSS score/score	5.0 (3.0, 5.0)	3.5 (2.0, 5.0)	0.001
Onset-to-admission time/min	230 (70, 222)	270 (86, 436)	0.209

Note: ^aCurrent or within the prior 5 years. ^bPatient self-report or family report. ICA—internal carotid artery; MCA—middle cerebral artery; VB—vertebral artery; BA—basilar artery.

2.2 早期有效性及安全性指标分析

对2组患者的早期有效性和安全性进行分析,结果(表2)显示早期有效率及END率的组间差异具有统计学意义(均P<0.05)。

表 2 2组患者的早期有效性和安全性的比较

Tab 2 Comparison of early efficacy and safety between the two groups of patients

Outcome	EVT group (n=31)	Control group (n=32)	χ^2	P value
Primary outcome/n(%)				
Early efficiency	16 (51.6)	8 (25.0)	4.729	0.030
Secondary outcome/n(%)				
mTICI 2b-3	29 (93.5)	6 ^① (46.2) ^②	13.089	0.000
END	1 (3.2)	8 (25.0)	6.097	0.014
Safety outcome				
sICH	1 (3.2)	1 (3.1)	0.001	0.982
Death in hospital	0	0	—	—

Note: ^①The n=6 was referred to the number of IVT patients' angiography showing revascularization in the EVT group; ^②The rate of mTICI 2b-3 in the control group was referred to the IVT data of EVT group (6/13)。

本研究中, EVT组患者的d7NIHSS评分为[1.0 (0, 3.0)分],低于对照组患者评分[2.0 (1.0, 5.8)分],且差异具有统计学意义($P=0.040$)。在EVT组中造影显示血管成功再通的患者为7例,其中6例为静脉溶栓后血管成功再通,1例造影显示为前交通微动脉瘤破裂出血,系静脉溶栓导致的微小动脉瘤破裂出血。该组中其余24例患者均实际进行了EVT,其基线NIHSS评分为5.0 (3.0, 5.0)分、治疗后24hNIHSS评分为2.0 (0.3, 3.8)分、d7NIHSS评分为1.0 (0, 2.8)分,且该3个NIHSS评分间差异具有统计学意义($H=16.997$, $P=0.000$),继而提示EVT治疗LVO-MIS是有效的。在上述24例患者中有2例未达血管成功再通,病因均为大动脉粥样硬化性狭窄。其中,1例为行单纯球囊扩张治疗,扩张后血流恢复不满意,遂使用血小板糖蛋白Ⅱb/Ⅲa受体抑制剂(platelet glycoprotein Ⅱb/Ⅲa inhibitor, GPI),最终血流仅恢复到mTICI 2a级;另1例为桥接治疗患者,行球囊扩张、支架置入治疗后血流恢复不满意,遂经GPI等治疗,最终血流仅恢复到mTICI 1级。

对未达早期有效和超溶栓时间窗的患者行进一步分析,结果发现:①在EVT组15例未达早期有效的患者中,4例患者的d7NIHSS较基线增加(1例发生END);在对照组的24例未达早期有效的患者中,9例患者的d7NIHSS较基线增加(8例发生END)。②在超溶栓时间窗的患者中,有5例发生END且均为对照组患者(占对照组END总人数的62.5%),提示行EVT治疗可降低LVO-MIS患者的END发生率。

3 讨论

临幊上, LVO-MIS患者病情不稳定^[16],再灌注治疗可显著改善其预后。针对静脉溶栓时间窗内的患者进行研究后发现,经EVT的LVO-MIS患者的预后不劣于静脉溶栓治疗^[1,6,8,17];且欧洲卒中组织推荐致残性神经功能缺损症状、静脉溶栓后临床恶化或存在静脉溶栓禁忌的LVO-MIS患者需行EVT^[18]。

本研究发现,与对照组相比,EVT组患者的早期有效率较高、END发生率较低;EVT组患者的血管成功再通率为93.5%,与静脉溶栓相比,EVT成功再通率更高。DA ROS等研究^[19]显示,采用EVT治疗LVO-MIS的再通率高于静脉溶栓治疗。在针对LVO-AIS的中国急性大血管闭塞性缺血性卒中直接动



脉治疗的疗效评估(Direct Intraarterial Thrombectomy to Revascularize Acute Ischemic Stroke Patients with Large Vessel Occlusion Efficiently in Chinese Tertiary Hospitals: a Multicenter Randomized Clinical Trial, DIRECT-MT)、急性缺血性卒中血管内治疗关键技术及急救流程改进研究(Endovascular Treatment Key Technique and Emergency Work Flow Improvement of Acute Ischemic Stroke, ANGEL-ACT)等研究^[20-22]的结果显示,直接行EVT不劣于桥接治疗。BHATIA等^[23]研究显示阿替普酶静脉溶栓在大脑中动脉M1段的再通率为32.3%,在颈内动脉的再通率仅为4.4%;这与本研究结果(46.2%)相比,LVO-MIS静脉溶栓治疗显然是获益的^[24-25]。本研究中静脉溶栓再通率(46.2%)相对较高,可能与LVO-MIS患者的早期血栓负荷小、血栓通透性高有关^[26]。静脉溶栓后观察和等待溶栓效果会延长入院到完成穿刺时间、增加sICH和栓子破碎导致的栓塞风险^[27]。在安全性方面,本研究的2组中各有1例患者发生sICH,且相关研究^[11]显示静脉溶栓出血风险低,微小动脉瘤(<10 mm)是溶栓的相对禁忌。在这2例sICH中,1例为合并颅内微小动脉瘤患者(EVT组)静脉溶栓后出血,直接行EVT或可避免静脉溶栓导致动脉瘤破裂出血的风险;另1例为脑梗死出血转化(对照组),且住院期间2组患者均未发生死亡。继而提示,患者在安全性方面的组间无差异。

本研究的EVT组中有2例LVO-MIS患者未成功再通,其病因均为大动脉粥样硬化性狭窄;针对该种情况,传统的支架取栓联合负压抽吸难以去除狭窄远端血栓,而采用远端取栓支架保护下的球囊血管成形术(balloon angioplasty with the distal protection of stent retriever, BASIS)同时应用GPI则可显著降低传统支架取栓后再闭塞的风险,从而可改善患者的预后^[28-30]。在本研究超溶栓时间窗的分析中发现EVT可显著降低患者的END,继而提示针对超溶栓时间

窗的LVO-MIS患者开展EVT或更有意义^[31]。既往研究发现,LVO-MIS患者的END与侧支循环衰竭、近端闭塞及血栓长度等高度相关^[14,32]。因此,结合影像学检查行综合评估以筛选END高危患者进而开展EVT干预可能更有意义。

本研究尚存在一定的局限性,比如仅为单中心回顾性研究、纳入的病例数偏少等,未来我们将开展多中心的随机对照研究,继续对LVO-MIS的治疗进行探索。综上所述,针对LVO-MIS患者行EVT是安全、有效的;与标准内科治疗相比,行EVT的LVO-MIS患者的END风险更低且不增加sICH风险。我们期待或将开展高级别的多中心、前瞻性、随机对照临床研究,为LVO-MIS的治疗提供相关循证学证据支持。

利益冲突声明/Conflict of Interests

所有作者声明不存在利益冲突。

All authors disclose no relevant conflict of interests.

伦理批准和知情同意/Ethics Approval and Patient Consent

本研究经上海交通大学医学院附属第六人民医院科学伦理委员会审核批准(文件号KY2017-048-01)。受试对象或其亲属已经签署知情同意书。

All experimental protocols in this study were reviewed and approved by Ethics Committee of Shanghai Sixth People's Hospital, Shanghai Jiao Tong University School of Medicine (No. KY2017-048-01). Consent letters have been signed by the research participants or their relatives.

作者贡献/Authors' Contributions

倪瑞隆负责数据分析和论文撰写,邓江山、曹立、赵飞负责研究设计和论文修改。所有作者均阅读并同意了最终稿件的提交。

NI Ruilong performed the statistical analysis and drafted the manuscript. DENG Jiangshan, CAO Li and ZHAO Fei were responsible for the research design and paper revision. All the authors have read the last version of paper and consented for submission.

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