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半量瑞替普酶溶栓后行转运 PCI 与直接转运 PCI 对急性 ST 段抬高型心肌梗死临床疗效的对比研究 *

孙丽红¹ 方喜波¹ 李 莉¹ 张英杰² 王 玲²

(1 辽宁省朝阳市第二医院心电图室 辽宁 朝阳 122000; 2 锦州医科大学第一附属医院循环内科 辽宁 锦州 121004)

摘要 目的:比较急性 ST 段抬高型心肌梗死(STEMI)使用半量瑞替普酶溶栓后行转运经皮冠状动脉介入治疗(PCI)与直接转运两种救治策略的临床效果。**方法:**回顾性分析 2015 年 6 月~2018 年 2 月我院收治的 100 例 STEMI 患者的病历资料,根据救治方案不同分为易化 PCI 组(先在基层医院经半量瑞替普酶溶栓后再转运至我院行 PCI,58 例)、直接转运 PCI 组(拒绝在基层医院接受溶栓治疗而要求直接转运 PCI,42 例)。比较两组 PCI 前后血管再通率、PCI 后无复流发生率和 ST 段回落率(STR)、住院期间主要不良心脏事件(MACE)及治疗期间出血并发症的发生情况及随访 1 年主要终点事件的发生情况。**结果:**入院后首次冠脉造影显示易化 PCI 组 PCI 前 TIMI 3 级血流者占 32.7%(19/59),显著高于直接转运 PCI 组[14.3%(6/42), $P<0.05$]。PCI 后 14 d 时,易化 PCI 组 TIMI 3 级血流者占 93.1%(54/58),较直接转运 PCI 组[90.5%(38/42)]差异无统计学意义($P>0.05$)。PCI 后即刻冠脉造影显示易化 PCI 组无复流发生率为 6.9%(4/58),较直接转运 PCI 组[21.4%(9/42)]显著降低($P<0.05$)。PCI 后 24 h 时,易化 PCI 组 STR 值为(61.53±11.27)%,显著高于直接转运 PCI 组[(52.40±12.63)%, $P<0.05$]。住院期间,易化 PCI 组 MACE 发生率为 10.3%(6/58),较直接转运 PCI 组[14.3%(6/42)]差异无统计意义($P>0.05$)。治疗期间,易化 PCI 组出血并发症总发生率为 19.0%(11/58),与直接转运 PCI 组的 14.3%(6/42)相比差异亦无统计学意义($P>0.05$)。随访 1 年,易化 PCI 组主要终点事件发生率为 19.0%(11/58),显著低于直接转运 PCI 组[40.5%(17/42), $P<0.05$]。**结论:**与直接转运 PCI 相比,STEMI 患者应用半量瑞替普酶溶栓后行转运 PCI 有利于早期开通梗死血管,提高介入干预效果,PCI 后获得优异的心肌灌注水平,从而改善远期预后,且安全性相当。

关键词:急性 ST 段抬高型心肌梗死;半量瑞替普酶溶栓;溶栓后转运 PCI;直接转运 PCI;心肌灌注水平;远期预后

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A Comparative Study of Clinical Efficacy of Half-dose Reteplase Thrombolytic Transporting PCI and Direct Transporting PCI in the Treatment of Patients with Acute ST-segment Elevation Myocardial Infarction*

SUN Li-hong¹, FANG Xi-bo¹, LI Li¹, ZHANG Ying-jie², WANG Ling²

(1 Department of Electrocardiography, Chaoyang Second Hospital, Liaoning Province, Chaoyang, Liaoning, 122000, China;

2 Three Departments of Circulation, the First Affiliated Hospital of Jinzhou Medical University, Jinzhou, Liaoning, 121004, China)

ABSTRACT Objective: To compare the clinical efficacy of transporting percutaneous coronary intervention (PCI) and direct transporting PCI after thrombolysis with half-dose reteplase in the treatment of patients with acute ST-segment elevation myocardial infarction (STEMI). **Methods:** The medical records of 100 cases of STEMI patients admitted to our hospital from June 2015 to February 2018 were retrospectively analyzed. According to the different treatment schemes, they were divided into facilitated PCI group (58 cases were transported to our hospital after half-dose reteplase thrombolysis) and direct transported PCI group (42 cases refused to receive thrombolysis treatment in primary hospital and required direct transported PCI). The vascular recanalization rate before and after PCI, the rate of no-reflow after PCI, the rate of ST segment fall-back (STR), major adverse cardiac events (MACE) during hospitalization and bleeding complications during treatment were compared between the two groups, and the occurrence of major end-point events during 1 year follow-up were compared. **Results:** The first coronary angiography after admission showed that 32.7%(19/59) of the patients in facilitated PCI group had TIMI grade 3 blood flow before PCI, which was significantly higher than that in direct PCI group [14.3% (6/42), $P<0.05$]. At 14 days after PCI, 93.1% (54/58) of TIMI grade 3 blood flow in facilitated PCI group had no significant difference compared with that in direct PCI group [90.5% (38/42)]($P>0.05$). Immediate coronary angiography after PCI showed that the incidence of no-reflow was 6.9% (4/58) in facilitated PCI group, which was significantly lower than that in direct PCI group [21.4% (9/42)]($P<0.05$). At 24 hours after PCI, the STR value of facilitated PCI group was (61.53 ± 11.27)%, which was significantly higher than that of direct transported PCI group [(52.40 ± 12.63)%, $P<0.05$]. During hospitalization, the incidence of MACE in facilitated PCI group was 10.3% (6/58). There was

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作者简介:孙丽红(1980-),女,硕士研究生,副主任医师,主要研究方向:心内科,电话:18004219198,E-mail: ggaa0166@sina.com

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no statistical difference between facilitated PCI group and direct PCI group (14.3% (6/42) ($P>0.05$)). During the treatment period, the total incidence of bleeding complications in facilitated PCI group was 19.0% (11/58), and there was no significant difference between facilitated PCI group and direct PCI group (14.3% (6/42) ($P>0.05$)). After 1 year follow-up, the incidence of major endpoint events in facilitated PCI group was 19.0% (11/58), significantly lower than that in direct transshipment PCI group [40.5% (17/42), $P<0.05$]. **Conclusion:** Compared with direct transporting PCI, transporting PCI after half-dose reteplase thrombolysis in STEMI patients is beneficial to early opening of infarcted vessels, improving the effect of interventional intervention, obtaining excellent myocardial perfusion level after PCI, thus improving the long-term prognosis of patients, and the safety is comparable.

Key words: Acute ST-segment elevation myocardial infarction; Half-dose reteplase thrombolysis; Transporting PCI after thrombolysis; Direct transporting PCI; Myocardial perfusion level; Long-term prognosis

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前言

急性 ST 段抬高型心肌梗死(STEMI)是急性心肌梗死(A-MI)的一种常见类型,极易导致恶性心律失常、心源性休克、猝死等严重并发症^[1,2]。通常认为 STEMI 意味着冠脉完全闭塞,早期开通患者梗死相关动脉(IRA)最有效的手段有溶栓和直接经皮冠脉介入治疗(PCI)两种。随着 PCI 技术的推广,我国 2001~2011 年 STEMI 患者中接受直接 PCI 的占比由 10.2%增至 27.6%,而接受溶栓治疗的占比却由 45%减至 27.4%,可见对溶栓的重视程度有所降低^[3]。与溶栓相比,尽管 PCI 具有出现并发症少、血管开通率高等优势,但受患者就诊医院的地理位置、技术能力及医疗条件的限制,在我国众多基层医院仍难以推广^[4,5]。溶栓治疗具有简便、易操作和快速的优点,仍是再灌注治疗不可或缺的方法^[6,7]。早期溶栓结合转运 PCI 是我国多数基层医院救治 STEMI 的首选策略,这符合我国现阶段的基本国情^[8]。

瑞替普酶属第三代特异性纤溶酶,有出血风险低、溶栓效果佳、可通过静脉推注直接给药(临床应用方便)等优点,已成为 STEMI 静脉溶栓治疗的常用药^[9,10]。为进一步降低溶栓治疗的出血风险,将溶栓治疗与 PCI 有机结合,在溶栓治疗时考虑采用半量瑞替普酶。因此本研究以 2015 年 6 月~2018 年 2 月我院收治的 STEMI 患者为研究对象,通过回顾性对比分析 STEMI 使用半量瑞替普酶溶栓后行转运 PCI 与直接转运 PCI 两种救治策略的治疗效果,来评价两者的临床应用价值,以期指导 STEMI 的临床救治。现报道如下。

1 资料与方法

1.1 一般资料

回顾性分析 2015 年 6 月~2018 年 2 月我院收治的 100 例 STEMI 患者的病历资料,本研究经我院医学伦理委员会同意。根据救治方案不同分为易化 PCI 组(在基层医院经半量瑞替普酶溶栓后转运至我院行 PCI,58 例)、直接转运 PCI 组(拒绝在基层医院接受溶栓治疗而要求直接转运 PCI,42 例)。

纳入标准:(1)符合 STEMI 诊断标准^[11];(2)由基层医院转运至我院行 PCI;(3)年龄<75 岁,性别不限;(4)符合 PCI 适应证^[12];(5)发病时间≤12 h;(6)溶栓治疗者满足溶栓适应证;(7)既往无心肌梗死史及 PCI 史。排除标准:(1)有心脏外科手术史者;(2)入院时合并严重 AMI 并发症者;(3)依从性较差者;(4)心功能 Killip 分级为Ⅳ级者;(5)患有恶性肿瘤、脑血管疾病者。

1.2 治疗方法

两组均采取相同的心电监护、必要时吸氧、合适体位、除颤准备等非药物治疗及一旦确诊后的抗凝、抗栓、抗交感、扩张血管等药物综合治疗。易化 PCI 组:在上述基础上,于首次医疗接触(FMC)后 30 min 内使用注射用瑞替普酶[北京爱德药业,规格 5.0 MU (9 mg)/支,产品批号 20150312、20160504、20170810]静脉溶栓治疗,18 mg 溶于 10 mL 无菌注射用水,缓慢静推 2 min 以上;溶栓后则继续给予抗凝、抗栓等常规治疗,并于 2~24 h 内转运行急诊 PCI。直接转运 PCI 组:经桡动脉入径,并运用 Seldinger 动脉插管技术行急诊 PCI,全部介入手术过程参照文献^[13]。两组急诊 PCI 后则继续予以相同的整体规范化救治,包括抗交感、抗凝、抗血小板及并发症防治等。

1.3 观察指标

(1)入院后收集病人基本信息资料,包括年龄、性别、吸烟史、入院时左室射血分数(LVEF)、发病时间、合并基础疾病等。(2)由两组入院后首次冠脉造影和 PCI 后 14 d 时冠脉造影的结果,统计两组心肌梗死溶栓(TIMI)Ⅲ级血流者的比例。(3)冠脉造影结果分析(TIMI 分级)^[14] 0 级:无灌注;Ⅰ级:渗透而无灌注;Ⅱ级:部分灌注;Ⅲ级:完全灌注。其中 TIMI 0~Ⅰ级表明冠脉未再通(即无复流),TIMI Ⅱ~Ⅲ级说明冠脉再通。(4)两组 PCI 后即刻冠脉造影,记录两组无复流发生情况。(5)病人于入院 10 min 内和 PCI 术后 24 h 时各常规描记 1 次 18 导联心电图,并由检查结果计算 ST 段抬高幅度之和($\sum ST$),运用公式“ST 段回落率(STR)=[($\sum ST_{入院}$ - $\sum ST_{术后}$)/ $\sum ST_{入院}$] $\times 100\%$ ”计算 STR;当 STR $\geq 50\%$ 时,判断为 ST 段回落良好;ST 段抬高幅度测量时以 J 点后 40 ms 处为测量点,以 TP 段为等电位线。(6)统计两组住院期间主要不良心脏事件(MACE)的发生情况,包括心源性休克、心律失常、心力衰竭等。(7)详细记录两组开始用药至出院期间(即治疗期间)可能出现的颅内出血、(肉眼)血尿、黑便、牙龈出血等出血并发症。(8)对两组患者至少进行为期 1 年(随访至 2019 年 3 月)的追踪随访,记录两组心力衰竭、复发心绞痛、休克等主要终点事件的发生情况。

1.4 统计学分析

采取统计软件 SPSS20.0 处理数据,计数资料以(%)表示,组间比较运用 χ^2 检验,计量资料以($\bar{x} \pm s$)表示,组间比较使用 t 检验,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组基线资料的比较

病等)对比差异均无统计学意义($P>0.05$),见表1。

两组临床基本特征(包括年龄、性别、吸烟史、合并基础疾

表1 两组基线资料的比较

Table 1 Comparison of the baseline data between the two groups

Items	Facilitation PCI group (n=58)	Cross-docking PCI group (n=42)	t/χ^2	P
Age (year, $\bar{x} \pm s$)	59.4 $\pm$ 8.2	60.6 $\pm$ 8.9	0.697	0.488
Male [n (%)]	36 (62.1)	29 (69.0)	0.521	0.470
Smoking history [n (%)]	23 (39.7)	19 (45.2)	0.312	0.577
Diabetes mellitus [n (%)]	13 (22.4)	12 (28.6)	0.493	0.483
Hyperlipidemia [n (%)]	30 (51.7)	19 (45.2)	0.410	0.522
Hypertension [n (%)]	39 (67.2)	25 (59.5)	0.630	0.427
On admission LVEF<40% [n (%)]	9 (15.5)	9 (21.4)	0.577	0.448
Disease time (h,)	6.2 $\pm$ 2.0	5.9 $\pm$ 1.9	0.756	0.451
Infarction area [n (%)]	24 (41.4)	20 (47.6)	0.510	0.972
Extensive anterior wall				
Inferior wall	21 (36.2)	13 (31.0)		
Inferior wall with right ventricle	3 (5.2)	2 (4.8)		
High sidewall	5 (8.6)	3 (7.1)		
Anteroseptal	5 (8.6)	4 (9.5)		
Killip classification of cardiac function [n (%)]				
Grade II	37 (63.8)	26 (61.9)	0.192	0.848
Grade III	21 (36.2)	16 (38.1)		

2.2 两组 PCI 前后血管再通率的比较

入院后首次冠脉造影显示易化 PCI 组 PCI 前 TIMI 3 级血流者占 32.7% (19/59), 显著高于直接转运 PCI 组的 14.3% (6/42) ($P=0.035$)。PCI 后 14 d 时, 易化 PCI 组 TIMI 3 级血流者占 93.1% (54/58), 较直接转运 PCI 组 [90.5% (38/42)] 差异无统计学意义 ($P=0.633$)。

2.3 两组 PCI 后无复流发生率、STR 比较

PCI 后即刻冠脉造影显示, 易化 PCI 组无复流发生率为 6.9% (4/58), 较直接转运 PCI 组 [21.4% (9/42)] 显著降低 ($P=0.033$)。PCI 后 24 h 时, 易化 PCI 组 STR 值为 (61.53 $\pm$ 11.27)%, 显著高于直接转运 PCI 组的 (52.40 $\pm$ 12.63)% ($P=0.000$)。

2.4 两组住院期间 MACE 比较

住院期间, 易化 PCI 组 MACE 发生率为 10.3% (6/58), 较直接转运 PCI 组 [14.3% (6/42)] 差异无统计意义 ($P>0.05$)。见表 2。

表2 两组住院期间 MACE 比较

Table 2 Comparison of MACE during hospitalization between the two groups

Groups	N	Cardiogenic shock	Acute heart failure	Severe arrhythmia	Total incidence rate (%)
Facilitation PCI group	58	1	2	3	10.3
Cross-docking PCI group	42	2	2	2	14.3
χ^2					0.358
P					0.549

2.5 两组出血并发症比较

治疗期间, 易化 PCI 组出血并发症总发生率为 19.0% (11/58), 与直接转运 PCI 组的 14.3% (6/42) 相比差异亦无统计学意义 ($P>0.05$)。见表 3。

2.6 两组随访 1 年主要终点事件比较

随访 1 年, 易化 PCI 组主要终点事件发生率为 19.0%

(11/58), 显著低于直接转运 PCI 组 [40.5% (17/42)], $P<0.05$ 。见表 4。

3 讨论

STEMI 是临床常见急危重症, 发病率及致残、致死率均较高, 尽可能缩短心肌总缺血时间是其救治的核心理念, 因此早

表 3 两组出血并发症比较

Table 3 Comparison of bleeding complications between the two groups

Groups	N	Hemoptysis	Puncture point bleeding	Microscopic hematuria	Gingiva bleeding	Nasal mucosal bleeding	Total incidence rate (%)
Facilitation PCI group	58	1	3	2	3	2	19.0
Cross-docking PCI group	42	0	2	1	2	1	14.3
χ^2							0.378
P							0.539

表 4 两组随访 1 年主要终点事件比较

Table 4 Comparison of primary endpoint events at 1-year follow-up between the two groups

Groups	N	Heart failure	Recurrent angina	Shock	All-cause death	Total incidence rate (%)
Facilitation PCI group	58	2	4	2	3	19.0
Cross-docking PCI group	42	4	5	3	5	40.5
χ^2						5.591
P						0.018

期正确的救治策略与方法对改善治疗效果与转归有积极作用。STEMI 患者的再灌注治疗策略包括直接 PCI、药物溶栓治疗及急诊外科冠状动脉旁路移植术,其中药物溶栓治疗是在无法及时行直接 PCI 的情况下所采取的一种重要的再灌注治疗策略。与直接 PCI 对比,STEMI 患者在院前早期进行溶栓治疗的效果相似。且院前溶栓治疗的早期死亡率较院内溶栓降低 17%,特别是对发病时间 <2 h 者^[15,16]。同时欧洲心脏病学会(ESC)于 2017 年亦提出 STEMI 发病 2 h 内溶栓效果与直接 PCI 相当,且若梗死血管无法在 120 min 内行直接 PCI 开通,则推荐在 FMC 后 10 min 内启动静脉溶栓治疗,甚至院前溶栓^[17]。此外,2018 年的一份中国专家共识也推荐在积极肝素化抗凝的基础上对 STEMI 患者进行院前溶栓是提高我国此类动脉血栓性疾病早期再灌注治疗率的有效手段^[18]。已有临床实践^[19]表明 STEMI 行直接 PCI 的 IRA 开通率在 90%以上,而发病 2 h 内采取第三代特异性纤溶酶静脉溶栓,IRA 开通率亦高于 90%,并能获得更佳的心肌微循环灌注水平,且溶栓治疗具有简便、价格低廉、易行、快捷等欧典,适用于基层医院。

研究^[23]发现中国农村 AMI 的病死率逐年增加,已超越城市,溶栓后转运 PCI 是救治 STEMI 患者的利器,并有望降低中国 AMI 病死率。有文献^[24]报道对于 STEMI 患者(发病 6 h 内)先予以特异性纤溶酶进行溶栓,而后行早期 PCI(溶栓后 3~24 h 内),在疗效和安全性上与直接 PCI 相似,且先溶栓再 PCI 甚至可获得更优异的心肌和心外膜再灌注水平,并有改善患者临床硬终点的趋势,另外也拓宽了后续介入治疗的时间窗。

瑞替普酶作为第三代溶栓剂,主要可通过特异性诱导纤溶蛋白溶解酶转化、降低纤维蛋白凝聚等途径,达到溶栓的目的^[20]。且本品溶栓时具有使用方便(直接静脉推注给药)、无免疫原性、与肝脏的清除受体结合力较低(故半衰期较长)、溶栓效果好且速度快、对全身纤溶与凝血系统影响小等特点^[21]。既往研究^[22]已发现 STEMI 采取半剂量瑞替普酶可达到较好的溶栓效果,且用药风险较全量瑞替普酶降低。此外,研究^[23]显示应

用半量瑞替普酶静脉溶栓对 STEMI 病人行易化 PCI(即溶栓后即刻 PCI)是安全、有效的。Pu 等^[26]研究指出 STEMI 患者(发病 6 h 内)给予半量(50 mg)阿替普酶溶栓后行 PCI 的临床效果与全量(100 mg)阿替普酶溶栓后行 PCI 相当,且优于直接 PCI。国内一项早期相关报道^[27]也发现 STEMI 溶栓后经桡动脉入径行 PCI 较直接 PCI,有助于明显减少无复流的发生,增加术后 TIMI 3 级血流比例,降低出血风险。鉴于此,半量溶栓结合转运 PCI 的模式在早期开通 STEMI 患者 IRA、改善心肌灌注方面具有一定的有效性和安全性。

对于没有条件直接 PCI 的 AMI 患者而言,规范的易化 PCI(溶栓后即刻 PCI)是安全的^[28]。且与直接 PCI 组对比,易化 PCI 组在术前 IRA 开通率(尤其是达 TIMI 3 级血流者占比)上优势突出,有益于改善患者的远期心功能。本研究回顾性分析显示易化 PCI 组(半量瑞替普酶溶栓后行转运 PCI)PCI 前 TIMI 3 级血流者比例达 32.7%,显著高于直接转运 PCI 组(14.3%),这与上述 Meta 分析的结果是相似的。分析原因可能与转运 PCI 前采取半量瑞替普酶溶栓可对冠脉内红血栓的发生发展起到迅速的阻抑作用,并使早期形成的疏松血栓得以溶解,甚至开通 IRA 有关^[29]。同时,本研究中易化 PCI 组无复流发生率仅为 6.9%,较直接转运 PCI 组(21.4%)显著降低,STR 值则显著更高,说明溶栓后行转运 PCI 有助于改善直接转运 PCI 的效果和心肌灌注水平。究其原因可能为采用半量瑞替普酶溶栓后在一定程度上减轻了 IRA 的血栓负荷,促使下游各级血管血流得到有效疏通,继而有助于心肌前向微循环灌注的恢复,有效挽救大片濒死心肌,使得缺血梗死面积缩小,保护了心室功能,亦为后续的 PCI 创造了良好的条件,从而降低了无复流的发生风险,还可延长 PCI 的治疗时间窗;但直接转运 PCI 组在有效恢复心肌灌注的时间上存在一定的滞后性,进而不利于患者病情转归和预后。

此外,本研究中易化 PCI 组 1 年主要终点事件发生率显著低于直接转运 PCI 组,可见半量瑞替普酶溶栓后行转运 PCI 有

利于改善 STEMI 患者远期预后, 这可能也与该治疗方案较早改善 IRA 血流, 有效恢复心肌微循环灌注密切相关。另外在出血并发症方面, 本研究中两组总发生率均不高, 且出血程度较轻。既往报道^[30]亦显示将全量瑞替普酶应用于 STEMI 直接 PCI 患者的效果显著, 可明显改善心肌再灌注及预后, 且出血风险较小, 出血发生率仅为 5.17%, 且均未见严重出血事件, 提示半量瑞替普酶溶栓后行转运 PCI 的安全性较高。

综上所述, 与直接转运 PCI 相比, STEMI 患者应用半量瑞替普酶溶栓后行转运 PCI 有助于早期开通 IRA 心肌灌注水平, 提高 PCI 效果及 PCI 后心肌灌注水平, 改善病人远期预后, 且安全性相当, 可作为现阶段我国基层医院首选的 STEMI 救治方案。

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