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参麦注射液联合阿替普酶治疗急性心肌梗死的临床效果研究 *

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摘要 目的:研究参麦注射液联合阿替普酶治疗急性心肌梗死的临床效果。**方法:**选择 2015 年 1 月～2016 年 12 月在我院进行诊治的急性心肌梗死患者 98 例,随机分为两组,每组各 49 例。对照组静脉滴注阿替普酶 100 mg 治疗,于 90 min 内滴注完毕,先静脉推注 15 mg,再于 30 min 内静脉滴注 50 mg 阿替普酶,最后于 60 min 内静脉滴注 35 mg,每天 1 次;观察组联合静脉滴注参麦注射液治疗,每次 100 mL,每天 1 次。比较两组的临床治疗效果,治疗前后左心室射血分数、左心室舒张末期内径、左心室后壁厚度等心功能指标及血清心肌肌钙蛋白 I(c TnI)、肌酸激酶同工酶(CK-MB)、超氧化物歧化酶以及(SOD)内皮素 1(ET-1)水平的变化。随访半年,观察两组的预后情况(再梗死、梗死后心绞痛、血管再通以及冠脉血栓的发生率)。**结果:**治疗后,观察组的有效率为 91.83%(45/49),明显高于对照组[71.43%(35/49)](*P<0.05*);两组的左心室射血分数、左心室舒张末期内径、左心室后壁厚度均较治疗前明显改善(*P<0.05*),且观察组的改善程度明显优于对照组(*P<0.05*);两组的血清 TnI、CK-MB、ET-1 水平均较治疗前明显降低(*P<0.05*),血清 SOD 水平均较治疗前明显升高(*P<0.05*),且观察组以上指标的改善情况较对照组更为明显(*P<0.05*);观察组再梗死、梗死后心绞痛以及冠脉血栓的发生率均明显低于对照组(*P<0.05*),血管再通的发生明显高于对照组(*P<0.05*)。**结论:**与单独使用阿替普酶对比,参麦注射液联合阿替普酶治疗急性心肌梗死临床疗效和安全性较好。

关键词:参麦注射液;阿替普酶;急性心肌梗死;临床效果

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A Clinical Study on Shenmai Injection Combined with Batroxobin in the Treatment of Acute Myocardial Infarction*

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ABSTRACT Objective: To investigate the clinical effect of Shenmai injection combined with batroxobin in the treatment of acute myocardial infarction. **Methods:** 98 cases of patients with acute myocardial infarction who were treated in our hospital from January 2015 to December 2016 were randomly divided into two groups. The control group was given intravenous alteplase 100 mg, 90 min infusion is completed, the first intravenous injection of 15 mg, and 50 mg intravenous infusion of alteplase in 30 min, finally intravenous infusion of 35 mg in 60 min, once a day. The observation group was treated with intravenous injection of Shenmai injection, 100 mL each time, once a day. The clinical effects, changes of the left ventricular ejection fraction, left ventricular end diastolic diameter, left ventricular posterior wall thickness and other cardiac functions, serum TnI, CK-MB, SOD, ET-1 levels were detected and compared before and after half a year follow-up between two groups, the prognosis of two groups were observed and compared. **Results:** After treatment, the effective rate of observation group was 91.83%(45/49), which was significantly higher than that of the control group[71.43%(35/49)](*P<0.05*). The left ventricular ejection fraction, left ventricular end diastolic diameter, and left posterior wall thickness of both groups were significantly improved after treatment (*P<0.05*), which improved better than those of the control group (*P<0.05*). After treatment, the serum levels of TnI, CK-MB and ET-1 of both groups were significantly lower than those before treatment (*P<0.05*), and the serum levels of SOD were significantly increased (*P<0.05*), which improved more obviously in the observation group than those of control group (*P<0.05*). The incidence of reinfarction, post infarction angina pectoris and coronary thrombosis of observation group were lower than those of the control group (*P<0.05*), and the incidence of recanalization was significantly higher than that of the control group (*P<0.05*). **Conclusions:** The clinical effect and safety of Shenmai injection combined with batroxobin in the treatment of acute myocardial infarction weer better than batroxobin alone.

Key words: Shenmai injection; Batroxobin; Acute myocardial infarction; Clinical effect

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前言

急性心肌梗死是冠状动脉急性、持续性缺血缺氧所引起的心肌坏死，属于临床危重急症[1]，临床上多表现为剧烈而持久的胸骨后疼痛，经过休息及硝酸酯类药物也不可完全缓解疼痛症状，心电检查中可见进行性心电图变化，可并发休克、心律失常、心力衰竭等，常危及患者生命健康。有报道显示美国每年约有 150 万人发生心肌梗死，中国心肌梗死的发病率也呈上升趋势，患者多发生在冠状动脉粥样硬化狭窄基础上由于某些诱因致使冠状动脉粥样斑块破裂，血中的血小板在破裂的斑块表面聚集，形成血块(血栓)，突然阻塞冠状动脉管腔，导致心肌缺血坏死。另外，心肌耗氧量剧烈增加或冠状动脉痉挛也可诱发急性心肌梗死[2,3]。

及时开通血管、减少心肌梗死面积是改善急性心肌梗死患者预后、降低病死率的关键[4]。目前临床上主要采用静脉溶栓治疗，以促进患者的心肌再灌注恢复，但治疗效果仍有待进一步提高[5,6]。中药参麦注射液在临床治疗急性心肌梗死中发挥着较为显著的治疗效果，但目前尚无关于参麦注射液联合阿替普酶治疗急性心肌梗死的研究报道。因此，本研究对参麦注射液联合阿替普酶治疗急性心肌梗死的临床效果和安全性进行了探讨。

1 资料与方法

1.1 一般资料

选择我院 98 例 2015 年 1 月～2016 年 12 月我院收治的急性心肌梗死患者并随机分为两组，均符合相关的诊断标准[7]，排除妊娠哺乳期妇女以及患有严重精神疾病者。观察组 49 例，男 29 例，女 20 例；年龄 45~79 岁，平均(63.27± 12.46)岁；发病到就诊时间 1～11 h，平均(3.26 ± 1.78)h；心功能分级：Ⅰ级 19 例，Ⅱ级 17 例，Ⅲ级 13 例；心肌梗死部位：19 例位于前间壁，20 例位于广泛前壁，6 例位于下壁，3 例位于前壁以及前间壁；合并高血脂症 16 例，高血压 21 例，糖尿病 8 例。对照组 49 例，男 28 例，女 21 例；年龄 45～81 岁，平均(63.78 ± 12.32)岁；发病到就诊时间 1～12 h，平均(3.57 ± 1.64)h；心功能分级：Ⅰ级 20 例，Ⅱ级 17 例，Ⅲ级 12 例；心肌梗死部位：19 例位于前间壁，19 例位于广泛前壁，7 例位于下壁，4 例位于前壁以及前间壁；合并高血脂症 18 例，高血压 20 例，糖尿病 8 例。本研究所有患者均知情同意，两组患者一般资料比较差异均无统计学意义(*P>0.05*)，具有可比性。

1.2 治疗方法

对照组静脉滴注阿替普酶(批号：S20110051，生产厂家：德国勃林格殷格翰药业有限公司，规格：20 mg/ 支)100 mg 治疗，于 90 min 内滴注完毕，先静脉推注 15 mg，再于 30 min 内静脉滴注 50 mg 阿替普酶，最后于 60 min 内静脉滴注 35 mg，每天 1 次；观察组联合静脉滴注参麦注射液（批号：国药准字 Z53021721，生产厂家：云南个旧生物药业有限公司，规格：10 mL)治疗，每次 100 mL，每天 1 次。两组均治疗半个月。

1.3 观察指标

比较两组的临床治疗效果，疗效标准[7]：① 显效：经过治疗后，患者的临床症状基本或者完全消失，2 h 内心电图抬高段降 >50%，胸痛在 2 h 内缓解；② 有效：经过治疗后，患者的临床症状有一定程度的改善，胸痛为出现明显的改善，2 h 内心电图抬高段回降 >50%；③ 无效：经过治疗后，患者的临床症状和体征均无明显改变。

分别于治疗前后采用飞利浦 Affiniti 50 彩色多普勒超声仪检测两组患者的左心室射血分数、左心室舒张末期内径、左心室后壁厚度等心功能。分别于治疗前后，采集两组的空腹外周静脉血 5 mL，采用贝克曼库尔特 AU680 全自动生化分析仪检测血清 c TnI、CK-MB、SOD 和 ET-1。并随访半年，观察两组的预后情况(再梗死、梗死后心绞痛、血管再通以及冠脉血栓的发生率)。

1.4 统计学分析

采用 SPSS15.00 软件，计量资料组间比较采用 t 检验，计数资料采用 x^2 检验，以 *P<0.05* 表明差异有统计学意义。

2 结果

2.1 两组临床疗效的对比

治疗后，观察组的有效率为 91.83%(45/49)，明显高于对照组[71.43%(35/49)](*P<0.05*)，见表 1。

表 1 两组临床疗效的比较[例(%)]

Table 1 Comparison of the clinical effect between two groups[n(%)]

Groups	n	Effective	Valid	Invalid	The total effect rate
Observation group	49	25	20	3	91.83*
Control group	49	19	16	14	71.43

Note: compared with the control group,**P<0.05*.

2.2 两组治疗前后心功能指标的对比

两组治疗后的左心室射血分数、左心室舒张末期内径、左心室后壁厚度均较治疗前明显改善(*P<0.05*)，与对照组相比，观察组的改善程度明显较好(*P<0.05*)，见表 2。

2.3 两组治疗前后血清检测指标的对比

治疗后，两组的血清 TnI、CK-MB、ET-1 水平均较治疗前明显降低(*P<0.05*)，血清 SOD 水平明显升高(*P<0.05*)，且观察组以上指标的改善情况较对照组更为明显(*P<0.05*)，见表 3。

2.4 两组预后情况的对比

治疗后，观察组再梗死、梗死后心绞痛以及冠脉血栓的发生率明显低于对照组(*P<0.05*)，血管再通的发生率明显高于对照组(*P<0.05*)，见表 4。

3 讨论

急性心肌梗死的发病主要是由于某些病变因素引发冠状动脉粥样斑块破裂、冠状动脉粥样硬化以及血小板凝聚，使冠

表 2 两组治疗前后心功能指标的对比($\bar{x}\pm s$)

Table 2 Comparison of the heart function between two groups before and after treatment($\bar{x}\pm s$)

Groups		n	Left ventricular ejection fraction(%)	Left ventricular end diastolic diameter(mm)	Left ventricular posterior wall thickness (mm)
Observation group	Before treatment	49	40.45 ± 5.37	62.29 ± 6.13	13.46 ± 1.15
	After treatment		43.65 ± 5.38 #	56.42 ± 6.39 #	11.59 ± 1.79 #
Control group	Before treatment	49	40.57 ± 5.82	62.43 ± 6.59	13.31 ± 1.13
	After treatment		48.97 ± 6.54 *#	50.32 ± 5.65 *#	9.87 ± 1.19*#

Note: compared with the control group,*$P<0.05$; compared with before treatment, #$P<0.05$.

表 3 两组治疗前后血清检测指标的对比($\bar{x}\pm s$)

Table 3 Comparison of the serum indicators between the two groups before and after treatment($\bar{x}\pm s$)

Groups		n	TnI(μg / L)	CK-MB(U / L)	SOD(U / L)	ET-1(ng / L)
Observation group	Before treatment	49	83.33 ± 8.15	55.19 ± 8.62	151.47 ± 12.38	81.37 ± 9.48
	After treatment		52.13 ± 7.46#	26.35 ± 6.64#	196.87± 15.32#	52.54 ± 7.46#
Control group	Before treatment	49	84.07 ± 9.31	56.18 ± 7.67	152.57 ± 13.62	82.35 ± 8.12
	After treatment		33.57± 6.24*#	18.85± 5.93*#	227.35± 19.42*#	39.34± 6.56*#

Note: compared with the control group, *$P<0.05$; compared with before treatment, #$P<0.05$.

表 4 两组预后情况的对比[例(%)]

Table 4 Comparison of the prognosis between the two groups[n(%)]

Groups	n	Re infarction	Post infarction angina pectoris	Recanalization	Coronary thrombosis
Observation group	49	8(16.33)	7(14.29)	21(42.86)	20(40.82)
Control group	49	3(6.12) *	2(4.08) *	35(71.43) *	13(26.53) *

Note: compared with the control group,*$P<0.05$.

状动脉管腔出现血栓性阻塞,造成心肌坏死,不能接受动脉的血液供给[8-15],属于中医学“胸痹”、“真心痛”、“心厥”范畴。参麦注射液的成分主要包括麦冬以及红参,具有养阴生津以及益气固脱的功效。其中,麦冬具有生津、养阴、润肺、清心之功效,红参具有补元气、固脉之功效;二药提取物组成的参麦注射液可以有效发挥生脉强心、益气回脱的功能。现代药理学研究显示参麦注射液能显著降低心肌耗能量以及耗氧量,增强心肌的收缩功能,从而增加心输出量,促进冠状动脉的扩张,有效防止再灌注时发生心肌缺血和心肌损伤,保护心肌细胞,与西药联合使用能取得更好的临床治疗效果[16-23]。

本研究结果显示观察组的治疗有效率明显高于对照组,治疗后左心室射血分数、左心室舒张末期内径、左心室后壁厚度均较对照组明显改善,表明参麦注射液联合阿替普酶对急性心肌梗死具有显著的临床效果,能有效改善患者的心功能。分析其原因为参麦注射液具有补心、益气固腾、复脉之功效,能改善患者再灌注时的血流动力学,改善机体的心肌代谢情况,从而对受损心肌进行保护;而阿替普酶能降解纤维蛋白凝胶,二者联合使用可以发挥协同作用,使治疗效果明显提高。cTn I 和 CK-MB 可以用于评估心肌损伤的严重程度,且具有极高的特异度以及敏感度[24-27]。ET-1 能增加外周血管阻力,改变机体的血流动力学,加速血栓的形成[28]。SOD 可以催化氧自由基转化为氧及过氧化氢,强有效地清除氧自由基,避免发生心肌再灌注损伤以及脂质过氧化损伤[29,30]。此外,观察组治疗后血清 TnI、CK-MB、ET-1 水平明显低于对照组,血清 SOD 水平明显高于对照组,表明参麦注射液联合阿替普酶能有效减轻急性心肌梗死患者的心肌损伤程度、溶解血栓,预防心肌再灌注损伤。观察组再梗死、梗死后心绞痛以及冠脉血栓的发生率明显低于对照组,血管再通的发生率明显高于对照组,表明参麦注射液通过有效的心肌保护,既改善了急性心肌梗死患者的心功能,又减少了再梗死、梗死后心绞痛以及冠脉血栓等心脏不良事件的发生。分析其原因为单独使用阿替普酶治疗易导致再灌注性损伤,而联合使用参麦注射液可以显著扩张冠状动脉,消除氧自由基,进而避免再灌注时心肌受到损伤。

综上所述,参麦注射液联合阿替普酶对急性心肌梗死患者具有较为显著的临床效果,能有效改善患者的心功能,提高抗凝效果,溶解血栓,防止心肌再灌注损伤,减少再梗死、梗死后心绞痛以及冠脉血栓等心脏不良事件的发生。

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