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银杏叶提取物注射液联合阿替普酶静脉溶栓治疗急性脑梗死的疗效 及对血液流变学和炎症因子的影响*

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摘要 目的:观察急性脑梗死(ACI)在溶栓治疗的基础上联合银杏叶提取物注射液治疗后的疗效,并分析该治疗方案对炎症因子、血液流变学的影响。**方法:**选择2019年6月到2020年10月期间来我院接受诊治的ACI患者60例,按照入院奇偶顺序法将患者分为对照组(奇,30例,阿替普酶静脉溶栓治疗)和观察组(偶,30例,银杏叶提取物注射液联合阿替普酶静脉溶栓治疗),疗程为7d。对比两组治疗7d后的疗效,对比两组治疗前、治疗7d后的血液流变学、美国国立卫生研究院卒中量表(NIHSS)评分、炎症因子、日常生活能力量表(ADL)评分,观察两组治疗期间不良反应发生情况。**结果:**观察组的临床总有效率较对照组高($P<0.05$)。观察组治疗7d后NIHSS评分低于对照组,ADL评分高于对照组($P<0.05$)。观察组治疗7d后超敏C-反应蛋白(hs-CRP)、白细胞介素-6(IL-6)水平低于对照组($P<0.05$)。观察组治疗7d后血小板压积、血小板分布宽度、纤维蛋白原低于对照组($P<0.05$)。两组不良反应发生率对比,差异无统计学意义($P>0.05$)。**结论:**银杏叶提取物注射液联合阿替普酶静脉溶栓治疗ACI患者疗效明确,可改善血液流变学,减少神经功能损伤,降低炎症因子水平,提高患者生活自理能力,且安全性好。

关键词:银杏叶提取物注射液;阿替普酶静脉溶栓;急性脑梗死;疗效;血液流变学;炎症因子

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Effect of Ginkgo Biloba Extract Injection Combined with Alteplase Intravenous Thrombolysis on Acute Cerebral Infarction and Its Influence on Hemorheology and Inflammatory Factors*

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ABSTRACT Objective: To observe the curative effect of acute cerebral infarction (ACI) combined with Ginkgo biloba extract injection on the basis of thrombolytic therapy, and to analyze the effect of the treatment on inflammatory factors and hemorheology. **Methods:** 60 patients with ACI who were admitted to our hospital from June 2019 to October 2020 were selected, they were divided into control group ($n=30$, intravenous thrombolytic therapy with alteplase) and observation group ($n=30$, intravenous thrombolytic therapy with Ginkgo biloba extract injection combined with alteplase) according to the parity order of admission. The course of treatment was 7 d. The curative effects of the two groups were compared 7 d after treatment, hemorheology, national Institutes of health Stroke Scale (NIHSS), inflammatory factors and activities of daily living scale (ADL) scores before and 7d after treatment were compared between the two groups, the incidence of adverse reactions in the two groups were observed. **Results:** The total effective rate of the observation group was higher than that of the control group ($P<0.05$). 7 d after treatment, NIHSS score of observation group was lower than that of control group, ADL score of observation group was higher than that of control group ($P<0.05$). 7 d after treatment, the levels of high sensitivity C-reactive protein (hs-CRP), interleukin-6 (IL-6) in the observation group were lower than those in the control group ($P<0.05$). 7 d after treatment, the hematocrit, platelet distribution width and fibrinogen in the observation group were lower than those in the control group ($P<0.05$). There was no significant difference in the incidence of adverse reactions between the two groups ($P>0.05$). **Conclusion:** Ginkgo biloba extract injection combined with alteplase intravenous thrombolytic therapy in patients with ACI has clear curative effect, can improve hemorheology, reduce nerve function damage, reduce the level of inflammatory factors, improve the self-care ability of patients with good safety.

Key words: Ginkgo biloba extract injection; Alteplase intravenous thrombolysis; Acute cerebral infarction; Curative effect; Hemorheology; Inflammatory factors

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前言

急性脑梗死(ACI)是威胁人们健康的最常见疾病之一,多发于中老年群体,约占所有脑血管疾病的70%^[1]。脑梗死发病后,梗死区域的脑细胞一部分产生变形坏死,另一部分产生可逆性的缺血性损伤,形成半暗带区域^[2]。此时若能及时的恢复半暗带区域的血供,可以有效挽救这部分可逆性的脑细胞,促使ACI患者病情和预后改善^[3]。阿替普酶静脉溶栓治疗可促使纤维蛋白降解,活化纤溶酶原,将纤溶酶原转为纤溶酶,溶解血块,既往用于ACI的治疗可取得不错的疗效^[4,5]。但也有不少患者经阿替普酶静脉溶栓治疗后出现了出血情况,仍需优化治疗^[6]。银杏叶提取物注射液具备抗炎、脑保护等功效,同时可抗血小板聚集^[7]。本研究对我院收治的ACI患者予以阿替普酶静脉溶栓联合银杏叶提取物注射液治疗,获得了较好的疗效,总结如下。

1 资料与方法

1.1 一般资料

选择2019年6月到2020年10月期间来我院接受诊治的ACI患者60例,按照入院奇偶顺序法将患者分为对照组(奇,30例)和观察组(偶,30例),其中对照组男13例,女17例,年龄32~86(56.91±5.38)岁;发病至入院时间0~6(4.59±0.92)h;梗死部位:小脑半球5例,大脑半球17例,脑干8例。观察组男14例,女16例,年龄34~86(56.28±5.09)岁;发病至入院时间0~6(4.61±0.88)h;梗死部位:小脑半球4例,大脑半球15例,脑干11例。两组一般资料比较差异无统计学意义($P>0.05$),均衡可比。

1.2 纳入排除标准

纳入标准:(1)参考《各类脑血管疾病诊断要点》^[8],并经磁共振成像、CT等影像学检查确诊;(2)年龄>18岁;(3)均为首次发病;(4)患者家属对研究内容知情,签署了同意书。排除标准:(1)对本次研究用药存在过敏者;(2)合并有出血者或凝血功能障碍者;(3)合并肝、肾功能重度障碍者;(4)纳入研究前采取抗血小板聚集、抗凝等治疗者;(5)合并脑部肿瘤、癫痫者;(6)既往有神经疾病与脑卒中史者;(7)既往有脑部手术史者。

1.3 方法

常规治疗:降低颅内压,控制基础性疾病,给予营养神经药物,抗感染,抗血小板聚集治疗,纠正酸碱平衡、水电解质紊乱。对照组:予以阿替普酶(Boehringer Ingelheim Pharma GmbH & Co. KG,注册证号:S20160054,规格:50 mg/支)静脉溶栓治疗,推荐剂量为0.9 mg/kg体重(最大剂量为90 mg),总剂量的10%先从静脉推入,剩余剂量在随后60 min持续静脉滴注。24 h后CT未见出血后口服吡拉格雷[深圳信立泰药业股份有限公司,国药准字H20203616,规格:75 mg(按 $C_{16}H_{16}ClNO_2S$ 计)]75 mg/d及阿司匹林肠溶片(Bayer Vital GmbH,国药准字H20130339,规格:100 mg)100 mg/d,共7 d。观察组:银杏叶提取物注射液[悦康药业集团股份有限公司,国药准字H20070226,规格:5 mL:17.5 mg(含银杏黄酮苷4.2 mg)]联合阿替普酶静脉溶栓治疗,阿替普酶静脉溶栓治疗方案同对照组,20 mL的银杏叶提取物注射液溶于250 mL 0.9%的生理盐水中,

液中,静脉滴注1 h,1次/d,共7 d。

1.4 疗效

记录两组治疗7 d后的临床总有效率。疗效判定标准如下^[9]:采用美国国立卫生研究院卒中量表(NIHSS)减分率判定临床疗效。总有效率=基本治愈率+显效率+有效率。基本治愈:NIHSS评分降低91%~100%,病程程度0级。显效:病程程度1~3级,NIHSS评分降低45%~90%。有效:NIHSS评分降低18%~44%。无效:NIHSS评分降低<18%或增加。

1.5 观察指标

(1)采用日常生活能力量表(ADL)^[10]、NIHSS评分评价两组治疗前、治疗7 d后的生活自理能力、神经功能缺损情况。其中ADL总分100分,分数越高,生活自理能力越强。NIHSS总分42分,分数越高神经功能缺损越严重。(2)抽取两组治疗前、治疗7 d后的晨起肘静脉血6 mL,经我院检验科常规离心处理,3100 r/min的离心速率,13 cm的离心半径,离心16 min,分离上清液待检。采用血液流变分析仪(北京中勤世帝公司生产的R80A)检测纤维蛋白原、血小板压积、血小板分布宽度。采用酶联免疫吸附法(试剂盒购自德国r-B iopharm公司)检测炎症因子:超敏C-反应蛋白(hs-CRP)、白细胞介素-6(IL-6),严格按照说明书操作并实施质量控制。(3)统计两组不良反应发生率。

1.6 统计学方法

采用SPSS26.0软件对数据进行统计学分析。计量资料用均值±标准差($\bar{x} \pm s$)的形式表示,采用t检验。计数资料以百分率(%)表示,采用 χ^2 检验。检验标准设置为 $\alpha=0.05$ 。

2 结果

2.1 两组疗效对比

治疗7 d后,观察组无效3例,有效12例,显效6例,基本治愈9例,临床总有效率为90.00%(27/30)。对照组无效10例,有效11例,显效3例,基本治愈6例,临床总有效率为66.67%(20/30)。观察组的临床总有效率较对照组高($\chi^2=4.812, P=0.028$)。

2.2 两组ADL、NIHSS评分对比

两组治疗前ADL、NIHSS评分对比,差异无统计学意义($P>0.05$),同组治疗前、治疗7 d后对比,ADL评分升高,NIHSS评分降低($P<0.05$),观察组治疗7 d后NIHSS评分低于对照组,ADL评分高于对照组($P<0.05$),详见表1。

2.3 两组炎症因子水平对比

两组治疗前hs-CRP、IL-6水平对比,差异无统计学意义($P>0.05$),同组治疗前、治疗7 d后对比,hs-CRP、IL-6水平降低($P<0.05$),观察组治疗7 d后hs-CRP、IL-6水平低于对照组($P<0.05$),详见表2。

2.4 两组血液流变学指标对比

两组治疗前血小板压积、纤维蛋白原、血小板分布宽度对比,差异无统计学意义($P>0.05$),同组治疗前、治疗7 d后对比,血小板压积、血小板分布宽度、纤维蛋白原降低($P<0.05$),观察组治疗7 d后血小板压积、血小板分布宽度、纤维蛋白原低于对照组($P<0.05$),详见表3。

2.5 两组不良反应发生率对比

对照组不良反应总发生率13.33%(4/30),观察组为20.00%(6/30),两组比较差异无统计学意义($P>0.05$),详见表4。

表 1 两组 ADL、NIHSS 评分对比($\bar{x} \pm s$, 分)Table 1 Comparison of ADL and NIHSS scores between the two groups($\bar{x} \pm s$, score)

Groups	ADL		NIHSS	
	Before treatment	7 d after treatment	Before treatment	7 d after treatment
Control group(n=30)	42.89 $\pm$ 6.14	69.76 $\pm$ 6.40 ^a	18.33 $\pm$ 2.35	12.35 $\pm$ 2.31 ^a
Observation group(n=30)	42.97 $\pm$ 8.27	83.54 $\pm$ 7.12 ^a	18.21 $\pm$ 3.26	8.34 $\pm$ 1.36 ^a
t	0.049	9.097	0.189	13.826
P	0.961	0.000	0.851	0.000

Note: compared with before treatment, ^a $P < 0.05$.表 2 两组炎症因子水平对比($\bar{x} \pm s$)Table 2 Comparison of inflammatory factors between the two groups($\bar{x} \pm s$)

Groups	hs-CRP(mg/L)		IL-6(mg/L)	
	Before treatment	7 d after treatment	Before treatment	7 d after treatment
Control group(n=30)	19.06 $\pm$ 3.73	12.32 $\pm$ 2.41 ^a	46.35 $\pm$ 7.29	31.06 $\pm$ 7.33 ^a
Observation group(n=30)	19.17 $\pm$ 7.64	7.58 $\pm$ 2.53 ^a	46.41 $\pm$ 9.33	19.74 $\pm$ 4.25 ^a
t	0.082	8.580	0.032	8.450
P	0.935	0.000	0.975	0.000

Note: compared with before treatment, ^a $P < 0.05$.表 3 两组血液流变学指标对比($\bar{x} \pm s$)Table 3 Comparison of hemorheological indexes between the two groups($\bar{x} \pm s$)

Groups	Hematocrit		Platelet distribution width(%)		Fibrinogen(g/L)	
	Before treatment	7 d after treatment	Before treatment	7 d after treatment	Before treatment	7 d after treatment
Control group(n=30)	0.96 $\pm$ 0.13	0.28 $\pm$ 0.06 ^a	20.91 $\pm$ 1.28	16.71 $\pm$ 1.57 ^a	5.88 $\pm$ 1.07	3.92 $\pm$ 0.93 ^a
Observation group(n=30)	0.94 $\pm$ 0.11	0.17 $\pm$ 0.02 ^a	20.93 $\pm$ 1.36	14.18 $\pm$ 1.66 ^a	5.82 $\pm$ 1.13	2.59 $\pm$ 0.81 ^a
t	0.329	8.515	0.406	7.003	0.244	6.821
P	0.743	0.000	0.868	0.000	0.808	0.000

Note: compared with before treatment, ^a $P < 0.05$.

表 4 两组不良反应发生率对比 例(%)

Table 4 Comparison of the incidence of adverse reactions between the two groups [n(%)]

Groups	Nausea	Vomit	Rash	Elevated transaminase	Total incidence
Control group(n=30)	1(2.50)	2(5.00)	1(2.50)	0(0.00)	4(13.33)
Observation group(n=30)	1(2.50)	2(5.00)	2(5.00)	1(2.50)	6(20.00)
χ^2					0.480
P					0.488

3 讨论

现代医学认为,ACI 的发生过程为多种原因引起的脑缺血缺氧,致使脑组织血容量灌注不足,缺血中心区神经元发生能量耗竭及酸中毒,氧自由基、兴奋性氨基酸被刺激后大量生成,最终引起局部炎症反应^[11,12]。溶栓治疗可以使闭塞的血管再通,是促进脑血流再通的主要措施之一^[13]。阿替普酶是一种纤溶酶原激活剂,进入血栓部位后与纤溶酶原、纤维蛋白原结合成为三聚体复合物,可转化为纤溶酶,从而促进血栓溶解^[14,15]。由于阿替

普酶对血液循环中的纤溶原亲和力低,而对血栓内的纤溶原亲和力强,具有特异性局部溶栓作用,故而作为 ACI 患者首选的溶栓用药^[16]。现临床采用阿替普酶静脉溶栓治疗 ACI 患者的疗效已到达瓶颈,为进一步改善 ACI 患者的整体治疗效果,临床尝试在其治疗基础上联合中药制剂进行治疗^[17]。银杏叶提取物注射液具有活血化瘀通络的功效,既往常用于心血管系统疾病、神经系统疾病的辅助治疗^[18]。

本次研究结果表明,银杏叶提取物注射液联合阿替普酶静脉溶栓治疗 ACI 疗效明确,可有效缓解患者病情,产生脑保护

效果,改善患者血液流变学,改善患者生活自理能力及神经功能。银杏叶提取物注射液的主要成分为银杏叶,而银杏叶主要成分为萜烯内酯(含有白果内酯和银杏内酯)、银杏黄酮^[9]。主要成分的效果如下:银杏黄酮具有广谱自由基清除效果,可有效抑制过氧化氢、清除ACI患者疾病损伤中出现的大量氧自由基、络合铁离子等,从而发挥脑保护作用^[20,21]。银杏内酯可拮抗血小板活化因子受体,有效抑制血栓再次形成。白果内酯可抑制内皮素的生成,抑制氧化磷酸化脱耦联反应,减轻钙离子超载,促进血管舒张,促进血液循环恢复^[22,23]。由于脑缺血时兴奋性氨基酸大量生成,神经元兴奋性升高,可加重脑损伤,而有动物研究表明银杏叶提取物可有效拮抗谷氨酸神经毒性,且具有延缓血液凝固、降低血液黏滞性、抑制血小板功能等多重作用^[24-26]。从上述研究结果可见,银杏叶提取物可发挥抗血栓形成、减轻氧自由基损伤、恢复血液循环等一系列脑保护作用。由于ACI患者常存在动脉粥样硬化、血栓形成、不稳定斑块破裂等因素导致脑部血管堵塞,而上述因素本质上是由机体局部炎症反应推动所致。ACI患者发病后,脑组织受损,进而刺激体内星型细胞、胶质细胞及内皮细胞大量分泌hs-CRP、IL-6等炎症因子^[27]。本次研究中,治疗7d后,观察组的炎症因子水平低于对照组。可见联合治疗可发挥更好的局部炎症控制效果。推测可能与银杏叶提取物注射液可通过强抗氧化作用、脑保护功能、溶解血栓等多方面作用来减轻炎症反应有关。而两组不良反应发生率对比也无明显差异,表明银杏叶提取物注射液联合阿替普酶静脉溶栓治疗是一种较为安全的治疗方案。本次研究仍存在一定不足,如样本量较小、仅观察了近期疗效而未设置随访观察远期疗效,数据准确性仍具有提升空间,有待进一步的大样本量、多中心的深入报道。

综上所述,银杏叶提取物注射液联合阿替普酶静脉溶栓治疗ACI患者,可改善血液流变学指标,减少神经功能损伤,降低炎症因子水平,提高患者生活自理能力。

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