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天丹通络胶囊联合丁苯酞软胶囊治疗急性脑梗死的疗效及对炎症因子和脑血流动力学的影响 *

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摘要 目的:探讨天丹通络胶囊联合丁苯酞软胶囊治疗急性脑梗死(ACI)的疗效及对炎症因子和脑血流动力学的影响。方法:按照随机数字表法将合肥市第一人民医院 2019 年 1 月-2021 年 12 月间接收的 100 例 ACI 患者分为对照组(50 例,丁苯酞软胶囊治疗)和观察组(50 例,天丹通络胶囊联合丁苯酞软胶囊治疗)。对比两组疗效、量表评分、炎症因子和脑血流动力学,统计两组治疗期间不良反应发生率。结果:观察组 84.00%的临床总有效率高于对照组 66.00%($P<0.05$)。与对照组比较,治疗后观察组 Barthel 指数评分升高,美国国立卫生研究院卒中量表(NIHSS)评分降低($P<0.05$)。观察组治疗后的白介素-6(IL-6)、超敏 C 反应蛋白(hs-CRP)低于对照组,白介素-10(IL-10)高于对照组($P<0.05$)。观察组治疗后的阻力指数(RI)低于对照组,脑血流收缩期峰值血流速度(Vs)、平均血流速度(Vm)、舒张期血流速度(Vd)较对照组高($P<0.05$)。不良反应发生率组间对比无差异($P>0.05$)。结论:天丹通络胶囊联合丁苯酞软胶囊有助于降低 ACI 患者的炎症因子水平,改善脑血流动力学,效果显著。

关键词:天丹通络胶囊;丁苯酞软胶囊;急性脑梗死;疗效;炎症因子;脑血流动力学

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Efficacy of Tiandan Tongluo Capsule Combined with Butylphthalide Soft Capsule on Acute Cerebral Infarction and its Effect on Inflammatory Factors and Cerebral Hemodynamics*

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ABSTRACT Objective: To investigate the efficacy of Tiandan Tongluo capsule combined with butylphthalide soft capsule in the treatment of acute cerebral infarction (ACI) and its effects on inflammatory factors and cerebral hemodynamics. **Methods:** According to the random number table method, 100 patients with ACI who were received in Hefei First People's Hospital from January 2019 to December 2021 were divided into control group (50 cases, treated with butylphthalide soft capsule) and observation group (50 cases, treated with Tiandan Tongluo capsule combined with butylphthalide soft capsule). The efficacy, scale score, inflammatory factors and cerebral hemodynamics in the two groups were compared, and the incidence of adverse reactions during treatment in the two groups was counted. **Results:** The total clinical effective rate in the observation group was 84.00% higher than 66.00% in the control group ($P<0.05$). Compared with the control group, after treatment, the Barthel index score in the observation group increased, and the score of national Institutes of Health Stroke Scale (NIHSS) decreased ($P<0.05$). After treatment, interleukin-6 (IL-6) and hypersensitive C-reactive protein (hs-CRP) in the observation group were lower than those in the control group, and interleukin-10 (IL-10) was higher than that in the control group ($P<0.05$). After treatment, the resistance index (RI) in the observation group was lower than that in the control group, and the peak systolic blood flow velocity (Vs), mean blood flow velocity (Vm) and diastolic blood flow velocity (Vd) were higher than those in the control group ($P<0.05$). There was no difference in the incidence of adverse reactions between the two groups ($P>0.05$). **Conclusion:** Tiandan Tongluo capsule combined with butylphthalide soft capsule can reduce the levels of inflammatory factors and improve cerebral hemodynamics in patients with ACI, the effect is remarkable.

Key words: Tiandan Tongluo capsule; Butylphthalide soft capsule; Acute cerebral infarction; Efficacy; Inflammatory factors; Cerebral hemodynamics

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前言

急性脑梗死(ACI)是一种发病急、病情进展快的脑部疾病,随着我国老龄化进程的加快,ACI的发病率逐渐升高^[1]。溶栓治疗可有效缓解ACI患者神经细胞损害,但因多数患者就诊时已错过最佳溶栓治疗时间^[2]。因此,寻找更有效的保守治疗方案十分重要。早期药物强化治疗是ACI患者常规治疗方案,丁苯酞软胶囊是临床常用的脑保护剂,可有效提高缺血缺氧耐受力,减少细胞凋亡,促进神经功能恢复^[3,4]。但也有部分患者经单一丁苯酞软胶囊治疗后,效果一般。除常规西药外,中成药治疗ACI也有较突出的临床价值,天丹通络胶囊具有抗氧化、抗炎、抗细胞凋亡和神经保护作用,既往主要用于ACI导致的相关症状治疗^[5,6]。炎症因子变化贯穿着ACI的整个发病过程,且ACI发病时可能导致脑血流动力学异常,故本次研究以此为考察方向,观察天丹通络胶囊联合丁苯酞软胶囊在ACI患者中的临床价值,旨在为临床治疗提供参考。

1 资料与方法

1.1 基线资料

按照随机数字表法将合肥市第一人民医院2019年1月-2021年12月间接收的100例ACI患者分为对照组(50例,丁苯酞软胶囊治疗)和观察组(50例,天丹通络胶囊联合丁苯酞软胶囊治疗)。其中对照组男28例,女22例;发病至入院时间6~24 h,平均 (13.59 ± 1.58) h;年龄49~73岁,平均年龄 (62.58 ± 4.31) 岁;主要梗死部位:额叶10例,基底节21例,颞叶6例,顶叶9例,枕叶4例;体质量指数 $19 \sim 26 \text{ kg/m}^2$,平均 $(22.69 \pm 1.34) \text{ kg/m}^2$;合并症:糖尿病13例,高血压16例,冠心病10例。观察组男27例,女23例;发病至入院时间6~24 h,平均 (13.87 ± 1.64) h;年龄47~72岁,平均年龄 (62.18 ± 5.26) 岁;主要梗死部位:额叶9例,基底节22例,颞叶7例,顶叶8例,枕叶4例;体质量指数 $18 \sim 26 \text{ kg/m}^2$,平均 $(22.35 \pm 1.28) \text{ kg/m}^2$;合并症:糖尿病16例,高血压19例,冠心病9例。两组一般资料具有可比性($P>0.05$),组间具有可比性。纳入标准:(1)符合《中国急性缺血性脑卒中诊治指南2018》^[7]的相关标准:出现半身乏力、语言不利等症状,经电子计算机断层扫描(CT)、磁共振成像(MRI)检查确诊;(2)均为住院患者,错过溶栓窗(发病6 h内),且发病时间在24 h内;(3)患者家属知情签署同意书;(4)均为初次发病。排除标准:(1)脑出血患者;(2)对研究所使采用的药物过敏者;(3)合并心肝肾等脏器器质性疾病者;(4)合并严重高血压病或糖尿病等疾病,经治疗疾病仍未能控制者;(5)有出血倾向,3个月内发生过严重出血者;(6)由于手术、外伤等因素导致的脑梗死。合肥市第一人民医院医学伦理委员会已批准本研究。

1.2 治疗方法

两组患者入院后均给予控制颅内高压、维持水电解质和酸碱平衡、降压、降糖、抗凝、扩容、降脂治疗,对照组接受丁苯酞软胶囊(国药准字H20050299,规格:0.1 g,石药集团恩必普药业有限公司),口服,0.2 g/次,3次/d,疗程14 d。观察组接受丁苯酞软胶囊联合天丹通络胶囊(山东凤凰制药股份有限公司,国药准字Z20010029,规格:每粒装0.4 g),口服,5粒/次,3次/d,

两组疗程为14 d。

1.3 疗效判定指标

美国国立卫生研究院卒中量表(NIHSS)评分增加>18%视为恶化。NIHSS减少或增加18%以内视为无变化。NIHSS减分率18%~45%视为进步。NIHSS减分率46%~89%,病残程度1~3级视为显著进步。NIHSS减分率90%~100%,病残程度0级视为基本痊愈。总有效率为基本痊愈率+显著进步率+进步率^[8]。

1.4 观察指标

(1)量表评分:治疗前后采用NIHSS评分^[8]、Barthel指数^[9]评估患者的神经功能缺损情况及日常生活活动能力。Barthel指数总分100分,其中生活不能自理,严重功能缺陷(<20分),大部分生活需要家人帮助完成(20~40分),生活需要家人帮助(41~60分),生活基本可以自理(>60分)。NIHSS评分包括肢体共济运动、视野、意识水平、体温、意识水平、凝视、上肢运动、下肢运动、意识水平指令、感觉、面瘫、语言、构音障碍、忽视等,总分42分,分数越高神经缺损功能越重。(2)炎症因子指标检测:治疗前、后采集血液标本6 mL,常温下静置半小时,随后进行低温低速离心(4℃,2900 r/min,离心时间12 min,离心半径12 cm),收集血清。血清白介素-6(IL-6)、超敏C反应蛋白(hs-CRP)、白介素-10(IL-10)水平采用酶联免疫吸附法检测,严格遵守试剂盒说明书(上海酶联生物工程有限公司)相关检测步骤进行。(3)脑血流动力学检查:采用Apogee 6800彩色多普勒超声检查仪(汕头市超声仪器研究所股份有限公司生产),探头频率为2 MHz,取3个心动周期,由经验丰富的超声科医师检测脑血流收缩期峰值流速(V_s)、平均流速(V_m)、舒张期流速(V_d),计算阻力指数(RI)= $(V_s - V_d)/V_s$ 。(4)安全性情况:记录不良反应,包括:转氨酶升高、恶心、腹部不适等。

1.5 统计学方法

采用SPSS 21.0软件处理数据。经Shapiro-Wilk检验计量资料符合正态分布以 $(\bar{x} \pm s)$ 表示,采用配对t检验或成组t检验。以率(%)表示计数资料,采用 χ^2 检验。 $\alpha=0.05$ 为检验水准。

2 结果

2.1 疗效对比

对照组中基本痊愈5例,显著进步12例,进步16例,无变化13例,恶化4例,临床总有效率为66.00%(33/50)。观察组中基本痊愈8例,显著进步16例,进步18例,无变化7例,恶化1例,临床总有效率为84.00%(42/50)。观察组84.00%(42/50)的临床总有效率较对照组66.00%(33/50)高($\chi^2=4.320, P=0.038$)。

2.2 量表评分对比

治疗前两组Barthel指数、NIHSS评分对比无差异($P>0.05$)。两组治疗后NIHSS评分下降,Barthel指数评分升高($P<0.05$)。与对照组比较,治疗后观察组Barthel指数评分升高,NIHSS评分降低($P<0.05$)。见表1。

2.3 炎症因子对比

研究结果显示,两组治疗前IL-6、hs-CRP、IL-10组间对比无差异($P>0.05$)。两组治疗后IL-6、hs-CRP下降,IL-10升高($P<0.05$)。与对照组比较,观察组治疗后IL-10升高,IL-6、hs-CRP降低($P<0.05$)。见表2。

表 1 相关量表评分对比($\bar{x} \pm s$, 分)Table 1 Comparison of related scales scores($\bar{x} \pm s$, scores)

Groups	Time	NIHSS	Barthel index
Control group(n=50)	Before treatment	14.43± 2.32	62.46± 7.34
	After treatment	8.39± 1.85	76.48± 8.42
t1, P1		14.393,0.000	-8.875,0.000
Observation group(n=50)	Before treatment	14.08± 2.65	63.02± 8.66
	After treatment	5.26± 1.34	85.98± 6.79
t2, P2		21.002,0.000	-14.753,0.000
t3, P3		9.689,0.000	-6.210,0.000

Note: t1 and P1 were the comparison before and after treatment in the control group, t2 and P2 were the comparison before and after treatment in the observation group, and t3 and P3 were the comparison between the two groups after treatment.

表 2 炎症因子对比($\bar{x} \pm s$)Table 2 Comparison of inflammatory factors($\bar{x} \pm s$)

Groups	Time	IL-6($\mu\text{g/mL}$)	hs-CRP(mg/L)	IL-10($\mu\text{g/mL}$)
Control group(n=50)	Before treatment	32.07± 4.22	8.68± 1.34	46.59± 6.37
	After treatment	19.89± 3.26	5.93± 1.05	62.83± 7.49
t1, P1		16.151,0.000	11.422,0.000	-11.679,0.000
Observation group(n=50)	Before treatment	31.52± 3.54	8.43± 1.51	47.68± 7.49
	After treatment	12.56± 3.61	3.47± 0.95	83.95± 9.35
t2, P2		26.516,0.000	19.660,0.000	-21.408,0.000
t3, P3		10.656,0.000	15.069,0.000	-17.438,0.000

Note: t1 and P1 were the comparison before and after treatment in the control group, t2 and P2 were the comparison before and after treatment in the observation group, and t3 and P3 were the comparison between the two groups after treatment.

2.4 脑血流动力学对比

治疗后观察组 Vs、Vm、Vd 较对照组高,RI 较对照组低($P<0.05$)。见表 3。

研究结果显示,两组治疗前 Vs、Vm、Vd、RI 组间对比无差异($P>0.05$)。治疗后两组 Vs、Vm、Vd 升高,RI 下降($P<0.05$)。

表 3 脑血流动力学对比($\bar{x} \pm s$)Table 3 Comparison of cerebral hemodynamics($\bar{x} \pm s$)

Groups	Time	Vs(cm/s)	Vm(cm/s)	Vd(cm/s)	RI
Control group(n=50)	Before treatment	119.67± 14.22	108.23± 14.39	93.21± 10.25	0.22± 0.06
	After treatment	127.53± 11.42	123.16± 19.62	105.17± 12.37	0.18± 0.05
t1, P1		-3.047,0.003	-4.339,0.000	-5.264,0.000	3.621,0.000
Observation group(n=50)	Before treatment	120.17± 10.52	107.91± 16.25	94.55± 14.31	0.21± 0.04
	After treatment	142.16± 15.48	146.25± 18.36	122.83± 16.22	0.14± 0.03
t2, P2		-8.308,0.000	-11.057,0.000	-9.425,0.000	9.899,0.000
t3, P3		-5.378,0.000	-6.076,0.000	-6.122,0.000	4.851,0.000

Note: t1 and P1 were the comparison before and after treatment in the control group, t2 and P2 were the comparison before and after treatment in the observation group, and t3 and P3 were the comparison between the two groups after treatment.

2.5 不良反应发生率

治疗期间,对照组出现 3 例不良反应,具体为:1 例转氨酶升高、1 例恶心、1 例腹部不适;不良反应发生率为 6.00%(3/50)。观察组出现 5 例不良反应,具体为:2 例转氨酶升高、2

例恶心、1 例腹部不适;不良反应发生率为 10.00%(5/50);两组不良反应发生率组间对比无差异($\chi^2=0.543, P=0.461$)。不良反应均较为轻微,未予以特殊处理,可在 1 d 内自行消失。

3 讨论

随着社会老龄化进程的逐渐加剧以及三高人群的增多, ACI 的发病率呈逐年上升^[10]。ACI 患者发病后可在极短时间内出现脑神经细胞坏死, 进而导致其支配的相关神经功能障碍。因此 ACI 的治疗关键在于改善或恢复缺血脑组织的血流灌注, 挽救脑梗死缺血半暗带区^[11,12]。此外, 随着研究的深入, 学者们发现在 ACI 的发生、发展过程中, 涉及一系列的炎症反应, 过度的炎症反应可导致机体产生过量的炎症因子和活性氧, 加重脑神经损伤^[13,14]。因此, 如何最大化的减轻 ACI 患者的炎症反应, 对于减轻脑损伤、改善患者预后具有积极的意义。丁苯酞软胶囊主要有效成分为丁基苯酞, 可阻断缺血性脑卒中所致脑损伤的多个病理环节, 具有较强的抗脑缺血、减轻脑水肿、改善能量代谢作用^[15]。有研究表明^[16], 将丁苯酞软胶囊与中成药辅助结合治疗, 可获得比单药治疗更好的疗效, 但有关具体的中成药临床尚未统一。天丹通络胶囊是一种中成类药物, 主要成分是丹参、川芎、水蛭、牛膝、天麻、黄芪等, 因上述药物均是活血化瘀、祛瘀通络的药物, 所以能够抑制血小板聚集、改善脑部血管通透性^[17]。动物实验结果证实^[18], 天丹通络胶囊能降低大鼠急性脑缺血所致的脑水肿和脑血管通透性, 减轻脑组织损伤, 并能改善血瘀大鼠的血液流变学。

本次研究结果发现, 与对照组相比, 观察组 NIHSS 评分更低, Barthel 指数评分更高, 临床总有效率也相对更高, 说明天丹通络胶囊与丁苯酞软胶囊联合治疗可减轻患者神经功能损伤, 提高治疗效果, 有助于生活能力的改善。丁苯酞软胶囊具有以下几个药理作用: 可增强机体组织能量代谢并减少神经细胞凋亡; 保护血管, 从而促进缺血区血流灌注, 促进侧支循环的建立^[19]; 通过抑制炎症反应来抑制神经细胞凋亡, 从而帮助神经功能恢复^[20]。另有研究显示^[21], 天丹通络胶囊可通过抑制血小板聚集、延长凝血酶原时间、降低血液纤维蛋白原、降低血液黏稠度, 改善脑血流灌注, 起到保护脑神经组织的作用。

既往的研究发现^[22], 血清炎症水平一定程度上反映了 ACI 的严重程度。主要体现在: ACI 发生后, 脑组织缺氧、缺血, 大量炎症细胞浸润, 诱发级联反应^[23]。IL-10 是一种抑炎因子, 对因缺血缺氧而受损的神经元具有保护作用^[24]。IL-6 水平是一种促炎因子, 其水平升高可促进斑块和血栓的形成, 加速脑神经元的凋亡^[25]。hs-CRP 是反应低水平炎症反应的灵敏指标, 与 ACI 的预后不良相关^[26]。此外, 炎症因子水平可影响机体的脑血流动力学, 上述促炎介质可招募更多的炎症细胞, 形成级联瀑布样炎症反应, 诱导斑块形成、破裂, 以及血栓负荷形成, 最终影响患者的脑血流动力学, 加重缺血、缺氧症状^[27,28]。本次研究结果显示, 天丹通络胶囊联合丁苯酞软胶囊有助于降低 ACI 患者的炎症反应, 改善其脑血流动力学。这主要是因为天丹通络胶囊可抗血小板聚集, 具有明显活血化瘀效果, 改善血液微循环; 还可以有效抑制炎症因子表达, 发挥脑神经组织保护作用^[29,30]。另不良反应发生率两组对比无差异, 说明二者联合治疗安全性较好。

综上所述, 天丹通络胶囊联合丁苯酞软胶囊治疗 ACI 患者疗效较好, 可促进脑血流动力学恢复, 降低炎症因子水平, 临床应用价值较好。

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