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复方丹参滴丸联合阿司匹林对冠心病患者血小板聚集功能及血脂水平的影响*

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摘要 目的:探讨复方丹参滴丸联合阿司匹林对冠心病(CHD)患者血小板聚集功能及血脂水平的影响。**方法:**选取2011年10月到2016年12月在我院接受治疗的CHD患者320例作为本次研究对象,采用乱数表法将所有患者分为对照组和观察组各160例,两组患者均采用扩冠、抗凝和降压药物等常规内科治疗,在此基础上对照组给予阿司匹林治疗,观察组给予复方丹参滴丸联合阿司匹林治疗,两组均治疗6个月。对比两组临床疗效、甘油三酯(TG)、总胆固醇(TC)、低密度脂蛋白(LDL)及高密度脂蛋白(HDL)、血栓素B₂(TXB₂)水平,记录血小板最大聚集率(PAGM)及不良事件发生率。**结果:**治疗后观察组的总有效率为93.13%,显著高于对照组的68.75%($P<0.05$)。治疗6个月后观察组HDL水平高于治疗前和对照组,LDL、TC、TG水平低于治疗前和对照组($P<0.05$)。治疗6个月后两组患者PAGM、TXB₂水平均有明显下降,且观察组PAGM、TXB₂水平低于对照组($P<0.05$)。观察组不良事件发生率为2.50%,显著低于对照组的18.13%($P<0.05$)。**结论:**复方丹参滴丸与阿司匹林联合治疗CHD临床疗效较好,可以有效抑制血小板凝聚,调节血脂,降低不良事件发生率,值得在临床上推广。

关键词:复方丹参滴丸;阿司匹林;冠心病;疗效;血小板聚集功能;血脂水平

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Effect of Compound Danshen Dripping Pills Combined with Aspirin on Platelet Aggregation Function and Blood Lipid Level in Patients with Coronary Heart Disease*

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ABSTRACT Objective: To investigate the effect of Compound Danshen dripping pills combined with aspirin on platelet aggregation function and blood lipid level in patients with coronary heart disease (CHD). **Methods:** 320 patients with CHD treated in our hospital from October 2011 to December 2016 were selected as the subjects. All patients were divided into the control group and the observation group by random number table method, 160 cases in each group. Two groups of patients were treated with expanding crown, anticoagulation and antihypertensive drugs and other routine medical treatment, on this basis, the control group were treated with aspirin, and the observation group were treated with Compound Danshen dripping pills combined with aspirin. The two groups were treated for 6 months. The clinical efficacy, triglyceride (TG), total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL) and thromboxane B₂ (TXB₂) levels between the two groups were compared. The maximum platelet aggregation rate (PAGM) and incidence of adverse events were recorded. **Results:** After treatment, the total effective rate of the observation group was 93.13%, which was significantly higher than 68.75% of the control group ($P<0.05$). 6 months after treatment, the levels of HDL in the observation group were higher than before treatment and control group, the levels of LDL, TC and TG were lower than before treatment and control group ($P<0.05$). 6 months after treatment, the levels of PAGM and TXB₂ were significantly decreased in the two groups, and the levels of PAGM and TXB₂ in the observation group were significantly lower than that in the control group ($P<0.05$). The incidence of adverse events in the observation group was 2.50%, which was significantly lower than 18.13% of the control group ($P<0.05$). **Conclusion:** Compound Danshen dripping pills combined with aspirin has good clinical efficacy in the treatment of CHD, can effectively inhibit platelet aggregation function, regulate blood lipids, reduce the incidence of adverse reactions, it is worthy of clinical promotion.

Key words: Compound Danshen dripping pills; Aspirin; Coronary heart disease; Curative effect; Platelet aggregation function; Blood lipid level

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前言

冠心病(coronary heart disease, CHD)是冠状动脉性心脏病的简称,是由冠状动脉粥样硬化引起血管腔狭窄或闭塞,导致心肌缺血缺氧而引发的心脏病^[1-3]。CHD 多见于 40 岁以上的中老年人,49 岁以后进展加快。随着近年来人口老龄化速度加快,CHD 的发病率及死亡率也逐年上升,已成为严重危害中老年人健康及影响其生活质量的疾病之一^[4-6]。CHD 治疗的措施有冠状动脉介入术、冠状动脉旁路移植术及药物治疗,由于 CHD 的发病人群多为中老年人,患者手术耐受性差、恢复慢,因此临床多以药物保守治疗为主^[7,8]。复方丹参滴丸是临床常用的活血化瘀类中药,具有抗血小板聚集、抗自由基等作用,并可以稳定血管内皮^[9]。目前以阿司匹林为代表的抗血小板药物能够有效抑制血小板聚集,大幅度降低 CHD 的致残率和死亡率,但服用阿司匹林的患者存在胃肠道不良反应以及抵抗现象,限制了其在临床上的应用^[10,11]。本文采用复方丹参滴丸联合阿司匹林治疗 CHD 患者,并探讨其对血小板聚集功能及血脂水平的影响,报道如下。

1 资料与方法

1.1 一般资料

选取 2011 年 10 月到 2016 年 12 月在我院接受治疗的 CHD 病患者 320 例。纳入标准:(1)所有患者均符合世界卫生组织制定的 CHD 诊断标准^[12];(2)治疗前 1 周内均未服用过抗血小板药物、抗凝药物;(3)所有患者均无消化道疾病或出血性倾向;(4)患者或家属知情同意并签署知情同意书。排除标准:(1)患有血液系统疾病者;(2)肝肾功能严重损害者;(3)患有感染性疾病或恶性肿瘤疾病者;(4)对本研究药物过敏者。(5)临床资料不全患者。采用乱数表法将所有患者分为对照组和观察组各 160 例。观察组男 75 例,女 85 例,年龄 53-83 岁,平均年龄(67.56±9.73)岁;病程 1-17 年,平均病程(12.20±2.08)年;其中合并高血压 22 例,心功能不全 15 例,糖尿病 20 例;对照组男 70 例,女 90 例,年龄 52-84 岁,平均年龄(66.98±10.25)岁;病程 2-18 年,平均病程(13.35±2.66)年;其中合并高血压 26 例,心功能不全 17 例,糖尿病 21 例。两组一般资料无明显差异($P>0.05$),均衡可比。本次研究经医院伦理会研究通过。

1.2 治疗方法

两组患者均采用扩冠、抗凝和降压药物等常规内科治疗,在此基础上对照组给予阿司匹林(拜耳医药保健有限公司,进口药批号:JX20060028)治疗,100 mg/次,1 次/d。观察组给予阿司匹林联合复方丹参滴丸(天士力医药集团股份有限公司,国药准字:Z10950111,规格:27 mg/丸)治疗,10 粒/次,3 次/d。两组患者均给予连续治疗 6 个月。

1.3 观察指标

1.3.1 疗效判定标准 显效:治疗后心绞痛发作频率显著减少甚至消失,静息时心电图恢复正常,基本能正常进行体力活动;有效:治疗后心绞痛发作频率有所减少,静息时心电图 ST 段回升 >0.05 mV, T 波变浅但未达正常状态;无效:治疗后心电图及临床症状无改善甚至加重,总有效例数 = 显效例数 + 有效例数。

1.3.2 血脂水平检测 分别于治疗前、治疗 6 个月后采集患者静脉血 5 mL,采用 3000 r/min 离心 10 min,提取上清液,通过全自动生化分析仪检测血脂水平,包含甘油三酯(triglyceride, TG)、总胆固醇(total cholesterol, TC)、低密度脂蛋白(low density lipoprotein, LDL)及高密度脂蛋白(high density lipoprotein, HDL)。

1.3.3 血小板聚集功能检测 分别于治疗前、治疗 6 个月后采集患者静脉血 5 mL,采用肝素抗凝,以 3000 r/min 的离心速度进行 10 min 的离心运动,提取血浆,采用比浊法测定血小板最大聚集率(maximum platelet aggregation rate, PAGM),采用放免法测定血栓素 B2(thromboxane B2, TXB2)水平。

1.3.4 不良事件 记录并比较两组治疗期间不良事件的发生率。

1.4 统计学方法

采用 SPSS20.0 行统计分析,临床疗效、不良事件发生率等计数资料以率(%)表示,采用 χ^2 检验,血脂水平、血小板聚集指标等计量资料以($\bar{x} \pm s$)表示,采用 t 检验。将 $\alpha=0.05$ 作为检验标准。

2 结果

2.1 两组患者临床疗效对比

治疗 6 个月后观察组的总有效率为 93.13%,显著高于对照组的 68.75%($\chi^2=30.807$, $P=0.000$)。详见表 1。

表 1 两组患者临床疗效对比[n(%)]

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

Groups	n	Effective	Valid	Invalid	Total effective rate
Observation group	160	101(63.13)	48(30.00)	11(6.87)	149(93.13)
Control group	160	75(46.88)	35(21.87)	50(31.25)	110(68.75)

2.2 两组患者治疗前后血脂水平对比

治疗前两组患者 HDL、LDL、TC、TG 水平均无明显差异($P>0.05$),治疗 6 个月后,对照组 HDL、LDL、TC、TG 水平均无明显差异($P>0.05$),观察组 HDL 水平高于治疗前和对照组,LDL、TC、TG 水平低于治疗前和对照组($P<0.05$)。详见表 2。

2.3 两组患者治疗前后血小板聚集功能对比

治疗前两组患者 PAGM、TXB2 水平无明显差异($P>0.05$),治疗 6 个月后两组患者 PAGM、TXB2 水平均有明显下降,且观察组 PAGM、TXB2 水平低于对照组($P<0.05$)。详见表 3。

2.4 两组患者不良事件对比

观察组不良事件发生率为 2.50%,显著低于对照组的 18.13%($\chi^2=21.117$, $P=0.000$)。详见表 4。

表 2 两组患者治疗前后血脂水平对比 (mmol/L, $\bar{x} \pm s$)Table 2 Comparison of blood lipid levels between the two groups before and after treatment (mmol/L, $\bar{x} \pm s$)

Groups	n		HDL	LDL	TC	TG
Observation group	160	Before treatment	1.01 $\pm$ 0.35	4.36 $\pm$ 0.68	6.68 $\pm$ 1.30	2.92 $\pm$ 1.26
		6 months after treatment	2.06 $\pm$ 0.59* [#]	2.30 $\pm$ 0.36* [#]	4.61 $\pm$ 0.96* [#]	1.45 $\pm$ 0.95* [#]
Control group	160	Before treatment	1.08 $\pm$ 0.36	4.30 $\pm$ 0.65	6.55 $\pm$ 1.21	2.86 $\pm$ 1.30
		6 months after treatment	1.21 $\pm$ 0.33	4.16 $\pm$ 0.59	5.83 $\pm$ 0.99	2.21 $\pm$ 0.91

Note: Compared with before treatment, *P<0.05; Compared with control group, [#]P<0.05.

表 3 两组患者治疗前后 PAGM、TXB2 水平对比 ($\bar{x} \pm s$)Table 3 Comparison of PAGM and TXB2 levels between the two groups before and after treatment ($\bar{x} \pm s$)

Groups	n	PAGM(%)		TXB2(pg/mL)	
		Before treatment	6 months after treatment	Before treatment	6 months after treatment
Observation group	160	69.23 $\pm$ 8.21	45.89 $\pm$ 7.25*	130.21 $\pm$ 36.25	62.53 $\pm$ 18.20*
Control group	160	68.68 $\pm$ 8.64	51.02 $\pm$ 6.35*	129.53 $\pm$ 35.66	72.34 $\pm$ 19.86*
t		0.584	6.733	0.169	4.606
P		0.560	0.000	0.866	0.000

Note: Compared with before treatment, *P<0.05.

表 4 两组患者不良事件对比 [n(%)]

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

Groups	n	Heart failure	Miocardial infarction	Cerebral hemorrhage	Cerebral infarction	Total incidence
Observation group	160	2(1.25)	2(1.25)	0(0.00)	0(0.00)	4(2.50)
Control group	160	10(6.25)	14(8.75)	5(3.13)	0(0.00)	29(18.13)

3 讨论

世界卫生组织将 CHD 分为心绞痛、心肌梗死、缺血性心力衰竭(缺血性心脏病)、无症状心肌缺血(隐匿性冠心病)及猝死等 5 大类,相关研究统计近年来 CHD 的发病率逐年增长且有年轻化趋势,已成为我国重要的公共卫生问题^[13,14]。CHD 的发病与高血压、血脂异常、高血糖、体型肥胖、吸烟饮酒、心理、社会压力过大及缺乏锻炼等相关,严重危害患者生活质量及危害生命健康^[15-17]。目前已有研究证实血小板的黏附和聚集在 CHD 发病过程中起着重要作用,因此抗血小板是治疗 CHD 的重要手段^[18]。阿司匹林作为经典的抗血小板药物,曾广泛应用于 CHD 二级预防中并取得显著疗效,但近年来研究发现以阿司匹林为代表的抗血小板药物不断出现抵抗情况,即使加大剂量也无法完全抑制血栓素的生成和血小板的聚集,同时会导致患者出现严重的肠胃不适反应,临床效果较差^[19,21]。中医认为 CHD 是由脏腑功能紊乱,气滞血瘀所致,与现代医学论相吻合。复方丹参滴丸主要成分为丹参、三七、冰片等,能起到通痹止痛、活血化瘀、抗自由基、抗血小板聚集及稳定血管内皮的作用^[2]。

本研究结果显示,观察组的疗效优于对照组,且治疗后两组患者 PAGM、TXB2 水平均有明显下降,且观察组 PAGM、TXB2 水平低于对照组(P<0.05),提示复方丹参滴丸联合阿司匹林在治疗冠心病过程中能有效抑制血小板凝聚功能。相关研究显示,当血液循环正常时血小板均处于休眠状态,在机体受

到生理或病理刺激时,血小板发生活化后 PAGM、TXB2 等多种活化血小板分子标志代表物将会表达在部分血小板膜上,活化的血小板将释放多种代谢产物,导致血管内皮损伤,促进血栓的形成^[23-25]。CHD 患者多存在血脂异常情况,动脉粥样硬化与斑块破裂可引发冠心病突发事件,而 HDL 降低及 LDL 升高是其主要危险因素^[26,27]。LDL 是冠状动脉粥样硬化灶沉积的脂质的主要来源,血管失调或受损后 LDL 可通过内皮层进入血管壁,加速冠状动脉粥样硬化进展,并可导致斑块的稳定性下降,进而诱发突发性心血管事件;HDL 是人体内具有抗动脉粥样硬化的脂蛋白,能有效分解和代谢周围组织中的胆固醇,通过抗炎、抗氧化及保护血管内皮功能达到抗动脉粥样硬化的目的^[28-30]。本研究结果显示治疗后观察组 HDL 水平明显升高,LDL、TC、TG 水平明显降低,并且观察组的 HDL 水平高于对照组,LDL、TC、TG 水平低于对照组(P<0.05)。提示复方丹参滴丸联合阿司匹林在治疗 CHD 过程中能起到调节血脂、预防动脉粥样硬化的功效。本研究结果还显示观察组不良事件发生率为 2.50%,显著低于对照组的 18.13%(P<0.05),提示复方丹参滴丸联合阿司匹林在治疗冠心病过程中不良事件发生率低,具有较好的临床疗效。

综上所述,复方丹参滴丸联合阿司匹林在治疗 CHD 临床疗效较好,不仅能有效抑制血小板凝聚功能,改善血脂,还能大幅度降低不良事件发生率,值得临床推广。

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