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葛兰心宁软胶囊联合替格瑞洛片对冠心病心绞痛患者心功能和血管内皮功能的影响*

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摘要 目的:观察葛兰心宁软胶囊联合替格瑞洛片治疗冠心病心绞痛的疗效及对心功能和血管内皮功能的影响。**方法:**选择我院心内科收治的 150 例冠心病心绞痛患者,按门诊号单双数分为对照组和研究组,各为 75 例。对照组给予替格瑞洛片治疗,研究组给予葛兰心宁软胶囊联合替格瑞洛片治疗,对比两组疗效、血管内皮功能、心功能、心绞痛发作次数和持续时间以及不良反应发生率。**结果:**治疗 1 个月后,研究组的临床总有效率 85.33%(64/75)高于对照组的 69.33%(52/75),差异有统计学意义($P<0.05$)。治疗 1 个月后,研究组左心室射血分数(LVEF)、心输出量(CO)、每搏输出量(SV)高于对照组($P<0.05$)。治疗 1 个月后,与对照组比较,研究组的心绞痛发作次数更少,持续时间更短($P<0.05$)。治疗 1 个月后,研究组一氧化氮(NO)、血流介导的舒张功能(FMD)高于对照组,内皮素-1(ET-1)、胞间黏附分子-1(ICAM-1)、血管紧张素 II(Ang II)低于对照组($P<0.05$)。两组不良反应发生率组间对比无明显差异($P>0.05$)。**结论:**冠心病心绞痛患者经葛兰心宁软胶囊联合替格瑞洛片治疗后,疗效明确,可缓解患者临床症状,促进心功能和血管内皮功能恢复。

关键词:葛兰心宁软胶囊;替格瑞洛片;冠心病心绞痛;心功能;血管内皮功能

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Effects of Gelan Xinning Soft Capsule Combined with Ticagrelor Tablets on Cardiac Function and Vascular Endothelial Function in Patients with Angina Pectoris of Coronary Heart Disease*

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ABSTRACT Objective: To observe the efficacy of Gelan Xinning soft capsule combined with ticagrelor tablets on angina pectoris of coronary heart disease and the effect on cardiac function and vascular endothelial function. **Methods:** 150 patients with angina pectoris of coronary heart disease who were admitted to the Department of Cardiology of our hospital were selected, they were divided into the control group and the study group according to the odd and even number of outpatient number, with 75 cases in each group. The control group was treated with ticagrelor tablets, and the study group was treated with Gelan Xinning soft capsule combined with ticagrelor tablets. The efficacy, vascular endothelial function, cardiac function, angina pectoris attack times and duration time, adverse reactions rate were compared between the two groups. **Results:** 1 month after treatment, the total effective rate of the study group 85.33% (64/75) was higher than 69.33% (52/75) of the control group, difference was statistically significant ($P<0.05$). 1 month after treatment, the left ventricular ejection fraction (LVEF), cardiac output (CO), and stroke volume (SV) of the study group were higher than those in the control group ($P<0.05$). 1 month after treatment, compared with the control group, the angina pectoris attack times of the study group was less, and the duration time was shorter ($P<0.05$). 1 month after treatment, the nitric oxide (NO), flow mediated diastolic function (FMD) of the study group were higher than those of the control group, and endothelin-1 (ET-1), intercellular adhesion molecule-1 (ICAM-1), angiotensin II (Ang II) was lower than those of the control group ($P<0.05$). There was no difference in the incidence of adverse reactions between the two groups ($P>0.05$). **Conclusion:** The patients with angina pectoris of coronary heart disease are treated with Gelan Xinning soft capsule combined with ticagrelor tablets, the efficacy is clear. It can relieve the clinical symptoms and promote the recovery of cardiac function and vascular endothelial function.

Key words: Gelan Xinning soft capsule; Ticagrelor tablets; Angina pectoris of coronary heart disease; Cardiac function; Vascular endothelial function

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前言

冠心病心绞痛是指由冠状动脉粥样硬化狭窄,或在此基础上造成的血栓聚集、动脉痉挛所致的心肌的供氧和需氧失衡而引起的心脏病^[1]。冠心病心绞痛的主要临床症状为心前区疼痛,并伴有焦虑感^[2]。替格瑞洛片是以往用于治疗冠心病、急性冠脉综合征的常用药物,具有预防血栓形成、抗血小板聚集等多种作用^[3],但仍有部分患者单独采用替格瑞洛片治疗后疗效一般,尚需优化该治疗方案。葛兰心宁软胶囊属于中成药,主要成份为山楂提取物、葛根总黄酮、绞股蓝总皂苷,功效为活血化瘀、通络止痛,以往常用于瘀血闭阻所致的冠心病^[4]、冠心病心绞痛^[5]。本研究观察了葛兰心宁软胶囊联合替格瑞洛片治疗冠心病心绞痛的疗效,发现其疗效优于单用替格瑞洛片治疗,具体整理报道如下。

1 资料与方法

1.1 一般资料

选择我院心内科 2019 年 1 月-2020 年 12 月期间收治的冠心病心绞痛患者 150 例,我院医学伦理委员会已批准本研究。按门诊号单双数分为对照组和研究组。研究组 75 例,男女例数分别为 46 例、29 例,病程 8 个月~9 年,平均病程(5.41±0.93)年;年龄 48~76 岁,平均年龄(62.28±4.84)岁;心绞痛分级:I 级、II 级、III 级患者例数分别为 30 例、25 例、20 例;合并症包括:高血压、高脂血症、糖尿病、脂肪肝分别为 11 例、6 例、7 例、7 例。对照组 75 例,男女例数分别为 44 例、31 例,病程 1~10 年,平均病程(5.36±1.07)年;年龄 46~79 岁,平均年龄(62.73±5.19)岁;心绞痛分级:I 级、II 级、III 级的患者分别为 29 例、26 例、20 例;合并症包括:高血压、高脂血症、糖尿病、脂肪肝分别为 9 例、7 例、8 例、6 例。两组患者一般资料无明显差异($P>0.05$),均衡可比。

1.2 纳排标准

纳入标准:(1)诊断标准参考欧洲心脏病学会制定的《稳定型心绞痛管理指南》^[6],并结合心电图、心脏 X 线、血管内超声显像等检查确诊;(2)心绞痛严重程度分级标准参考加拿大心血管学会提出相关标准^[7],诊断为 I 级~III 级心绞痛的患者;(3)每周发作心绞痛超过 2 次;(4)对葛兰心宁软胶囊、替格瑞洛片无禁忌者;(5)所有患者均知情同意研究,治疗期间未使用规定外的其它药物。排除标准:(1)处于外伤、急性感染等应激状态;(2)存在严重先天性心脏病、风湿性心脏病、心律失常等其他心脏病变的患者;(3)近一年内有消化道出血、胃或十二指肠溃疡史;(4)合并严重造血系统病变、严重内分泌系统病变;(5)合并肝、肺、肾、脑等重要器官病变。

1.3 方法

对照组口服替格瑞洛片(厂家:深圳信立泰药业股份有限公司,国药准字 H20183320,规格:90 mg)治疗,每次 90 mg,1 天 2 次。研究组则在替格瑞洛片治疗的基础上联合葛兰心宁软胶囊(厂家:西安千禾药业股份有限公司,国药准字 Z20025490,规格:每粒装 0.58 g)治疗,替格瑞洛片治疗方法参照对照组,葛兰心宁软胶囊每次 2 粒,1 天 3 次,口服。两组治疗期间均调节饮食,禁绝烟酒,口服阿司匹林及硝酸甘油,减轻

精神负担,保持适当的体力活动。两组均于治疗 1 个月后评价治疗效果。

1.4 疗效评价

疗效判定标准^[8]:无效:经治疗后发作次数无明显减少,疼痛无缓解。好转:经治疗后疼痛缓解,发作次数明显减少。治愈:治疗后症状消失,运动试验转阴,休息时心电图恢复正常。总有效率=好转率+治愈率。

1.5 观察指标

(1)于治疗前、治疗 1 个月后采用荷兰 PHILIPS 公司生产 Philips Sonos 7500 型彩色多普勒超声诊断仪检测两组心功能指标,患者取平卧位,探头频率 2.5~6.0MHz,检测心输出量(CO)、左心室射血分数(LVEF)、每搏输出量(SV),均由经验丰富的科主任进行检查。(2)两组分别于治疗前、治疗 1 个月后,抽取清晨空腹静脉血 5~6 mL,置于肝素钠抗凝试剂管中,4℃下,2h 内分离血清,分离参数:3100 r/min 离心 13 min,离心半径 10 cm,分离血清,分装后,保存于 -80℃冰箱中。采用酶联免疫吸附法测定血清中胞间黏附分子-1(ICAM-1)、血管紧张素 II(Ang II)、一氧化氮(NO)、内皮素-1(ET-1)水平,检测过程中所用试剂盒购自武汉博士德生物工程有限公司。(3)于治疗前、治疗 1 个月后采用深圳市科曼医疗设备有限公司生产的 STAR8000E 心电监护仪检测患者血流介导的舒张功能(FMD),选择右侧上臂肱动脉,扫描探头为 10 MHz 线性排列探头,在肘关节上 5~10 cm 进行扫描。记录肱动脉基础内径以及肱动脉血流频谱,之后将袖带放置于肘关节上 2 cm 处,袖带充气,持续阻断血流 5 min 后迅速放气,记录放气后 1 min 内肱动脉内径和肱动脉血流频谱。 $FMD=(\text{动脉反应性充血后内径}-\text{基础内径})/\text{基础内径}$ 。(4)对比两组治疗前、治疗 1 个月后的心绞痛发作次数及持续时间。(5)观察两组不良反应发生情况。

1.6 统计学方法

以 SPSS27.0 分析数据。血管内皮功能指标、心功能指标、年龄等计量资料经 D-W 检验符合正态分布,以($\bar{x}\pm s$)表示,采用配对 t 检验或成组 t 检验。心绞痛分级、合并症、疗效等计数资料采用率表示,实施卡方检验。检验标准设置为 $\alpha=0.05$ 。

2 结果

2.1 疗效对比

治疗 1 个月后,与对照组的临床总有效率 69.33%(52/75)相比,研究组的 85.33%(64/75)明显更高($P<0.05$),见表 1。

2.2 两组心功能指标对比

治疗前两组 CO、LVEF、SV 组间对比无统计学差异($P>0.05$)。治疗 1 个月后两组 CO、LVEF、SV 较同组治疗前明显升高($P<0.05$),且研究组高于对照组($P<0.05$),见表 2。

2.3 两组血管内皮功能指标对比

治疗前两组 ICAM-1、Ang II、NO、ET-1、FMD 组间对比无统计学差异($P>0.05$)。治疗 1 个月后两组 ICAM-1、Ang II、ET-1 较同组治疗前明显降低,NO、FMD 较同组治疗前明显升高($P<0.05$),研究组 NO、FMD 高于对照组,ICAM-1、Ang II、ET-1 低于对照组($P<0.05$),见表 3。

2.4 两组心绞痛发作次数及持续时间

治疗前两组心绞痛发作次数及持续时间对比无明显差异

($P>0.05$)。两组治疗 1 个月后心绞痛发作次数减少,持续时间 ($P<0.05$),见表 4。
缩短($P<0.05$),且研究组心绞痛发作次数更少、持续时间更短

表 1 疗效对比[n(%)]
Table 1 Comparison of efficacy[n(%)]

Groups	Cure	Improve	Invalid	Total effective rate
Control group(n=75)	0(0.00)	52(69.33)	23(30.67)	52(69.33)
Study group(n=75)	1(1.33)	63(84.00)	11(14.67)	64(85.33)
χ^2				5.477
P				0.019

表 2 两组心功能指标对比($\bar{x}\pm s$)
Table 2 Comparison of cardiac function indexes between the two groups($\bar{x}\pm s$)

Groups	LVEF(%)		CO(L/min)		SV(mL)	
	Before treatment	1 month after treatment	Before treatment	1 month after treatment	Before treatment	1 month after treatment
Control group(n=75)	43.29±4.61	47.34±4.75 ^a	4.98±0.82	6.38±0.63 ^a	64.59±7.61	72.64±8.75 ^a
Study group(n=75)	43.16±5.28	52.14±4.39 ^a	4.93±0.91	7.62±0.81 ^a	64.15±8.59	83.12±7.43 ^a
t	0.161	-6.427	0.353	-10.465	0.332	-7.907
P	0.873	0.000	0.724	0.000	0.740	0.000

Note: Compared with before treatment in the same group, ^a $P<0.05$.

表 3 两组血管内皮功能指标对比($\bar{x}\pm s$)
Table 3 Comparison of vascular endothelial function indexes between the two groups($\bar{x}\pm s$)

Groups	ICAM-1(pg/mL)		Ang II (ng/mL)		NO(μ mol/mL)		ET-1(pg/mL)		FMD(%)	
	Before treatment	1 month after treatment	Before treatment	1 month after treatment	Before treatment	1 month after treatment	Before treatment	1 month after treatment	Before treatment	1 month after treatment
Control group(n=75)	118.29±15.25	81.36±10.32 ^a	1.23±0.19	0.97±0.16 ^a	44.23±5.19	53.24±6.24 ^a	68.63±5.27	52.37±6.38 ^a	8.91±1.27	11.28±2.34 ^a
Study group(n=75)	117.03±13.26	56.88±9.71 ^a	1.19±0.18	0.71±0.15 ^a	43.97±6.29	61.28±7.37 ^a	68.92±6.91	43.15±5.84 ^a	8.86±1.13	14.83±1.95 ^a
t	0.540	14.961	1.324	10.267	0.276	-7.210	-0.289	9.232	0.255	-10.093
P	0.590	0.000	0.188	0.000	0.783	0.000	0.773	0.000	0.799	0.000

Note: compared with before treatment in the same group, ^a $P<0.05$.

表 4 两组心绞痛发作次数及持续时间($\bar{x}\pm s$)
Table 4 The angina pectoris attack times and duration time in the two groups($\bar{x}\pm s$)

Groups	Angina pectoris attack times(times/d)		Duration time(min)	
	Before treatment	1 month after treatment	Before treatment	1 month after treatment
Control group(n=75)	2.05±0.26	1.61±0.31 ^a	9.15±0.73	6.28±0.64 ^a
Study group(n=75)	2.09±0.29	1.17±0.27 ^a	9.18±0.82	3.97±0.59 ^a
t	-0.889	9.269	-0.237	22.982
P	0.375	0.000	0.813	0.000

Note: compared with before treatment in the same group, ^a $P<0.05$.

2.5 两组不良反应发生情况

1 例呼吸不畅、1 例恶心呕吐, 研究组出现 1 例胃肠道出血、1 例血尿酸升高、2 例呼吸不畅, 经停药处理后均自行缓解, 两组治疗期间, 对照组出现 1 例胃肠道出血、2 例血尿酸升高、

不良反应发生率组间对比无统计学差异($\chi^2=0.118, P=0.731$)。

3 讨论

以往的研究已证实^[9],动脉粥样硬化是冠心病心绞痛的主要病理基础,炎症反应、血管内皮障碍、血栓形成、血小板激活聚集均是其主要病理机制。而在这之中,血管内皮障碍的作用尤为显著。ICAM-1 是临床反映血管内皮炎症损害程度的重要指标之一,其含量的增多可导致斑块的不稳定性,并加快斑块分裂速度,同时 ICAM-1 还具有黏附心肌细胞而释放细胞毒素的作用,可造成心肌组织损伤,加重病情^[10,11]。Ang II 是肾素-血管紧张素系统中主要的血管活性物质,主要是血管紧张素 I 在血管紧张素转换酶的作用下产生的多肽物质^[12,13]。NO、ET-1、FMD 的异常可激活肾素-血管紧张素系统,使全身微动脉收缩,还可诱导血管外膜成纤维细胞表达分泌 ICAM-1,促进斑块破裂,导致疾病进展^[14,15]。以往也有不少研究证实冠心病心绞痛患者其斑块不稳定性会随其血清 Ang II、ICAM-1 水平的增高而增加^[16,17]。目前临床有关冠心病心绞痛的治疗尚无特异性方案,主要治疗目的在于减轻心绞痛症状,阻止疾病进展^[18]。

替格瑞洛片为二磷酸腺苷受体拮抗剂,是一种抗血小板药物,主要通过有效抑制二磷酸腺苷介导的血小板聚集和活化发挥抗血小板作用^[19,21];此外,还能通过抑制红细胞上平衡型核苷转运体-1 对腺苷的摄取来抑制血小板活性^[22,23];有效减少心绞痛的发作频率。但长期使用此类西药治疗会增加不良反应发生风险,部分患者无法接受。中西医结合治疗冠心病心绞痛近年来取得了不错的进展^[24,25]。葛兰心宁软胶囊中葛根总黄酮活血化瘀、引药上行,山楂提取物活血散瘀降脂,绞股蓝总皂苷益气健脾化痰,以上药物成分共同发挥活血化瘀、通络止痛之效^[26]。本研究结果显示,与对照组比较,研究组心绞痛发作次数更少,持续时间更短,心功能改善优于对照组,且疗效明确,可见葛兰心宁软胶囊联合替格瑞洛片治疗效果优于单用替格瑞洛片治疗。

NO 为血管内皮生长因子,可有效防治动脉硬化的形成,降低血管炎症防止凝血,清除血栓^[27];ET-1 为重要的心血管调节因子,其与 NO 保持动态平衡,共同维持血管张力^[28];以往的研究证实^[29],冠心病患者的 FMD 明显低于正常群体,且内皮损伤是导致 FMD 下降的主要原因。本次治疗后,研究组的 NO、FMD、ET-1、ICAM-1、Ang II 水平改善均更为显著,提示葛兰心宁软胶囊联合替格瑞洛片治疗可有效减少血管内皮损伤,促进血管内皮功能恢复。主要可能与葛兰心宁软胶囊中的葛根总黄酮具有抑制血小板聚集、保护心肌和血管、改善微循环等作用有关;山楂提取物具有降血脂、保护心血管、改善微循环等作用^[30,31]。但其具体作用机制目前尚不清楚,仍需进一步的动物试验或分子实验论证。观察两组治疗期间不良反应发生情况可知,葛兰心宁软胶囊联合替格瑞洛片治疗安全性较好,未见明显的不良反应增加,患者易于接受。

综上所述,冠心病心绞痛患者应用葛兰心宁软胶囊联合替格瑞洛片治疗,可获得比单纯的西药治疗更好的疗效,可有效促进患者症状改善,同时还可改善患者心功能和血管内皮功能。

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