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芪苈强心胶囊治疗气虚血瘀型冠心病心绞痛的临床疗效及机制*

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摘要 目的:探讨芪苈强心胶囊治疗气虚血瘀型冠心病心绞痛的临床疗效及机制。**方法:**选择我院 2015 年 1 月至 2017 年 12 月收治的 61 例气虚血瘀型冠心病心绞痛患者,根据随机数字表法分为观察组(31 例)及对照组(30 例)。对照组给予基础治疗,观察组在对照组基础上加用芪苈强心胶囊,对比两组治疗前后的血清 IL-6 水平的变化、治疗后患者的临床疗效、中医症候疗效、心电图疗效及治疗中不良反应的发生情况。**结果:**治疗后,观察组的临床总有效率(93.5%)、中医症候疗效总有效率(67.7%)、心电图总有效率(93.5%)均显著高于对照组(73.3%、40.0%、70.0%)($P<0.05$)。治疗后,两组血清 IL-6 水平均较治疗前明显下降,且观察组治疗后的血清 IL-6 水平明显低于对照组($P<0.05$)。两组均未发生明显不良反应。**结论:**芪苈强心胶囊可能通过降低机体血清 IL-6 水平提高气虚血瘀型冠心病心绞痛的中西医临床症状,改善患者的心功能,且安全性较好。

关键词:芪苈强心胶囊;气虚血瘀型;冠心病心绞痛;临床疗效

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Clinical Efficacy and Mechanism of Qiliqiangxin Capsule in the Treatment of Qi Deficiency Blood Stasis Coronary Heart Disease Angina Pectoris*

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ABSTRACT Objective: To investigate the clinical efficacy and mechanism of qiliqiangxin capsule in the treatment of qi deficiency blood stasis coronary heart disease angina pectoris. **Methods:** From January 2015 to December 2017, 61 cases with qi deficiency blood stasis coronary heart disease angina pectoris in our hospital were chosen and randomly divided into the observation group (31 cases) and the control group (30 cases) according to random numbers table method. The control group was given basic treatment, the observation group was given qiliqiangxin capsule, the clinical efficacy, curative effect of traditional Chinese medicine, ECG efficacy, the changes of serum IL-6 level before and after treatment and incidence of adverse reactions were compared between two groups. **Results:** After treatment, the total clinical efficacy of observation group(93.5%), curative effect of traditional Chinese medicine(67.7%) and ECG efficacy of observation group were significantly higher than those of the control group(73.3%, 40.0%, 70.0%)($P<0.05$). The serum IL-6 levels of two groups after treatment were obviously decreased than those before treatment, while the IL-6 level of observation group was lower than that of the control group($P<0.05$). No obvious adverse reaction was found in both groups. **Conclusions:** Qiliqiangxin capsule could effectively enhance the clinical symptoms of Chinese and western medicine in the treatment of qi deficiency blood stasis coronary heart disease angina pectoris, improve the heart function with high safety via decreasing the serum IL-6 level.

Key words: Qiliqiangxin capsule; Qi deficiency; Coronary heart disease angina pectoris; Clinical efficacy

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前言

冠状动脉粥样硬化性心脏病简称冠心病,是常见的心血管疾病之一^[1]。随着我国社会、经济的发展,人口老龄化发展日益加剧,其发病率呈现出逐年上升的趋势^[2],严重危害国民健康^[3],故冠心病的防治是全世界医务人员共同面临的重大课题^[4]。冠心病在中医中属于“心痛”、“胸痹”、“心痹”等范畴,其致病

因素多为寒邪内侵、情志失调、饮食不节、年迈体虚等因素,以上因素共同致病或单独为病,使机体产生血瘀、气滞、寒凝、痰浊等症状,最终引起脏腑功能紊乱导致发病^[5]。其病机为本虚标实,病机特点为心脉脾阻、久病入络或气滞血瘀。胸痹心痛病位涉及心、肝、肾等器官,心病会导致血行涩滞,脾失健运,聚湿生痰,痰浊痹阻,失于濡养;肝病失于疏泄,气滞血瘀;肾阴亏损,心血失于濡养,肾阳衰微,君火失于温煦,都可导致心脉痹阻、

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胸阳失运导致胸痹^[6]。

中医在治疗胸痹心痛方面有独特的优势,评价中医药临床药效,对评价中药的国际化、现代化有重要意义。芪苈强心胶囊是在络病学基础上开发的一种中药复方制剂,由附子、黄芪、丹参、人参等组成,具有益气温阳、利水消肿、活血通络之效果^[7]。本研究主要探讨了芪苈强心胶囊对气虚血瘀型冠心病心绞痛的临床疗效,以为中医药治疗胸痹心痛提供参考依据。

1 资料与方法

1.1 一般资料

选择 2015 年 1 月至 2017 年 12 月我院收治的气虚血瘀型

冠心病心绞痛者共 61 例,根据随机数字表法分为观察组(31 例)及对照组(30 例)。纳入标准:符合稳定型心绞痛标准^[8];符合中医中气虚血瘀证胸痹心痛的诊断标准^[9]。排除标准:急性冠脉综合征者;非冠心病所致的胸痛者;非冠状动脉粥样硬化性心脏病者;急性脑梗塞及脑出血者;合并严重原发性疾病者;严重心律失常且未控制血压者;哺乳期妇女、过敏体质者。其中,男 27 例,女 34 例,年龄范围为 40~73 岁,平均年龄 56.3 ± 5.6 岁,病程 1~10 年,平均病程 5.3 ± 1.1 年。两组一般资料对比差异均无统计学意义($P > 0.05$),具有可比性。本研究所有患者知情同意,且经医院伦理委员会批准同意。

表 1 两组一般资料的对比

Table 1 Comparison of the general data between two groups

Groups	n	Sex		Average age(year)	Average disease course (year)
		Male	Female		
Observation group	31	14	17	56.5 ± 5.5	5.0 ± 1.5
Control group	30	13	17	57.1 ± 6.0	5.7 ± 1.6
P		0.886		0.685	0.616

1.2 方法

基础治疗:两组均给予低盐低脂饮食、注意休息,必要时吸氧,消除相关诱因,针对基本病应进行治疗。

对照组:给予常规西医治疗,包括 100 mg 阿司匹林,1 次/日,10 mg 阿托伐他汀钙(立普妥),1 次/日,均口服,必要舌下含服 5 mg 硝酸甘油。观察组在对照组基础上,给予芪苈强心胶囊(石家庄以岭药业股份有限公司,国药准字:Z20040141,规格:0.3 g 36 粒)4 粒/次,3 次/日。两组总疗程均为 2 个月。

1.3 观察指标

(1)临床疗效^[10]:治愈:治疗后症状及体征基本消失,患者超负荷体力活动时,不出现心绞痛症状;显效:偶尔出现心绞痛时硝酸甘油用量减少 $\geq 80\%$;有效:心绞痛发作次数减少时硝酸甘油用量减少 $\geq 50\%$;无效:心绞痛发作次数、程度均未减轻,硝酸甘油用量未减少。(2)中医症候疗效^[11]:显效:症状、体征明显改善,症候积分减少 $\geq 70\%$;有效:症状、体征均好转,症候积分减少在 30%~70%间;无效:症状、体征无明显改善甚至加重,症候积分减少 $< 30\%$;加重:症状、体征加重,症候积分增加。(3)心电图疗效^[12]:显效:心电图恢复正常;有效:有关导联 ST 段治

疗后回升超过 0.05 mV 但未达到正常,主要导联倒置 T 波变浅 50%以上或 T 波转成直立;无效:心电图较治疗前无变化;加重:有关导联降低 ST 段较治疗前下降 0.05 mV 以上,主要导联倒置 T 波加深超过 50%以上,出现房室传导阻滞或异位心律,或室性传导阻滞 T 波转为平坦。(4)治疗前后 1 天清晨空腹抽取肘静脉血,以 3000 r/min 的速度离心 10 min,用酶联免疫吸附法用 ELISA 试剂盒检测 IL-6。(5)不良反应:观察两组治疗过程中的血常规、尿常规、肝功能、肾功能及不良反应的发生情况。

1.4 统计学方法

采用 SPSS17.0 进行统计学分析,两组间计量资料的比较采用 t 检验,计数资料组间比价采用 χ^2 检验,以 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 两组的临床疗效对比

治疗后,观察组的临床总有效率(93.5%)显著高于对照组(73.3%)($P < 0.05$),见表 2。

表 2 两组的临床疗效对比

Table 2 Comparison of the clinical efficacy between two groups

Groups	n	Excellent	Effective	Invalid	Total effective rate
Observation group	31	21	8	2	93.5(29/31)
Control group	30	12	10	8	73.3(22/30)
P					0.043*

Note: Fisher precise chi-square test was adopted.

2.2 两组治疗后的中医症候疗效对比

治疗后,观察组的中医症候疗效总有效率为 67.7%,对照组为 40.0%,观察组明显高于对照组($P < 0.05$),见表 3。

2.3 两组治疗后的心电图疗效对比

治疗后,观察组的心电图总有效率为 93.5%,对照组为 70.0%,观察组明显高于对照组($P < 0.05$),见表 4。

表 3 两组治疗后的中医症候疗效对比

Table 3 Comparison of the clinical symptoms of traditional Chinese medicine between two groups

Groups	n	Excellent	Effective	Invalid	Added	Total effective rate
Observation group	31	6	15	5	5	67.7(21/31)
Control group	30	0	12	5	13	40.0(12/30)
P						0.030

表 4 两组治疗后的心电图疗效对比

Table 4 Comparison of the ECG efficacy between two groups

Groups	n	Excellent	Effective	Invalid	Added	Total effective rate
Observation group	31	20	9	2	0	93.5(29/31)
Control group	30	13	8	6	3	70.0(21/30)
P						0.017

2.4 两组治疗前后血清 IL-6 水平对比

察组治疗后的血清 IL-6 水平明显低于对照组($P<0.05$),见表 5。

与治疗前对比,两组治疗后的血清 IL-6 均明显下降,而观

表 5 两组治疗前后的血清 IL-6 水平对比

Table 5 Comparison of the serum IL-6 between two groups

Groups	n	Time	IL-6(ng/L)
Observation group	31	After treatment	9.7± 2.8
		Before treatment	3.1± 0.8**
P			<0.001
Control group	30	Before treatment	9.8± 3.0
		After treatment	5.8± 1.5*
P			<0.001

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

2.5 两组不良反应发生情况的对比

本研究中,两组的血常规、尿常规、肝功能、肾功能对比差异均无统计学意义($P>0.05$)。两组均未发生明显不良反应。

3 讨论

中西医结合对于冠心病心绞痛的治疗并不是将任意中药联合西药进行治疗,而是根据具体病情将二者有机结合,发挥心绞痛治疗中祖国医学与西医学的互补性,以提高临床疗效^[12]。硝酸酯类药物可快速扩张冠状动脉,缓解患者的心绞痛症状,而耐药性问题日益突出^[13]。中药是根据中医理论指导在治疗心脏局部症状同时调节阴阳气血,使之达到平衡,可作用于致病的多个环节,对机体进行整体调节,适合长期持续应用^[14]。有研究显示中药可改善冠心病心绞痛患者血液循环,起到整体调节作用,这是西药难以取代的长处^[15]。故适宜的中西医结合治疗方法可起到取长补短的作用,有效缓解冠心病心绞痛临床症状,取得更好疗效^[16]。冠心病心绞痛气虚血瘀证患者主要临床表现为胸闷、胸痛、心悸、气短、神疲乏力、舌质紫暗、面色紫暗,治疗中应当以健脾益气为主,兼顾活血化瘀,达到调和气血、通则不痛的最终目的^[17]。

本研究选择了芪苈强心胶囊,其是在中医络病学基础上研制出来的一种成药^[18]。方中的黄芪具有益气之效,附子具有温

阳之效,是治疗气虚的君药。丹参具有活血之效,葶苈子具有泄肺之效,人参具有补气之效,三者共为臣药。红花具有活血之效,陈皮具有理气之效,玉竹具有养心之效,均为佐药,桂枝具有温阳之效,引药入络,从而改善患者的冠状动脉、缺血症状及微循环状态,加快血液流速、防止血栓形成,改善患者的心绞痛症状,提高患者生活质量^[19,20]。本研究结果显示观察组的临床、中医症候、心电图疗效总有效率均明显高于对照组,提示芪苈强心胶囊可有效改善患者的中西医临床症状,改善患者的心功能,主要是由于络病学认为冠心病心绞痛气虚血瘀证治疗应以益气温阳、化瘀通络为主。

冠心病病因与高血压、糖尿病等引起的冠状动脉内皮功能紊乱、管壁形成粥样斑块等有关^[21-23],最终导致管腔狭窄,炎症反应是引起冠心病的重要病因^[24]。IL-6 是单核细胞、激活的淋巴细胞、巨噬细胞分泌的多功能炎症因子,是反映机体炎症反应的一个重要指标^[25],参与了动脉粥样硬化的形成^[26,27]。当单核巨噬细胞释放大量的 IL-6 时,血液中 IL-6 明显升高,可激活巨噬细胞分泌单核细胞,使单核细胞进入血管内皮中,参与斑块形成^[28-30]。本研究中,两组治疗后的血清 IL-6 水平均较治疗前明显下降,而观察组治疗后血清 IL-6 水平明显低于对照组,表明芪苈强心胶囊可能通过降低血清 IL-6 水平治疗冠心病心绞痛。此外,两组均未发生明显或严重不良反应,表明芪苈强心胶

囊用于气虚血瘀型冠心病心绞痛安全性较好。但本研究样本量较少,未对芪蒯强心胶囊长期疗效进行探讨,有待进一步研究。综上所述,芪蒯强心胶囊可能通过降低机体血清 IL-6 水平提高气虚血瘀型冠心病心绞痛的中西医临床症状,改善患者的心功能,且安全性较好。

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