

临床研究

精制血府胶囊治疗冠心病心绞痛 30 例临床观察

王 伟¹ 马晓昌² 汪晓芳² 史大卓² 陈可冀²

摘要 91 例冠心病心绞痛患者,随机单盲分为精制血府胶囊组 30 例(常规西药加精制血府胶囊治疗)、血府逐瘀胶囊组 34 例(常规西药加血府逐瘀胶囊治疗)和常规西药治疗组 27 例(单用西药治疗)。结果:精制血府胶囊组、血府逐瘀胶囊组、常规治疗组的心绞痛的总有效率分别为 96.1%、73.5%、70.4%,前一组与后两组比较差异均有显著性($P<0.05$);3 组的心电图总有效率分别为 73.3%、41.2%、37.0%,前一组与后两组比较均有显著性差异($P<0.05$)。治疗后血浆内皮素-1 浓度下降,前两组相比差异有显著性($P<0.05$),前两组与后一组相比差异有显著性($P<0.01$);治疗后血清降钙素基因相关肽上升,前两组与后一组相比差异均有显著性($P<0.01$)。结论:加用精制血府胶囊治疗冠心病比用血府逐瘀胶囊和单用西药效果更好。

主题词 冠状动脉疾病/中医药疗法 心绞痛/中医药疗法
④ 血府胶囊

本研究在以往临床观察与实验研究的基础上,进一步研究精制血府胶囊抗心肌缺血的临床疗效及部分机制,为揭示中医理气活血法的实质提供依据。

1 临床资料

1.1 病证诊断标准:冠心病心绞痛的诊断根据 1979 年 WHO 制定的《缺血性心脏病的命名及诊断标准》^[1],共 91 例,随机单盲法分为 3 组。其中精制血府胶囊组 30 例,血府逐瘀胶囊组 34 例,常规治疗组 27 例,所有入选病例均为住院患者,疗效全过程观察均在病房完成。各观察组停用其它中药(观察药除外)2 周后入选,且基础西药一致。根据卫生部 1993 年制定的中药新药治疗胸痹(冠心病心绞痛)的临床研究指导原则^[2],确定中医证型和冠心病心绞痛轻重分级标准。中医证型分为:心血瘀阻、痰浊壅塞、气阴两虚、心肾阴虚、阴寒凝滞、阳气虚衰 6 型,本研究中全部病例均为前 3 种证型。

1.2 各组病例临床资料:精制血府胶囊组:男 20 例,女 10 例,平均年龄 58.7 ± 8.9 岁,平均病程 6.7 ± 6.9 年。心血瘀阻型 17 例,气阴两虚型 3 例,痰浊壅塞型

10 例。初发劳累型心绞痛 4 例,稳定劳累型心绞痛 20 例,恶化劳累型心绞痛 3 例,自发型心绞痛 3 例。心绞痛轻度者 27 例,心绞痛中度者 3 例。血府逐瘀胶囊组:男 22 例,女 12 例,平均年龄 56.9 ± 9.4 岁,平均病程 5.7 ± 5.9 年。心血瘀阻型 19 例,气阴两虚型 4 例,痰浊壅塞型 11 例。初发劳累型心绞痛 4 例,稳定劳累型心绞痛 22 例,恶化劳累型心绞痛 4 例,自发型心绞痛 4 例。心绞痛轻度者 29 例,心绞痛中度者 5 例。常规治疗组:男 18 例,女 9 例,平均年龄 59.2 ± 6.7 岁,平均病程 6.9 ± 6.3 年。心血瘀阻型 15 例,气阴两虚型 3 例,痰浊壅塞型 9 例。初发劳累型心绞痛 3 例,稳定劳累型心绞痛 18 例,恶化劳累型心绞痛 3 例,自发型心绞痛 3 例。心绞痛轻度者 24 例,心绞痛中度者 3 例。各组患者性别、年龄、病程、心绞痛类型、心绞痛轻重分级、中医证型构成等,差异均无显著意义,3 组患者均无重度高血压、心律失常、糖尿病等合并症,具有可比性($P>0.05$)。

1.3 冠心病轻重分级标准为:(1)轻度:有较典型的心绞痛发作,但疼痛不重,有时需含硝酸甘油。(2)中度:每天有数次较典型的心绞痛发作,每次持续数分钟至 10 分钟,一般都需口含硝酸甘油。(3)较重度:每天有多次典型心绞痛发作,因而影响日常生活活动,每次发作持续时间较长,需多次口含硝酸甘油。(4)重度:疼痛发作次数及程度,均比较重度为重。

2 治疗及观察方法

2.1 治疗方法:精制血府胶囊、血府逐瘀胶囊均由西苑医院中药制剂室提供(每粒胶囊相当于生药量分别为 5g、9g),口服给药,每日 3 次,每次 3 粒,疗程为 4 周。常规西药治疗组:以常规西药治疗为主,不使用任何中药,疗程为 4 周。精制血府胶囊组和血府逐瘀胶囊组均在与常规治疗组相同处理的基础上分别加用该两种药物。

2.2 观察方法:每周观察 1 次,了解临床症状、体征、舌象、脉象及有关反应,心率、血压等一般体格检查项目,并做详细记录,服药前后做两次血、尿、便常规化验及心、肝、肾功能检查。每两周做常规 12 导联心电图检查,服药前后共做心电图 3 次。血浆内皮素(ET-1)和

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1 北京中医药大学东直门医院气血研究室,北京市东直门内海运仓(100700)

2 中国中医研究院西苑医院心血管内科

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降钙素基因相关肽(cGRP)按照试剂盒(均由中国人民解放军总医院东亚免疫技术研究所提供)的说明书做放射免疫测定。

3 结果

3.1 疗效评定标准:按1993年卫生部制定并颁布的中药新药临床研究指导原则进行。疗效评定指标主要为心绞痛、心电图^[2]。心绞痛症状疗效评定标准按轻度、中度分别评定。轻度:显效:症状消失或基本消失。有效:疼痛发作次数、程度及持续时间有明显减轻。无效:症状基本与治疗前相同。加重:疼痛发作次数、程度及持续时间有所加重(或达到“中度”、“较重度”的标准)。中度:显效:症状消失或基本消失。有效:症状减轻到“轻度”的标准。无效:症状基本与治疗前相同。加重:疼痛发作次数、程度及持续时间有所加重(或达到“较重度”的标准)。心电图疗效评定标准:显效:心电图恢复到“大致正常”或达到“正常心电图”。有效:ST段降低,以治疗后回升0.05mV以上,但未达正常水平,在主要导联倒置T波变浅(达25%以上者);或T波由平坦变为直立,房室或室内传导阻滞改善者。无效:心电图基本与治疗前相同。加重ST段较治疗前降低0.05mV以上,在主要导联倒置T波加深(达25%以上),或直立T波变平坦,平坦T波变倒置,以及出现异位心律。房室传导阻滞或室内传导阻滞。

3.2 3组心绞痛临床疗效比较:表1示,精制血府胶囊组、血府逐瘀胶囊组、常规治疗组的总有效率分别为96.7%,73.5%,70.4%,前两组比较差异有显著性($P<0.05$);后两组比较无显著意义($P>0.05$),精制血府胶囊组与常规治疗组比较差异有显著性($P<0.01$),精制血府胶囊抑制心绞痛作用优于其他两组。

3.3 3组心电图疗效比较:表2示,精制血府胶囊组、血府逐瘀胶囊组、常规治疗组的总有效率分别为73.3%,41.2%,37.0%,前两组比较有显著意义($P<0.05$);后两组比较无显著意义($P>0.05$);精制血府胶囊组与血府逐瘀胶囊组比较有显著意义($P<0.01$)。提示精制血府胶囊组改善缺血心电图的效果优于其它两组。

3.4 3组治疗前后ET-1、cGRP比较:表3、表4示,治疗后精制血府胶囊组ET-1显著降低($P<0.05$),

3组cGRP升高($P<0.01$)。精制血府胶囊组ET-1下降幅度与血府逐瘀胶囊组比较有显著意义($P<0.05$),精制血府胶囊组与常规治疗组比较有极显著意义($P<0.01$);精制血府胶囊组、血府逐瘀胶囊组cGRP升高幅度与常规治疗组比较均有显著意义($P<0.01$)。提示精制血府胶囊可明显降低冠心病心绞痛患者血清ET-1水平,升高cGRP水平,血府逐瘀胶囊亦可明显升高cGRP水平。

3.5 副反应比较:用药期间,着重观察是否出现头痛、头胀、恶心等症状,3组均无上述反应。

表1 3组心绞痛疗效比较

分 组	例数	显效 例(%)	有效 例(%)	无效 例(%)	加重 例(%)
精制血府胶囊组	30	14(46.7)	15(50)	1(3.3)	0
血府逐瘀胶囊组	34	10(29.4)	15(44.1)	8(23.5)	1(3)
常规治疗组	27	4(14.8)	15(55.6)	6(22.2)	2(7.4)

表2 3组心电图疗效比较

分 组	例数	显效 例(%)	有效 例(%)	无效 例(%)	加重 例(%)
精制血府胶囊组	30	4(13.3)	18(60)	8(26.7)	0
血府逐瘀胶囊组	34	3(8.8)	11(32.4)	18(52.9)	2(5.9)
常规治疗组	27	2(7.4)	8(29.6)	16(59.3)	1(3.7)

4 讨论

血府逐瘀汤是清代王清任《医林改错》中的重要方剂,具有理气活血的功效,是中医治疗气滞血瘀之胸痹的常用方剂,而冠心病常归属于中医“胸痹”、“心痛”等范畴。经多年临床实践证明,该方治疗冠心病心绞痛有良好的疗效,近年来实验研究亦证明,该方可明显改善冠心病患者血液流变性的高、凝、粘、聚状态,抑制血小板聚集,防止血栓形成,抑制动脉粥样硬化^[3]。但对其抗心肌缺血的研究尚少。本研究的结果表明,血府逐瘀胶囊(血府逐瘀汤原方)与其化裁方精制血府胶囊均有明显的抗心肌缺血作用,且后者优于前者。精制血府胶囊是由原方化裁后,由赤芍、川芎、枳壳等6味药组成,且各味药的剂量与各药比例与原方完全相同,保留原方理气活血的核心药物。显示出较原方好的疗效,说明古方的构成不一定是行使其抗心肌缺血核心功效的最佳形式,有进一步简化和优选的必要,这对于降低成本研制高效小复方,以及深入开展中医方剂、治则的理

表3 3组治疗前后ET-1、cGRP比较(pg/ml $\bar{x}\pm s$)

分 组	例数	ET-1		cGRP	
		治疗前	治疗后	治疗前	治疗后
精制血府胶囊组	23	85.09 $\pm$ 37.56	61.19 $\pm$ 41.02*	58.64 $\pm$ 19.30	88.87 $\pm$ 20.41**
血府逐瘀胶囊组	20	89.42 $\pm$ 34.02	78.18 $\pm$ 30.17	61.24 $\pm$ 17.81	90.01 $\pm$ 23.73**
常规治疗组	19	81.71 $\pm$ 26.84	73.73 $\pm$ 27.84	60.37 $\pm$ 16.04	80.79 $\pm$ 15.09**

与本组治疗前比较,* $P<0.05$,** $P<0.01$

表 4 3 组治疗前后 ET-1, cGRP 差值的比较 (pg/ml $\bar{x} \pm s$)

分 组	例数	ET-1	cGRP
精制血府胶囊组	23	18.68 $\pm$ 13.97	30.23 $\pm$ 11.39 Δ
血府逐瘀胶囊组	20	11.24 $\pm$ 5.44*	28.77 $\pm$ 6.97 Δ
常规治疗组	19	7.98 $\pm$ 7.08**	20.42 $\pm$ 4.78

与精制血府胶囊组比较, * $P < 0.05$, ** $P < 0.01$; 与常规治疗组比较, $\Delta P < 0.01$

论研究均有重要意义。

内皮素(ET)是作用强而持久的缩血管活性多肽^[4]。其主要的生物学效应有:收缩血管平滑肌,促进细胞增殖^[5];抑制肾素释放,加强去甲肾上腺素、血管紧张素 I、精氨酸血管加压素等缩血管作用^[6],对心脏功能有抑制作用。降钙素基因相关肽(cGRP)是一种扩张血管的活性多肽,可导致血压下降,对微血管有强烈的舒张作用。可有效防治心、脑、肝、肾等组织的缺血再灌注损伤,对心肌缺血有明显的保护作用,增加心肌收缩力和心排血量,阻止或减少心律失常的发生^[7], cGRP 可明显降低血浆 ET 的含量^[8],可显著拮抗 ET 的升压、增加血管阻力、促进平滑肌细胞增殖、心肌损伤等作用。本研究结果显示,冠心病心绞痛患者血浆 cGRP 水平与病情轻重有一定关系,精制血府胶囊与血

府逐瘀胶囊可明显升高血浆 cGRP 水平($P < 0.01$),同时取得明显的临床疗效;精制血府胶囊可显著降低血浆 ET 水平($P < 0.05$)。提示精制血府胶囊治疗冠心病心绞痛取效与其降低血浆 ET 水平,升高血浆 cGRP 水平有关,详细机理值得进一步研究。

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ABSTRACTS FROM ORIGINAL ARTICLES

A Clinical Observation on 30 Cases with Angina Pectoris Treated with Refined Xue Fu Capsules

Wang Wei, Ma Xiaochang, Wang Xiaofang, et al.

In addition to Routine Remedy for Angina Pectoris for all the patients, Refined Xue Fu Capsules and Xue Fu Capsules were prescribed for the first group (N=30) and the second group (N=34). The third group (N=27) received only routine remedy as control in this single-blinded clinical trial. The total effective rate in these three groups were 96.6%, 73.5% and 70.4%. The effect in the first group was significantly higher than the rest two groups ($P < 0.05$). On EEG examination, it was 73.3%, 41.2% and 37.0%, which favored the first group than the rest two ($P < 0.05$). Significant or very significant difference in serum endothelin-1 content was found between the first two ($P < 0.05$) or between the first two vs. the third group ($P < 0.01$). Addition of Refined Xue Fu Capsules could produce much better therapeutic effects than with addition of Xue Fu Capsules or treated with routine remedy only.

Authors' address: Dongzhimen Hospital, Beijing 100700

Key words: coronary diseases/TCM therapy angina pectoris/TCM therapy

(Original article on page 471)

Effect of Recipe for Supplementing Qi, Nourishing Yin and Expelling Turbid Pathogens on Cellular Immunity in Treatment of 30 Cases with Chronic Renal Failure of Deficiency of both Qi and Yin Type

Xu Limei

To determine the effect of TCM drugs on cellular immunity of patients with chronic renal failure of deficiency of both qi and yin type, the lymphocyte subsets, NK cells and sIL-2R were evaluated. A significant decrease in CD₃, CD₄, CD₄/CD₈ ratio and the NK cells ($P < 0.01$), a significant increase in CD₈ ($P < 0.05$) and a very significant increase in sIL-2R ($P < 0.01$) than the normal control group was found in the determination. CD₄/CD₈ ratio and the amount of NK cells were negatively correlated with sIL-2R. Scr and CD₈ were positively correlated with sIL-2R and negatively correlated with CD₄/CD₈ ratio and the amount of NK cells. The increase of CD₃, CD₄, CD₄/CD₈ ratio and the NK cells and decrease in CD₈ and sIL-2R suggested that this recipe could adjust the disturbed cellular immunity and was indicated for cases with chronic renal failure of deficiency of both qi and yin type.

Author's address: The General Air-Force Hospital, Beijing 100036

Key words: renal failure, chronic/TCM therapy deficiency of both qi and yin/TCM therapy

(Original article on page 474)

An Analysis of Efficacy of TCM Drugs in Treating 102 Patients with Gastric Carcinoma in Middle and Late Stages

Yang Jiquan, Zhang Binbin

Drugs for expelling pathogenic cold to resolving stasis, descending the stomach-fire by invigorating the spleen and treating cancer by detoxifying were used in the controlled clinical trial. The one-year, three-year and five-year survival rates in the treatment group (N=69) were 84%, 56.4% and 45.4%, respectively (median, 2.45 years). In comparison with the control group with TCM drugs plus chemotherapy (N=30) it was 76.7%, 53.3% and 43.3%, (median, 1.73 years) respectively. Clinical observation favored the treatment group in improving the symptoms, prolong the survival period, less toxic, less recurrence and metastasis, however, the difference was not significant in statistical analysis.

Authors' address: Kunshan Municipal TCM Hospital, 215300

Key words: tumors of stomach/TCM therapy stages of tumors
(Original article on page 483)

Correlation of Typing Based on Differentiation of Symptoms and Signs in Chronic Gastritis and Its Significance

Zheng Jiagang, Lu Lingeng, Duan Yanxia, et al.

Correlation between TCM typing of chronic gastritis and the findings about the mucosa in gastroscopic examination was analyzed. In GLM and DUNCAN analyses, the sufferers of insufficiency of both the spleen and stomach were much older than of the damp-heat in the spleen and the stomach ($P < 0.05$), while the latter were much younger than blood stasis in stomach-collaterals ($P < 0.05$). Chronic gastritis caused by *Helicobacter pylori* was irrelevant with its types in TCM. Correspondence and scatter diagram analyses showed that chronic superficial gastritis was in correspondence with the types of damp-heat in the spleen and the stomach and that of incoordination between the liver and the spleen, while atrophic gastritis with proliferation and intestinal metaplasia were in correspondence with the types of insufficiency of both the spleen and stomach, blood stasis in stomach-collaterals and insufficiency of stomach yin. Findings in gastroscopy support the nature of chronic gastritis in TCM that the initial stage is often manifested in excess or heat syndromes. Lingering of the disease is bound to be of deficiency or invasion of heat into the collaterals, or impairment of yin.

Authors' address: Longhua Hospital, Shanghai 200032

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