

临床报道

血府逐瘀浓缩丸预防冠心病病人经皮冠状动脉腔内成形术后再狭窄的临床观察

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摘要 选择经皮冠状动脉腔内成形术(PTCA)成功的冠心病患者,观察血府逐瘀浓缩丸对PTCA后再狭窄的预防作用。结果表明:西药常规治疗组复发心绞痛15例(15/38),其中12例重复冠状动脉造影证实有11例再狭窄形成,另3例心电图活动平板复查示相关导联阳性,治疗前后血瘀证候积分值无明显变化($P>0.05$);加血府逐瘀浓缩丸组6例复发心绞痛(6/35),心绞痛复发率显著低于西药常规治疗组($P<0.01$),其中5例重复冠状动脉造影复查证实有4例再狭窄形成,4例无心绞痛复发者重复冠状动脉造影证实无再狭窄形成,治疗后血瘀证候积分值比治疗前明显下降($P<0.01$)。PTCA后心绞痛复发与“血瘀证”关系的分析发现,复发心绞痛患者血瘀证候积分值显著高于未复发心绞痛患者。血府逐瘀浓缩丸可改善PTCA患者的血瘀症状,对预防PTCA后再狭窄有一定的作用。

主题词 冠状动脉疾病/外科手术 冠状动脉分流术 狭窄,病理性/预防和控制 @ 血府逐瘀浓缩丸

经皮冠状动脉腔内成形术(PTCA)作为冠心病的有效治疗方法已被广泛用于临床,但PTCA后半年内达30~35%的再狭窄率一直是影响其疗效的主要因素^[1]。由于人们对再狭窄发生机理尚未有比较清楚的认识,其防治也未有突破性进展。传统中医认为再狭窄的发生属于血瘀证的范畴,血府逐瘀汤是传统中医活血化瘀的代表方剂。因此,本文在实验证明血府逐瘀汤制剂血府逐瘀浓缩丸具有预防家兔髂动脉粥样硬化(AS)经皮血管腔内成形术(PTA)后再狭窄作用的基础上,进一步观察其防治冠心病病人PTCA后再狭窄的作用。

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1 基本情况

1.1 临床资料:选择1991~1995年北京医科大学第三临床医学院PTCA成功的冠心病患者73例,随机分为西药常规治疗加血府逐瘀浓缩丸组(简称加中药组)35例和西药常规治疗组(简称西药组)38例。PTCA成功的判定方法参照 Subcommittee on PTCA 制定的方案^[2]。两组病情基本相似,具有可比性,见表1。

表1 两组PTCA成功的冠心病患者的临床资料

	加中药组	西药组
例数	35	38
年龄(岁)	52.15±7.18	54.76±13.48
男/女	29/6	36/2
吸烟	15	19
高血压病史	10	15
糖尿病	3	4
不稳定心绞痛	12	11
稳定性心绞痛	6	7
陈旧性心肌梗塞	8	8
急性心肌梗塞	12	14
PTCA+溶栓	10	14
冠脉病变支数		
单支	14	18
双支	5	2
三支	6	7
PTCA前冠脉狭窄程度(%)	90.50±7.26	90.95±9.41
<70	10	8
70~89	9	9
90~99	40	29
100	5	10
PTCA后残余狭窄(%)	7.09±12.08	6.56±13.60
PTCA+stent	9	7

1.2 血瘀征象:参照中国中西医结合学会活血化瘀专业委员会制定的血瘀证诊断标准^[3],结合冠心病患者的发病特点,血瘀征象的观察内容包括:心绞痛、舌质紫暗或有瘀斑、口唇及齿

龈紫暗、舌下脉络曲张、脉涩或结代等。对以上各项血瘀症状和体征,参照血瘀证诊断标准的研究^[4],按表现的不同程度进行评分。两组患者的血瘀表现如表2所示,各项血瘀症状和体征大致相近,有可比性。

表2 两组患者血瘀表现分析

血瘀表现	加中药组 例数	35例 (%)	西药组 例数	38例 (%)
心绞痛	28	(80.0)	31	(81.6)
舌质紫暗瘀斑	35	(100)	38	(100)
口唇齿龈暗	26	(74.3)	28	(73.7)
舌下脉曲张	7	(20.0)	9	(23.7)
脉涩或结代	4	(11.4)	6	(15.8)

1.3 PTCA方法及重复冠脉造影再狭窄的判定标准:PTCA参照陈明哲等介绍的方法^[5];冠脉造影复查再狭窄的判定标准为:(1)血管狭窄程度比PTCA后即刻造影所见增加30%以上;(2)术后即刻血管狭窄程度 $<50\%$,而随访时 $\geq 70\%$;(3)随访时血管狭窄程度比术前增加 $\leq 10\%$;(4)成功的PTCA后获得扩张的管腔减少至少50%。

2 给药方法及观察方法

西药常规治疗组,PTCA后继续使用肝素抗凝3~5天,每小时静注3000U。同时口服抗血小板药、硝酸酯类药、钙拮抗剂等药物。放支架者加服华法令;加血府逐瘀浓缩丸组,在以上治疗基础上,于手术日开始服用血府逐瘀浓缩丸(王清任原方比例不变,由福建省厦门中药厂提供,每克相当于生药3g),每次6g,每日3次,至PTCA后6个月。

追踪观察方法:(1)每月1次门诊复查,追踪复查时间一般为6个月,观察患者有无心绞痛、心律失常以及血压、血脂、心电图变化等。并观察患者舌、脉等血瘀症状变化。分别在给药前一天和疗程结束时,在自然光线下,观察各项血瘀征象,并按评分标准记分,各项血瘀症状和体征分数总和为该患者血瘀证候的分数;(2)运动一静息心肌断层显像检查;(3)冠脉造影复查,本组有25例完成冠脉造影复查;(4)心电图活动平板运动试验、超声心动图检查等。

3 结果

3.1 PTCA后心绞痛发作情况:PTCA成功的病例,心绞痛消失或减轻,原有的心电图ST-T缺血改变好转。在临床追踪观察中,加中药组6例复发心绞痛(6/35);西药组有15例复发心绞痛(15/38),另有2例出现室性早搏(2/38),1例出现心衰(1/38)。加中药组心绞痛复发率显著低于西药常规治疗组($P<0.05$)。

3.2 两组复发心绞痛患者的复查情况:西药组复发心绞痛患者15例,12例重复冠状动脉造影复查证实有再狭窄形成11例,另3例复查心电图运动试验示相关导联阳性;加中药组复发心绞痛患者6例,5例重复冠状动脉造影复查,证实有再狭窄形成4例,另1例原扩张部位(右冠状动脉)无再狭窄形成,但在左冠状动脉有新的病变产生。

3.3 冠状动脉重复造影及心肌断层显像复查:在临床观察过程中,西药组16例、加中药组9例,进行冠状动脉造影复查。结果显示,形成再狭窄,西药组12例(1例无心绞痛复发),加中药组4例;9例无再狭窄形成,其中西药组4例(1例有新病变产生),加中药组5例(1例有新病变产生)。对19例病人复查心肌断层显像(西药组10例,加中药组9例),结果5例为正常(西药组2例,加中药组3例),4例心肌轻度缺血(西药组2例,加中药组2例),11例有心肌梗塞、缺血指征(西药组6例,加中药组5例)。

3.4 临床随访中“血瘀”症状的变化:两组治疗前后血瘀证候的变化,加中药组患者,血瘀症状如舌脉等皆有明显改善,治疗后该组患者血瘀证候积分值明显下降($P<0.01$);而西药常规治疗组舌脉变化不明显,胸痛发作例数比加中药组多,并有2例患者有结代脉,见表3。

表3 两组PTCA后患者治疗前后血瘀证候积分值比较

组别	例数	治疗前 均值±标准差	治疗后 均值±标准差	治疗后-治疗前 均值±标准差
加中药组	35	20.6±8.6	12.2±9.6*	8.5±0.61*△
西药组	38	20.3±7.5	16.8±8.8	4.0±0.45*

* 治疗前后自身比较, $P<0.01$;△两组比较 $P<0.01$

3.5 心绞痛复发与血瘀证的关系:20例复发

心绞痛患者均有显著的胸痛、舌质紫暗或有瘀斑、脉涩等血瘀症状,其血瘀证候积分值明显升高(19.6 ± 4.8 分);未复发心绞痛患者则血瘀症状不明显,血瘀证候积分值(13.5 ± 4.3 分)显著低于复发心绞痛患者($P < 0.01$)。

4 讨论

4.1 临床追踪指标在评价 PTCA 远期疗效中的意义:重复冠脉造影是判定 PTCA 后再狭窄最可靠的指标,但限于国情,多数病人 PTCA 后较难接受重复冠脉造影检查。因此,只能对患者临床症状、超声心动图、心电图运动试验、心肌断层显像等检查进行综合分析,推断 PTCA 后有无再狭窄的形成。资料表明 PTCA 后随访期间有心绞痛发作的患者再狭窄发生率为 50%,无症状者为 15%^[6],表明临床症状对判定再狭窄有一定的参考价值。当临床症状出现时,进一步做相应的物理检查,判定再狭窄发生的确诊率可进一步提高^[7]。本文临床观察复发心绞痛患者 20 例,17 例重复冠状动脉造影,15 例再狭窄形成(1 例原部位无再狭窄形成,但有新病变产生;1 例无病变产生)。其中 9 例在重复冠脉造影之前进行心肌断层显像均示阳性,2 例示心肌轻度缺血,而 2 例无症状者,复查心肌断层显像阴性,重复冠状动脉造影亦示无再狭窄形成。以上结果表明,心肌断层显像及临床症状与冠状动脉造影所见有较好的相关性。

4.2 血瘀证和再狭窄形成的关系:再狭窄形成的病理过程,与“心脉痹阻”、“心脉不通”有类同之处,其病因病机为血管内膜损伤,导致瘀血阻滞、血脉不通,属于血瘀证范畴。从 PTCA 后复发心绞痛患者舌脉及临床症状看,患者都有舌暗、脉弦或涩,或胸闷、胸痛等血瘀征象,血瘀证候积分值升高;未复发心绞痛患者多无血瘀征象或血瘀征象不明显,血瘀证候积分值显著低于复发心绞痛患者($P < 0.01$),表明再狭窄的发生与血瘀证的轻重有一定的关系。

4.3 血府逐瘀浓缩丸防治 PTCA 后再狭窄的机理:血府逐瘀汤的活血化瘀作用可表现在如下方面:改善微循环,舒张血管,调节凝血和抗凝系统,防止血栓形成,抑制结缔组织增生。我

们研究发现,血府逐瘀浓缩丸具有抑制血小板粘附聚集,抑制 SMC 增生及相关基因表达的作用^[8]。此外还观察到血府逐瘀浓缩丸对家兔 AS 狭窄病变 PTA 后模型有良好的减轻内膜厚度、抑制平滑细胞增生、防治 PTA 后再狭窄形成的作用^[9]。可见本方的活血化瘀作用可影响再狭窄形成的许多病理因素。本临床随访观察提示,西药组病人 PTCA 后心绞痛复发率为 39.5%(15/38),12 例重复冠脉造影证实有 11 例再狭窄;加血府逐瘀浓缩丸组心绞痛复发率为 17.1%(6/35),重复冠脉造影 5 例,有再狭窄形成 4 例,4 例无复发心绞痛患者重复造影证实无再狭窄形成。初步显示血府逐瘀浓缩丸有一定的防治 PTCA 后再狭窄作用。

5 参考文献

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1995 年度国家中医药管理局科技进步一等奖

ABSTRACTS OF ORIGINAL ARTICLES

Clinical Observation on Prevention of Restenosis in Cases with Coronary Heart Disease after Percutaneous Transluminal Coronary Angioplasty with Concentrated Xuefu Zhuyu Pill

Shi Dazhuo, Li Jing, Ma Xiaochang, et al.

Cases with coronary heart disease after successful PTCA were selected for observation of the preventive action of CXZP on restenosis of the vessel. Results revealed that (1) In the western medicine group 15 cases experienced recurrent angina pectoris. Among them, 12 cases received repeated angiography, 11 of them were confirmed to have restenosis while the 3 other cases were positive in ECG exercise treadmill test. No obvious changes were observed in stasis integration before and after treatment ($P < 0.05$). (2) Only six cases had recurrent angina in the group with CXZP, markedly lower than that of the control group ($P < 0.01$). Of them, 4 cases were confirmed to have restenosis, whereas the 4 cases without angina were confirmed to have no restenosis and the stasis integration was markedly lowered than that before treatment ($P < 0.01$). Analysis on the relation between recurrent angina and "blood stasis syndrome" after PTCA revealed that the stasis integration in recurrent group was markedly higher than that in nonrecurrent group, demonstrating that CXZP can distinctively improve the stasis symptoms and yield certain action on the prevention of restenosis in PTCA.

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Key Words: Coronary arterial diseases/surgical operation coronary shunt stenosis, pathological/prevention and control @ CXZP

(Original article on page 27)

Abstracts Idiopathic Diffusive Pulmonary Interstitial Fibrosis: Report of 13 Cases

Tang Linghua, Li Chunsheng

With difficulty in breathing, dry coughing, clubbed fingers and Velcro's rales as distinctive manifestations, 13 cases of IPF were all treated with integrated traditional Chinese and western medicine, with another group treated with western method alone

(self and before — after) as control. Indices for observation included integration of main manifestations, analysis on blood — gas, changes in pulmonary function, and the frequency of catching cold before and after treatment. Results showed that the improvement in arterial partial pressure of oxygen and lung ventilation in the integrated medicine group were superior to the control group. The amelioration of subjective symptoms was also distinctive and persistent in the treatment group, with marked decrease in the rate of relapse, marked prolongation of survival time and improvement of their living quality.

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Key Words: Pulmonary fibrosis/treatment of integrated Chinese and western medicine

(Original article on page 34)

Clinical Observation on 100 Cases of E — Type Viral Hepatitis Treated by Differentiation of Symptoms and Signs (Bian Zheng) : with Comparative Observation on 100 Cases of A — Type Viral Hepatitis as Control

Zhang Wei, Xing Lianjun, Wang Yunong, et al.

Three hundred cases of E type viral hepatitis were observed with 100 cases of A type as control. We held that the etiology and pathogenesis of E and A types of viral hepatitis were wind, dampness, heat, poisons and stasis, each with its predominance; For A type, its predominant etiology being wind, heat and stasis, while that of E type, dampness, poisons and stasis. For their therapy, the principle of "similar treatment for different diseases" should be adopted. After treatment, ALT, TB, and a markedly decreased, signs and symptoms markedly improved, Epr, IgG also improved to different extents, the cured rate (rate of negative virus exam) being 80% and 78% for A type and E type respectively. The effect was especially good for simple infection, and rather poor for mixed infection type.

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Key Words: Hepatitis, E — type/TCM therapy treatment based on differentiation of syndromes

(Original article on page 37)