

临床研究

舒心益脉胶囊预防冠状动脉介入治疗后
再狭窄 22 例临床观察杨丁友¹ 段学忠¹ 张蕴慧² 指导:周次清²

摘要 以舒心益脉胶囊配合西药常规治疗冠状动脉介入治疗后成功患者 22 例(中西药组),并与 26 例单独西药常规治疗的患者(西药组)对照,观察治疗前后心绞痛复发率,结果中西药组复发率显著低于西药组($P < 0.05$)。两组患者中有 28 例复查冠状动脉造影,中西药组 12 例中再狭窄 4 例,西药组 16 例中再狭窄 12 例,两组比较再狭窄发生率差异有显著性($P < 0.05$)。两组患者用药前后以流式细胞仪、比浊法,对血小板活化分子 CD62P(α -颗粒膜蛋白)、CD63(溶酶体完整膜蛋白)及 CD41(糖蛋白 IIb)的表达进行了定量研究,治疗前组间比较差异无显著性,治疗后组间比较差异有显著性($P < 0.05$)。

主题词 冠状动脉疾病/中药疗法 @ 舒心益脉胶囊 @ 冠状动脉介入疗法

预防经皮腔内冠状动脉成形术(PTCA)及冠状动脉内支架植入术后再狭窄(RS)的发生,已成为当前心脏病学研究领域所面临的主要课题之一。RS 的发生机制现尚不清楚,尽管术后予抗血小板制剂、冠状动脉扩张剂、血管紧张素转换酶抑制剂等治疗,但结果尚不令人满意。在西药常规治疗的基础上,我们配合舒心益脉胶囊显示有较好的降低 RS 发生的趋势,现报告如下。

1 临床资料

1.1 冠心病诊断标准:参考 WHO 缺血性心脏病的相关标准^[1]。

1.2 气滞血瘀证诊断标准:参考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^[2],并结合冠心病患者易随情志抑郁而诱发的特点,对心前区刺痛、气促、口唇爪甲青紫,兼心烦、胸闷、腕胀、易怒、舌质紫暗或有瘀斑,脉沉涩或结代等气滞血瘀证^[3]予以诊断。

1.3 纳入标准:年龄 38~71 岁,近期冠状动脉造影证实冠状动脉有显著狭窄($>50\%$),有心绞痛症状和(或)心肌缺血的客观证据,行 PTCA 及冠状动脉内支

架植入术成功的冠心病患者。

1.4 排除标准:重型心衰,未控制的严重高血压、胰岛素依赖性糖尿病,肝肾功能严重损害及用药前 2 周应用其他中药制剂者。

1.5 病例选择:选择 1999 年 3~12 月济南军区总医院及山东中医药大学附属医院心内科经 PTCA 及冠状动脉内支架植入术成功的冠心病患者 48 例,随机分为西药常规治疗组(简称西药组)和西药常规治疗加服舒心益脉胶囊组(简称中西药组)。西药组 26 例中,男 22 例,女 4 例,年龄 40~70 岁,平均 58.2 ± 9.6 岁,有高血压病病史 11 例,糖尿病病史 4 例,稳定型心绞痛(SA)3 例,不稳定型心绞痛(UA)17 例,急性心肌梗塞(AMI)20 例;中西药组 22 例,男 19 例,女 3 例,年龄 38~71 岁,平均 57.4 ± 10.3 岁,SA 2 例、UA 14 例、AMI 11 例。两组患者一般情况、诊断、冠状动脉病变支数、冠状动脉病变部位及冠状动脉病变类型等方面,具有可比性($P > 0.05$)。

2 治疗及观察方法

2.1 治疗方法:采用股动脉径路按常规标准方法进行 PTCA 及冠状动脉内支架植入术^[4],术后西药组 28 例患者常规应用阿司匹林、抵克力得、硝酸甘油、肝素等药物,中西药组在与西药常规治疗相同的基础上加服舒心益脉胶囊(由丹参、川芎、延胡索、前胡、香附、玫瑰花等组成),每粒 0.3g,每克药粉相当于 6.78g 生药,山东药业集团公司生产,批号 990431。每次服 3 粒,每日 3 次。两组疗程均为 5 个月,观察时间为 1999 年 3 月~2000 年 5 月。

2.2 观察指标及方法:患者每 20 天复诊 1 次,询问有无心绞痛复发,在 48 例患者中有 28 例术后用药 5 个月时进行了冠状动脉造影复查。48 例患者行冠状动脉介入术后于用药前及用药 5 个月后分别在空腹状态下,抽取肘静脉血 2.0ml,加入枸橼酸钠 0.2ml 抗凝后注入特制的硅化试管中,离心、制备富血小板血浆,在测定管中加入 20 μ l 荧光素标记单克隆抗体(FIFC-CD62P、PFIFC-CD63、PE-CD41,批号分别为 Cat. No. 1164、Cat. No. 1165、PNIM1416,由法国国际免疫

1 中国人民解放军济南军区总医院中医科,山东省济南市师范路 25 号(250031)

2 山东中医药大学附属医院心内科

收稿日期:2000-09-23;修回日期:2001-01-21

技术有限公司提供)。对照管中加入 20 μ l 荧光素标记兔抗鼠单克隆抗体(批号为 Cat 349042,由美国 BD 公司提供),混匀,置 4℃避光保存 30 分钟,加缓冲液 1ml,混匀后置于流式细胞仪(美国 BD 公司生产)中,用软件 FACS-Caliber 分析结果,由 HP1200C/PS 打印结果。计算方法:血小板 CD62P(或 CD63、CD41)含量=CD62P(或 CD63、CD41)阳性血小板数÷[CD62P(或 CD63、CD41)阳性+阴性血小板数]×100%—非特异结合细胞%(注:非特异结合细胞是免疫反应中非特异结合的细胞,是试验结果的干扰因素)。

2.3 统计学方法:采用 t 检验、Ridit 分析及 χ^2 分析。

3 结果

3.1 两组患者术后复发心绞痛比较:在术后 5 个月的临床随访中,中西药组和西药组复发心绞痛分别为 4 例、13 例,其他无症状或仅有胸闷及心前区不适者,中西药组 18 例,西药组 15 例,两组在复发心绞痛方面差异有显著性($P<0.05$)。

3.2 两组患者术后冠状动脉造影比较:两组患者中有 28 例术后用药 5 个月时行冠状动脉造影复查,中西药组 12 例中再狭窄 4 例,复发率为 33.3%;西药组 16 例中再狭窄 12 例,复发率为 75%,两组比较差异有显著性($P<0.05$)。冠状动脉造影复查的 28 例患者中,共有 45 处接受介入治疗,中西药组 17 处中再狭窄 6 处,再狭窄率为 35.3%,西药组 28 处中再狭窄 21 处,再狭窄率为 75%,两组差异有显著性($P<0.01$)。

3.3 两组血小板 CD62P、CD63、CD41 表达量比较:附表表示,两组患者 CD62P、CD63、CD41 治疗后均有明显下降,但西药组患者治疗后 CD62P、CD63 及 CD41 表达量明显高于中西药组($P<0.05$)。

附表 两组患者 CD62P、CD63、CD41 治疗前后比较($\bar{x}\pm s$)

组别	例数	CD62P(%)	CD63(%)	CD41(%)
西药组 疗前	26	15.54 $\pm$ 2.28	11.26 $\pm$ 2.22	94.43 $\pm$ 1.85
疗后	26	5.79 $\pm$ 0.92	4.78 $\pm$ 1.22	86.97 $\pm$ 2.32
中西药组 疗前	22	16.55 $\pm$ 3.28	10.74 $\pm$ 1.61	93.46 $\pm$ 2.02
疗后	22	3.53 $\pm$ 0.83*	2.22 $\pm$ 0.85*	77.62 $\pm$ 3.39*

* 与西药组治疗后比较, $P<0.05$

4 讨论

在冠状动脉介入性治疗过程中存在的血管损伤、造影剂的刺激及支架作为一种异物均可能构成血小板活化的促进因素,血小板在冠心病的发生发展过程中起着非常重要的作用^[5]。已有报道提示,在稳定性心绞痛、不稳定性心绞痛、非 Q 波心肌梗塞及急性心肌梗塞患者,血小板膜 CD62P、CD63 及 GP II b-III a 表达率明显高于对照组^[6,7]。大量实验资料表明:CD62P、

CD63 是血小板粘附、聚集和释放功能的分子基础,当血小板与内皮下组织接触后,在粘附开始阶段是血流中血小板停滞,在粘附过程中,最早起作用的是作为血小板外层表面上的重要成分——膜糖蛋白,而 CD41 是血小板膜糖蛋白中的一个重要区带,这些变化是血小板聚集性增高的早期指征和结构基础。本研究结果表明,两组冠状动脉介入术后的患者,用药前 CD62P、CD63、CD41(GP II b)的值差异均无显著性,而用药 5 个月后中西药组明显低于西药组,表明舒心益脉胶囊可明显抑制血小板的活化,并降低心绞痛的复发率。冠脉造影复查表明,该中药确有预防冠状动脉介入术后再狭窄的作用,但本研究所选接受冠脉造影复查者,多为术后心绞痛复发的患者,术后无症状的患者多数难以接受冠脉造影复查,故本研究的再狭窄率较实际可能为高。

冠状动脉介入治疗后,发生再狭窄的机理现尚不十分清楚,多数学者认为,与术中球囊扩张造成对血管壁的直接损伤,血管壁的弹性回缩及血小板的粘附聚集和释放,启动了血栓形成,形成血管壁炎症、细胞增生和基质堆积等有关。此与中医学“胸痹”、“真心痛”有类同之处,其病机为血管内膜损伤致“心脉痹阻”。中医学认为“气行则血行”,结合“胸痹”、“真心痛”常随情志抑郁而诱发的特点,以理气活血法,拟舒心益脉胶囊剂,达气行血活痛止之目的,而降低再狭窄的发生。

舒心益脉胶囊中香附、前胡、玫瑰花分别具疏肝、宣肺、理脾之功,丹参合前胡理心肺之气而活心经之血为主,川芎合香附理肝经气滞而活血为辅,延胡索活血止痛合玫瑰花调和肝脾而助心血之运行为佐使,诸药合之共奏理气活血、化瘀止痛之功。

参考文献

- 1 陈灏珠主编.内科学.第 3 版.北京:人民卫生出版社,1995:263—264.
- 2 中国中西医结合学会活血化瘀专业委员会.血瘀证诊断标准.中西医结合杂志,1987,7(3):129.
- 3 苏诚炼,沈绍功主编.现代中医心病学.北京:北京科学技术出版社,1997:535—536.
- 4 陈在嘉主编.临床冠心病学.北京:人民军医出版社,1994:345—351.
- 5 李贵双.冠心病患者血小板活化及其影响因素.中国循环杂志,2000,15(4):248—249.
- 6 Giles H,Smith RE,Martin JF. Platelet glycoprotein II b-III a and size are increased in acute myocardial infarction. Eur J Clin Invest, 1994,24(1):69—72.
- 7 Amrani DL,Stojanovic L,Mosesson MN,et al. Development of a whole platelet ELISA to detect circulating activated platelets. J Lab Clin Med,1995,126(6):603—611.

ABSTRACTS FROM ORIGINAL ARTICLES

Clinical Observation on Treatment of Tonoclonic Attack of Infantile Epilepsy with Acupuncture Plus Xi Feng Capsul

Mu Rong, Zhang Xilian, Liu Yuzhen, et al.

In order to probe into clinical effect of acupuncture plus Xi Feng Capsule for treatment of tonoclonic attack of infantile epilepsy, 60 infantile patients were randomly divided into two groups, 30 cases in each group. The treatment group were treated with acupuncture plus Xi Feng Capsule and the control group with simple Xi Feng Capsule. The clinical attack frequency, lasting time and symptoms of attack, and electroencephalogram were observed to valuate the therapeutic effects. Results showed that the markedly effective rate was 76.7% and 50.0%, the total effective rate 96.7% and 90.0% in the treatment group and the control group, respectively, with no statistically significant difference between the two groups ($P > 0.05$), but the therapeutic effects of the treatment group in frequency and lasting time of attack, and electroencephalogram were superior to those in the control group with significant difference ($P < 0.05$). It is suggested that acupuncture plus Xi Feng Capsule has a higher therapeutic effect.

Authors' Address: The First Affiliated Hospital of Tianjin College of TCM, Tianjin 300193

Key Words: epilepsy, general/ acup — mox ther, epilepsy, general/Chinese medicinal herb ther, @Xi Feng Capsule

(Original article on page 276)

Clinical Investigation on Shu Xin Yi Mai Capsule for Prevention of Restrenosis after Coronary Intervention Treatment in 22 Cases

Yang Dingyou, Duan Xuezhong, Zhang Yunhui, et al.

Shu Xin Yi Mai Capsule combined with Western medical routine treatment was used for 22 successful cases of coronary intervention treatment (Chinese — Western Medicine group) and 28 cases routinely treated with simple Western medicine were used as control (Western medicine group). Recurrence rates of angina pectoris before and after treatment were observed. Results indicated that the recurrence rate in the Chinese — Western medicine group was significantly lower than that in the Western medicine group ($P < 0.01$). There were 28 cases in the two groups in whom coronary contrast reexamination was made. Of 12 cases in the Chinese — Western medicine group, 4 cases had restrenosis, and of 16 cases in the Western medicine group, 12 had restrenosis. There was a significant difference in the recurrence rate of restrenosis between the two groups ($P < 0.05$). Quantitative study on expressions of platelet activating factor CD62P (a — granular membrane protein), CD63 (lysosome intact membrane protein) and CD41 (glucoprotein IIb) was made with

flowcytometer and turbidimetric method before and after treatment in the two groups indicated that there was no significant difference between the two groups before treatment and a significant difference after treatment between the two groups ($P < 0.05$).

Authors' address: Department of TCM, PLA Jinan Military Region General Hospital, Jinan 250031, Shandong Province

Key words: coronary diseases/Chinese medicinal herb ther, @coronary intervention therapy, @Shu Xin Yi Mai Capsule

(Original article on page 280)

Analysis on Changes of Electric Frequency Spectrum of the Colon in 163 Cases of Abnormal Defecation with Different Syndromes

Lian Zhicheng, Liang Xuefen, Chen Weijing, et al.

Statistical analysis of TCM syndrome differentiation and clinical symptoms were made in 163 cases of diseases of digestive tract. It was found that the patients of abnormal defecation or tendency of abnormal defecation with the hyperactive liver — Qi attacking the spleen, stagnation of liver — Qi due to hypofunction of the spleen, loose stool due to deficiency of the spleen, constipation due to Qi — deficiency, constipation due to Qi — stagnation syndromes accounted for 60% ~ 100%. Electric examination of colon on the body surface and analysis of frequency spectrum found that hyperelectroactivity of low — frequency and high — frequency segment of colon and contractive complex myoelectric hyperactivity in the patients of the hyperactive liver — Qi attacking the spleen; hyperelectroactivity of high — frequency segment of the ascending and descending colon and contractive complex myoelectric hyperactivity and decrease of electric activity of high — frequency segment of the sigmoid colon in the patients of loose stool due to hypofunction of the spleen; obvious decrease of electric activity of low — frequency and high — frequency of the colon and contractive complex myoelectric hyperactivity in the patients of constipation due to deficiency of Qi or Qi — stagnation, but electric activity of the high — frequency segment of the colon and contractive complex myoelectric activity after meal in the patients of constipation due to Qi — stagnation was stronger than that in the patients of constipation due to Qi — deficiency. Electric frequency spectrum of colon can indirectly reflect changes of colon dynamics of different syndromes, and it can partially explain the changes of stool and the mechanism of relative symptoms.

Authors' address: Guangzhou University of TCM, Guangzhou 510405

Key words: cololitis, ulceral / pathophysiology, @electric frequency spectrum of colon

(Original article on page 294)