

## • 临床论著 •

## 人工虫草治疗高脂血症临床报告

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**内容提要** 本文报告用双盲随机安慰剂对照方法观察人工虫草治疗高脂血症 273 例的疗效,结果总胆固醇平均下降 17.5% ( $P < 0.001$ ),总有效率 61.2% ( $P < 0.005$ )。甘油三酯平均下降 9.93% ( $P < 0.05$ ),总有效率 56.7% ( $P < 0.001$ )。高密度脂蛋白胆固醇上升 27.19% ( $P < 0.05$ ),总有效率 76.2% ( $P > 0.05$ ),未发现严重副作用。

冬虫夏草是一种真菌——冬虫夏草菌 (*Cordyceps sinensis* (Berk) Sacc) 寄生在虫草蝙蝠蛾幼虫上所形成的子座与幼虫僵体干燥而得。五十年代美国、日本就进行过冬虫夏草人工培养的研究。1982 年中国医科院药物研究所经过多年研究后,从青海采集的新鲜虫草上分离得到菌株 C<sub>5</sub>4,该菌株经发酵培养所得菌丝体经化学分析及药理作用的研究,认为和天然冬虫夏草基本相同,定名为人工虫草。动物实验说明人工虫草有降血脂及抑制动脉粥样斑块形成作用。1982 年江西国药厂进行了工业发酵培养,并于 1983 年提供临床作降血脂研究,参加本研究的 9 家医院于 1983 年讨论议定了统一研究方案,自 1984 年 5~10 月完成本研究。共观察高脂血症 273 例,包括高胆固醇血症 215 例及/或高甘油三酯血症 245 例。

## 研究对象及方案

采用双盲随机安慰剂对照方法。药物 (每胶囊含人工虫草 0.33g) 及安慰剂为外形相同的胶囊,每日 3 次,每次 3 丸。

## 一、病例选择:原发性高胆固醇血症及

或高甘油三酯血症患者,肝、肾功能及血象正常,可合并高血压、冠心病,排除糖尿病、甲状腺功能低下、肝胆疾病、肾病综合征等继发性高脂血症。

二、服药前一周停用其他降脂药物,空腹取血作血脂测定,作为服药前基础血脂值,同时作肝、肾功能及血常规检查。开始服药后每月复查一次血脂及其他化验。在服药期间,饮食习惯、生活规律和体力活动如常。疗程为 1~2 个月,1 个月后显效或无效可不再观察,如为有效则再观察 1 个月。

三、服药方法:按参加顺序,患者随机分配入安慰剂组或治疗组。每 2 周随诊一次,询问服药情况,有无副作用等。

四、血脂测定指标:血清总胆固醇 (TC)、甘油三酯 (TG) 为各院必须观察指标,高密度脂蛋白胆固醇 (HDL-C) 有条件者亦作为观察指标。

五、疗效评定标准:由于各院测定 TC、TG 及 HDL-C 的化验方法不同,正常值不一,故以治疗前后血脂变化百分率作为疗效评定指标:(1) 治疗组和对照组平均变化百分率作 t 检验。(2) 治疗组和对照组的显效率、有效率及无效率,作  $\chi^2$  检验。显效、有效、无效标准如下:

- |              |              |
|--------------|--------------|
| 1. 北京医科大学一附院 | 2. 南京医学院一附院  |
| 3. 上海瑞金医院    | 4. 浙江医科大学一附院 |
| 5. 苏州医学院一附院  | 6. 上海华山医院    |
| 7. 江西医学院二附院  | 8. 南昌中西医结合医院 |
| 9. 南昌市三院     |              |

	TC	TG	HDL-C
	治疗后下降	治疗后下降	治疗后上升
显效	$\geq 20\%$	$\geq 30\%$	$\geq 20\%$
有效	$\geq 10\%$	$\geq 20\%$	$\geq 10\%$
无效	未达上述指标	未达上述指标	未达上述指标

## 结 果

一、TC: 治疗组平均下降 17.5%,  $P < 0.001$ ; 总有效率 61.2%,  $P < 0.005$  (表 1)。

表 1 人工虫草治疗高胆固醇血症疗效

疗程	组 别	治疗后平均下降%	t检验	显 效	有 效	无 效	总 有 效	$\chi^2$ 检验
1 个月	对照组(93例)	3.72%	$P < 0.001$	10例(10.7%)	13例(14%)	70例(75.3%)	23例(24.7%)	$P < 0.001$
	治疗组(122例)	12.03%		35例(28.7%)	23例(27%)	54例(44.3%)	68例(55.7%)	
2 个月	对照组(45例)	1.17%	$P < 0.001$	6例(13.3%)	7例(15.5%)	32例(71.2%)	13例(28.8%)	$P < 0.005$
	治疗组(85例)	17.5%		34例(40%)	18例(21.2%)	33例(38.8%)	52例(61.2%)	

二、TG: 治疗组平均下降 9.93% (一个月),  $P < 0.05$ ; 总有效率 56.7% (一个月),  $P < 0.001$ 。但二个月时治疗组平均下降百分率及总

有效率虽仍高于对照组, 但差别无显著性 ( $P > 0.5$ ) (表 2)。

三、HDL-C: 治疗组平均上升 27.19% (二

表 2 人工虫草治疗高甘油三酯血症疗效

疗程	组 别	治疗后平均下降%	t检验	显 效	有 效	无 效	总 有 效	$\chi^2$ 检验
1 个月	对照组(118例)	2.31%	$P < 0.05$	15例(12.7%)	6例(5%)	97例(82.2%)	21例(17.8%)	$P < 0.001$
	治疗组(127例)	9.93%		45例(35.4%)	27例(21.3%)	55例(43.3%)	72例(56.7%)	
2 个月	对照组(62例)	6.66%	$P > 0.05$	19例(30.6%)	9例(14.5%)	34例(54.8%)	28例(45.2%)	$P > 0.05$
	治疗组(86例)	9.21%		37例(43%)	6例(7%)	43例(50%)	43例(50%)	

表 3 人工虫草对高密度脂蛋白的作用

疗程	组 别	治疗后平均上升%	t检验	显 效	有 效	无 效	总 有 效	$\chi^2$ 检验
1 个月	对照组(29例)	9.45%	$P > 0.05$	5例(17.2%)	1例(3.4%)	23例(79.4%)	6例(20.6%)	$P < 0.05$
	治疗组(26例)	20.30%		13例(50%)	6例(23%)	7例(26.9%)	19例(73%)	
2 个月	对照组(16例)	10.40%	$P < 0.05$	4例(25%)	4例(25%)	8例(50%)	8例(50%)	$P > 0.05$
	治疗组(21例)	27.19%		13例(61.9%)	3例(14.3%)	5例(23.8%)	16例(76.2%)	

个月),  $P < 0.05$ ; 总有效率 76.2% (二个月),  $P > 0.05$  (表 3)。

四、副作用: 尚未发现严重副作用, 少数患者出现口干, 个别患者恶心、胃部不适。GPT升高者治疗组、对照组各有 2 人, 血小板降低者治疗组 1 人, 对照组 2 人。因副作用而停药者 3 例 (治疗组): 1 例因稀便, 1 例因嗜睡、头昏, 1 例因皮疹。

## 讨 论

控制高脂血症是防治动脉粥样硬化的途径之一。控制高脂血症的有效措施不外饮食控制和降脂药物的应用。目前公认疗效较可靠的降脂西药为烟酸、消胆胺及安妥明等。前二者降脂作用好, 但剂量过大, 副作用多, 始终未能在国内推广应用。安妥明副作用较少, 在国内应用较广泛, 但以降 TG (降 20~25%) 为主,

降胆固醇疗效较差。祖国医药是一个伟大宝库,有降脂作用的中草药见诸报道的为数甚多,但可惜未做严格的双盲随机安慰剂对照的临床研究,其真正降脂作用未能得到客观的证实。有鉴于此,本文对人工虫草的降脂作用作了双盲随机安慰剂对照的临床观察。结果说明人工虫草降低 TC 17.5%,总有效率 61.2%,和安慰剂对照组的差别有高度显著性(P 值分别为  $<0.001$  和  $<0.005$ )。人工虫草服用一个月时可使 TG 下降 9.93%,总有效率 56.7%,和对照组比较, P 值分别  $<0.05$  和  $<0.001$ ,但在服用二个月时,治疗组平均下降百分率和总有效率虽皆高于对照组,但二组差别无显著性(P 皆  $>0.05$ )。说明人工虫草降低胆固醇的疗效较为可靠,可试用以治疗高胆固醇血症,其降

TG 疗效尚待进一步观察。值得注意的是人工虫草尚有提高 HDL-C 的作用, HDL-C 和动脉粥样硬化的发生呈负相关关系,人工虫草的这一作用当可进一步提高其防治动脉粥样硬化的作用。人工虫草在观察期间未见严重副作用,为绝大多数患者所接受,这是其另一重要优点。根据中国医学科学院药物研究所的药理研究,人工虫草除降脂,减轻动脉粥样硬化病变外,尚有促进心肌与脑组织对<sup>86</sup>Rb 的摄取,抑制血小板聚集、抗缺氧、抗炎、镇静等作用。

人工虫草降脂作用,升 HDL-C 的作用机制不明,有待进一步研究。

(本文统计分析主要由郭夏玲同志完成,邓筱安同志参加部分工作,特此致谢。)

## 肌肉注射板蓝根注射液致过敏性休克1例

甘肃省民勤县人民医院内科 徐创贵

**病历摘要** 仲××,女,12岁,学生。因双侧腮腺部弥漫性肿大二天,于1985年5月15日下午来我院就诊,确诊为流行性腮腺炎。单纯肌肉注射板蓝根注射液2ml(系广东郁南制药厂,批文号:粤卫药准字(83)第G3—049号,批号:8307088),7分钟后全身皮肤搔痒发红、腹痛、咳嗽、气短、心悸、头晕及视物不清。10分钟后出现眼球上吊,牙关紧闭、口吐白沫、四肢抽动、小便失禁、不省人事、即刻返回医院抢救。查体:昏迷状态,牙关紧闭,口吐白沫,双眼紧闭,双侧瞳孔散大,对光反射迟钝,四肢及躯干抽搐,全身皮肤充血呈紫红色及风团,呼吸急促,心率136次/分,血压58/40mmHg,脉搏细弱。立即肌肉注射肾上腺素0.5mg,异丙嗪25mg肌肉注射,氢化可的松50mg加入50%葡萄糖液20ml静脉注射及高流量吸氧。12分钟后神志渐清,抽搐停止,呼吸平稳,

两侧瞳孔等圆正常大小,对光反射灵敏,血压升至92/66mmHg,观察4小时完全恢复正常。追问病史,患儿既往无药物过敏史,青霉素、链霉素多次肌肉注射均未发生过敏,但未用过板蓝根注射液,亦无癫痫病史。同时检查板蓝根注射液为棕色液体,无杂质,无浑浊,无沉淀,出厂日期1983年7月。没有过期。为进一步明确过敏原因,于1985年6月29日用板蓝根注射液稀释50倍给患儿做皮内试验,10分钟皮肤出现强阳性反应。

**讨论** 板蓝根注射液近年来临床上大量用于治疗上呼吸道感染、流行性感冒、流行性腮腺炎、流行性乙型脑炎、病毒性肝炎等。不良反应少,文献报道个别患者用药后出现荨麻疹、气短紫绀及唇周水肿。本例患者肌肉注射板蓝根注射液,短时间内发生严重过敏性休克,提示临床在使用该药时应引起注意。

### 《黄帝内经专题研究》一书即将出版

该书设《内经》的研究思路方法、目录版本、运气干支、时空四维、气象地理、体质心理、脏

象经络等20个专题,运用现代多学科知识进行了深入探讨。是一部以多学科知识整体考察研究《内经》的专著,可供广大中医和西学中同志参考。该书由中医研究院王琦主编,山东科学技术出版社1986年1月出版。



## Abstracts of Original Articles

### Treatment of Hyperlipidemia with Cultivated Cordyceps —A Double Blind, Randomized Placebo Control Trial

Shao Geng (邵耕), et al

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Cultivated Cordyceps is the cultivated product of strain Cs 4 isolated from *Cordyceps Sinensis*. Its therapeutic effects on hyperlipidemia were studied by double blind, randomized placebo control trial. Two hundred and seventy-three cases of primary hyperlipidemia were studied. The duration of observation was one to two months. Total cholesterol (TC) blood level was lowered by 17.5% after two months treatment ( $P < 0.001$ ), the percentage of patients who had their TC blood level lowered  $\geq 10\%$  as compared with that in the pretreatment stage was 61.2% ( $P < 0.005$ ). Triglyceride (TG) blood level was lowered by 9.9% after one month treatment ( $P < 0.005$ ). The percentage of patients who had their TG blood level lowered  $\geq 20\%$  as compared with that in the pretreatment stage was 56.7% ( $P < 0.001$ ). HDL-C blood level was increased by 27.2% after two months treatment. The percentage of patients who had their HDL-C blood level increased  $\geq 10\%$  as compared with that in the pretreatment stage was 76.2% ( $P < 0.05$ ). No serious side effect was observed. (Original article on page 652)

### Treatment of Premature Ventricular Beat by TCM: A Clinical Study of 403 Cases

Li Guijun (李桂君), Xu Jingshu (徐敬书)

*Harbin First Hospital Affiliated to Harbin Medical University*

403 cases of premature ventricular beat caused by various causes were treated with traditional Chinese medicine after they had been treated with western medicines without any clinical effects. The rate of disappearance of premature ventricular beat was 34.9%, total cure rate being 88%. Better curative effects were achieved. The effect of treatment was found similar in various diseases. It was observed that the disappearance rate of premature ventricular beat was high in patients with viral myocarditis, rheumatic myocarditis, autonomic nervous dysfunction, with average rate over 40%. The differences were statistically significant. The longer the time, the better the result. The shorter time did the premature ventricular beat last, the better was the curative effect. The disappearance rate was 50.9% within one month. The effect of treatment varied with the onset with statistically pronounced difference.

The success of treatment with traditional Chinese medicines lies in adhering to the mechanism of the disease and compatibility of medicines which should be used selectively and to the point.

(Original article on page 655)

### Clinical and Experimental Studies of Yiqi-Huoxue (益气活血) Therapy in Treating Coronary Heart Disease

Chen Junjie (陈俊杰), Liao Jiazhen (廖家桢), et al

*Dong Zhimen Hospital Affiliated to Beijing College of TCM, Beijing*

Therapeutic effects of Qixue Injection (气血注射液 QXI, consisting of three Chinese herbal medicines: Radix Ginseng, Radix Astragali, Radix Angelicae Sinensis) and placebo (10% dextrose) were compared in 32 patients with stable effort-induced angina by means of single-blind method. The results are as follows: (1) 1 hr. after 20 ml QXI i. v., the treadmill exercise endurance increased from pre-treatment level of  $368.00 \pm 32.75$  ( $\bar{X} \pm SE$ )/sec to  $528.11 \pm 63.43$ /sec post-QXI ( $P < 0.01$ ), the ST segment depression was reduced from  $0.11 \pm 0.007$  mV pre-treatment to  $0.082 \pm 0.008$  mV ( $P < 0.05$ ), the PEPI, PEP/LVET ratio were reduced, the LVETI, SV, CO,  $\Delta D\%$  and EF were increased significantly, which suggested that the left ventricular performance was strengthened; (2) QXI 20 ml in 10% dextrose 250 ml intravenous effusion daily for 2 weeks, after that the treadmill exercise endurance increased from  $319.45 \pm 42.12$  sec to  $583.20 \pm 62.59$  sec ( $P < 0.001$ ), the ST segment depression was reduced from  $0.14 \pm 0.016$  mV to  $0.09 \pm 0.014$  mV ( $P < 0.01$ ), the left ventricular performance was more improved than that in cases treated with single dose of 20 ml intravenously. The rheologic parameters such as whole blood viscosity, plasma viscosity and erythrocyte electrophoretic time as well as the microcirculation in nail improved too after treatment with QXI for 2 weeks; (3) 18 of the 32 patients were selected randomly for placebo control, whom the placebo solution (10% dextrose) 250 ml daily were given intravenously for 2 weeks, the results showed no effect whatsoever. The experiments on rats showed that  $[Na^+ - K^+]$  ATPase activity could be partly inhibited and the volume of nutritious blood supply to myocardium was increased by QXI. (Original article on page 658)