

# 丹参川芎嗪注射液联合曲美他嗪治疗病毒性心肌炎急性期的临床观察

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中图分类号 R542.2\*1 文献标志码 A 文章编号 1001-0408(2016)32-4568-03

DOI 10.6039/j.issn.1001-0408.2016.32.34

**摘要** 目的:观察丹参川芎嗪注射液联合曲美他嗪治疗病毒性心肌炎急性期的临床疗效及安全性。方法:将110例病毒性心肌炎急性期患者按随机数字表法分为对照组和观察组,各55例。两组患者均给予果糖二磷酸钠、高蛋白质饮食等基础治疗。对照组患者给予盐酸曲美他嗪片20 mg, po, tid;观察组患者在对照组基础上给予丹参川芎嗪注射液5 ml加入5%葡萄糖注射液250 ml中, ivgtt, qd。两组患者均连续治疗30 d。比较两组患者临床疗效及心电图S-T段疗效,并观察两组患者治疗前后血清炎症因子[白细胞介素(IL)-6、超敏C反应蛋白(hs-CRP)]、氧化应激因子[丙二醛(MDA)、超氧化物歧化酶(SOD)]、心肌酶谱[肌酸激酶(CK)及乳酸脱氢酶(LDH)]及不良反应发生情况。结果:观察组患者临床总有效率与心电图S-T段总有效率分别为94.5%、90.9%,显著高于对照组的85.4%和81.8%,差异有统计学意义( $P<0.05$ )。两组患者治疗前IL-6、hs-CRP、MDA、CK、LDH、SOD水平比较,差异无统计学意义( $P<0.05$ );治疗后,两组患者IL-6、hs-CRP、SOD、CK及LDH显著降低,MDA显著升高,且观察组明显优于对照组,差异均有统计学意义( $P<0.05$ )。两组患者不良反应发生率比较,差异无统计学意义( $P>0.05$ )。结论:丹参川芎嗪注射液联合曲美他嗪治疗病毒性心肌炎急性期疗效显著,能有效改善患者心电图情况及实验室检查指标,且安全性较好。

**关键词** 丹参川芎嗪注射液;曲美他嗪;病毒性心肌炎;心电图;临床疗效

## Clinical Observation of Salvia Tetramethylpyrazine Injection Combined with Trimetazidine in the Treatment of Acute Phase of Viral Myocarditis

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**ABSTRACT** **OBJECTIVE:** To observe clinical efficacy and safety of Salvia tetramethylpyrazine injection combined with trimetazidine in the treatment of acute phase of viral myocarditis. **METHODS:** 110 patients with acute phase of viral myocarditis were divided into control group and observation group according to random number table, with 55 cases in each group. Both groups received basic treatment as fructose sodium diplosphate, high-protein diet. Control group was given Trimetazidine hydrochloride tablet 20 mg, po, tid; observation group was additionally given Salvia tetramethylpyrazine injection 5 ml added into 5% Glucose injection 250 ml, ivgtt, qd. Both groups received treatment for consecutive 30 d. The clinical efficacy and therapeutic efficacy of electrocardiogram S-T segment were compared between 2 groups. The levels of serum inflammatory factors (IL-6, hs-CRP), oxidative stress factors (MDA, SOD), cardiac enzymes (CK, LDH) and the occurrence of ADR were compared between 2 groups before and after treatment. **RESULTS:** The total effective rate and total effective rate of electrocardiogram S-T segment in observation group were 94.5% and 90.9%, which was significantly higher than those of control group (85.4% and 81.8%), with statistical significance ( $P<0.05$ ). There was no statistical significance in the levels of IL-6, hs-CRP, MDA, SOD, CK and LDH between 2 groups before treatment ( $P>0.05$ ). After treatment, the levels of IL-6, hs-CRP, MDA, SOD, CK and LDH were decreased significantly in 2 groups, while MDA was significantly increased; the observation group was significantly better than the control group, with statistical significance ( $P<0.05$ ). There was no statistical significance in the incidence of ADR between 2 groups ( $P>0.05$ ). **CONCLUSIONS:** Salvia tetramethylpyrazine injection combined with trimetazidine is effective in the treatment of acute phase of viral myocarditis, can effectively improve electrocardiogram and lab indexes with good safety.

**KEYWORDS** Salvia tetramethylpyrazine injection; Trimetazidine; Viral myocarditis; Electrocardiogram; Clinical efficacy

病毒性心肌炎(VMC)是由病毒等感染所引起的心肌弥漫性或局限性病变,早期临床表现为发热、咳嗽、流鼻涕、腹痛及呕吐等,症状极易导致误诊的发生。若不及时治疗,病情可转化至慢性期,导致各种心律失常的发生,部分患者可出现心力衰竭、扩张型心肌病等,直接威胁生命<sup>[1-2]</sup>。丹参川芎嗪注射液是心血管疾病治疗的常用药物,不仅可有效清除体内自由基,减少患者心肌组织的损伤,还能有效减少血栓形成,降低血液黏度,改善心脏局部微循环<sup>[3]</sup>。因此,本研究观察了丹参川芎

嗪注射液联合曲美他嗪治疗VMC急性期的临床疗效及安全性。

### 1 资料与方法

#### 1.1 纳入与排除标准

纳入标准:(1)符合《成人急性病毒性心肌炎的诊断参考标准》<sup>[4]</sup>中相关诊断标准者;(2)结合病毒抗体检测结果,确诊为病毒性心肌炎急性期的患者;(3)年龄 $>18$ 岁;(4)出现心悸、胸痛等症状,且心电图出现异常;(5)病程 $<3$ 个月。

排除标准:(1)合并严重心功能不全、高血压及心律失常等严重心血管疾病者;(2)合并晚期癌症等其他严重疾病者;

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(3)妊娠及哺乳期妇女;(4)对本研究药物严重过敏者。

### 1.2 研究对象

选择2014年5月—2015年5月我院收治的VMC急性期患者110例,按随机数字表法分为观察组与对照组,各55例。两组患者一般资料比较,差异无统计学意义( $P>0.05$ ),具有可比性,详见表1。本研究方案经医院医学伦理委员会批准,患者知情同意并签署知情同意书。

表1 两组患者一般资料比较( $\bar{x}\pm s$ )

Tab 1 Comparison of general information between 2 groups ( $\bar{x}\pm s$ )

组别	n	性别,例		病程,d	年龄,岁
		男	女		
观察组	55	29	26	25.1±7.1	43.3±7.5
对照组	55	28	27	25.5±7.4	43.9±7.9
$\chi^2$		0.690		1.012	0.771
P		0.418		0.297	0.390

### 1.3 治疗方法

两组患者均限制活动、充分休息,采取富含蛋白质及维生素的饮食,给予肌苷注射液400 mg, ivgtt, qd,同时给予果糖二磷酸钠100 ml, qd,滴注速度为5 ml/min。对照组患者口服盐酸曲美他嗪片(北京万生药业有限责任公司,批准文号:国药准字H20065167,规格:20 mg/片)20 mg, qd。观察组患者在对照组基础上给予丹参川芎嗪注射液(贵州拜特制药有限公司,批准文号:国药准字H52020959,规格:5 ml/支)5 ml加入5%葡萄糖注射液250 ml中, ivgtt, qd。两组患者疗程均为30 d。

### 1.4 观察指标

(1)观察两组患者临床疗效。疗效评价标准<sup>[5]</sup>——显效:患者体征与临床症状基本消失,且其血清酶恢复正常;有效:患者体征与临床症状有所改善,且其血清酶恢复正常或基本恢复正常;无效:患者症状与体征均无改善或有加重趋势。总有效率=(显效例数+有效例数)/总例数×100%。(2)观察两组患者心电图S-T段疗效。疗效判定标准<sup>[5]</sup>——显效:患者的心律失常基本消失,且S-T段基本恢复正常;有效:患者心律失常的发作频率降低,且S-T段出现不同程度的恢复;无效:患者心律失常及S-T段无明显改善。总有效率=(显效例数+有效例数)/总例数×100%。(3)观察两组患者实验室检查指标,包括白细胞介素(IL)-6、超敏C反应蛋白(hs-CRP)、丙二醛(MDA)、超氧化物歧化酶(SOD)、肌酸激酶(CK)、乳酸脱氢酶(LDH)水平。(4)观察两组患者不良反应发生情况。

### 1.5 统计学方法

采用SPSS 19.0软件进行数据统计分析。计量资料以 $\bar{x}\pm s$ 表示,采用t检验;计数资料以例或率表示,采用 $\chi^2$ 检验。 $P<0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 两组患者临床疗效比较

观察组患者临床总有效率(94.5%)明显高于对照组(85.4%),差异有统计学意义( $P<0.05$ ),详见表2。

### 2.2 两组患者心电图S-T段疗效比较

观察组患者心电图S-T段总有效率(90.9%)明显高于对照组(81.8%),差异有统计学意义( $P<0.05$ ),详见表3。

### 2.3 两组患者实验室检查指标比较

两组患者治疗前IL-6、hs-CRP、MDA、CK、LDH、SOD水平比较,差异均无统计学意义( $P>0.05$ )。治疗后,两组患者IL-6、hs-CRP、SOD、CK和LDH显著降低,MDA显著升高,且观察组明显优于对照组,差异均有统计学意义( $P<0.05$ ),详见

表4。

表2 两组患者临床疗效比较[例(%)]

Tab 2 Comparison of clinical efficacies between 2 groups [case(%)]

组别	n	显效	有效	无效	总有效
观察组	55	33(60.0)	19(34.5)	3(5.4)	52(94.5)
对照组	55	24(43.6)	23(41.8)	8(14.5)	47(85.4)
$\chi^2$					3.582
P					0.046

表3 两组患者心电图S-T段疗效比较[例(%)]

Tab 3 Comparison of therapeutic efficacy of electrocardiogram S-T segment between 2 groups [case(%)]

组别	n	显效	有效	无效	总有效率
观察组	55	40(72.7)	10(18.2)	5(9.1)	50(90.9)
对照组	55	34(61.8)	11(20.0)	10(18.2)	45(81.8)
$\chi^2$					3.902
P					0.040

表4 两组患者实验室检查指标比较( $\bar{x}\pm s$ )

Tab 4 Comparison of lab indexes between 2 groups ( $\bar{x}\pm s$ )

组别	n	时期	IL-6, ng/L	hs-CRP, mg/L	MDA, nmol/mg prot	SOD, U/mg prot	CK, ng/L	LDH, ng/L
观察组	55	治疗前	54.4±15.1	9.21±0.82	102.1±8.3	290.6±10.8	206.1±37.2	232.1±15.2
		治疗后	38.3±12.2**	4.52±0.43**	215.2±12.2**	145.2±7.1**	110.4±18.1**	95.2±7.2**
对照组	55	治疗前	54.5±16.1	9.29±0.81	104.2±8.5	292.3±10.5	212.7±38.5	234.2±16.1
		治疗后	46.4±14.3*	4.01±0.37*	182.4±7.8*	215.3±8.0*	136.1±21.2*	142.2±9.8*

注:与治疗前比较,\* $P<0.05$ ;与对照组比较,\*\* $P<0.05$

Note: vs. before treatment, \* $P<0.05$ ; vs. control group, \*\* $P<0.05$

### 2.4 不良反应

观察组有3例患者出现恶心、2例患者出现皮疹;对照组有2例患者出现恶心、2例患者出现皮疹。两组患者不良反应发生率(9.1% vs. 7.3%)比较,差异无统计学意义( $P>0.05$ )。

## 3 讨论

目前,对于VMC的治疗,临床多以化学药治疗为主,但疗效一般,恢复较慢,且不良反应较多<sup>[6]</sup>。丹参川芎嗪注射液是中药现代化制剂,其中的重要成分川芎嗪不仅可有效抑制血小板聚集、减少血栓形成、降低血液黏度、改善患者心脏局部微循环,还能够通过对机体炎性介质释放的抑制作用来达到抗炎及促进疾病恢复的目的<sup>[7]</sup>;其另一主要成分丹参则可通过抑制机体白细胞自由基释放等作用机制清除体内自由基,进一步控制炎症的发展,从而减少心肌组织的损伤<sup>[8]</sup>。

本研究结果显示,观察组患者临床疗效及心电图S-T段总有效率均明显高于对照组,提示该方案可有效提高治疗效果,改善患者心电图情况。此外,尽管目前对于VMC治疗的相关研究较多,但对于急性期患者治疗前后氧化应激、炎性因子及心肌酶谱等关键指标的综合性检测较为少见。为此,本研究选取IL-6与hs-CRP、MDA与SOD、LDH与CK分别作为炎性因子、氧化应激及心肌酶谱的代表性指标。本研究结果显示,治疗后两组患者上述指标均得到显著改善,且观察组患者改善程度明显优于对照组,提示丹参川芎嗪注射液的加用可有效提高患者氧化应激水平、缓解炎症的发生及保护心脏<sup>[9-10]</sup>。

综上所述,丹参川芎嗪注射液联合曲美他嗪治疗VMC急性期疗效显著,能有效改善患者心电图情况及实验室检查指标,且安全性较好。但本研究对其具体作用机制探讨并不深入,各项综合性检测指标较少,在后期研究中仍需要开展大量而深入的工作。

### 参考文献

# 芪胶升白胶囊在心肌梗死伴高血压患者治疗中的作用

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中图分类号 R542 文献标志码 A 文章编号 1001-0408(2016)32-4570-04  
DOI 10.6039/j.issn.1001-0408.2016.32.35

**摘要** 目的:观察芪胶升白胶囊对心肌梗死伴高血压患者心脏功能、肾功能、外周血常规、细胞免疫指标的影响及安全性。方法:选择我院心肌梗死伴高血压患者58例,按住院号单双号顺序分为对照组和观察组,各29例。对照组患者均给予降压、调脂和预防心肌梗死的常规治疗,观察组患者在此基础上加用芪胶升白胶囊2.0 g,po,tid。两组患者疗程均为6个月。观察两组患者治疗前后心脏功能、肾功能、外周血常规、T细胞亚群指标水平和不良反应发生情况。结果:治疗前,两组患者以上指标比较,差异均无统计学意义( $P>0.05$ )。治疗后,两组患者左室收缩末期径(LVSd)、左室舒张末期径(LVDd)、室间隔舒张期厚度(IVSd)、左室后壁舒张期厚度(LVPWT)均明显降低,差异有统计学意义( $P<0.05$ );但组间比较差异无统计学意义( $P>0.05$ )。治疗后,观察组患者尿微量白蛋白(MAU)、尿酸(UA)以及对照组患者MAU均明显降低,观察组患者肾小球滤过率(eGFR)明显升高,差异均有统计学意义( $P<0.05$ );且观察组患者以上指标改善程度均明显优于对照组,差异有统计学意义( $P<0.05$ )。对照组患者外周血常规指标和T细胞亚群指标改变程度均大于观察组,差异均有统计学意义( $P<0.05$ )。观察组患者未见明显不良反应发生。结论:芪胶升白胶囊不会影响心肌梗死伴高血压患者的心脏功能,对肾功能具有保护作用,可强化机体免疫功能,安全性较高。

**关键词** 心肌梗死伴高血压;芪胶升白胶囊;心脏功能;肾功能;T细胞亚群

## Effect of Qijiao Shengbai Capsule in the Treatment of Myocardial Infarction Complicated with Hypertension

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**ABSTRACT** OBJECTIVE: To observe the effects and safety of Qijiao shengbai capsule on cardiac function, renal function, peripheral routine blood test and cellular immunity indexes of patients with myocardial infarction complicated with hypertension. METHODS: 58 patients with myocardial infarction complicated with hypertension in our hospital were selected and divided into control group and the observation group, with 29 cases in each group according to the even and odd number of hospitalization order. Control group was given symptomatic treatment as bringing down high blood pressure, regulating blood lipid and preventing myocardial infarction. On this basis, observation group was additionally treated with Qijiao shengbai capsule 2.0 g, po, tid. Treatment course of 2 groups lasted for 6 months. Cardiac function, renal function, peripheral routine blood test, T cell subset and the occurrence of ADR were observed in 2 groups before and after treatment. RESULTS: Before treatment, there were no statistical significance in above indexes between 2 groups ( $P>0.05$ ). After treatment, LVSd, LVDd, IVSd and LVPWT of 2 groups were all decreased significantly, with statistical significance ( $P<0.05$ ); there was no statistical significance between 2 groups ( $P>0.05$ ). MAU and UA of observation group and MAU of control group were decreased significantly after treatment; eGFR of observation group was increased significantly, with statistical significance ( $P<0.05$ ). The improvement of above indexes in observation group were significantly better than in control group, with statistical significance ( $P<0.05$ ). The change of peripheral routine blood indexes and T lymphocyte subset in observation group were greater than in control group, with statistical significance ( $P<0.05$ ). No obvious ADR was found in observation group. CONCLUSIONS: Qijiao shengbai capsule do not influence cardiac function of myocardial infarction patients with hypertension, can protect renal function and strengthen body immunity function with good safety.

**KEYWORDS** Myocardial infarction complicated with hypertension; Qijiao shengbai capsule; Cardiac function; Renal function; T cell subset

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(收稿日期:2016-05-23 修回日期:2016-08-30)

(编辑:黄欢)