Effect of Shenmai Injection on Cardiac Function and Cellular Immunity of Patients with Infantile Viral Myocarditis

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ABSTRACT Objective: To evaluate the clinical effect of Shenmai injection (SMI) on infantile viral myocarditis. Methods: Fifty patients were treated with SMI combined with routine Western medicines, the effects were observed and compared with those treated with Western medicines alone or compound Salviae liquid. Results: The cardiac function and cellular immunity of patients treated with SMI were significantly improved. The effect of SMI was superior to that of control groups. Conclusion: Using SMI as supplementary treatment in treating infantile viral myocarditis was helpful in recovery of cardiac function and cellular immunity.

Viral myocarditis is a common encountered disease caused by invasion of virus in myocardium, characterized by the myocardial necrosis and interstitial monocyte infiltration as main pathologic changes. In this study Shenmai injection (SMI) was used combining with routine therapy of Western medicines in treating patients of viral myocarditis and good effect was obtained. The results were reported as following.

METHODS

Clinical Materials

Fifty patients of viral myocarditis conformed to the diagnostic standard of viral myocarditis worked out in Weihai Meeting, 1994(1), were divided randomly into 3 groups. (1) SMI group: 20 cases, 11 males and 9 females; their ages ranged from 4 to 12 years, with average of 7.8 years; the course of disease lasted from 5 days to 3 months, 51 days in average; the severities of disease were mild in 11 cases, moderate in 8 and severe in 1 case (in reference to the standard on typing myocarditis described in “Practical Pediatrics”). (2) Control A group (Western medicine treated group): 15 patients, 10 males and 5 females; aged 4～13 years, 8 years in average; course of disease ranged 3 days to 4 months, averaging 46 days; severity of them was 7, 7 and 1 of mild, moderate and severe respectively. (3) Control B group (Salviae miltiorrhiza treated group): 15 patients, 10 males and 5 females; aged 4～13 years, 8 years in average; course of disease ranged 3 days to 4 months, averaging 46 days; severity of them was 7, 7 and 1 of mild, moderate and severe respectively.

A normal control group was set up in addition, 20 healthy children enrolled in this group were 10 males and 10 females, aged 2～12 years, 8.9 years in average.

There was no significant difference among the four groups in sex and age.

Treatment

1. Control A group: Treated by routine Western medicines, which included virazole 0.1 g given orally, energy mixture (ATP 20 mg, coenzyme A 100 u, cytochrome C 15 mg and Vitamin C 3 g) given by adding in 10% glucose solution 100 ml drip intravenously once every day for 14 days.

2. SMI group: Besides the routine Western medicines same as former, SMI 20 ml (product of Zhengda Qingchunbao Pharmaceutical Ltd. Co. batch number 941116, each
milliliter containing Radix Ginseng 0.1 g and Radix Ophiopogonis 0.1 g) added into 10% glucose solution 100 ml was given by intravenous drip every day for 14 days.

3. Control B group: Compound Salviae liquid 2 ml (product of the First Pharmaceutical Factory of Shanghai, containing Radix Salviae Miltiorrhizae and Lignum Dalbergiae Odoriferae each 1 g/ml) was added in 10% glucose solution 20 ml for intravenous drip every day for 14 days successively, and the above-mentioned routine Western medicines were also given in the period.

**Observation**

The following parameters of the SMI group and the two control groups were measured during admission and 1 month after treatment. As for healthy control group, the parameters were determined once only.

1. Serum myocardiac enzymes and isoenzymes, including lactic dehydrogenase (LDH), aspartate aminotransferase (AST), creatine phosphokinase (CPK) and its isoenzyme (CPKMB).

2. Cardiac functions including cardiac index (CI), ejection fraction (EF), fractional shrinkage of ventricular minor axis (FS).

3. Measurement of subset of peripheral T-lymphocyte by indirect immunofluorescence method, including CD3, CD4, CD8 and CD4/CD8 ratio.

**Statistical Analysis**

Data determined were all treated with t-test or variance analysis.

**RESULTS**

**Clinical Effectiveness**

Evaluation of effectiveness was according to the standard published in literature\(^3\). The results were: In 20 cases of SMI group, 9 cases were cured, 6 markedly improved, 3 improved and 1 ineffective, the total effective rate was 95.0%. In 15 cases of the control B group, 6 were cured, 4 markedly improved, 3 improved and 2 ineffective, the total effective rate was 86.7%. In 15 cases of the control A group, 5, 3, 3 and 4 cases of cured, markedly improved, improved and ineffective respectively, and the total effective rate was 73.3%. The effectiveness of SMI was higher than that of control A group, the difference between them was significant statistically, \(P < 0.05\). That indicated that the SMI was superior to routine Western medicine in symptom improving.

**Changes on Cardiac Enzymes**

As shown in table 1, results showed before treatment the level of cardiac enzymes in the three groups were all higher than normal, they were lowered in different degree after treatment, as compared with those before treatment, the differences were significant. But no significant difference could be found between groups, indicating that the three therapeutic methods were not very different in effect on cardiac enzymes.

**Effect on Cardiac Functions**

Results listed in table 2 showed that the CI, EF and FS of patients of three groups were all lower than those of healthy control group, \(P < 0.05\). After treatment, although the parameters were all elevated in three groups, only the elevations in SMI group were significant statistically, \(P < 0.05\). This results displayed that the SMI was more effective in improving cardiac functions than the other two therapies.

**Changes of Peripheral T-lymphocyte Subset**

The CD3, CD4 and CD4/CD8 of patients were lower than those of healthy person, \(P < 0.05\). All these parameters were elevated after SMI treatment, as compared with before treatment, \(P < 0.01\); as compared with control A and B groups, \(P < 0.05\), suggesting that SMI had action of improving cellular immunity (see table 3).