Systemic lupus erythematosus (SLE) is a typical refractory rheumatic disease and the current therapy for it is still glucocorticoids, which shows definite effect on the disease, but can lead to such adverse reactions and complications as hyperlipidemia, hypertension, osteoporosis, femoral head necrosis, and secondary infection. It has been found in the authors’ previous study that the combined use of corticoids and TCM therapy for detoxification, removing stasis, and nourishing yin could not only enhance the clinical efficacy in treating SLE, but also show certain advantage in preventing and treating these complications (1-3). This study is conducted to observe the TCM therapy in regulating serum lipids.

METHODS

General Data

All the SLE patients observed were female out- or inpatients from the authors’ hospital visiting or hospitalized from Sep. 1999 to Dec. 2004, with their diagnosis matching the revised version of diagnostic standard issued by the American Rheumatism Association in 1997(4).

The activity phase of the disease in the patients was differentiated in reference to the SLE-DAI scoring (5), i.e., as severe phase when SLE-DAI > 15 scores; as mild-moderate phase when SLE-DAI > 5 scores and <14 scores; and as stable

ABSTRACT Objective: To observe the effect of TCM therapy for detoxification, removing stasis, and nourishing yin on corticosteroid-induced hyperlipemia in patients with systemic lupus erythematosus (SLE), and to investigate its mechanism. Methods: One hundred and seventy patients with SLE were randomly assigned to the integrative medicine group (IM group) and the Western medicine group (WM group), 85 in each group. Also, 30 healthy subjects selected from blood donors were enrolled in the normal control (NC) group. All patients were treated mainly with prednisone, while those in the IM group were given TCM therapy additionally, and the therapeutic course for both groups was 6 successive months. The changes of serum total cholesterol (TC), triglyceride (TG), high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), very low density lipoprotein cholesterol (VLDL-C) and apolipoprotein A (ApoA) were determined and observed. A 2-year follow-up study was carried out in 16 patients of the WM group and 25 of the IM group. Results: Before treatment, no significant difference had been found among the three groups in the serum levels of lipids and lipoproteins. After the 6-month treatment, as compared with the WM group, the IM group showed lower levels of TC, TG, LDL-C, and VLDL-C (P<0.05 or P<0.01) and higher levels of HDL-C and ApoA (P<0.05). A similar effect was also shown by the follow-up study in the IM group (P<0.05 or P<0.01). Conclusion: TCM therapy for detoxification, removing stasis, and nourishing yin can effectively regulate the levels of serum lipids and lipoproteins in preventing and treating SLE patients with corticosteroid-induced hyperlipemia.

KEY WORDS systemic lupus erythematosus, corticosteroid-induced hyperlipidemia, prednisone, TCM therapy for detoxification, removing stasis and nourishing yin

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phase when SLE-DAI ≤ 4 scores.

The following cases were excluded: patients of primary hyperlipidemia; nephrotic syndrome; acute or chronic diseases of the liver and bile; those who took drugs that could induce abnormality of blood lipids such as phenothiazines, β-receptor blocking agents and some anticonciipients lately and those below 18 years old or women in the menopausal, pregnant or lactation period.

All the 170 patients enrolled were randomly assigned equally to two groups by lottery, the integrative medicine treated group (IM group) and the Western medicine treated group (WM group). Among the 85 patients in the IM group, 12 were initially diagnosed and 73 revisited, their age between 19 and 48 years, 29.5 on average, 15 in the course of illness ≤ 3 months, 54 > 3 months and ≤ 2 years, 16 > 2 years, 8.4 months on average; 14 in the severe activity phase, 57 in the mild-moderate phase and 14 in the stable phase, with nine of them complicated with hyperlipidemia.

Among the 85 patients in the WM group, 13 were initially diagnosed and 72 revisited, their age between 20 and 49 years, 30.4 on average, the course of illness ≤ 3 months in 16, > 3 months and ≤ 2 years in 24, 8.3 months on average; 13 in the severe activity phase, 59 in the mild-moderate phase and 13 in the stable phase, with eight of them complicated with hyperlipidemia.

The two groups were not significantly different in sex, age, course and activity of illness, as well as in the levels of blood lipids.

Besides, a group of 30 healthy women selected from blood donors, 19-48 years old, mean 29.6 years was set up as the normal control (NC).

Treatment
Prednisone as the Western medicine applied to the WM group was mainly orally administered, according to the requirements in various circumstances. For patients in the severe active phase, large dosage of prednisone (> 1 mg/kg per day) was given and, if necessary, combined with the standard impulsive therapy of cyclophosphane (0.5 g/m² body surface area, once every 4 weeks); and for those in the mild-moderate phase and stable phase, the middle (0.5 mg/kg per day) and small (< 15 mg per day) dosage was given respectively. The dosage used was gradually reduced after the patients' condition had been improved strictly depending on the regulation.

Besides the same Western medicine as that for the WM group, TCM therapy for detoxification, removing stasis, and nourishing yin was given additionally to the IM group, which consisted of cimicifuga rhizome 9 g, oldenlandia herb 18 g, southernwood 15 g, red peony root 12 g, moutan bark 12 g, rehmannia root 15 g, and turtle shell 12 g, etc. one dose per day, decocted with water and the decoction obtained was taken orally in two portions, once in the morning and once in the evening. The therapeutic course for both groups was 3 months and the observation lasted for two therapeutic courses.

A 2-year follow-up study was carried out in 16 patients of the WM group and 25 patients of the IM group, who were willing to cooperate and capable of periodical visiting for re-check and treatment.

Items and Methods of Observation
Fasting venous blood (5 mL) of patients and control subjects was drawn in the morning before treatment, placed steadily to isolate the serum, which was preserved under -30 °C to determine serum lipids and lipoproteins. The same tests were repeated in patients after the 6-month treatment. For some selected patients, the test was repeated again at the end of the 2-year follow-up.

The indexes, including serum total cholesterol (TC), triglyceride (TG), high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), very low density lipoprotein cholesterol (VLDL-C), and apolipoprotein A (ApoA), were all tested using the CX4 full automatic biochemical analyser produced by Bechman Coulter Co., USA.