Clinical Studies on Liangxue Piyan Granule No. 2 (凉血皮炎 2 号冲剂) in Treatment of Psoriasis

MAO Shu-he (毛舒和), QIN Jian-zhong (秦建中), LI Ying-kui (李颖奎) and XIN Hong (辛红)

Tianjin Changzheng Hospital, Tianjing (300021)

ABSTRACT

Objective: To evaluate the therapeutic mechanism of Liangxue Piyan Granule No. 2 (LPG, 凉血皮炎 2 号冲剂) on psoriasis. Methods: Ninety six patients with psoriasis were treated with LPG, another 32 patients treated with Fufang Qingdai Capsule (FQC, 复方青黛胶囊) were taken as control; clinical comparison was done with experimental studies. Results: The total effective rate of LPG group was 84.7 %, that of the control 71.9 %, there was no significant difference (P < 0.05). However, the recurrence rate of LPG group (3.6 %) was significantly lower than that of the control (21.7 %), P<0.01. Conclusions: LPG could modulate the immune function of the body, by inhibiting directly the proliferation of epidermal cells and the production of interleukin-6.

KEY WORDS Liangxue Piyan Granule No. 2, psoriasis, keratin cell, interleukin-6

Liangxue Piyan Granule No. 2 is an effective preparation derived from Liangxue Xiao feng (凉血清风) decoction with modification, prepared by the Herbal Preparation Department of the Hospital. It was used mainly in treating erythematous dermatitic skin diseases. From February 1994 to August 1995 this preparation was used to treat psoriasis with satisfactory results. Clinical trials and experimental studies were made to evaluate the therapeutic mechanism of Liangxue Piyan Granule No.2 in the treatment of psoriasis, to further study the effect of this medicinal herb on keratin cell proliferation in vitro culture and on the production of interleukin-6 (II-6) by in vitro human peripheral leucocytes.

METHODS

Clinical Data

The diagnostic criteria of psoriasis met with the documental standards(1). All patients were of the blood-heat type psoriasis (symptoms and signs: generalized erythema, scaling dryness of mouth desiring drinking, afraid of hot temperature and itching , dark red colored urine, constipation, red tongue with yellow, dry coating, taut and slippery pulse)(2). All patients were randomized into two groups; 98 were in the LPG group (treated group), 62 males and 36 females; aged 6~64 years, averaging 46 years; duration of illness 14 days to 15 years, averaging 4.15 years; 71 were at the progressive stage and 27 the static stage. Thirty-two patients were in the control group, 24 males and 8 females, aged 9~54 years, averaging 30 years; duration of illness 3 months to 11 years, averaging 3.88 years; 22 were at the progressive stage, 10 at the static stage. Skin lesions of both groups were papules and erythema, generalized and of varying sizes, with silvery scalings. The clinical information of both groups were similar, hence were comparable.

Methods of Treatment

In the treated group was used Liangxue Piyan Granule No. 2, composed of medicinal herbs like Radix Rehmanniae, Radix Scrophulariae, Radix Paeoniae Alba, Rhizoma Imperatae, Fructus Arctii, Gypsum, Rhizoma Anemarrhenae, Herba Schizonepetae, Radix Ledebouriellae, Rhizoma Cimicifugae, Flos Lonicerae, Radix Glycyrrhizae, and Cornu Bubali, produced by the Pharmaceutical Department of the Hospital. Each package was 10 g, containing 10 g of raw herbs. The dosage for adults was one package orally, twice a day, and half the dosage for children. Fufang Qingdai Capsule (FQC) produced by Herbal Pharmaceutical Factory of Yulin District, Shanxi Province was given to patients in the control group, 4 capsules orally for adults, thrice a day, and reduced dosage for children.
The therapeutic course for both groups was 1~3 months before the results were observed.

**RESULTS**

Evaluation criteria of results: Cure, complete resolution of skin lesions; markedly effective, 60% ~ 90% resolution of skin lesions; effective, 30% ~ 60% resolution of skin lesions; ineffective, <30% resolution or no change of skin lesions. Of the treated group, 20 were cured, 48 markedly effective, 15 effective and 15 ineffective, the total effective rate being 84.7%. Of the control, 3 were cured, 8 markedly effective, 12 effective and 9 ineffective, the overall effective rate being 71.9%. The overall effective rates in both groups were not significantly different, however, in the treated group no adverse reaction was found throughout the course of 1~3 months, and 12 patients (37.5%) in the control had gastrointestinal tract reactions like nausea and vomiting. Follow-up half a year later showed 3 (3.6%) of the treated group recurred and 5 (21.7%) of the control group recurred, the recurrence rates were significantly different (P<0.05).

**EXPERIMENTAL STUDIES**

**Effect of LPG on Human Keratin Cell Proliferation Determination**

Human Keratin cell strain (Colo-16) provided by Beijing Medical University, was poured into a 96-well plate in a concentration of 1 x 10^4/well for culture 24 hours. When the cells were adhered to the walls, culture fluids of varying concentrations of LPG (identical prescription of Liangxue Piyan Granule used clinically) was exchanged for continuous culture for 72 hours. The MTT colorimetry method was used in the determination. The results were expressed in (x ± s), and t-tests used to test the significance of difference between groups. The results showed when LPG fluid was 5 mg/ml, 10 mg/ml, 25 mg/ml, 50 mg/ml and 100 mg/ml, the cellular growth rates (%) were respectively 0.93 ± 0.09, 0.80 ± 0.06, 0.57 ± 0.09, 0.22 ± 0.09, 0.25 ± 0.09 and the blank control cell being 1.0; all concentrations except 5 mg/ml had significant differences as compared with blank control (P<0.05, P<0.01).

**Effect of LPG on Peripheral Blood Interleukin-6**

Nine volunteer healthy personnel of the Hospital, 4 males and 5 females, were selected to join in the experiment. Venous blood samples were drawn for whole blood cell cultures following a documented method. Cellular endotoxin (LPS, Sigma production) was added as an inducer of interleukin-6 to a final concentration of 1 μg/ml, then to the experimental well was added LPG to the final concentrations of 50 mg/ml and of 100 mg/ml for culture of 24 hours. The supernatant liquid was collected to determine the IL-6 activity. The results revealed that healthy human peripheral leucocytes secreted IL-6 under stimulation of LPG to the amount of 195.6 ± 63.9 (u/ml); after adding in different dosages of LPG, the IL-6 activity markedly decreased to 104.2 ± 47.2 (u/ml) at 50 mg/ml and 10.6 ± 4.7 (u/ml) at 100mg/ml, showing a certain degree of dosage-dependency.

**DISCUSSION**

In traditional Chinese medicine the pathogenesis of psoriasis is explained as: The invading Wind (pathogenic factor) stays in blood inside the body and expressed on the skin; with prolonged time of invasion Heat is transformed, so the expressions of fights of blood-Heat and Wind-Heat were on the skin forming erythema and scaling. Effects of ingredients of LPG are as follows: Radix Rehmanniae, Rhizoma Imperatae, as assisted by Radix Scrophulariae and Radix Paeoniae Alba, are clearing Heat and cooling blood; Gypsum and Rhizoma Anemarrhenae are clearing Qifen (气分) heat, Fructus Arctii is clearing Heat to soothe the throat; Herba Schizonepetae and Radix Ledebouriellae are relieving exterior symptoms and dispelling Wind. Hence LPG has the effects of clearing Heat and cooling blood, detoxicating and dispelling Wind.

FQC is one of the well-recognized