

Materials and Methods

Study Patients and Samples

15 patients (5 males and 10 females, age 25–61 years) with moderate to severe psoriasis vulgaris (age ≥ 18 , PASI ≥ 10) were enrolled in this study from October 2012 to October 2013 in the Peking University First Hospital. Clinical diagnosis of psoriasis and evaluation of PASI score were performed by dermatologists at Peking University First Hospital. The patients were randomly assigned to one of two treatment groups: adalimumab group (45 mg per injection, group A, $n = 12$) and placebo group (normal saline, group B, $n = 3$) at a ratio of A:B = 4:1. Patients were injected with study drugs at the baseline and every 2 weeks after baseline till week 12. Evaluations were performed at baseline, week 3 and week 12. For healthy controls, serum samples from healthy volunteers were collected.

Blood samples were obtained, and the sera were stored at -80°C until the assay procedure. This study was approved by the Ethics Committee of Peking University First Hospital. Written informed consent was obtained before the treatment from the patients in accordance with the Declaration of Helsinki.

Quantitative Analysis of Psoriasis Body Surface Area

We employed a computer-aided analysis method with manual depiction of the lesions, which has been reported to be a “gold standard” for evaluation of the psoriasis area involved [10]. Briefly, standardized pictures at fixed positions were taken at each visit. After opening the picture in Adobe Photoshop CS5, the “paint brush” tool was used to depict all the lesions (the rigidity of the brush was set at 100%, and the color also was fixed at GREEN). Another fully trained physician reviewed each manually depicted picture to ensure all the lesions were properly covered. After being depicted, the pictures were imported into Image J, and the areas of the depicted plaques were automatically selected and measured. Then the quantitative body surface area (qBSA) was calculated by dividing the psoriasis area involved by the total body area [11].

Assays

The serum levels of SCCA were analyzed by microparticle enzyme immunoassay, operated by the clinical laboratory of Peking University First Hospital using an Abbott ARCHITECT i2000 automated chemiluminescence immunoassay analyzer (Abbott, USA), according to the operational instructions. Briefly, 500 μl of each sample were added to respective reaction cells, and the analysis was automatically performed. The values were read and stored in a computer automatically.

TNF- α in the sera were simultaneously detected by using enzyme-linked immunosorbent assay (human TNF- α platinum ELISA BMS223/4TEN ELISA kit, Bioscience) according to the operational protocol. The serum SCCA and TNF- α were also tested in the samples from the healthy volunteers as normal control.

Statistical Analysis

Comparisons of serum biomarker between the groups (controls and psoriasis patients) were tested for statistical significance with the t test, and the comparisons between different visits with 1-way

ANOVA. Correlations between SCCA with PASI or qBSA were evaluated with the Spearman rank correlation coefficient; all data from different visits were pooled in these analyses. The sensitivity and specificity of serum SCCA levels for detecting psoriasis severity were analyzed by using a receiver-operating characteristic curve. At least 35 tests would be required for an expected sensitivity of 0.90, assuming a 95% confidence interval in sensitivity of ± 0.1 .

Statistical analysis was performed using SPSS software (version 13.0), R3.03. *p* values < 0.05 were considered statistically significant.