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Treatment of Chronic Plaque Psoriasis in Adults by a Corticosteroid-Free Herbal

Combination (Soratinex®):

Final Results of An Open German Trial

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Background

Psoriasis is a major chronic inflammatory skin disease affecting about 5 % to 6 % of the World population.

Chronic plaque psoriasis is characterized by infiltration, redness, pruritus and scaling of the affected skin. Psoriasis can have negative impact on self-esteem, body image and quality of life. Appropriate self-treatment may result in improved self-determination and reduced stress.

German open trial

A single-center open trial has been performed at the Department of Dermatology, Academic Teaching Hospital Dresden, Germany. Soratinex® (Dr Michaels®) herbal complex skin-care products were tested in patients with mild to moderate plaque psoriasis, who did not show further improvement during the last 6 weeks, in an adjuvant setting. Patients ≥ 18 years with proved plaque psoriasis were included randomly. Exclusion criteria were younger age, pustular or exanthematic psoriasis, known allergies to any of the ingredients of Soratinex® and absence of a written agreement.

The tested products consist of a triphasic application: Successive use of Soratinex® (Dr Michaels®) Cleansing Gel, Scalp & Body Ointment and Skin Conditioner.

a) Soratinex® (Dr Michaels®) Scalp and Body Cleansing Gel is an easily applicable topical preparation to decrease parakeratosis.

b) Soratinex® (Dr Michaels®) Scalp and Body Ointment is a yellowish-white ointment with characteristic scent. It decreases inflammation and infiltration.

c) Soratinex® (Dr Michaels®) Skin Conditioner is a white colored, viscous substance with characteristic scent. It improves flexibility and elasticity of the skin.

The anti-psoriatic activity was measured by affected body surface area (BSA) and Psoriasis Area and Severity Index score (PASI). The difference of BSA and PASI before and at the end of treatment was analyzed by paired Student's t-test. A p-value < 0.05 was considered statistically significant. Photographs of the worst lesions were taken. At the end of the 8-week trial, patients were asked about their satisfaction with the treatment. Possible adverse events were registered.

Results

In this open trial, 18 patients were enrolled: 11 males, 7 females (mean age 45.5 ± 12.9 years). The patients suffered from psoriasis on average by 20.5 ± 15.6 years. The initial mean BSA was 10.5 ± 10.9 , the mean PASI was 13.1 ± 7.1 .

At week 8 the mean BSA dropped down to 1.5 ± 1.4 and the mean PASI was 1.0 ± 1.0 . The difference reached statistical significance the reduction of BSA ($p < 0.001$) and PASI ($p < 0.001$), respectively (Figure 1 and 2 and Table 1).

All patients achieved a PASI 50 response, 94.4 % achieved a PASI 75, 66.7 % achieved PASI 90, and 22.2 % achieved a PASI 100. In week 8, 94.4 % of patients were satisfied or very satisfied with the treatment. Clinical examples are shown in figures 3 to 5.

No severe adverse events were recorded.

Conclusions

Herbal products have gained increasing interest in dermatology in general and in psoriasis in particular as a substitute for topical corticosteroids.

The herbal complex skin-care products Soratinex® (Dr Michaels®), which are corticosteroid-free, have shown treatment success and immediate response in the German open trial and in various other trials for mild to moderate plaque psoriasis within 8 weeks (Table 2). The data have been validated for children and adults. Altogether more than 2,500 psoriasis patients were analyzed in these studies.

The mode of action of the herbal complex is explained by significantly reduced production of potentially damaging reactive oxygen species and other anti-inflammatory activities.

The efficacy and the safety profile recommend herbal complex for self-treatment in the outpatient setting.

Table 1: Mean reduction of BSA and PASI (\pm standard deviation, SD)

| Parameter | Week 0 | Week 2 | Week 4 | Week 6 | Week 8 |
|-----------|-----------------|---------------|---------------|---------------|---------------|
| BSA | 10.5 \pm 10.9 | 6.0 \pm 6.0 | 8 \pm 3.1 | 2.5 \pm 1.9 | 1.5 \pm 1.4 |
| PASI | 13,1 \pm 7.1 | 3.2 \pm 4.0 | 1.8 \pm 4.9 | 1.6 \pm 2.5 | 1.0 \pm 1.0 |

Table 2: Overview on studies of herbal complex in psoriasis

| Authors & Year | n | Response | | Remarks |
|-------------------------|-----|-----------------------|------------|--|
| | | >PASI 75 | PASI 50-75 | |
| Wollina et al. 2016 | 722 | 67.0% | 14.1% | multi-centered open trial, adults |
| Hercogová et al. 2016 | 270 | 81.5% | 9.7% | open trial, children & adults |
| Hercogová et al. 2016 | 286 | 40.25 | 26.9% | multi-centered open trial, children & adults |
| Fioranelli et al. 2016 | 30 | 16.6% | 40.0% | open trial, adults |
| Gianfaldoni et al. 2016 | 62 | 48.3% | 17.7% | open trial, adults |
| França et al. 2016 | 75 | 66.7% | 18.3% | open trial, adults |
| França et al. 2016 | 142 | PASI reduction of 86% | | randomized, placebo-controlled, double-blind trial |

Hercogová et al. 2016 30 77% 7% controlled trial vs. steroid

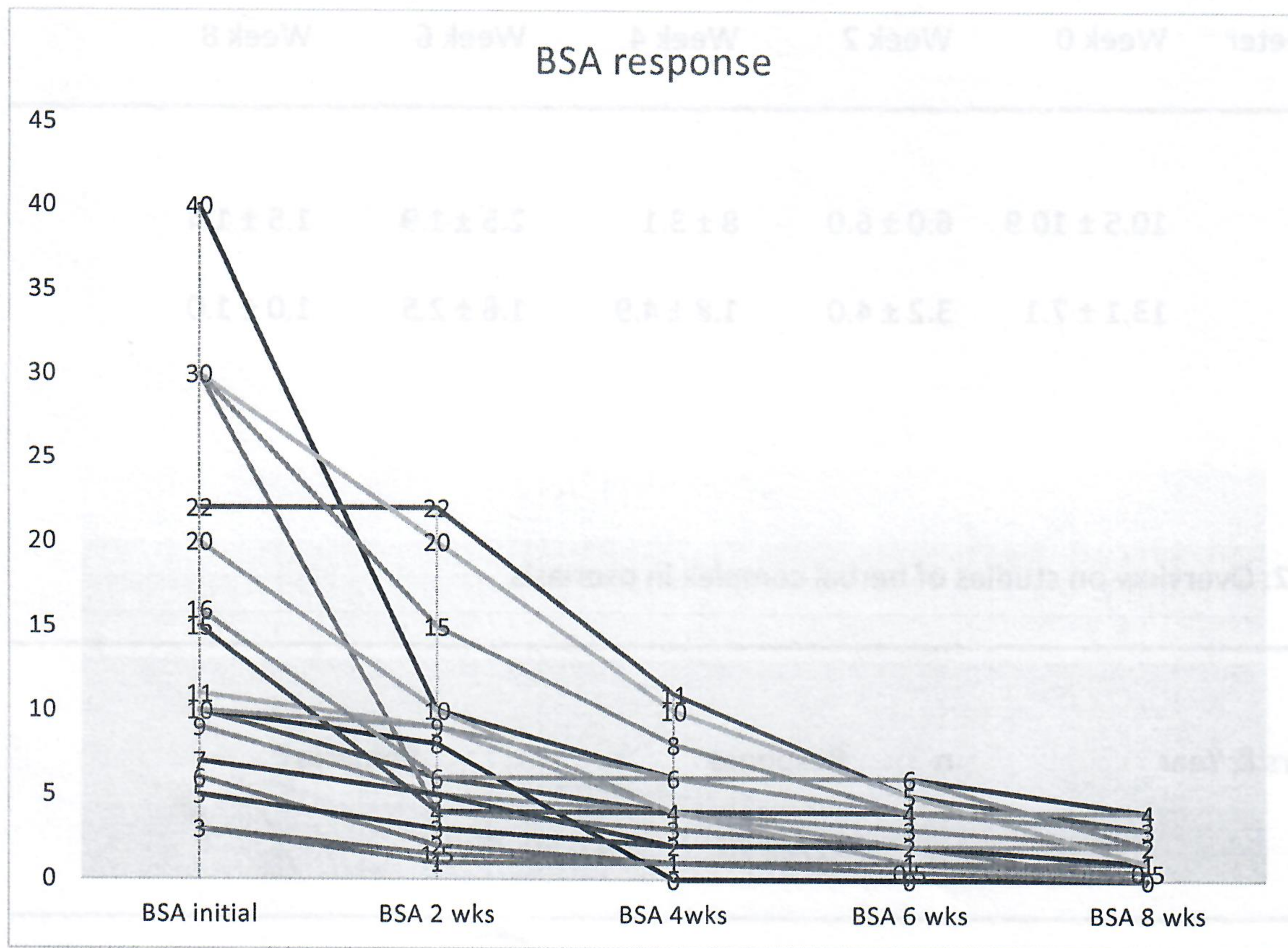


Fig. 1. Involved body surface area (BSA) before and during treatment with herbal complex.

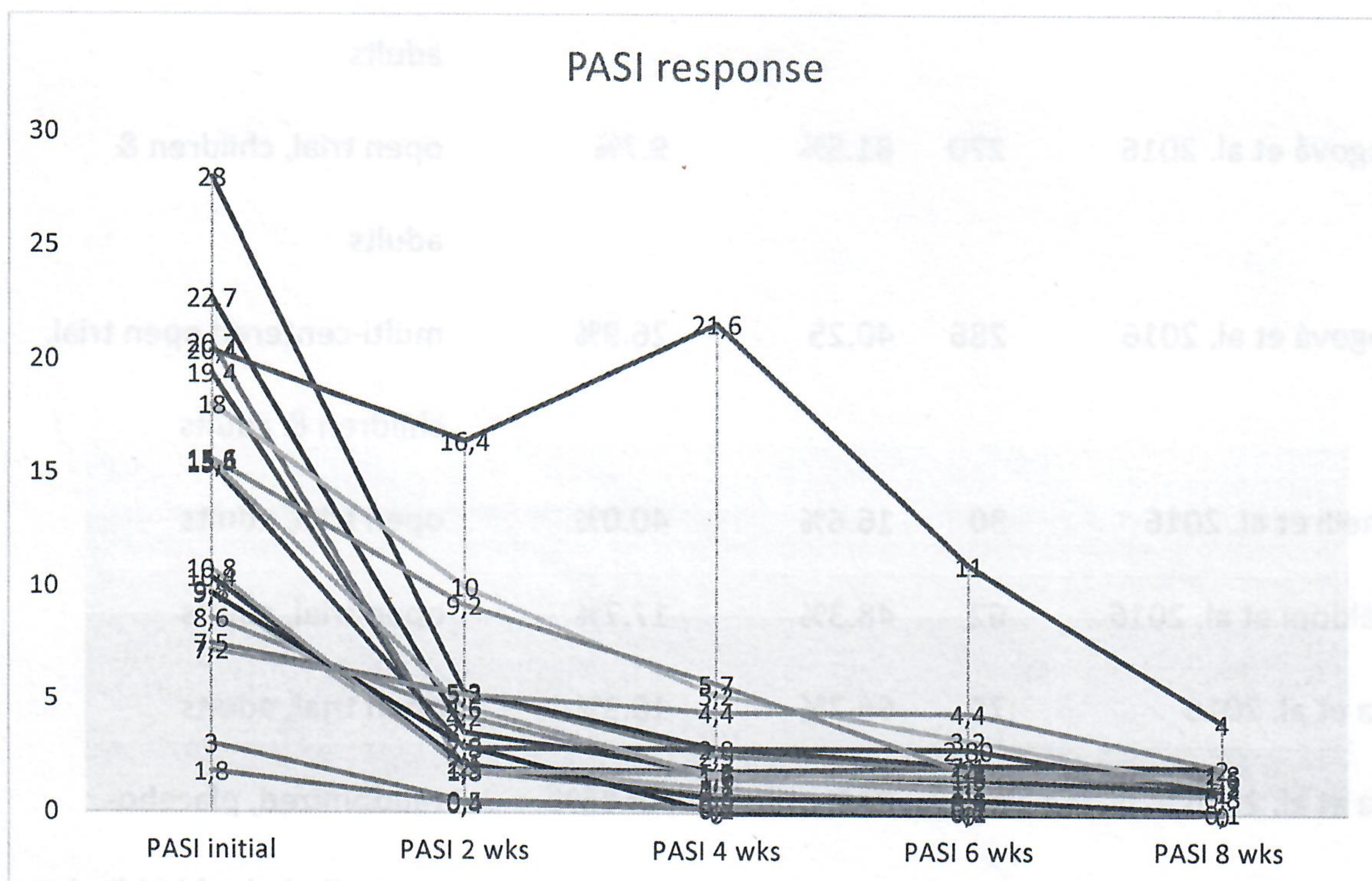


Fig. 2. PASI response before and during treatment with herbal complex.

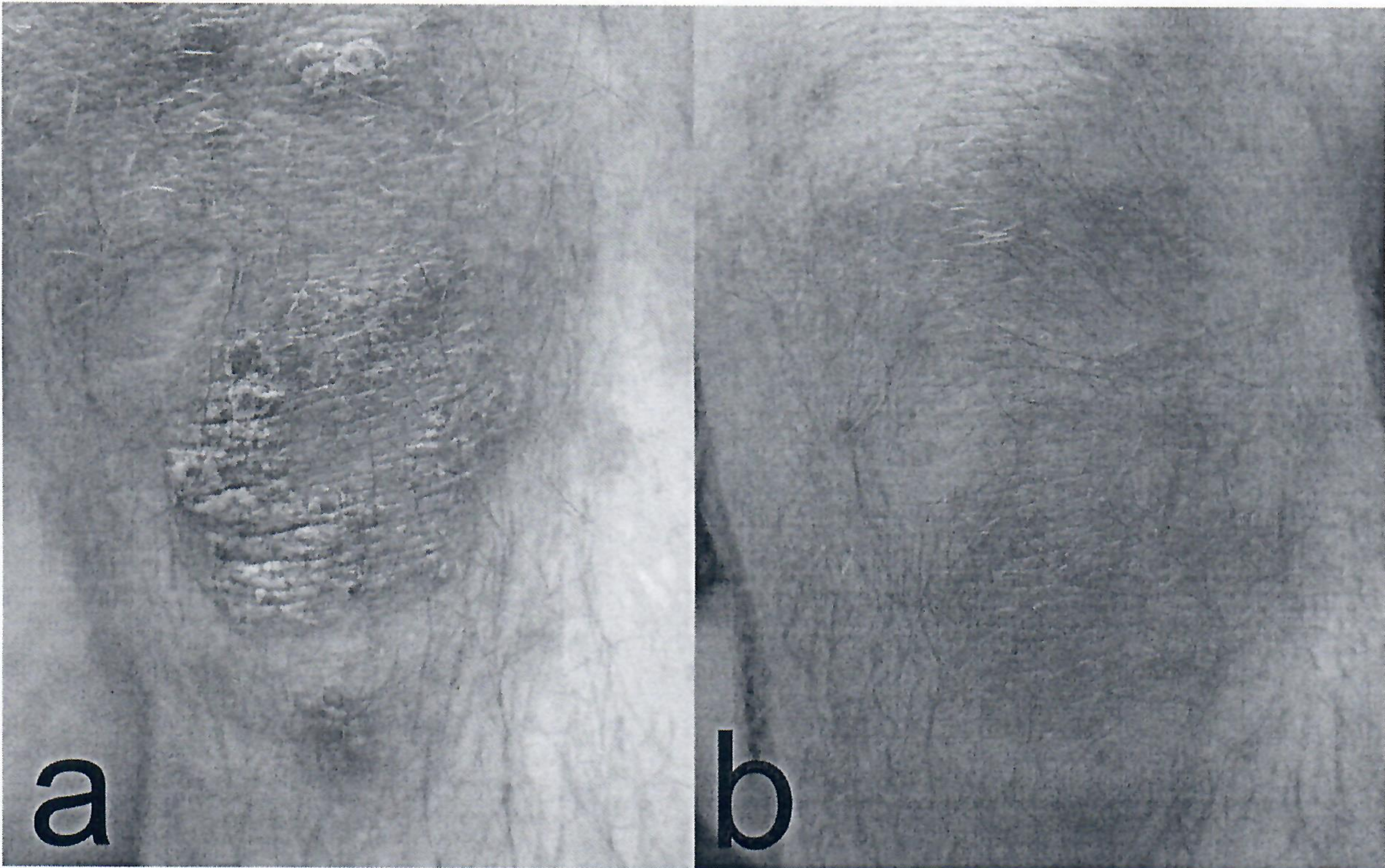


Fig. 3: 51-year-old male patient before (a) and after 8 weeks (b) treatment with herbal complex.

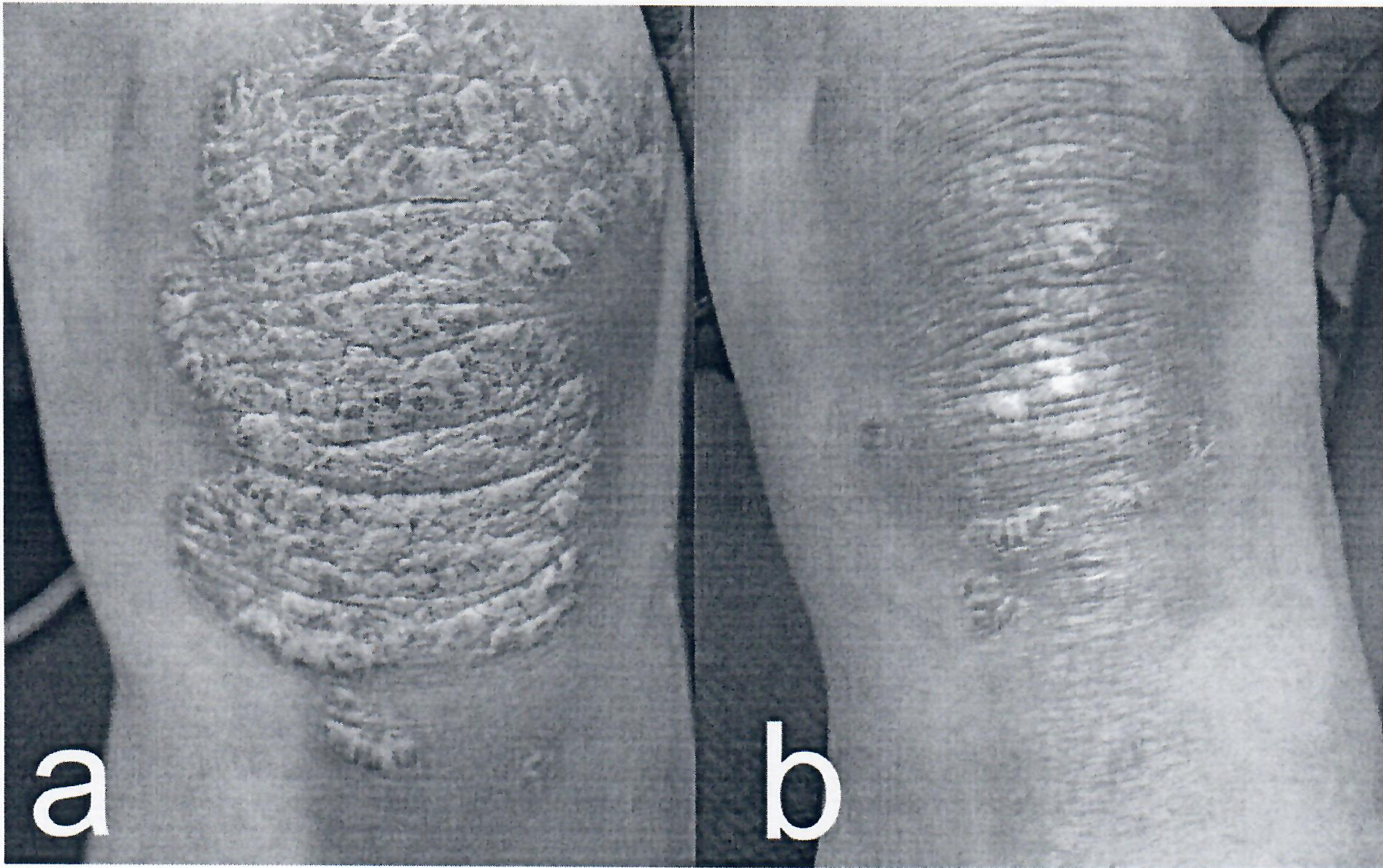


Fig. 4: 58-year-old male patient before (a) and after 8 weeks (b) treatment with herbal complex.

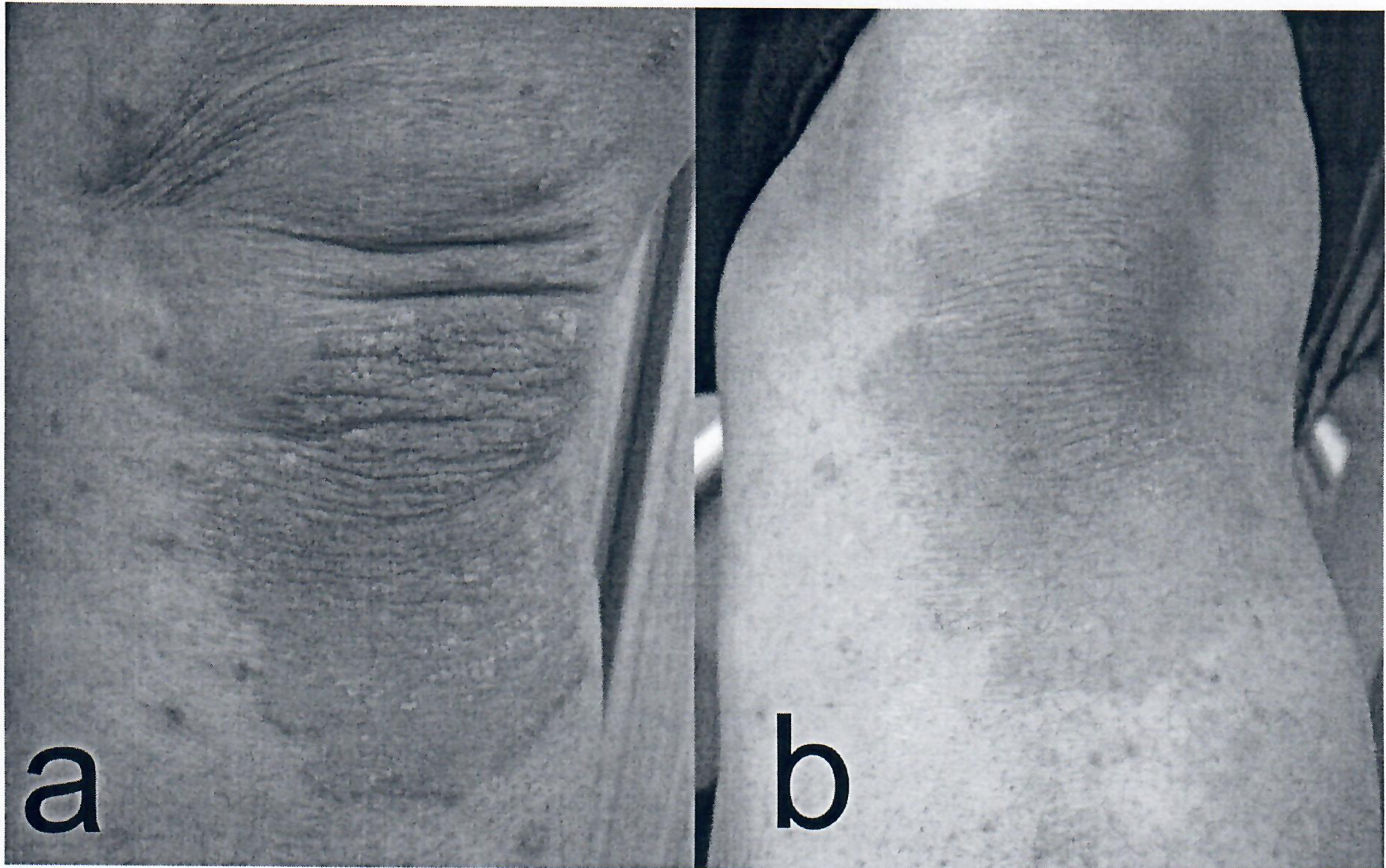


Fig. 5: 46-year-old female patient before (a) and after 8 weeks (b) treatment with herbal complex.

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