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AN OPEN-LABEL STUDY OF HERBAL TOPICAL MEDICATION (PSIRELAX) FOR PATIENTS WITH CHRONIC PLAQUE PSORIASIS.

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ABSTRACT

Psirelax is an herbal topical medication indicated for the treatment of patients with psoriasis. Its efficacy was determined in an open-label study in 22 patients (15 men, 7 women) with a mean age of 48.9±11.8 years suffering from chronic plaque psoriasis. The patients were treated by application of Psirelax twice a day for a period of 4 weeks. Clinical assessment was performed using the Psoriasis Area and Severity Index (PASI) and the Beer-Sheva Psoriasis Severity Score (BPSS). The results shows that Psirelax was well tolerated and there no local or systemic side effects. There was 59% reduction in PASI, from a mean of 5.9 ± 4.0 before treatment to 2.4 ± 2.4 after treatment (p<0.001). In 8 patients (36%) PASI decreased in more than 75% (PASI75). In 16 patients (73%) PASI decreased in more than 50% (PASI50). Application of Psirelax was associated with a decrease in disease severity, as assessed by the patients and physicians. It is concluded that Psirelax treatment was well tolerated in patients with chronic plaque psoriasis.

Key Words: Psoriasis, Herbal treatment, complementary medicine, alternative medicine

INTRODUCTION

Psoriasis is a chronic disorder which occurs in 2% of the general population. Patients with psoriasis have decreased quality of life and high rates of depression. Patients with mild to moderate psoriasis are usually treated with topical medications whereas systemic therapy is usually reserved to patients with moderate to severe disease.

In recent years, complementary and alternative medicine has been used by patients with psoriasis. In a study from Israel, Ben-Arye *et al.,* (2003) showed that many patients with psoriasis use herbal treatments.

Psirelax is herbal topical medication indicated for the treatment of patients with psoriasis. The formulation includes natural ingredients such as quince seeds jelly, base cream, anti-oxidants (e.g. palm tree oil, wheat germ oil), skin softening agents (e.g. sweet almond oil), absorption aids (e.g. jojoba oil), tissue regenerating and protecting agents (e.g. grape seed oil), preservatives (e.g. paraben) and thickening agents (e.g. bee wax). Preliminary uncontrolled observations have shown a beneficial effect of Psirelax in some patients with psoriasis. The primary objective of this study was to determine the efficacy of Psirelax topical treatment in patients with chronic plaque psoriasis.

MATERIALS AND METHODS

This was an open-label study to evaluate the tolerability of Psirelax treatment. Approval for the study was obtained from an institutional review board and written informed consent was obtained from each patient prior to enrolment into the study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and GCP guidelines.

Population: The study included men and women between 18 and 75 years old with a clinical diagnosis of psoriasis. All patients were in good general health and were free of any disease or physical condition which might have impaired the evaluation of plaque psoriasis. Excluded from the study were women who were pregnant, lactating, planning to become pregnant or women of child-bearing potential who have not successfully been using the same medically acceptable contraceptive methods over the previous 3 months, patients who used topical anti psoriatic therapy on the areas to be treated within one week prior to the beginning of the study, patients who received systemic biologic therapy to treat psoriasis within 12 weeks prior to the beginning of the study, patients who received systemic psoriasis therapy within 4 weeks prior to the beginning of the study, patients who received phototherapy within 4 weeks prior to the beginning of the study, patients with a recent history (within past 12 months) of alcohol or substance abuse, patients with a history of noncompliance to medical regimens and patients who had serious or unstable medical or psychological conditions that in the opinion of the Investigator could compromise the subject's safety or successful participation in the study.

Treatment: Psirelax is herbal topical medication indicated for the treatment of patients with psoriasis. Psirelax includes the following ingredients: 5%-15% quince seeds jelly, 10%-40% natural base cream (e.g. bee wax, cera alba), 55%-75% mixture of natural anti-oxidants (e.g. vitamin E, wheat germ oil, safflower oil), natural skin softening agents (e.g. sweet almond oil, sesame oil), natural absorption aids (e.g. jojoba oil, vegetable squalene), natural tissue regenerating and protecting agents (e.g. grape seed oil, sunflower oil), natural preservatives (e.g. paraben, tea trea essential oil, thyme essential oil, grapefruit seed extract, vitamin E) and natural thickening agents (e.g. alovera, medicinal vaseline, coconut oil, guar gum, palm tree oil).

Study design: The study was designed as an open-label study and included efficacy and safety assessments at weeks 2 and 4 after enrollment in the study.

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Efficacy assessments: Clinical response was measured using psoriasis area and severity index (PASI) and the Beer-Sheva Psoriasis Severity Score (BPSS). The PASI ranges from 0 to 72 and is based on an equation that combines the percentage of affected body surface area (BSA) with an assessment of the extent and severity (erythema, desquamation and induration) of the psoriatic lesions at four anatomic sites (head, upper extremities, trunk and lower extremities).

In addition to the PASI, the BPSS was also used. This is a novel tool for the ambulatory assessment of patients with psoriasis which has been described previously (Cohen *et al.,* 2005; Cohen *et al.,* 2007; Cohen, *et al.,* 2008). In the current study BPSS version IIB was used which has a total number of 21 items, 12 patient's items (with 6 scale marks within the patient's categories: 0-5), 9 physician's items (with 5 scale marks within the physician's categories: 0-4). The score of BPSS, version IIB is the sum of the patient's items and physician's items and ranges between 0–96. The percent of score assessed by the patient is 62.5% as compared to 37.5% of the of score which is assessed by the physician.

Additional objective of this study was an assessment of the tolerability of Psirelax which was achieved by assessing local and systemic side effects at each visit.

Sample Size Calculation: A calculation assuming a 40% response rate in patients treated with Psirelax demonstrated that a target sample size of 20 patients is sufficient to demonstrate preliminary effectiveness of treatment.

Statistical analyses: Safety analyses were carried out on all patients who received Psirelax. Analyses of efficacy measures were based on the intent-to-treat cohort. Descriptive statistics were used to summarize efficacy end-points. Results of continuous variables are shown as means ± SD. To analyze statistically significant differences in continuous parameters before and after treatment Wilcoxon test were used. Dichotomous variables were analyzed using Fisher exact tests. Logistic and linear regressions were used for multivariate analyses. P values ≤ .05 were considered statistically significant.

RESULTS

The study included 22 patients (15 men, 7 women) with a mean age of 48.9±11.8 years. Psirelax was well tolerated and there no local or systemic side effects. All patients included in the study completed the 4 week follow-up period. The screening process identified 3 other patients that were excluded from analysis for technical reasons.

Application of Psirelax was associated with a decrease in disease severity, as assessed by PASI and BPSS. There was a 59% reduction in PASI, from a mean of 5.9 ± 4.0 before treatment to 2.4 ± 2.4 after treatment (p=0.0001) (Table 1).

The reduction in PASI was pronounced in women as compared to men (57% of women achieved PASI75 as compared to 26% in men), and showed a tendency for better results in patients younger then 40 years (PASI75 was 40% in patients younger than 40 years, 36% in patients between 40-60 years and 33% in patients above 60 years) (Table 2).

In 8 patients (36%) PASI decreased in more than 75% (PASI75). In 16 patients (73%) PASI decreased in more than 50% (PASI50) (Table 3). There was a 23% reduction in BPSS, from a mean of 19.0 ± 9.0 before treatment to 14.7 ± 9.1 after treatment (p=0.012) (Table 1).

TABLE 1. ASSESSMENT OF PSORIASIS SEVERITY BEFORE AND AFTER PSIRELAX TREATMENT, USING PASI AND THE BEER-SHEVA PSORIASIS SEVERITY SCORE (BPSS)

Patients' assessment	Before Psirelax treatment				After Psirelax treatment				p-value
	Mean	SD	Min	Max	Mean	SD	Min	Max	
General assessment	2.05	1	1	4	1.71	1.01	0	4	**0.02**
Pruritis	1.59	1.3	0	5	1.43	1.16	0	4	0.699
Scalp involvement	1.27	1.58	0	5	1.05	1.17	0	4	0.347
Face involvement	0.55	0.96	0	4	0.45	0.91	0	3	0.483
Hands involvement	1.82	1.47	0	5	1.23	1.19	0	4	**0.09**
Palms involvement	0.59	0.96	0	4	0.41	0.8	0	3	0.314
Chest involvement	0.68	0.99	0	3	0.55	0.86	0	3	0.276
Trunk involvement	0.59	1.1	0	4	0.5	0.8	0	3	0.18
Legs involvement	2.32	1.52	0	5	1.68	1.55	0	4	**0.03**
Soles involvement	1	1.41	0	4	0.55	0.74	0	2	0.205
Nails involvement	0.86	1.2	0	4	0.64	1	0	3	**0.014**
Genital involvement	0.68	1.32	0	5	0.5	1.1	0	4	0.461
Patients' total score	13.9	7.8	3	30	10.5	7.5	2	28	0.109
Physians' assessment									
General assessment	1.52	0.6	1	3	1.42	0.61	1	3	0.317
Scalp involvement	0.41	0.73	0	3	0.18	0.5	0	2	**0.059**
Face involvement	0	0	0	0	0.05	0.21	0	1	0.317
Chest and abdomen involvement	0.41	0.67	0	2	0.29	0.46	0	1	0.317
Back involvement	0.41	0.73	0	2	0.36	0.66	0	2	0.317
Upper limb involvement	1.41	0.8	0	3	1.05	0.65	0	3	**0.005**
Palms involvement	0.05	0.22	0	1	0.05	0.21	0	1	1
Lower limbs involvement	1.27	0.88	0	3	1	0.82	0	3	0.014
Soles involvement	0.05	0.21	0	1	0	0	0	0	0.001
Physicians' total score	5.5	2.2	2	10	4.2	2.3	1	10	**0.001**
BPSS	19.4	9.3	8	40	14.7	9.1	4	34	0.012
PASI	5.9	4	1.6	16.1	2.4	2.4	0.3	10.4	<0.001

TABLE 2. ASSESSMENT OF PSORIASIS SEVERITY BEFORE AND AFTER PSIRELAX TREATMENT, USING PASI AND THE BEER-SHEVA PSORIASIS SEVERITY SCORE (BPSS), STRATIFIED BY GENDER.

	Before Psirelax treatment				After Psirelax treatment				p-value
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Men									
Patients'total score	15.6	7.9	3	30	12.5	8.3	3	28	0.197
Physicians'total score	6.1	2.3	3	10	4.8	2.5	2	10	**0.006**
BPSS	21.7	9.5	9	40	17.3	9.8	6	34	**0.048**
PASI	6.5	4.3	1.8	16.1	2.8	2.7	0.6	10.4	**0.001**
Women									
Patients'total score	10.3	6.9	4	21	6.4	3.1	2	12	0.307
Physicians'total score	4	1.4	2	6	2.9	1.4	1	5	0.084
BPSS	14.3	7.1	8	25	9.3	3.2	4	14	**0.104**
PASI	4.7	3.2	1.6	10.4	1.6	1.3	0.3	3.5	**0.018**

TABLE 3. PERCENT OF PATIENTS WHO ACHIEVE 50% AND 75% REDUCTION IN PASI AND BPSS STRATIFIED ACCORDING TO AGE AND GENDER (N=22).

	PASI50	PASI75
Gender		
All	16/22 (73%)	8/22 (36%)
Male	11/15 (73%)	4/15 (26%)
Female	5/7 (71%)	4/7 (57%)
Age		
All	16/22 (73%)	8/22 (36%)
<40 yrs	3/5 (60%)	2/5 (40%)
40-60 yrs	11/14 (78%)	5/14 (36%)
>60 yrs	2/3 (665)	1/3 (335)

DISCUSSION

In the current study we tested the safety and efficacy of a novel herbal topical medication (Psirelax) for patients with chronic plaque psoriasis. Psirelax includes natural ingredients such as quince seeds, sweet almond oil, jojoba oil, grape seed oil and bee wax.

The results of the study show that Psirelax was well tolerated. No adverse events were observed. Application of Psirelax was associated with a decrease in disease severity, as assessed by the patients and physicians. Psirelax contains a unique blend of natural herbal oils and seeds that have effects of oiling and emulsifying the skin with possible anti-inflammatory and immune modulating activities.

Psirelax ingredients include sunflower seed oil which contains high levels of essential fatty acids (e.g. linoleic acid) that have skin barrier-enhancing properties. A sunflower oleodistillate has been shown to increase the epidermal key lipid synthesis and to reduce inflammation *in vitro* and in animal models. Sunflower oleodistillate has been shown to activate peroxisome proliferative-activated receptor-alpha *in vitro*, which stimulates keratinocyte differentiation, improve barrier function, and enhance lipid metabolism in the skin. Some studies have shown the efficacy of sunflower seed oil in atopic dermatitis (Eichenfield *et al.,* 2009).

Complementary medicine includes therapeutic modalities that derive from traditional and philosophical systems of medicine, which view health and disease in the context of human totality of body and mind. The effect of Psirelax observed in our patients demonstrates the beneficial effect of this new complementary medication in patients with psoriasis.

Psirelax also contains wheat germ oil was which was never studied in the treatment of psoriasis. A study showing improvement in rheumatoid arthritis patients taking wheat germ, proposed that a modulation of apoptosis is responsible for the effect (Balint *et al.,* 2006). Other natural oils used in Psirelax include sweet almond oil and jojoba oil. The oil form makes these natural oils effective as emollient and moisturizer for human skin (Natural medicines comprehensive database). Sweet almond oil has a weak anti bacterial effect and may be used as demulcent, while jojoba oil has healing effects on acne, sunburn, and chapped skin. Small scale studies have proven that sweet almond oil and jojoba oil has a beneficial effect in patients with psoriasis by the skin's inflammatory process. Patients treated with the oils showed clinical improvement after treatment (Meyer *et al.,* 2008; Natural medicines comprehensive database, 2011).

Quince is used topically as a compression for injuries, inflammation of the joints, injuries of the nipples, and skin lacerations. A topical lotion is used to soothe the eyes. Sweet almond is used topically as an emollient for chapped skin, to soothe mucous membranes and as a weak antibacterial (Natural medicines comprehensive database, 2011). Applications of 5% extract cream of Aloe Vera (Barbadensis) topically 3 times daily for 4 weeks significantly improved and increased the resolution of psoriatic plaques compared to placebo (Klein & Penneys, 1988). Aloe extract cream seems to reduce desquamation, erythema, infiltration and generate significant improvement of lesions in a double blind placebo controlled studies (Syed *et al.,* 1996; Paulsen *et al.,* 2005).

Beeswax is used by honey bees to build their honeycomb cells. Beeswax provides protective effects to human skin against contact irritants and allergens (Zhai *et al.,* 1998; Teichmann *et al.,* 2006). The benefits of beeswax for psoriasis treatment are supported by the findings of Al-Waili, (2003) who studied the healing effect of the combination beeswax, honey, and olive oil on patients with psoriasis and atopic dermatitis.

It is possible that the outcome of Psirelax treatment observed in the current study is attributed to placebo effect or to the lubrication affect of Psirelax formula. However, these preliminary results are encouraging and suggest that a double blind placebo controlled study should be conducted to further assess the efficacy of Psirelax in patients with psoriasis.

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