



Psori Silk in Mild to Moderate Psoriasis: Randomized Phase I-II Study

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Abstract

Objectives: To assess efficacy and safety of Psori Silk in mild to moderate plaque psoriasis.

Material and Methods: Randomized double blind Psori Silk versus vehicle, 12 weeks treatment and 4 weeks follow up study. The primary endpoint was Modified PASI 50 at week 12, while the secondary endpoint included life quality assessment by DLQI.

Results: The Psori Silk group consisted of 23 patients with 34 lesions treated versus 22 and 36 in the vehicle group, respectively. Modified PASI 50 seen in 59% versus 22.7% of patients in the active and the vehicle group, respectively ($p < 0.001$). Mean 33% DLQI improvement was observed in 65.2 versus 27.2% ($p < 0.001$) of active medicine and vehicle group patients, respectively. Mild and temporary discomfort at the application site was observed in 39 and 23% of the active medicine and vehicle group patients, respectively.

Conclusions: Psori Silk appear to be effective and safe treatment for mild to moderate plaque psoriasis.

Keywords: plaque psoriasis; natural medicine; Psori Silk; Modified PASI 50; DLQI

Introduction

Around 80% of patients with psoriasis have mild to moderate (localized) disease [1]. For those patients, topical agents are usually the first-line treatment, with corticosteroids most used. Despite their effectiveness, quick relapse and/or rebound are common following discontinuation of those conventional topical treatments [2,3]. Thus, continuous therapy is often needed, however, not feasible due to lack of compliance and/or the possibility of the side effects, especially concerning corticosteroids [4]. Hence, the use of complementary medicine in general and plant-origin topical treatment in particular in up to 69% of the patients [5] is a common practice, and mostly on their own initiative. However, so far most of the issue related studies have shown a limited efficacy, inconvenience of use, significant adverse events [5-7] and/or a non-randomized design [8-10]. The purpose of the present study was to examine the efficacy and the safety of the novel Psori Silk multi fruit and vegetable compound in mild to moderate plaque psoriasis.

Methods and Patients

The study was approved by the institutional Helsinki board committee. Eligible patients were at least 18 years of age with mild to moderate plaque type psoriasis for at least 6 months before entering the study. The exclusion criteria included treatment by

any type of phototherapy, and/or topical anti psoriatic drug 4 weeks prior to entering the study and/or systemic or biologic agents 3 months prior to entering the study. Patients assessed at weeks 0, 2, 4, 8, 12 and 16. At week 0 two representative lesions on different anatomical areas selected. Patients randomized, to either the PSG or the vehicle. To assure double blinding, the PSG and the vehicle gels were indistinguishable regards to texture, smell and visual appearance. Either gel application performed for 12 weeks, followed up by 4 weeks observation without any kind of treatment or lubrication. Patients stopping treatment due to non-compliance during the first two weeks were excluded from the final analysis. The primary efficacy endpoint was Modified PASI (MPASI) 50 at week 12, as previously described [11]. Secondary efficacy endpoints were investigator global assessment (IGA), patient's global assessment (PGA), and DLQI, all at week 12 [12]. Relapse at the final visit on week 16 was defined, as return of MPASI to the baseline value, while rebound as an increase above baseline MPASI. At week 0 visit, PSG and the vehicle gels monitored for immediate adverse events, while patients applied the assigned products to the chosen lesions and remained in the clinic for 45 minutes. Delayed adverse events were assessed every follow up visit. Statistical intent to treat analysis performed using the R Studio software, version

3.5.1 (2018-07-02) for all the efficacy endpoints. The differences between the PSG and the vehicle groups analyzed using two-tailed one sample T-tests.

Results

Forty-five included patients' (70 treated lesions), demographics and mean baseline MPASI by treatment group are shown in Table 1. The main reason for dropout during the first two weeks were the lack of significant improvement in 13 vs 36.3% of the PSG and vehicle patients, respectively. Thus, 28 (62%) patients and 45 lesions (64%) were available for the final analysis. There was no significant difference between the treatment groups regarding age, gender, weight, disease duration and treatment selected lesions number and/or baseline MPASI. MPASI 50 was achieved in 68.2 vs 4.3% of the lesions in PSG and vehicle groups, respectively ($P < 0.0001$). As shown in Table 2, among the individual MPASI ingredients, the lesion's extent, erythema and desquamation decreased significantly, while Infiltration and erosion showed

a pronounced non-significant decrease. All those compared to borderline significant reduction in erythema and infiltration only in the vehicle group. The significant mean MPASI reduction was seen in both groups, however, highly more pronounced in the PSG treated group. At week 12, the IGA score < 1 was achieved in 22.8 vs. 8.3% ($P \leq 0.01$) in PSG and vehicle treated lesions, respectively. Similarly, at week 12, the PGA score < 1 was achieved in 31.4 vs. 11.4% ($P \leq 0.01$) in PSG and vehicle treated lesions, respectively. As shown in Table 3, there was a significant improvement in DLQI and most of its individual components in the PSG group only. At week 16, relapse occurred in single lesion in either of the PSG and the vehicle groups. Rebound occurred in a single lesion from the vehicle group, only. Thirty-nine and 23% of the PSG and the vehicle treated patients, respectively, reported mild warm feeling and/or erythema at the application site. The first lasting for 5-10 minutes and the latest resolving up to the second week of treatment in most patients. No other side effects were observed.

Table 1: Study population characteristics by the treatment group.

	Vehicle	Psori Silk	p
0.77	13	16	Males (n)
0.88	9	7	Females (n)
0.88	51.7±2.8	51.4±3.2	Mean age (years)
0.55	76.7±3.8	80.6±4.2	Mean weight (kg)
0.77	19.1±2.9	18.6±3.2	Mean psoriasis duration (years)
0.88	36	34	Treated lesions (n)
0.88	11.2±1.4	11.7±1.3	Mean baseline MPASI

Table 2: Baseline and 12th week MPASI by treatment group.

MPASI components	Vehicle 16 patients (23 lesions)		p	Psori Silk 12 patients (22 lesions)		p
	Baseline	Week 12		Baseline	Week 12	
Extent (0-6)	4.6	4.6	1	4.5	2.4	0.001
Desquamation (0-4)	2.1	1.5	0.9	2.2	1.1	0.05
Erythema (0-4)	2.6	1.5	0.05	2.7	0.9	0.03
Erosion (0-4)	0.05	0.02	0.9	0.26	0.04	0.0001
Infiltration (0-4)	1.8	0.7	0.05	1.9	0.2	0.03
Mean MPASI (0-22)	11.5	8.32	0.01	11.56	4.64	0.0001

Table 3: Baseline and 12th week DLQI by treatment group.

DLQI components	Vehicle 16 patients (23 lesions)		P	Psori Silk 12 patients (22 lesions)		P
	Baseline	Week 12		Baseline	Week 12	
Symptoms & feelings	2	2.2	0.9	2.3	1.5	0.07
Daily activities	1.2	1.2	1.0	2.3	1.2	0.05
Leisure	1.1	1	1.0	2	0.7	0.04
Work and school	1.3	1.1	0.9	1.2	1.2	1
Personal relationships	0.7	0.9	0.9	1.6	0.8	0.07
Treatment compliance	1.1	1.1	1.0	1.3	0.7	0.09
Total	7.4	7.5	1.0	10.7	7.1	0.001

Discussion

The two cardinal reasons for patients choosing naturally based topical remedies for plaque psoriasis lesions are the partial efficacy of the traditional ones and the perceived lower risk of the herbal therapies [7,13]. In spite of this public need, the latest have not been successful so far in becoming the front lines choice by most of the physicians or pharmacists. That is mainly due to the fact, that the studies regarding natural plant topical therapies have mostly shown inconclusive/ disappointing results due to limited efficacy, inconvenience of use, adverse events 6-8 and/or non-randomized design [9-11]. All the above, studied the effect of the different single whole plants or their extracts. Thus, the food synergy concept bolstered by the lack of effect of many isolated compounds, as summarized by the American National Institutes of Health [14]. There are studies indicating that combination phytochemical remedies lead to improved additive therapeutic results [15,16] and especially phenols and polyphenols from a combination of the whole (including peel, pulp and seeds) fruits and vegetables [17-20]. Some of those combinations were shown for their various anti-inflammatory actions [17,21,22]. *Gloriosa superba* and *catharanthus roseus* extracts have shown a negative synergistic effect on IFN- γ -induced keratin 17 expression in HaCaT human keratinocytes [23]. Taken along the synergistic effects of both soluble free and bound phytochemicals (present only in whole or extract form of fruits and vegetables) on the anti-proliferative activity [19,24] makes those compounds potentially applicable for psoriasis. According to this concept, Psori Silk was composed of two gels (PSG), each containing a specific variety and concentration of 11 different whole (including pulp, peel and seeds) fresh fruits and vegetables. The first, Psori Silk Calm gel intended for soothing/softening and removing scales, and the second, Psori Silk gel is responsible for the anti-inflammatory action. Due to the low (<500 Da) molecular weight of its mixture fruits and vegetables along the high-water content, the PSG mixture has an easy permeation through the stratum corneum, [25] thickened in the psoriatic process. A preliminary open-label uncontrolled trial of Psori Silk use in 27 plaque psoriasis lesions showed promising results (unpublished observation: E. Ben-Ari, Research Unit, Secret of Youth Ltd. 2015). The purpose of the present study was to evaluate the efficacy and safety of PSG in patients with mild to moderate plaque psoriasis in a randomized double-blind setting. PSG was significantly more effective than the vehicle gel in achieving MPASI 50, along with IGA, PGA and DLQI major improvements. Essentially, only single relapse and/or no rebound shown in our study for four week follow up. The therapy was tolerated extremely well, excluding 3-5 minutes duration of mild warm sensation and slight erythema at the application site during the first 2 weeks of application. The present study, though including relatively small number of patients and treated lesions, shows that in mild to moderate plaque psoriasis, the unique Psori Silk combination of whole fruits and vegetables is effective and safe. Further, larger scale clinical studies are needed, including long-term maintenance use and the possible combination of the later with a short initial topical corticosteroid addition to increase the efficacy and compliance.

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