

Sea buckthorn extract in the treatment of psoriasis

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Abstract. Psoriasis is one of the most common chronic dermatological conditions, with a strong impact on patients' quality of life. Currently, psoriasis benefits from conventional therapy with a high rate of adverse effects and an increase in non-compliance and self-medication of patients. As such, there is a need to pinpoint low-adverse effects and accessible remedies for this condition. Our single-blind, placebo-controlled study assessed the effect of sea buckthorn extract on psoriasis lesions in previously untreated patients. Our results showed an improvement in Psoriasis Area Severity Index (PASI) scores and in Dermatology Life Quality Index (DLQI) scores when compared to the baseline values, as well as at the 4- and 8-week time marks for the lesions treated with sea buckthorn extract. By contrast, the measurements for the placebo treated lesions showed no alteration at the 4-week mark, and significant worsening at the end of the trial. These findings provide a solid, optimistic base for the in-depth research of sea buckthorn as an adjuvant or a component in psoriasis care protocols.

Introduction

Psoriasis is a chronic inflammatory disease and it is considered one of the most prevalent autoimmune (1) conditions, affecting 1.5-4% of the world's population, steadily increasing in incidence and prevalence (2). Clinically, psoriasis presents as round, erythematous, well-delimited plaques which may be covered with silvery scales, having a significant effect on quality of life in patients (3).

Psoriasis is a condition with a complex etiopathogenesis (4), classically managed with immunosuppressive therapy and

biologic agents. These therapies, however effective, are plagued by long-term adverse effects (5) impacting long-term treatment (6,7), decreasing compliance and increasing self-medication (8).

Complementary and alternative medicine (CAM) is a popular option in self-medicating patients suffering from psoriasis, with 30-40% of patients using or having used these remedies in combination with conventional psoriasis therapy (9). However, the lack of standardization and research on the safety profiles and effects of these products leaves CAM classed as 'anecdotal evidence' among dermatologists (5). With these products increasing in popularity, further research is needed to clarify their effects and, hopefully, provide new options to patients suffering from psoriasis.

The purpose of our study was to analyze the effects of the sea buckthorn extract on patients diagnosed with psoriasis. Pending analysis of its content, sea buckthorn was found to contain more than 190 compounds, including vitamins, fatty acids, amino acids, phenols, terpenes and tannins (10,11). This analysis, combined with anecdotal evidence from traditional medicine, makes sea buckthorn extract a valid candidate for our research.

Materials and methods

Preparations. In order to obtain the sea buckthorn extract, the fruit of the White Sea Buckthorn was selected. The fruits were washed, then dried at 45°C, mixed and fragmented into large granules, then processed using the high pressure method in order to obtain the oily extract used in this study. The obtained oily extract was suspended in corn oil, and the placebo preparation was made of pure corn oil. The preparation of the final products, both the sea buckthorn preparation and the placebo, were prepared at the Department of Clinical Pharmacology of the 'Iuliu Hatieganu' University of Medicine and Pharmacy (Cluj-Napoca, Romania).

Subjects. The study included 10 patients, who met the following inclusion criteria: i) patients were over 18 years of age; ii) patients presented a Psoriasis Area Severity Index (PASI) score between 1-12; iii) patients presented psoriatic lesions on both right and left sides of the body; iv) patients were not under systemic or topical treatment

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Table I. Progression of PASI score throughout the experiment, in sea buckthorn-treated lesions.

Sea buckthorn PASI score	Initial value	At 4 weeks	At 4 weeks (%)	At 8 weeks	At 8 weeks (%)
1	5	3	40.00	3	60.00
2	4	5	-25.00	5	125.00
3	7	4	42.86	2	28.57
4	3	1	66.67	1	33.33
5	2	1	50.00	1	50.00
6	4	1	75.00	2	50.00
7	5	3	40.00	2	40.00
8	2	1	50.00	1	50.00
9	3	2	33.33	2	66.67
10	2	1	50.00	1	50.00

Table II. Progression of PASI score throughout the experiment, in placebo-treated lesions.

Placebo PASI score	Initial value	At 4 weeks	At 4 weeks (%)	At 8 weeks	At 8 weeks (%)
1	4	5	-25.00	6	150.00
2	5	7	-40.00	9	180.00
3	4	4	0.00	5	125.00
4	4	3	25.00	3	75.00
5	3	3	0.00	5	166.67
6	1	2	-100.00	5	500.00
7	3	4	-33.33	6	200.00
8	2	1	50.00	3	150.00
9	3	4	-33.33	3	100.00
10	1	1	0.00	3	300.00

for psoriasis; v) patients were not suffering from any other comorbidities; vi) patients were willing to participate in the study and signed an informed consent form. The design of this study involving human subjects was approved by the Ethics Committee of 'Iuliu Hatieganu' University of Medicine and Pharmacy (Cluj-Napoca, Romania), and it is in accordance with the Declaration of Helsinki. All patients provided written informed consent prior to participation in this study.

The patients were selected and underwent an initial consultation with PASI and Dermatology Life Quality Index (DLQI) assessment, followed by reassessment after 4 and 8 weeks of treatment. The patients were supervised by a Dermatology specialist at the Department of Dermatology of the County Emergency Hospital (Cluj-Napoca, Romania).

The patients were each provided with a herbal extract preparation and a placebo preparation, delivered in containers which were marked as 'right' or 'left', without mentioning the ingredients in each batch. The patients were instructed to apply the Sea buckthorn extract (containers marked as 'right') on the psoriasis lesions on the right side of their bodies and the placebo (containers marked as 'left') on the psoriasis lesions on the left side of their bodies. The patients were instructed to apply the formulations twice daily and return for reassess-

ment at 4 and 8 weeks of treatment. All 10 patients enrolled completed the 8 weeks of therapy.

The following parameters were analyzed for the three measurements (initial, 4 and 8 weeks of treatment): i) PASI score for sea buckthorn-treated psoriatic lesions; ii) PASI score for the placebo-treated psoriatic lesions; iii) global PASI score evaluating placebo and sea buckthorn treated lesions; and iv) DLQI assessment of quality of life.

Statistical analysis. The data obtained were collected in a Microsoft Excel (Microsoft, Redmond, VA, USA) form and subsequently analyzed using SPSS v 2.0 (SPSS Inc., Chicago, IL, USA), considering a confidence interval of 95% and a statistical significance at $P < 0.05$. Comparisons between the groups, regarding the different visits, were performed using the two-way repeated measures ANOVA followed by Tukey's post hoc test. The study was designed as a single-blind, placebo controlled, randomized study.

Results

General. The results regarding the PASI score for sea buckthorn-treated psoriatic lesions are presented in Table I, and the

Table III. The progression of the global PASI score, throughout the experiment.

Global PASI score	Initial value	At 4 weeks	At 8 weeks
1	9	8	9
2	9	12	14
3	11	8	7
4	7	4	4
5	5	4	6
6	5	3	7
7	8	7	8
8	4	2	4
9	6	6	5
10	3	2	4

placebo-treated lesions in Table II. The global PASI scores are depicted in Table III and the results from the DLQI assessment are presented in Table IV.

Changes in parameters after four weeks of treatment. After 4 weeks of treatment the sea buckthorn-treated lesions showed statistically significant improvement ($P=0.003$) compared to the initial value, while on the placebo treated side the PASI score remained statistically stable ($P=0.223$). For the DLQI values there was a significant improvement during the first 4 weeks of treatment ($P=0.001$). After analyzing the global PASI there were no statistically significant changes ($P=0.132$). The data showed that the percentage of PASI score was significantly superior on the Sea buckthorn treated side than on the placebo side ($P=0.001$).

Changes in parameters after eight weeks of treatment. After eight weeks of treatment a statistically significant improvement of the PASI score for the sea buckthorn-treated lesions ($P=0.008$) was noted in comparison to the initial PASI score. The placebo-treated lesions noted a statistically significant worsening of the PASI score ($P=0.007$) when compared to the initial value. The global PASI did not show statistically significant changes ($P=0.132$). The DLQI showed an improvement when comparing the values after eight weeks of treatment to the initial value ($P=0.002$), but it did not improve significantly when comparing it to the DLQI values after four weeks of treatment ($P=0.678$). After 8 weeks of treatment the percentage of PASI score improvement was superior for the Sea buckthorn extract treated lesions when compared to the placebo treated lesions.

Changes in the analyzed parameters over the entire treatment period. When analyzing the changes over 8 weeks of treatment, the collected data showed statistically significant changes in the PASI score for the sea buckthorn-treated lesions ($P=0.001$), for the placebo treated lesions ($P=0.003$), and for DLQI values. Statistically significant differences were found as well when comparing the Sea buckthorn treated lesions to the placebo treated lesions.

Table IV. The progression of quality of life, as measured by DLQI, throughout the study.

DLQI	T0	T4	T8
1	7	7	5
2	12	10	11
3	10	7	5
4	8	5	3
5	3	3	2
6	5	2	4
7	7	6	6
8	6	3	4
9	6	4	4
10	4	1	2

Discussion

The results of our study show that the use of sea buckthorn extract was correlated with an improved PASI in treated lesions, compared to the baseline (initial evaluation), 4-week mark and while compared to placebo. The placebo group noted a worsening of the psoriasis lesions during the 8-week trial. The overall PASI score did not vary, as it was influenced by both the improved, treated side as well as the worsened, placebo-treated lesions. The DLQI score showed an improvement over the 8-week treatment. This enables us to report that the sea buckthorn extract proved useful in the treatment of psoriasis lesions in our experimental group.

Sea buckthorn is traditionally considered a panacea, with reported anti-atherogenic, hypoglycemic, anti-aggregant, antioxidant, antibacterial, anti-ulcer, anti-inflammatory, antihypertensive and anticancer properties. Studies have described beneficial effects of sea buckthorn in hepatic disease, wound healing (12), atopic dermatitis and radiation protection (10,11,13). However, we did not identify studies exploring the efficacy of this extract when applied topically to psoriasis lesions.

Our study was conducted on newly-diagnosed patients, which ensured that the obtained progress was a result of our experimental therapy, not of previous treatment. All patients were diagnosed with mild to moderate psoriasis; patients with severe forms of psoriasis were excluded, as to minimize the interference of other systemic therapies with the results of the sea buckthorn preparation (14-16). All 10 patients completed the 8 weeks of therapy and follow-up successfully, suggesting that this form of herbal therapy is well accepted and tolerated by patients on a subjective level.

While offering conclusive results, our study does present a series of limitations. The sample size taken into consideration was small (10 subjects), with follow-up being relatively short: eight weeks. Furthermore, considering the small PASI scores, the obtained results may be amplified in their effect: For instance, for a PASI of 2, an increase to 3 reflects as a 50% worsening, whereas in larger PASI scores, 1 point of difference will reflect in a less powerful manner.

Another source of bias resides in the study design due to logistical reasons, only a single-blind study design was feasible

at this point, which introduces the concern of observer bias towards the lesions.

One strong aspect of the study lies in the formulations used; the sea buckthorn oily extract is orange in color, and has a distinctive scent. To camouflage this, we suspended the oily extract in corn oil, a very pungent, bright orange oil. The placebo preparation was pure corn oil, and undistinguishable from the sea buckthorn oil.

As such, our results constitute a preliminary, encouraging finding on the subject of CAM in psoriasis. Studies on larger groups of subjects, with more elaborate measurements and spanning longer time intervals would be useful in confirming our findings, potentially leading to the consecration of sea buckthorn as either a primary treatment in psoriasis, or an adjuvant in combination with conventional medication.

Exploring the effect of sea buckthorn on psoriasis lesions may benefit from more techniques which have proven themselves as valuable tools for skin monitoring, such as dermoscopy or *in vivo* reflectance confocal microscopy (17,18). Furthermore, applying other scores such as PGA alongside PASI and DLQI would improve the accuracy of the study.

The results of our study offer the base incentive for further studying this extract, which could offer affordable, low-adverse-effects and accessible therapies for the increasingly stringent problem of psoriasis.

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Availability of data and materials

The datasets used during the present study are available from the corresponding author upon reasonable request.

Authors' contributions

ANB, JS and RFI contributed to the conception and design of the study, the questionnaires, the acquisition and interpretation of data. RP elaborated the formulations and assisted in the patient follow-up together with ANB. SV was responsible for analysis of data. ANB and RFI contributed to writing the manuscript. ADB and ADT were responsible for design of the study, data analysis and critical revision of it for important intellectual content. All authors read and approved the final version of manuscript.

Ethics approval and consent to participate

The present study was approved by the Ethics Committee of 'Iuliu Hatieganu' University of Medicine and Pharmacy (Cluj-Napoca, Romania), and written informed consent was obtained from all patients.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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