

**OBSERVATIONAL STUDY WITH PSORADIN
CAPSULES, PLUS A TOPICAL CREAM WITH
BORAGE OIL, IN MILD-MODERATE PSORIASIS**

INTRODUCTION

Psoriasis is an immunological disease based on inflammatory symptoms and hyperplasia of the skin; it has a chronic and relapsing trend and it affects, in the western world, about 3-4% of the population.

It is a disease with a strong negative impact on quality of life. It appears in various forms and doesn't exist today a definitive therapy, but it can be controlled by appropriate treatment strategies. Recent studies have demonstrated that patients with psoriasis have a high prevalence of metabolic disorder, such a hypertension, diabetes and hyperlipidemia.

Different studies have demonstrated that some substances can be helpful to integrate therapy and/or produce positive evidence of symptomatic picture of psoriasis. All vitamins that have a role to maintain the health of skin, the vitamins A and the vitamin D give positive results in the treatment of some cases of psoriasis. Some researchers have discovered that vitamin E is effective in the treatment of psoriasis. Also the integration with zinc (10 to 20 mg daily) and omega 3, with the aim to reduce inflammation, may help to improve the symptomatic picture of skin, integrating the appropriate therapies.

Psoradin is the first nutraceutical based on omega 3, Vitamin A, E, D, Zinc, Selenium and Chromium, useful to supplement the diet of the patient with psoriasis. Therefore we propose to verify the efficacy of the product through a controlled clinical study.

OBJECTIVE

To evaluate the efficacy of Psoradin associated with topical therapy with borage oil (Obasol) in a homogenous group of patient by sex, age and clinical features (mild-moderate psoriasis, interesting between 10 and 20% of body surface area) for a period of 3 months. The study was conducted in the private surgery of doctor. In the study were involved 13 dermatology (7 in the Veneto, 1 in the Toscana, 1 in the Lazio and 4 in the Campania) who have treated 10 patients each.

PATIENT AND METHODS

129 patient affected by various form of psoriasis were included in the study; 72 males, 57 females, aged between 13 and 83 years.

35 smokers, 61 non-smokers and 33 unspecified.

Type of injuries: 81 desquamative erythematous psoriasis, 27 plaque psoriasis, 9 guttate psoriasis, 4 psoriasis vulgaris, 4 hyperkeratosis, 2 inverse psoriasis, 1 palmar psoriasis, 1 pustular psoriasis.

The patients have taken a daily dose of 3 tablets of Psoradin for 12 week (equivalent to a daily total of 600 mg of linolenic acid; 300 mg of EPA; 201 mg of DHA; 10 mg of Vitamin E; 800 mg of Vitamin A; 5 mg of Vitamin D; 11,25 mg of Zinc; 150 mg of trivalent Chromium; 75 mg of Selenium), associated with a topical therapy with an emollient cream, Obasol (borage oil) 2 times a day.

The minimum dosage of Omega 3 recommended by OMS varies from 300 mg to 500 mg of EPA and DHA at day. The patients didn't received in contemporary topical and/or systemic therapies potentially active on the psoriasis, or phototherapy or exposure to the sun or UV lamps. For each patient was filled a data card with controls at time 0, 6 and 12 weeks. Were measured both objective data such the presence of erythema, infiltration and desquamation, that those subjective such a itching and burning, through a simple score with a scale from 1 to 3.(mild-moderate-severe). The measurement were made by the same operator to avoid inter-individual variability in the evaluation.

RESULTS

The data study were collected:

- At time 0 → Enrollment
- At time 6 → After 6 week
- At time 12 → After 12 week

No patient dropped out the study due to the tolerability.

Survey symptoms for total patient at time T0

	NO SYMPTOMS	MILD	MODERATE	SEVERE
ERYTHEMA	0	28	89	12
INFILTRATION	3	44	65	17
DESQUAMATION	1	25	81	22
ITCHING	12	34	60	23
BURNING	23	66	35	5

Survey symptoms for a total patient at time T6

	NO SYMPTOMS	MILD	MODERATE	SEVERE
ERYTHEMA	4	71	54	0
INFILTRATION	8	67	50	4
DESQUAMATION	5	65	56	3
ITCHING	23	73	29	4
BURNING	34	77	16	2

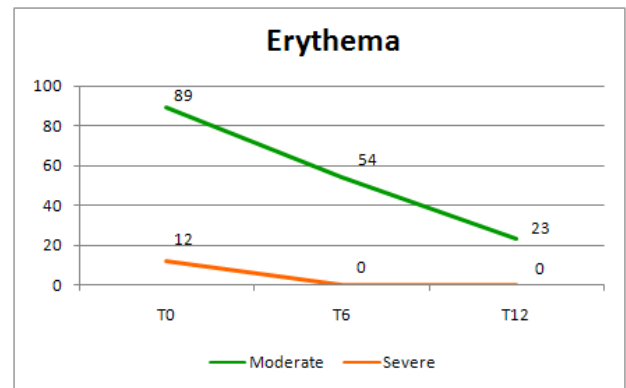
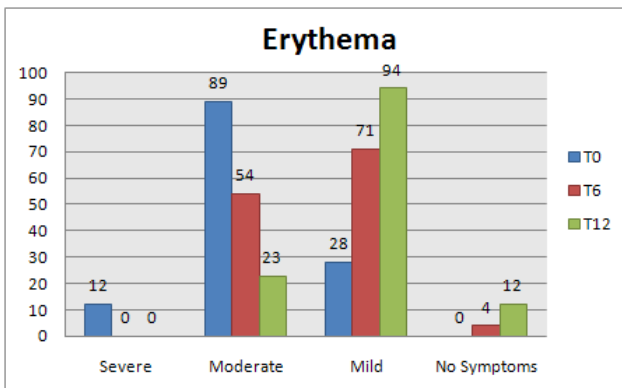
Survey symptoms for a total patient at time T12

	NO SYMPTOMS	MILD	MODERATE	SEVERE
ERYTHEMA	12	94	23	0
INFILTRATION	19	83	27	0
DESQUAMATION	10	93	26	0
ITCHING	35	77	17	0
BURNING	48	72	9	0

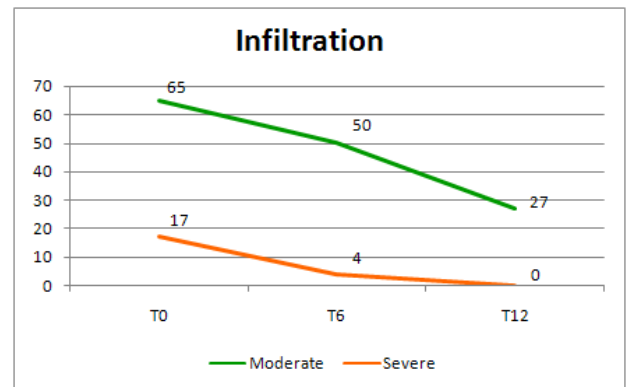
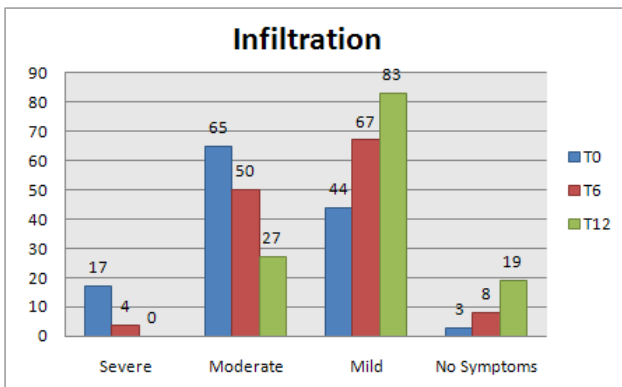
DISCUSSION

This study was conducted to verify the efficacy, on the characteristic symptoms of psoriasis, of a nutraceutical treatment based on Omega 3 associated with a topical treatment based on borage oil. The Omega 3 have mainly anti-inflammatory and immune-modulating effects as demonstrated in the prevention of cardiovascular disease and metabolic syndrome. The fatty acids Omega 3 (EPA and DHA) reduce the symptoms in different inflammatory skin pathologies, limiting the diffusion of inflammation. The psoriasis is a chronic, genetic and inflammatory disease of the skin, which can take improvement from a treatment with Omega 3, as demonstrate by the analysis of the results obtain on the symptoms reported in the study described. In all parameters examined from T0 to T12 decrease the patient with severe and moderate degree and increase patient with mild and no symptoms degree, an unequivocal sign of decrease of symptoms severity after treatment.

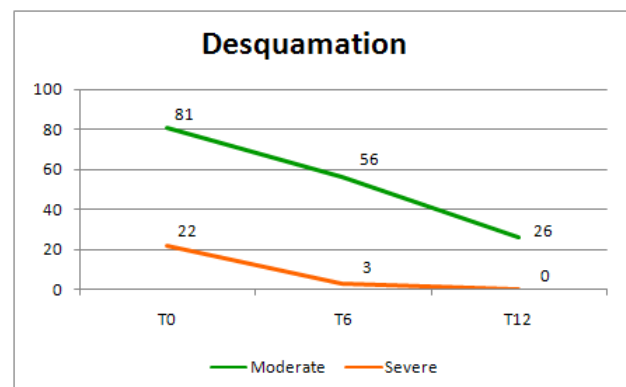
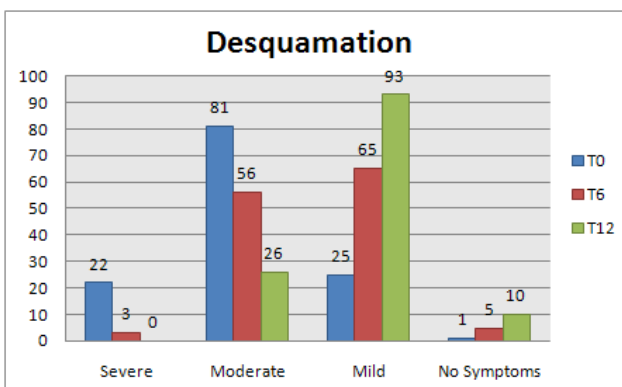
ERYTHEMA



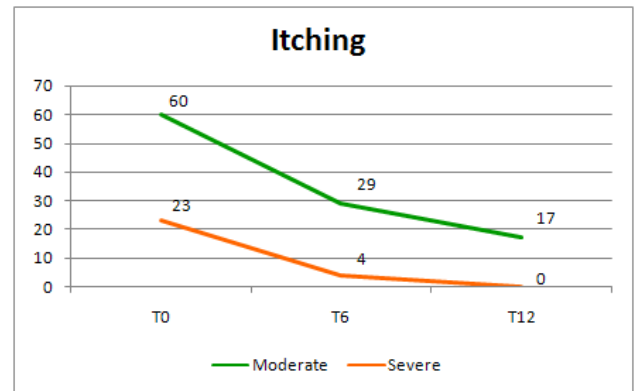
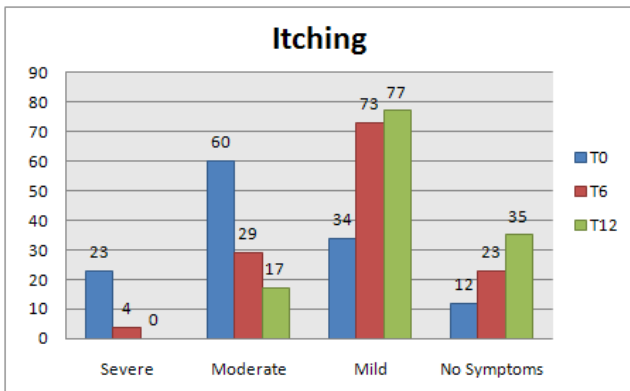
INFILTRATION



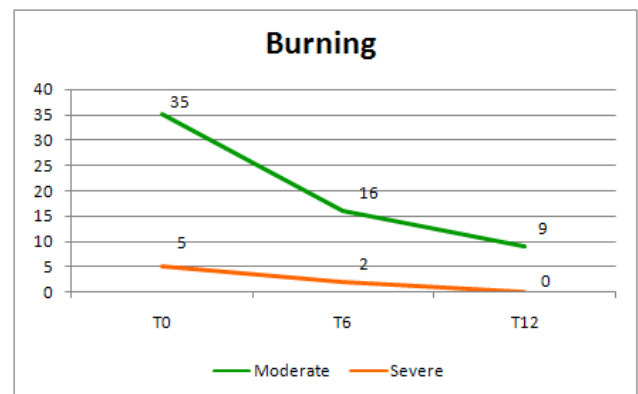
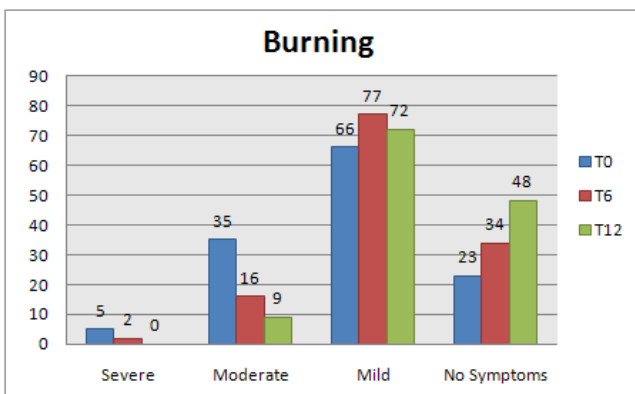
DESQUAMATION



ITCHING



BURNING



CONCLUSIONS

The analysis of all parameters measured, both objective:

- erythema
- infiltration
- desquamation

that subjective:

- itching
- burning

indicates that the treatment with Psoradin associated with topical treatment with Obasol reduce the symptoms severity in all patient treated. No reaction or effects regarding the tolerability of the products have not been reported.

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