

EVALUATION OF THE EFFICACY OF PSORADIN® CAPSULES IN PSORIASIS MILD TO MODERATE IN PATIENTS WITH CARDIO-METABOLIC CO-MORBIDITY

Multicenter clinical study observational

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INTRODUCTION

Psoriasis is a skin disease, chronic-relapsing; affects, in the Western world, about 3-4% of the population, in Italy affects nearly 3 million inhabitants and does not only affect the skin. It is a disease with a strong negative impact on quality of life. It comes in various forms and to date there is no curative therapy, but it can be kept under control with appropriate therapeutic strategies.

Recent studies have shown that psoriasis patients have a high prevalence of metabolic disorders such as hypertension, diabetes and hyperlipidemia, and also show a high incidence of "comorbidities" affecting almost half of the patients (47.1%). Each patient has an average of two other diseases (co-morbidity). The psoriatic arthropathy is the most widespread and in some studies is present in one third of the population observed (31.4%), followed by hypertension in 29%, dall'iperlipidemia in 13% and diabetes in 10% 1-2 . Diseases, the latter which increase cardiovascular risks 3.

In addition to drugs, nutrients may also be helpful. All vitamins that play a role in maintaining healthy skin, vitamin A and vitamin D , have showed positive results in the treatment of some cases of psoriasis. Some researchers have found that vitamin E is effective in the treatment of psoriasis, zinc improves the barrier function of the skin, and the chromium is useful for the treatment of insulin-resistance . The integration with omega-3 , with the dual objective of reducing inflammation, cholesterol and triglycerides , can help improve the skin and the general set of symptoms, integrating appropriate therapies.

Psoradin® is the first nutraceutical-based omega-3, vitamins A, E, D, Zinc, Selenium and Chromium, which is useful to supplement the diet of patients with psoriasis.

The aim of this observational study is evaluating the efficacy of a treatment Psoradin after 4 months. For this reason, we analyzed the data of 50 patients homogeneous for sex, age and clinical features (mild to moderate psoriasis interesting between 10 and 20% of the body surface), of which 45 with documented and concomitant co-morbidity (hyperlipidemia and / or hypertriglyceridemia and / or hypercholesterolemia and / or hyperglycemia).

MATERIAL AND METHODS

50 patients aged between 32 and 76 years with psoriasis, of which 45 with documented co-morbidity.

The analysis aims to:

1. Verify the efficacy of the treatment in mild to moderate psoriasis, through the assessment of PASI and symptoms such as erythema, desquamation, infiltration, itching and burning, before treatment and at the end.
2. Evaluate the efficacy of Psoradin in modifying blood parameters of glucose, cholesterol, HDL / LDL, triglycerides, blood pressure and BMI.

To each was compiled a data card. Were detected:

1. Enrollment (T0): PASI index, BMI, blood pressure, objective data such as the presence of erythema, infiltration, desquamation, and subjective ones such as itching and burning, through a simple numerical score with scale from 3 to 1, Glucose, Cholesterol, HDL and LDL, triglycerides.
2. At T8: objective data such as the presence of erythema, infiltration, desquamation, and subjective ones such as itching and burning, through a simple numerical score with scale 3 to 1.
3. To T16: PASI index, BMI, blood pressure, objective data such as the presence of erythema, infiltration, desquamation, and subjective ones such as itching and burning, through a simple numerical score with scale from 3 to 1, blood glucose, cholesterol, HDL and LDL, triglycerides.

The patients were informed about the need to reduce the consumption of alcohol, fats, and to establish an adequate diet with the aim to reduce cardiovascular risk.

RESULTS

Were included in the study 50 patients with various forms of psoriasis, 28 males and 21 females and 1 not indicated. The PASI improved by 57.5% (median 8 to 3.4). The BMI decreases from 28.4 to 26.6. The blood pressure decreases from 145/90 to 138/80.

No patients withdrew from the study for reasons of tolerability. Also decrease the levels blood glucose, cholesterol and triglycerides.

The results are reported in Tables 1, 2, 3, 4, 5 and Graph 1, 2, 3, 4, 5.

DISCUSSION

The present study was carried out to verify the efficacy of a nutraceutical treatment based on omega-3 against of the characteristic symptoms of psoriasis in patients with cardio-metabolic co-morbidity.

The omega-3 have predominantly anti-inflammatory and immune-modulating ¹² effect, as amply demonstrated in the prevention of cardiovascular disease and metabolic syndrome. The omega-3 fatty acids (EPA and DHA) reduce the symptoms in various inflammatory skin diseases, limiting the spread of inflammation.

Psoriasis is a chronic, genetic, inflammatory skin, which can improve with a treatment based on omega-3, as demonstrated by the analysis of the results .

In all parameters examined the symptoms decrease in patients of severe and moderate and increase those mild and no symptoms, unequivocal sign of decrease in severity of symptoms after treatment.

Concerning the blood parameters, all are reduced markedly.

The study highlights the efficacy of a integrative treatment based on omega-3 in the management of psoriasis, as already highlighted by other studies .

The particular formulation of Psoradin is able to successfully integrate treatment of psoriasis and provide added value in respect of co-morbidity of a cardio-metabolic 3.

Table 1

MALES	28
FEMALES	21
NOT SUITABLE	1
AGE	From 32 to 76 years
SMOKING	15
NO SMOKING	25
NOT SUITABLE	10
NEVER TREATED	49
ALREADY TREATED	0
NOT SUITABLE	1
TOPICAL THERAPY	45
SYSTEMIC THERAPY	7
PUVA	4
TIPE OF INJURY	
ERITEMATOUS DESQUAMATIVE	23
PLATES	18
PLATES + SCALES	9

Table 2: Survey median PASI at T0 and at time T16.

	T0	T16	
Median	8	3,4	↓

Table 3: Survey median BMI at T0 and at time T16.

	T0	T16	
BMI	28,4	26,6	↓

Table 4: Survey median blood pressure at T0 and at time T16.

Exclusion criteria: Excluding patients with blood pressure <140/90.

	T0	T6	
Blood pressure	145/90	135/80	↓

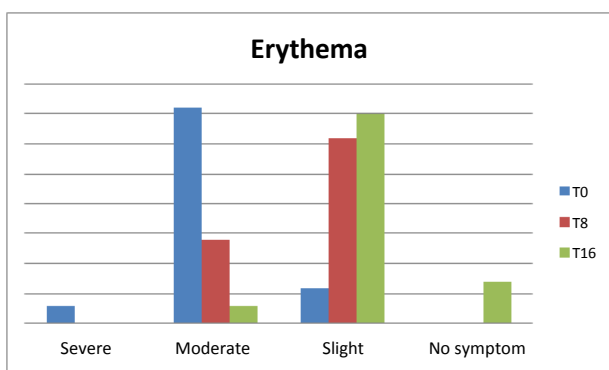
Table 5: Survey median blood tests at T0 and at time T16.

Exclusion criteria: Excluding patients with glucose ≤ 100

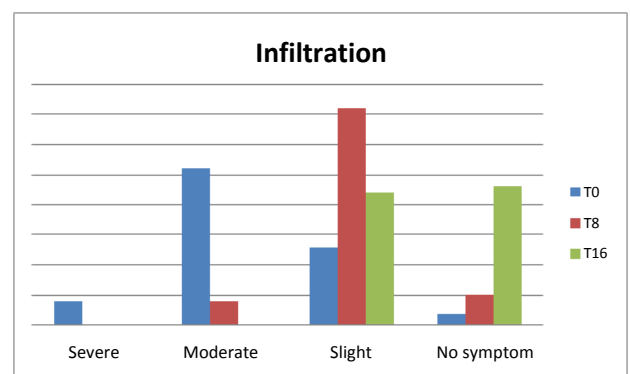
Excluding patients with cholesterol ≤ 190

Excluded patients with serum triglycerides ≤ 150

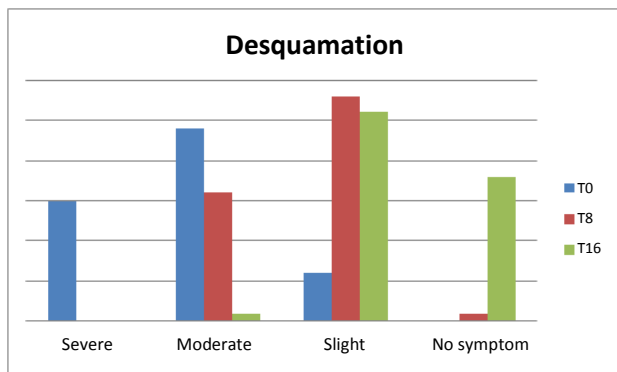
Glucose			Cholesterol			HDL			LDL			Tryglycerides		
T0	T16		T0	T16		T0	T16		T0	T16		T0	T16	
125	108	↓	220	205	↓	45,5	45	↓	150	130	↓	180	170	↓

Graph 1

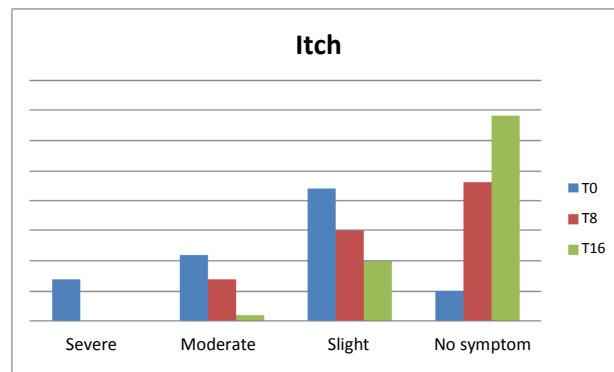
T0: 3 severe, 36 moderate, mild 6, 0 no symptom
T8: 0 severe, 14 moderate, 31 mild, 0 no symptom
T16: 0 severe, 3 moderate, 35 mild, 7 no symptom

Graph 2

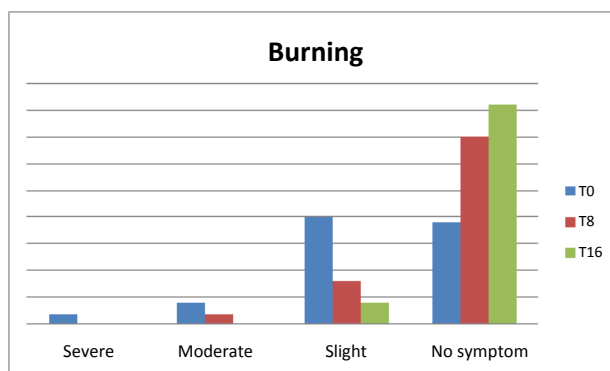
T0: 4 severe, 26 moderate, 13 mild, 2 no symptom
T8: 4 moderate, 36 mild, 5 no symptom
T16: 22 mild, 23 no symptom

Graph 3

T0: 15 severe, 24 moderate, mild 6, 0 no symptom
 T8: 0 severe, 16 moderate, 28 mild, no one symptom
 T16: 0 severe, 1 moderate, 26 mild, 18 no symptom

Graph 4

T0: 7 severe, 11 moderate, 22 mild, 5 no symptom
 T8: 7 moderate, 15 mild, 23 no symptom
 T16: 0 severe, 1 moderate, 10 mild, 34 no symptom

Graph 5

T0: 2 severe, 4 moderate, 20 mild, 19 no symptom
 T8: 2 moderate, mild 8, 35 no symptom
 T16: 4 mild, 41 no symptom

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