Evaluation of "Imuspora Tablets and Ointment (Multi-Ingredient Herbal Formulation)" In the Management of Psoriasis: An Open Trial

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Background:

Psoriasis a chronic, genetic, non-contagious skin disorder appears in many different forms and can affect any part of the body, including the nails and scalp. Psoriasis is categorized as mild, moderate, or severe, depending on the percentage of body surface involved and the impact on the patient's quality of life (QOL). Treatment is determined by the location, severity and history of psoriasis in each individual. There is no one way of treatment, for each person with psoriasis may respond differently.

Many complementary therapies are available, which some people find helpful. The study formulation is a ayurvedic preparation whose major ingredient includes Rubia cordifolia, Tinospora cordifolia, Fumaria officinalis, Acacia catechu, Melia azadirachta, Curcuma longa and others. The objective of this study is to assess the efficacy and safety of these formulations in patients with mild to moderate psoriasis.

Methodology:

This was an open labeled study of ayurvedic preparations Imuspora Tablets and ointment in 50 sequential patients of either sex between 18 to 55 years suffering from mild to moderate psoriasis attending our OPD and willing to participate and give written informed consent. Patients enrolled in the study were followed-up for 3 months Necessary approval for the protocol was obtained from our Institutional Ethics Committee before initiation of the trial.

Ambulatory patients of both sexes freshly diagnosed as well as pre existing patients (with a wash-out interval of 2 weeks if on treatment) with psoriasis and clinical diagnosis of psoriasis in any location of the body were included. The patients had clinical symptoms associated with psoriasis like itching, scaling, desquamation

The exclusion criteria included patients with infected lesions, history of ischemic heart disease, pregnant and lactating females; patients receiving corticosteroid treatment; patients with H/O gastritis, peptic ulcer, bleeding ulcers; HIV, HBV, known allergic reaction to systemic / topical study drugs; other concomitant medications like anti-hypertensives, oral hypoglycemic agents must have been used at stable dosage for at least 1 month.

Patients could be withdrawn from the study at their own request or if they experienced intolerable adverse experiences, showed insufficient therapeutic effect, or needed deviations from the protocol at the discretion of the investigator.

A thorough physical examination and necessary laboratory investigations which included hemoglobin, CBC count, ESR, Liver & Renal function tests were carried out before drug administration & after completion of treatment.

After confirmation of diagnosis, patients meeting the inclusion & exclusion criteria were included in the study and received 2 Imuspora Tablets BID for 3 months and Imuspora Ointment to be applied over the affected area/s thrice daily as a thin film and rubbed in gently and completely for 3 months.

Safety & efficacy evaluation of patients' clinical response to treatment was monitored from screening (day 0) till end of therapy (end of 3 months). All data were carefully entered in the Case Record Form provided. Side-effects were closely monitored in all patients. All adverse events were recorded by the investigator, and rated for severity and relationship to the study medication. However, significant exacerbations or worsening of pre-existing conditions were recorded. Drop out cases with reasons (non-compliance, side-effects or others) were noted. Any abnormal laboratory values were also noted.

The efficacy was evaluated on the basis of parameters of modified psoriasis area sensitivity index (PASI), physicians and patients global evaluation at follow-up visits. Scoring each area for intensity of erythema, scaling, indurations, pruritus on a 0–3 scale (0=none, 1=slight, 2=moderate and 3=severe).

The investigator global assessment (IGA) on efficacy & tolerability was made on a scale of 1–5, namely, Very Good = 5, Good = 4, Fair = 3, Poor = 2 and Very Poor = 1. Patient's global assessment on the efficacy & tolerability of treatment was similarly made.

Patients lost to follow-up or withdrawn from the study at any time whether due to inadequate response or adverse events was considered as failure.

The results analyzed on intention to treat analysis. The t-test has been used to compare the statistical significance of outcome over baseline at 95% confidence limits.

Results:

Of the 50 patients enrolled in the trial, 5 were lost to follow-up while 45 completed the study with reduction in symptoms of psoriasis to varying degrees.

The demographic characteristics of these are as given in Table 1.

Table 1

Demographic Characteristics of Patients		
Age (years)	**Male**	**Female**
18-29	6	4
30-39	14	8
40-49	6	5
above 49	2	5
Sub total	**28**	**22**
Total	**50**	

Treatment with the Imuspora Tablets and Imuspora Ointment did not lead to any significant changes or abnormalities in the laboratory investigations as compared to the baseline values. Patients tolerated the trial medications without any major adverse events that needed discontinuation. However a few patients did experience minor adverse effects which are summarized in the Table 2 below

Table 2

Adverse Events	**No. of Patients (n=50)**	**(%)**
Nausea	2	4
Vomiting	1	2
Total	**3**	**6**

Table 3 shows the changes in the mean score of erythema, scaling, indurations, pruritus. At the end of 1st, 2nd and 3rd month mean score of erythema had a reduction of 6.76%, 51.35% and 81.08% respectively from baseline. At the end of 1st, 2nd and 3rd month mean score of scaling had a fall of 8%, 45.33% and 68% respectively from baseline. At the end of 1st, 2nd and 3rd month mean score of indurations had a fall of 1.45%, 43.48% and 57.97% respectively. At the end of 1st, 2nd and 3rd month mean score of pruritus had a fall of 14.42%, 42.31% and 55.77% respectively from baseline.

Table 3

Symptoms	**Changes in Mean Score ± SD**				
	Baseline	**1 month**	**2 months**	**3 months**	t value
Erythema	1.48+0.84	1.38+0.75	0.72+0.50	*0.28+0.45	6.15
Scaling	1.50+0.74	1.38+0.64	0.82+0.62	*0.48+0.68	5.23
Indurations	1.38+0.70	1.36+0.66	0.78+0.51	*0.58+0.57	4.10
Pruritus	2.08+0.87	1.78+0.71	1.2+0.71	*0.92+0.72	5.64

*$p < 0.05$

Figure I
Investigator Global Assessment (IGA) On Efficacy & Tolerability

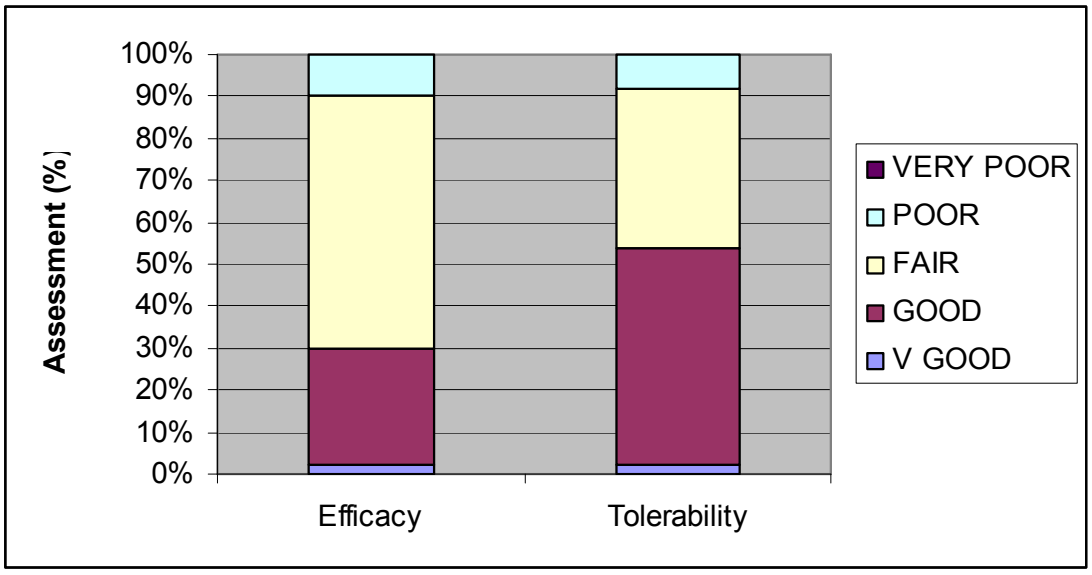
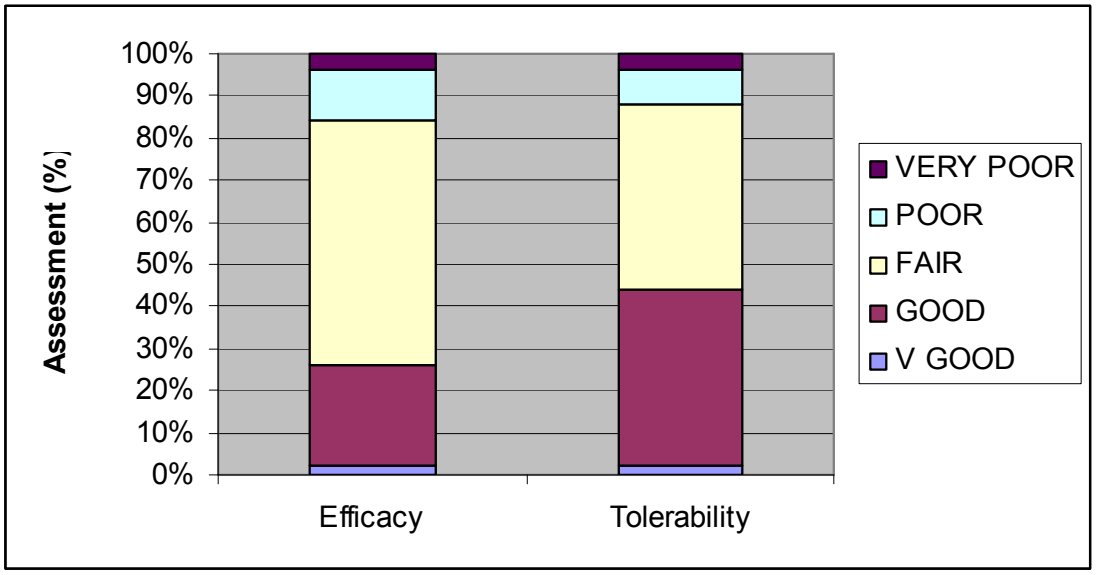
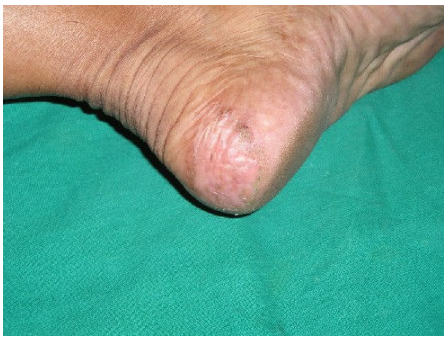


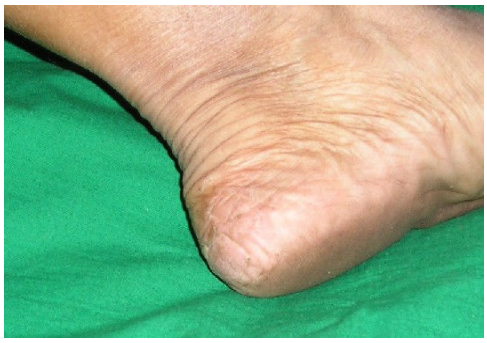
Figure II
Patients Global Assessment (IGA) On Efficacy & Tolerability



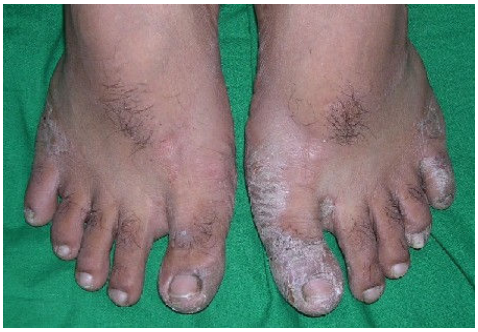
Picture 1A: Pre-treatment



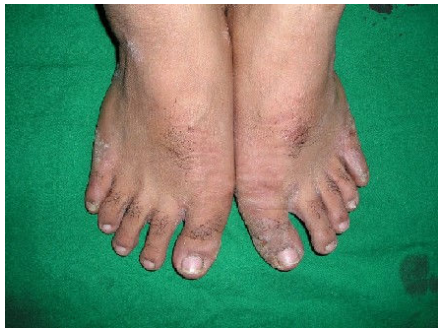
Picture 1B : Post-treatment



Picture 2A: Pre-treatment



Picture 2B : Post-treatment



Picture 3A: Pre-treatment

Picture 3B : Post-treatment

	Doctor		Patient	
Assessment (%)	Efficacy	Tolerability	Efficacy	Tolerability
V GOOD	2	2	2	2
GOOD	28	52	24	42
FAIR	60	38	58	44
POOR	10	8	12	8
VERY POOR	0	0	4	4

At the end of 3 months intensity of the individual parameters like erythema, scaling, indurations, pruritus showed moderate but statistically significant ($p<0.05$) improvement from the baseline (Picture 1A, 1B, 2A, 2B, 3A and 3B). The global assessment of response by physicians showed that 28% of patients showed a good improvement while another 60% showed fair improvement in their condition by the end of 3 months of treatment. Similarly 84% of the patients global assessment indicated fair or better response at the end of treatment. These findings confirm the efficacy of the drug in study population.

In conclusion, this study confirms the efficacy and safety of Imuspora Tablets and Imuspora Ointment in Indian patients of mild to moderate psoriasis.

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