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A prospective, open-label, non-randomised clinical trial to evaluate the safety and efficacy of Imupsora in the treatment of Psoriasis

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ABSTRACT

Objectives: To evaluate the clinical efficacy and safety of Imupsora Tablet and Ointment in Psoriasis. **Material and Methods:** A prospective, interventional clinical study was conducted on 50 patients of both sexes, aged between 18-55 years, confirmed with Psoriasis from clinical examination and who were willing to give informed consent. All patients received Imupsora Tablet at a dose of 2 tablets twice a day for 12 weeks and Imupsora Ointment to be applied over the affected areas thrice daily as a thin film and rubbed gently. All patients were evaluated at baseline, 4 weeks, 8 weeks and 12 weeks for parameters of Psoriasis Area Severity Index (PASI); Physician's and Patient's global assessment at end of the study. **Observation:** Imupsora Tablet and Ointment therapy reduced erythema, scaling, indurations and pruritus by 78.01%, 69.74%, 58.45%, and 56.80% respectively at the end of 12 weeks from baseline. 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 12 weeks of treatment. Similarly, 46% and 42% of the patient's global assessment indicated fair and good response at the end of treatment respectively. **Result:** Imupsora Tablet and Ointment produced a significant reduction in all the inflammatory/metabolic parameters associated with Psoriasis assessed after 12 weeks of treatment. In addition, a significant improvement in Clinical Global Impression in efficacy and tolerability was also observed. No adverse events were reported by any patients. This indicates that Imupsora Tablet and Ointment is clinically effective and safe for Psoriasis.

Key words: *Psoriasis, Pruritus, Erythema, Imupsora Tablet*

INTRODUCTION

Psoriasis is a heterogeneous, immune-mediated inflammatory skin disease that presents in multiple forms such as plaque, flexural, guttate, pustular or erythrodermic patches. It is associated with multiple comorbidities and substantially diminishes patients' quality of life. Its association with psoriatic arthritis and increased rates of cardiometabolic, hepatic and psychological comorbidity requires a holistic and multidisciplinary care approach.

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Epidemiology

Psoriasis affects both males and females, with earlier onset in those with a family history. Its age of onset shows a bimodal distribution with peaks at 30–39 years and 60–69 years. In 2014, the World Health Organization recognised psoriasis as a serious non-communicable disease and highlighted the distress related to misdiagnosis, inadequate treatment and stigmatisation of this disease.[1] The Global Burden of Disease Study estimated that psoriasis accounted for 5.6 million all-age disability-adjusted life-years (DALYs) in 2016; at least three-fold that of inflammatory bowel disease.[2] On the basis of current evidence derived from hospital-based studies, mostly from North India,

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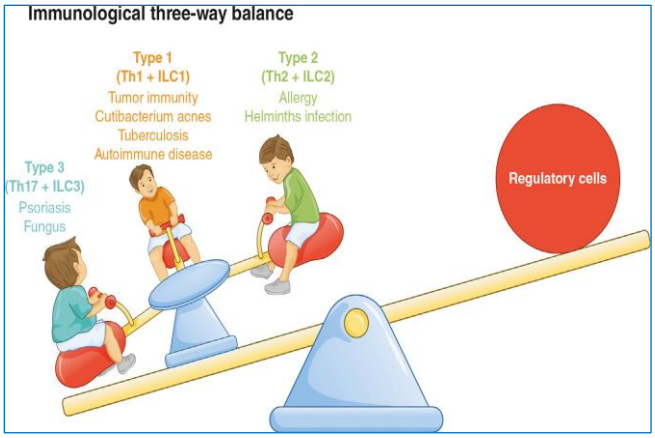
the prevalence of psoriasis in adults varies from 0.44 to 2.8%. The peak age at onset in adults is in the 3rd and 4th decade of life, with a slight male preponderance.[3]

Pathogenesis

Psoriasis is a complex chronic inflammatory skin disease caused by the dynamic interplay between multiple genetic risk foci, environmental risk factors, and excessive immunological abnormalities. Recent progress in biological therapies has revealed the fundamental roles of tumor necrosis factor-α, interleukin (IL)-23p19, and the IL-17A axis together with skin-resident immune cells and major signal transduction pathways in the pathogenesis of psoriasis. In addition to IL-17- producing T helper17 cells, innate lymphoid cell (ILC)3 induces psoriasis rashes directly without T-cell/ antigen interaction in response to the released anti-microbial peptides from activated keratinocytes and inflammatory cytokines. ILC3 typically expresses retinoic acid receptor-related orphan receptor gamma in the nucleus, matures in the presence of IL-7 and IL-23, and produces IL-17 and IL-22. The number of ILC3s is increased in the blood, psoriasis rash, and even in non-rash areas of psoriatic skin. Psoriasis is significantly associated with cardiovascular disease, metabolic syndrome, and inflammatory disorders, particularly the severe type. The similarity of enterobacteria in the psoriasis gut to that in diabetic patients may be related to its pathogenesis.[4]



Clinical Presentation

Psoriasis is a chronic skin disease with no known cure at this time. However, the severity of psoriasis can oscillate over time, and its symptoms can be effectively controlled with treatments. 3 key clinical features of psoriasis include erythema, thickening, and scales. Psoriasis appears as red, scaly, raised patches or plaques. It is often diagnosed clinically, but a biopsy can be used to confirm the diagnosis. It is recommended that patients with psoriasis be screened for psoriatic arthritis, psychological illnesses such as depression, cardiometabolic diseases, and inflammatory bowel disease.

Classification of Psoriasis

Classifying cases of psoriasis according to severity is a common technique and is often used in practice to help guide the appropriate treatment and management of the condition.

- **Mild psoriasis:** Less than 3% of the body surface area is affected
- **Moderate psoriasis:** 3 - 10% of the body surface area is affected
- **Severe psoriasis:** More than 10% of the body surface area is affected

Conventional Treatment

Advances in the understanding of its pathophysiology have led to development of highly effective and targeted treatments. For patients with mild psoriasis, treatment options include topical corticosteroids, vitamin D analogues, calcineurin inhibitors, keratolytics, and targeted phototherapy [narrow band ultraviolet B radiation (NB-UVB) and ultraviolet A radiation (PUVA)]. Systemic medications can also be used for localized disease involving special areas such as the scalp, palms, soles, and genitals, or recalcitrant local psoriasis unresponsive to topical therapies. The American Academy of Dermatology- National Psoriasis Foundation guidelines recommend consideration of prescribing biologics (TNF-α Inhibitors, IL-12/23 Inhibitor, IL-17 Inhibitors and IL-23 Inhibitors), oral agents (methotrexate, apremilast, acitretin, and cyclosporine), and phototherapy concurrently for patients with moderate to severe psoriasis.

Biologics accompany adverse effects that include injection site reaction, nasopharyngitis, and upper

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respiratory tract infections. Certain biologics like TNF-α are contraindicated in several populations, including those with active tuberculosis, advanced congestive heart failure, hepatitis-B infection, or demyelinating diseases such as multiple sclerosis. IL-17 inhibitors have been reported to exacerbate mucocutaneous candidiasis and inflammatory bowel disease. Oral systemic treatments substantially differ in adverse effect profiles. Thus, careful consideration is necessary when selecting an oral agent due to the multiple contra-indications and precautions associated with some of these oral agents. Topical therapies remain the cornerstone for treating mild psoriasis but can be used as adjunct treatments and not as monotherapy in treating moderate to severe psoriasis.[5]

Patients with psoriasis do not have access to a remedy that cures the condition. Some preparations inhibit the action of immune factors or suppress the effects of psoriasis. Current therapeutic substances possess certain drawbacks, including the frustration of the patients due to the ineffectiveness of drugs and possible side-effects such as mood swings, diarrhea, and vomiting. There is a lack of an effective and long-term treatment plan in the fight against psoriasis. There is a great need for the continuous development of new, safe, and effective treatment of psoriasis. Among the many active compounds that have been studied for the relief of psoriasis, extracts from plants and specific phyto-chemicals from natural resources have been of great interest in recent decades. Several studies evaluating psoriasis therapy based on natural sources revealed potential activity, especially anti-proliferative effects, reduction of itching, and lowering the levels of inflammation cytokines. Natural substances, in comparison with medicament, do not cause frustration of the patients, mood swings, diarrhea, and vomiting, which is the positive side of their use.[6]

In the present study, Imupsora Tablet and Ointment, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with psoriasis. The formulation has been standardized after formulating SOPs along with an acute toxicity study.

Objectives of the Study

The main objective of the study was to evaluate the clinical efficacy of Imupsora Tablet and Ointment in Psoriasis. Further, the study also observed the clinical safety of Imupsora Tablet and Ointment in Psoriasis.

Materials and Methods

Study Design

Prospective, open-label, non-randomised clinical trial.

Inclusion Criteria

Patients of either sex, aged 18 to 55 years and visiting the outpatient department, freshly diagnosed by the attending Physician as well as pre-existing patients (with a wash-out interval of two weeks if on treatment) with psoriasis and clinical diagnosis of psoriasis in any location of the body were included. Patients willing to provide informed consent; comply with study requirements, attending study visits and adhering to treatment protocols; having adequate understanding of the study procedures and ability to communicate effectively with study staff; to be available for the duration of the study period. The patients had clinical symptoms associated with psoriasis-like itching, scaling and desquamation.

Exclusion Criteria

Patients with infectious lesions, other significant dermatological conditions, history of ischemic heart disease, pregnant and lactating females; patients receiving corticosteroid treatment or immune-suppressive therapies, patients with history of gastritis, peptic ulcer, bleeding ulcers; HIV, HBV and known allergic reaction to systemic or topical study drugs; Patients with active infections or malignancies that may impact the ability to participate safely in the study; history of substance abuse or psychiatric disorders that may affect the ability to provide informed consent or adhere to study requirements were excluded. Patients with any other condition or circumstance that, in the judgment of the investigator, would make the participant unsuitable for participation in the study

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were excluded. Patients with significant alcohol consumption, pregnancy or breastfeeding mothers, suffering from malignancies, cardiovascular, respiratory, kidney diseases, with serious medical conditions that could confound study outcomes or increase the risk of complications during the study period, who are unable or unwilling to provide informed consent or comply with study procedures and follow-up assessments were excluded.

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

Study Design

A non-randomized phase 4, prospective open label clinical trial in 50 patients diagnosed with Psoriasis was planned following required GCP guidelines. After careful selection in terms of the eligibility criteria, screened subjects willing to enrol after explaining the clinical study procedure were requested to sign the Patient Consent Form. At baseline visit at 0 weeks, Patient information sheet was provided to each subject in their language of preference. Case record form (CRF) was filled by the attending physician with complete medical history and required personal details of the subject at the start of the study. A thorough physical examination and necessary laboratory investigations were carried out before drug administration and after completion of treatment.

Safety and efficacy evaluation of patients' clinical response to treatment was monitored from baseline till end of 12 weeks. 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.

Clinical assessments

The patients were evaluated at baseline, 4 weeks, 8 weeks & 12 weeks after onset of treatment. Efficacy was evaluated on the basis of parameters of Psoriasis Area Severity Index (PASI), at follow-up visits, scoring each area for intensity of erythema, scaling, indurations, pruritus on a 0-4 scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe). The Physician global assessment and Patient's global assessment (at end of the study) on efficacy and tolerability were made on a scale of 1- 5, namely, Very Good = 5, Good = 4, Fair = 3, Poor = 2 and Very Poor = 1.

Intervention

Imupsora Tablet and Ointment, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with Psoriasis, in a dose of 2 tablets twice a day and Imupsora Ointment to be applied over the affected areas thrice daily as a thin film and rubbed in gently. Imupsora Tablet contains *Rubia cordifolia, Acacia catechu, Tinospora cordifolia, Hemidesmus indicus, Picrorrhiza kurroa, Ocimum sanctum* and *Fumaria indica*. Imupsora Ointment contains *Melia azadirachta, Pongamia glabra, Curcuma longa, Glycyrrhiza glabra* and *Aloe barbadensis*.

OBSERVATION

All 50 patients enrolled in the trial completed the study with reduction in symptoms of psoriasis to varying degrees. Table 1 shows Demographic data of Patients who participated in our study before intervention. Treatment with the Imupsora tablet and ointment did not lead to any abnormalities in the laboratory investigations as compared to the baseline values. Patients tolerated the trial medications without any adverse events that needed discontinuation. Table 2 shows the changes in the mean score of erythema, scaling, indurations and pruritus. Table 3 shows Percentage change in the mean symptom scores after 4, 8 and 12 weeks of therapy. Table 4 and 5 shows Global assessment of response by Physicians and Patients respectively after 12 weeks of treatment.

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Table 1: Demographic Data of Patients at Baseline

Patient ID	Age	Gender	Marital Status	Occupation	Education Level	Location	Psoriasis Severity
1	35	Male	Married	Software Engineer	Bachelor's	Urban	Moderate
2	45	Female	Single	Nurse	Master's	Suburban	Severe
3	28	Male	Single	Retail Manager	High School	Urban	Mild
4	50	Female	Married	Accountant	Bachelor's	Urban	Severe
5	62	Male	Widowed	Retired	Doctorate	Rural	Severe
6	39	Female	Divorced	Teacher	Master's	Suburban	Moderate
7	31	Male	Single	Construction Worker	High School	Urban	Mild
8	55	Female	Married	Lawyer	Doctorate	Suburban	Moderate
9	42	Male	Married	Sales Manager	Bachelor's	Urban	Severe
10	48	Female	Married	Physician	Doctorate	Urban	Moderate
11	29	Male	Single	Graphic Designer	Bachelor's	Urban	Mild
12	37	Female	Married	Social Worker	Master's	Suburban	Severe
13	44	Male	Divorced	Chef	High School	Rural	Moderate
14	56	Female	Married	Marketing Manager	Bachelor's	Suburban	Severe
15	34	Male	Single	Pharmacist	Doctorate	Urban	Moderate
16	41	Female	Married	Engineer	Bachelor's	Urban	Moderate
17	59	Male	Married	Professor	Doctorate	Suburban	Severe
18	33	Female	Single	Financial Analyst	Bachelor's	Urban	Mild
19	46	Male	Married	IT Consultant	Master's	Urban	Severe
20	52	Female	Married	Dentist	Doctorate	Suburban	Severe
21	30	Male	Single	Artist	Bachelor's	Urban	Mild
22	38	Female	Divorced	Writer	High School	Rural	Moderate
23	54	Male	Married	Entrepreneur	Bachelor's	Suburban	Severe
24	36	Female	Married	Psychologist	Master's	Suburban	Moderate
25	47	Male	Married	Police Officer	Bachelor's	Urban	Severe
26	60	Female	Married	Surgeon	Doctorate	Urban	Severe
27	32	Male	Single	Software Developer	Bachelor's	Urban	Mild
28	40	Female	Married	Nurse Practitioner	Master's	Suburban	Moderate
29	49	Male	Married	Financial Manager	Bachelor's	Urban	Severe
30	31	Female	Single	Receptionist	High School	Urban	Mild

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31	51	Male	Married	Real Estate Agent	Master's	Urban	Severe
32	27	Female	Single	Research Scientist	Doctorate	Urban	Mild
33	43	Male	Married	Electrician	High School	Rural	Severe
34	57	Female	Divorced	Librarian	Bachelor's	Suburban	Severe
35	35	Male	Married	Web Developer	Bachelor's	Urban	Moderate
36	39	Female	Single	Physical Therapist	Master's	Urban	Moderate
37	45	Male	Married	Chef	High School	Suburban	Severe
38	58	Female	Married	Executive Assistant	Bachelor's	Urban	Severe
39	33	Male	Single	Journalist	Bachelor's	Urban	Mild
40	41	Female	Married	Veterinarian	Doctorate	Rural	Moderate
41	55	Male	Married	Architect	Master's	Suburban	Severe
42	29	Female	Single	Flight Attendant	High School	Urban	Mild
43	47	Male	Married	Sales Representative	Bachelor's	Urban	Severe
44	59	Female	Married	HR Manager	Master's	Suburban	Severe
45	31	Male	Single	Financial Advisor	Bachelor's	Urban	Mild
46	36	Female	Married	Dental Hygienist	High School	Urban	Moderate
47	52	Male	Married	Physician Assistant	Master's	Suburban	Severe
48	30	Female	Single	Retail Salesperson	High School	Urban	Mild
49	38	Male	Married	Police Officer	Bachelor's	Urban	Severe
50	43	Female	Married	Pharmacist	Doctorate	Suburban	Severe

Table 2: Changes in the mean symptom scores after 4, 8 and 12 weeks of therapy (Changes in Mean Score ± SD).

Inflammatory biomarkers	Baseline	4 Weeks	8 Weeks	12 Weeks
Erythema	1.41 ± 0.84	1.36 ± 0.75	0.70 ± 0.50	*0.31 ± 0.45
Scaling	1.52 ± 0.74	1.39 ± 0.64	0.84 ± 0.62	*0.46 ± 0.68
Indurations	1.42 ± 0.70	1.38 ± 0.66	0.76 ± 0.51	*0.59 ± 0.57
Pruritus	2.06 ± 0.87	1.79 ± 0.71	1.23 ± 0.71	*0.89 ± 0.72

*p< 0.05

Table 3: Percentage change in the mean symptom scores after 4, 8 and 12 weeks of therapy

Inflammatory biomarkers	4 Weeks	8 Weeks	12 Weeks
Erythema	3.55	50.35	78.01
Scaling	8.55	44.74	69.74
Indurations	2.82	46.48	58.45
Pruritus	13.11	40.29	56.80

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Table 4: Global assessment of response by Physicians after 12 weeks of treatment (%)

Assessment by Physicians	Very Poor	Poor	Fair	Good	Very Good
Efficacy	0	8	60	28	4
Tolerability	0	6	38	50	6

Table 5: Global assessment of response by Patients after 12 weeks of treatment (%)

Assessment by Physicians	Very Poor	Poor	Fair	Good	Very Good
Efficacy	4	10	60	24	2
Tolerability	4	6	46	42	2

RESULTS

At the end of 4th, 8th and 12th weeks, mean score of erythema had a reduction of 3.55, 50.35 and 78.01%, respectively, from baseline. At the end of 4th, 8th and 12th weeks, mean score of scaling had a fall of 8.55, 44.74 and 69.74%, respectively, from baseline. At the end of 4th, 8th and 12th weeks, mean score of indurations had a fall of 2.82, 46.48 and 58.45%, respectively. At the end of 4th, 8th and 12th weeks, mean score of pruritus had a fall of 13.11, 40.29 and 56.80% respectively from baseline.

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 12 weeks of treatment. Similarly, 46% and 42% of the patient's global assessment indicated fair and good response at the end of treatment respectively. These findings confirm the efficacy of the drug in the study population during the study period.

DISCUSSION

Psoriasis is a common, chronic systemic inflammatory disease affecting 125 million people worldwide. It is associated with several important conditions, including psoriatic arthritis, cardio-metabolic syndrome, and depression, leading to a significant reduction in patients' quality of life.[7] Psoriasis is classified as an autoimmune disease caused by malfunctioning pathways and elements of the immune system T cells, dendritic cells, cytokines such as interleukin-23, interleukin-17, and tumor necrosis factor.[8] It is the most common genetic skin disease, which leads to the increased risk of developing metabolic syndrome (MS) and cardiovascular disease. Moreover, severe psoriasis patients present, increased chances for the development of components of metabolic syndrome as obesity, dyslipidemia, diabetes mellitus, and hypertensionIt is mainly manifested by gradually magnifying and exfoliating psoriatic plaques with accompanying pustules and spots. The first lesions occur in the highest layer of the dermis–the papillary dermis. Blood vessels become dilated and curvy. Herein the abnormal proliferation and migration of keratinocytes begin. Subsequently, the epidermis thickens, and keratinocytes stop to differentiate completely, which leads to loss of a granular layer and occurrence of parakeratosis (keratosis of the stratum corneum, induced by nuclei bearing keratinocytes). With psoriasis progression, some skin cell populations excessively proliferate, expanding the spinous layer of epithelium and leading to acanthosis nigricans. The epidermis's stratum corneum completely disappears, the granular layer disappears, T cells with glycoprotein are dispersed between keratinocytes, and neutron-absorbent granulocytes accumulate in parakeratotic plates, forming Munro's microabscesses. Dilated blood vessels extend to the highest layer of the dermis, causing bleeding after removing psoriatic plaque.[9] Usually, this type of psoriasis appears as red patches of inflamed skin, raised, coated with silvery-white scales. Often, the patches show in a symmetrical pattern.

Current treatments only reduce symptoms, do not cure. Presently, most of the conventional therapies can diminish psoriasis symptoms. However, there is not yet a known treatment that could cure this condition completely. Furthermore, many of those strategies can cause various side-effects among patients, such as atrophy, organ toxicity, immune-suppression,

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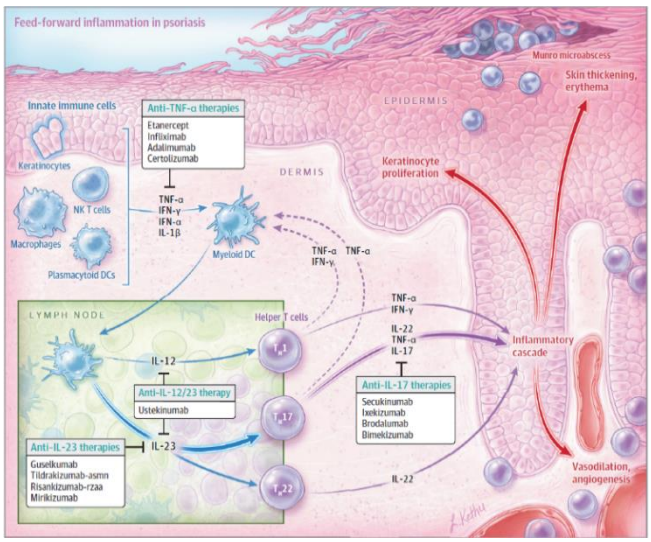
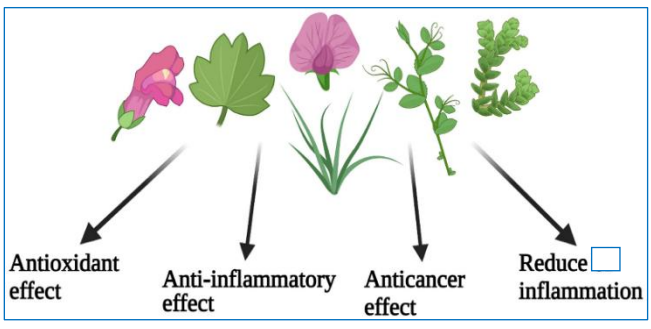
infection, and carcinogenesis, limiting these therapies' application in long-term use. Hence, further development of safe, effective, and possibly less expensive methods of treating psoriasis is needed.



Pathophysiology of Psoriasis from Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. *JAMA*. 2020;323(19):1945–1960. doi:10.1001/jama.2020.4006

Research reveals that one of the possible ways to modulate the response of the cells engaging in the psoriasis course is to use herbal drugs and exploit their immunoregulatory and antioxidative role in the treatment.[10] Literature reviews document the usefulness of herbal remedies for psoriasis and the supportive role of phytochemicals in this autoimmune disease treatment.[11]



Rubia cotdifolia possesses highly potent anti-proliferative and apoptogenic effects on human keratinocytes, and it promotes keratinocyte differentiation, possessing promising anti-psoriatic action.[12] Khadir has since long been used to treat skin ailments including psoriasis in a traditional practice. It helps to purify the blood and has immunomodulatory action that may activate both cell-mediated as well as humoral immunity. Among various phyto-constituents present in Khadir, catechins contribute to its anti-inflammatory and antioxidant activities. In an experimental study, the water extract of Khadir showed inhibition of pro-inflammatory cytokine TNF-α and a significant increase in cytokine IL-10. IL-10 helps to control the secretion of pro-inflammatory cytokines by augmenting the proliferation of B cells, mast cells, and thymocytes.[13] *Tinospora cordifolia* is a rich source of trace elements (zinc and copper), which acts as antioxidant and protects cells from the damaging effects of oxygen radicals generated during immune activation. The anti-stress actions of Guduchi makes it therapeutically more important. It is clear that zinc affects multiple aspects of the immune system, from the barrier of the skin to the gene regulation within lymphocyte.[14] *Hemidesmus indicus* helps in skin diseases by blood purification as it possesses several biological activities like hepato-protective, anti-thrombotic, anti-ulcerogenic, anti-inflammatory, immune-modulatory, etc.[15] Organic *Melia azadirachta* oil has been used to treat skin disorders, such as acne, psoriasis, eczema, mycosis and warts. Interestingly, neem was reported as a nutritional strategy for psoriasis in a recent study since it is rich in nimbidin which inhibits prostaglandin synthetase.[16] Two RCTs have reported the treatment of Psoriasis with Curcumin and *Curcuma longa* extract. It improved the Psoriasis Area and Severity Index (PASI) scores. Curcumin has anti-inflammatory, antioxidant, anti-tumor, and anti-vascular remodeling effects. Existing evidence suggests that it has therapeutic potential for a variety of human diseases. It regulates various cell signaling molecules, including phosphorylase kinase; transferrin receptor; total cholesterol; transforming growth factor-β; pro-inflammatory cytokines (e.g., TNF-α, IL-17, IL-1β, and IL-6); STAT3; endothelin-1 apoptosis protein; nuclear factor-κB (NF-κB); cyclooxygenase-2; and antioxidants.[17]

CONCLUSION

The present interventional study indicates that Imupsora Tablet and Ointment are effective and safe in

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controlling the signs and symptoms of Psoriasis and its associated complications. There were no clinically significant adverse events either reported or observed during the entire study period. The overall compliance with the treatment was good and no treatment discontinuations were reported. Imupsora Tablet and ointment typically target immune, inflammatory, metabolic alterations and free radicals. Imupsora aims at reverting pathogenic skin metabolism with an alternative approach to disconnect the injury from inflammation and to reduce dry, thick, cracked and itchy skin patches.

Cost of Study

All medications required during the 12 weeks of trial were provided by the sponsor. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision Chaudhari Clinic HCP who are not associated with the sponsors.

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