ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 11 | November - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

CLINICAL STUDY OF IMPACT OF TREATMENT ON QUALITY OF LIFE AND SEVERITY OF DISEASE IIN PATIENTS WITH PSORIASIS

Dermatology

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ABSTRACT

Background: Psoriasis significantly impacts patients' quality of life (QOL), comparable to major medical diseases. Effective treatment should address both skin symptoms and health-related QOL. **Objectives:** To evaluate clinical severity, physical disability, psychosocial disability, and metabolic syndrome prevalence in chronic plaque psoriasis patients, and assess treatment outcomes. **Methods:** The present study included 150 patients with chronic plaque psoriasis. Patients received methotrexate (0.2mg/kg/week) and topical treatments. Metabolic syndrome was analysed among these patients. Psoriasis Area and Severity Index (PASI), Psoriasis Life Stress Inventory (PLSI), and Psoriasis Disability Index (PDI) assessed disease severity and QOL. **Results:** Significant improvements in mean PLSI (16.4 to 5.0), PASI (19.6 to 4.9), and PDI (21.3 to 6.9) scores were observed after 8 weeks ($p<0.01$). Correlations between PASI and PDI ($r=0.627$, $p<0.001$) and PLSI ($r=0.923$, $p<0.001$) were found. Metabolic syndrome prevalence was 35.3%. No significant differences in PLSI, PASI, or PDI scores were observed between patients with and without metabolic syndrome. **Conclusion:** This study highlights the impact of psoriasis on QOL and demonstrates significant improvements in disease severity and QOL following treatment. Metabolic syndrome prevalence was substantial, but its presence did not significantly affect treatment outcomes.

KEYWORDS

Psoriasis; Quality of Life; Metabolic Syndrome; PASI; PLSI; PDI; Methotrexate.

INTRODUCTION

Psoriasis is one of the most common dermatological conditions that might lower quality of life (QOL).[1] The impact of psoriasis on HRQL is comparable to that of other major medical diseases. Patients with psoriasis has reported decline in physical as well as mental functioning analogous to that seen in cancer, arthritis, hypertension, heart disease, diabetes, and depression.[2] Hence, the treatment of psoriasis should not only focus on skin affectations but also weigh the parameters for health-related quality of life (HRQOL), thereby tackling the concept of cumulative life course impairment (CLCI) and treating the patient from a holistic perspective.[3]

Numerous research studies have demonstrated the immense distress, tension, and disturbance individuals with psoriasis have in their day-to-day lives, interpersonal connections, and self-perceptions.[4] As of now, a number of methods have been developed to assess the quality of life of psoriasis patients as well as those suffering from other dermatological conditions. These questionnaires, which comprise patient-completed, self-administered questionnaires, aim to capture how patients view and respond to their current state of health by evaluating either subjective or objective well-being. It is intriguing to investigate whether there is any correlation between these measurements and indicators of illness status, even though they do not provide any direct information on clinical severity.[5] The Psoriasis Area and Severity Index (PASI) is the most extensively used measure of the objective severity of psoriasis symptoms. Both the body surface area (BSA) that is affected by psoriasis, as well as degrees of redness, swelling, and scaliness, contribute to a higher score. The PASI score ranges from 0 to 72, with a score higher than 10 corresponding to moderate-to-severe psoriasis.[6]

Increasing physicians' awareness of the disease's morbidity could enhance their ability to treat psoriasis. This knowledge might enable a physician to prescribe more potent treatments to patients, particularly in cases when systemic medications or phototherapy are required due to severe psoriasis.[4] Hence, the present study was undertaken to assess the clinical severity of psoriasis and its relation to physical disability and psychosocial disability pre and post treatment as well as to find the prevalence of metabolic syndrome and its correlation with severity in psoriasis.

MATERIALS AND METHOD

The present cross-sectional interventional study was conducted among 150 patients diagnosed with chronic plaque psoriasis in the Department of Dermatology, Venereology, and Leprosy at Subharti Medical College, Meerut, over a period of 1.5 years. After obtaining ethical clearance from the ethical committee and the informed consent from patients, patients of Psoriasis were enrolled in the study who fulfilled the inclusion criteria.

The inclusion criteria comprised of patients aged 18-60 years, with no significant underlying medical conditions, and a minimum duration of illness of three months. Additionally, patients were required to have a clinically diagnosed case of chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score greater than 10. Participants were also required to provide consent for enrollment in the study. The exclusion criteria comprised of patients who were under 18 years or above 60 years of age, had serious mental illness, pregnancy, lactation, or significant laboratory abnormalities (hemoglobin <8g/dl, TLC <4000 cells/mm3, platelet count <1 lakh/mm3, lymphocytes <1500 cells/mm3, elevated liver enzymes, total bilirubin >1.2, or serum creatinine >1.4 mg/dl). Patients with acute illnesses (fever, joint pain, abdominal complaints, malignancy, chest pain, or infections) or those taking active systemic therapy were also excluded. Furthermore, individuals with chronic diseases (tuberculosis, hepatitis, arthritis, autoimmune disorders, liver or renal problems), excessive alcohol consumption, or those who failed to provide consent for the study were not eligible for participation.

The study period for each subject was of 8 weeks and follow up for every patient once in 2 weeks but assessment done at baseline and after 8 weeks, if a patient did not report for 2 consecutive follow-ups, he was considered lost to follow-up.

Dermatological examination was carried out under bright light. Detailed examination of the nails, hair, genitals, oral cavity, eyes, scalp and whole body was done in order to record the findings. The diagnosis was made according to detailed history and dermatological examination.

Severity of psoriasis was assessed according to psoriasis area and severity index (PASI). Psoriasis life stress inventory (PLSI) and Psoriasis Disability Index (PDI) was used to study the quality of life. The psoriasis disability index was constructed by analysis of a group of patients who had chronic plaque psoriasis, focusing on which specific questions and on factor analysis, correlated best with disability and symptoms.

Metabolic syndrome was diagnosed by the presence of three or more of the five criteria of the National Cholesterol Education Programme's

Adult Panel III (ATPIII):

- Waist circumference ≥ 102 cm in men or ≥ 88 cm in women;
- Hypertriglyceridaemia≥ 1.7 mmol/1 (≥ 150mg/di);
- High density lipoprotein (HDL) cholesterol ≤1.0mmoll (≤40mg/di) in men or ≤1.3mmol/d1 (≤50mg/dI) in women;
- Blood pressure ≥130/85 mmHg
- Fasting plasma glucose of ≥ 6. 1 mmoll (≥ 100mg/dt)

Routine blood investigations with lipid profile and fasting blood sugar and urine examination were done for all patients. The questionnaire were given to the patients for filling up their responses after that a standard treatment (tablet METHOTREXATE 0.2mg/kg body weight/week) along with some topical medication like topical coal tar with salicylic acid and high potent topical corticosteroid with salicylic acid were given to all clinically diagnosed cases of chronic plaque psoriasis.

The patients were subjected to a repeat questionnaire after 8 weeks of therapy and repeat CBC, SGOT, SGPT, SERUM CREATINE was done after that. Based on their responses, the effect of psoriasis on the quality of life was assessed.

Statistical analysis was done by using Statistical Package for Social Sciences (SPSS) version 21.0. The observations were described in terms of proportions. Results were subjected for appropriate statistical analysis group wise comparison was done by unpaired T test. Categorical data was analyzed by chi-square test, correlation analysis was done by Pearson's correlation coefficient. 'p'- value of' 0.05 was considered as statistically significant.

RESULTS

Table 1: Pre-post Comparison Of Mean PLSI Scores Among Subjects

	Time line	Mean	Std. Deviation	t value	p value
Mean PLSI scores	Baseline	16.4	7.5	22.872	<0.01*
	8 weeks	5.0	3.3		
Mean PASI scores	Baseline	19.6	8.6	26.484	<0.01*
	8 weeks	4.9	3.7		
Mean PDI scores	Baseline	21.3	8.0	28.049	<0.01*
	8 weeks	6.9	3.8		

Table 1 shows pre-post comparison of mean PLSI scores among subjects results revealed that mean PSLI score was found 16.4 at baseline and 5.0 after 8 weeks it was found statistically significant (P<0.01). The mean PASI score was found 19.6 at baseline and 4.9 after 8 weeks it was found statistically significant (P<0.01). The mean PDI score was found 21.3 at baseline and 6.9 after 8 weeks it was found statistically significant (P<0.01)

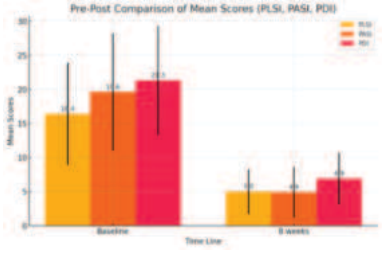


Table 2: Prevalence Of Metabolic Syndrome Among Study Subjects

Metabolic syndrome	Frequency	Percent
Absent	97	64.7
Present	53	35.3

Table 2 shows 35.3 prevalence of metabolic syndrome among study subjects.

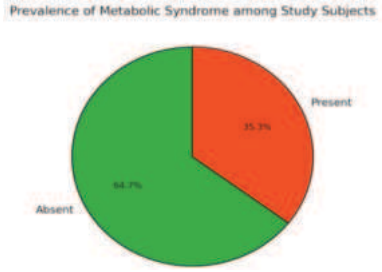


Table 3: Comparison Of Mean PLSI Of Study Subjects At Different Time Poins According To Presence Of Metabolic Syndrome

Time line	Mets	Mean	Std. Deviation	t value	p value
Baseline	Absent	16.23	7.24	-.013	0.989
	Present	16.25	8.53		
8 weeks	Absent	4.90	3.43	-.283	0.778
	Present	5.07	3.01		

Table 3 shows Comparison of mean PLSI of study subjects at different time points according to presence of metabolic syndrome results revealed that mean PLSI score was found 16.25 at baseline and 5.07 after 8 weeks among subjects in which Mets present it was found statistically non significant at baseline (P=0.989) and at 8 weeks (0.778).

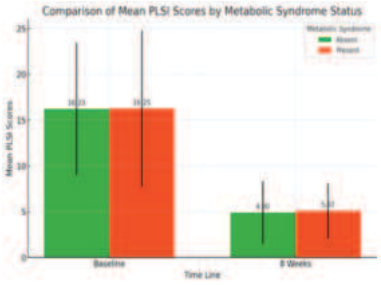


Table 4: Comparison Of Mean PASI Of Study Subjects At Different Time Points According To Presence Of Metabolic Syndrome

Time line	Mets	Mean	Std. Deviation	t value	p value
Baseline	Absent	19.96	8.73	0.440	0.661
	Present	19.26	9.64		
8 weeks	Absent	4.87	3.73	-.066	0.948
	Present	4.91	3.84		

Table 4 shows Comparison of mean PASI of study subjects at different time points according to presence of metabolic syndrome results revealed that mean PASI score was found 19.26 at baseline and 4.91 after 8 weeks among subjects in which Mets present it was found statistically non significant at baseline (P=0.989) and at 8 weeks (0.778).

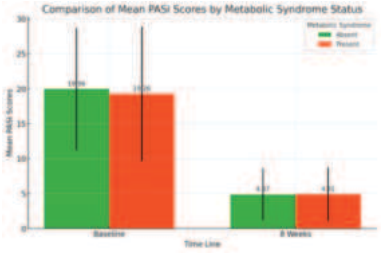


Table 5: Comparison Of Mean PDI Of Study Subjects At Different Time Points According To Presence Of Metabolic Syndrome

Time line	Mets	Mean	Std. Deviation	t value	p value
Baseline	Absent	21.64	8.86	0.823	0.412
	Present	20.57	6.87		
8 weeks	Absent	7.05	4.25	0.846	0.399
	Present	6.51	2.79		

Table 5 shows Comparison of mean PDI of study subjects at different time points according to presence of metabolic syndrome results revealed that mean PDI score was found 20.57 at baseline and 6.51 after 8 weeks among subjects in which Mets present it was found statistically non significant at baseline (P=0.412) and at 8 weeks (0.399).

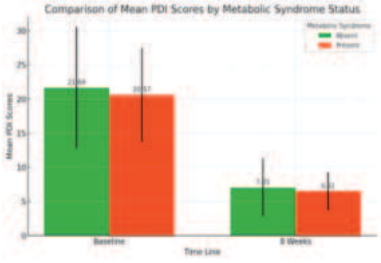


Table 6: Gender With Pre-post Treatment Wise PLSI, PDI, PASI Score

	Gender	Mean	Std. Deviation	t value	p value
PLSI Baseline	Male	17.05	7.64	2.081	0.041
	Female	14.21	7.51		
PLSI 8 Weeks	Male	5.01	3.19	.266	0.791
	Female	4.83	3.54		
PASI Baseline	Male	20.88	9.27	2.723	0.008
	Female	16.83	7.79		
PASI 8 Weeks	Male	4.92	3.67	0.179	0.858
	Female	4.78	4.00		
PDI Baseline	Male	22.25	8.20	2.426	0.017
	Female	18.79	7.78		
PDI 8 Weeks	Male	6.89	3.70	0.110	0.913
	Female	6.80	4.11		

Table 6 shows gender with pre-post treatment wise PLSI, PDI ,PASI score results revealed that mean PLSI score was found significant (P=0.041) with gender wise at base line and non significant after 8 weeks (P=0.791), mean PASI score was found significant (P=0.008) with gender wise at base line and non significant after 8 weeks (P=0.858) and PDI score was found significant (P=0.017) with gender wise at base line and non significant after 8 weeks (P=0.913)

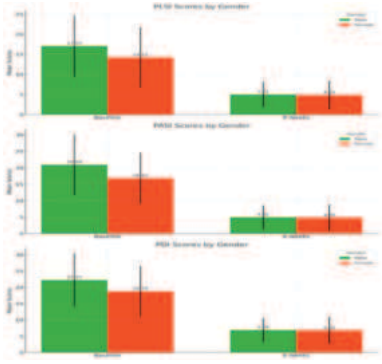


Table 7: History Of Alcohol And Smoking Wise Pre-treatment Wise PLSI, PDI, PASI Score

Time-	Variables		Mean	Std. Deviation	t value	p value
PLSI Baseline	History of alcohol	Absent	14.99	6.73	-3.511	0.001
		Present	21.84	9.27		
	History of Smoking	Absent	16.25	7.64	0.052	0.959
		Present	16.18	7.89		
PASI Baseline	History of alcohol	Absent	18.04	7.36	-3.744	0.001
		Present	27.14	11.68		
	History of Smoking	Absent	19.38	8.86	-.682	0.497
		Present	20.52	9.50		
TOTAL PDI Baseline	History of alcohol	Absent	20.13	6.85	-2.529	0.017
		Present	26.16	11.52		
	History of Smoking	Absent	21.22	8.06		
		Present	21.36	8.65		

Tabe 7 shows history of alcohol wise pre-treatment wise PLSI, PDI, PASI score results revealed that PSLI was found statistically significant (P=0.001), PASI was found statistically significant (P=0.001) and PDI was found statistically significant (P=0.017); and baseline history of smoking wise pre-post treatment wise PLSI, PDI, PASI score results revealed that PSLI was found statistically non-significant (P=0.959) , PASI was found statistically non-significant (P=0.497) and PDI was found statistically non-significant (P=0.923) at baseline.

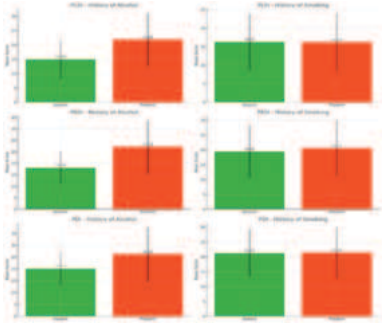
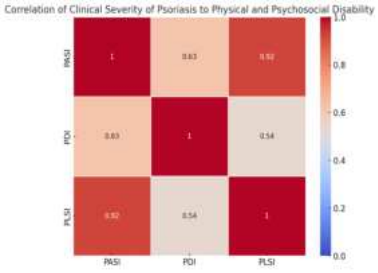


Table 8: Correlation Of Clinical Severity Of Psoriasis To Physical Disability And Psychosocial Disability Before Treatment.

		PASI	PDI	PLSI
PASI	r value	1	0.627**	0.923**
	p value		0.000	0.000
PDI	r value	0.627**	1	0.537**
	p value	0.000		0.000
PLSI	r value	0.923**	.537**	1
	p value	0.000	0.000	

Table 8 shows correlation of clinical severity of psoriasis to physical disability and psychosocial disability before treatment results revealed that PASI score was found significant with PDI (P=0.000) and PLSI (P=0.000) and PDI score was fond statistically significant PLSI (P=0.000).



DISCUSSION

The current study included patients aged 18-60 years who had a clinical diagnosis of chronic plaque psoriasis with a PASI score more than 10, and who did not have any other relevant medical disorders. The patients were provided with a questionnaire to record their responses. Following that, all clinically diagnosed cases of chronic plaque psoriasis were treated with a standard treatment consisting of tablet methotrexate at a dosage of 0.2mg/kg body weight per week. Additionally, topical medication such as topical coal tar with salicylic acid and high-potency topical corticosteroid with salicylic acid were administered. After 8 weeks of medication, the patients underwent a follow-up questionnaire and had their CBC, SGOT, SGPT, and serum creatinine levels retested.

Maximum (26%) patients were aged 21-30 years followed by 41-50 years (25.3%), 31-40 years (22%), 51-60 years (20.7%) and least were aged <20 years. In a similar study, Vora R et al[7] found that among a total of 120 participants, 60% were males and 40%females with the most prevalent age group impacted was individuals between the ages of 41 and 60 (55%) which corresponds to our study. Additional studies have also documented similar age ranges. Manjula VD et al[8] found a mean age of 45 years, Vettuparambil A et al[9] recorded an average age of 45.46 years, Aghaei S et al[10] noted a mean age of 34 years, Rakesh SV et al observed an age of 38.42 years, our study revealed a higher proportion of males compared to females, which aligns with findings from previous studies.

The Psoriasis Disability Index (PDI) questionnaire was specifically developed to assess the impact of psoriasis on individuals. The questionnaire is inherently comprehensible and can be given directly to the patient, who is instructed to complete it without requiring a thorough explanation. The PDI is determined by summing the scores of all 15 questions, resulting in a range of values from zero to a maximum of 45. As the score increases, the quality of life is increasingly affected. The scores can alternatively be represented as percentages. [87] A statistically significant ($p<0.01$) PDI scores (21.3±8.0 to 6.9±3.8) ($t=28.049$) at baseline to after 8 weeks respectively. Vora R et al[11] in an alike study found that the average PDI, was 21.62 (standard deviation = 14.21) correspondingly and similar to our study, a strong positive association between PDI and PASI ($r=0.9666$, $p=0.001$).) Similar study by Manjula VD et al (2011)[8] found that among the PDI subsets, daily activities were affected the most (90.6%), followed by work (84.4%), leisure activities (71.9%), problems with treatment (68.7%) and the least affected was personal relations (62.5%). Overall PDI score (median 14.5, interquartile range 4.5–22) showed that the QoL was affected in 75% of which 9.4% were mild (score < 9), 31.2% were moderate (score 10–18) and 34.4% were severe (score > 18). There was no association between the total PDI score and age or gender. Rakhesh S V et al (2008)[12] reported that the clinical PASI scores correlated significantly with the overall physical disability (PDI), individual aspects of the PDI (except the treatment-related

activities), and the measurement of stress incurred (PLSI). Pakran J (2011)[13] measured the clinical severity using psoriasis area severity index and health-related quality of life using psoriasis disability index (PDI) and identified that a younger age at onset of disease and self-reported stress exacerbators suffer greater disability in most aspects of quality of life. On the basis of this study, it was recommended that psoriasis patients especially with severe disease require a more holistic treatment approach that encompasses both medical and psychological measures.

The PASI score is a comprehensive measure that evaluates both the severity of skin lesions and the extent of affected area. It ranges from 0 (indicating no disease) to 72 (representing the most severe disease).[7] A statistically significant ($p<0.01$) difference was found in pre and post mean PASI scores (19.6±8.6 to 4.9±3.7) (t=26.484) at baseline to after 8 weeks respectively. Vora R et al[11] in an alike study found that the average PASI scores were 12.79 (standard deviation = 9.79. Rakhesh S V et al (2008)[12] found that the clinical PASI scores correlated significantly with the overall physical disability (PDI), individual aspects of the PDI (except the treatment- related activities), and the measurement of stress incurred (PLSI). A PASI score of more than 18 delineated a subgroup of patients with higher overall physical disability and higher stress rating and provided a compelling evidence that psoriasis affects the quality of life, and it highlights the importance of adopting a multidimensional assessment of psoriasis.

The psychosocial impact of psoriasis may result in significant daily stress for the patient. The Psoriasis Life Stress Inventory (PLSI), provides a rating of psoriasis- related stress. A statistically significant ($p<0.01$) and a positive correlation difference was found in pre and post mean PLSI scores (16.4 ±7.5 to 5.0±3.3) (t=22.872) at baseline to after 8 weeks respectively. Similar study by Gupta MA et al[14] found that a PLSI score over 10 was associated with patients who had higher overall psoriasis severity ($P = 0.007$), more visibly disfiguring psoriasis, more frequent flare-ups of psoriasis, and more severe itching. To the nutshell, with the treatment over a span of 8 months, present study found improvement in the quality of life (reduction in Psoriasis Disability Index (PDI), decrease in the severity of skin lesions and the extent of affected area (reduction PASI score) and decrease of psychosocial impact of psoriasis (reduction of PLSI score) among the psoriasis patients. The Psoriasis Disability Index (PDI) questionnaire was specifically developed to assess the impact of psoriasis on individuals. The PDI is determined by summing the scores of all 15 questions, resulting in a range of values from zero to a maximum of 45. As the score increases, more the quality of life is impacted.

A statistically significant correlation of clinical severity of psoriasis to physical disability and psychosocial disability i.e. with PDI (p=0.000) and PLSI (p=0.000) and PDI score (p=0.000) before and after treatment was found. Similar to our study, Mathew TL et al[15] reported that although the average values of PASI, PDI, and PLSI were greater during the stressful event, a highly significant correlation between the clinical severity (PASI) and total PDI score ($r = 0.418$, $p < 0.001$), however, their study did not find any significant variations in illness severity, quality of life (QoL) variables, and stress. Another concomitant study by Rakhesh SV et al[12] found that the overall PASI score exhibited a strong correlation with both the total PDI ($r = 0.598$; $P < 0.001$) and the whole PLSI ($r = 0.529$; $P < 0.001$). The proportion of the variability in PASI that can be accounted for by a change in PDI is 36%, whereas the proportion explained by a change in PLSI is 28%. The total PDI showed a strong positive correlation ($r = 0.866$; $P < 0.001$) with PLSI, explaining 76% of the variability in PLSI. The total PDI, PASI, and PLSI scores exhibited a positive correlation, and this association was determined to be statistically significant.

Fortune DG et al[16] also discovered that his patients with psoriasis who experienced significant levels of stress saw themselves as impaired in all aspects of daily life, as evaluated by PDI. Psychological discomfort, manifested as excessive anxiety, has a substantial and adverse impact on the outcome of treatment in individuals with psoriasis. Psoriasis patients who are categorized as high-level worriers may experience advantages from additional psychological intervention prior to and during treatment. These findings offer more proof of the presence of a brain-skin axis.[16]

A non-significant relation was found between gender with pre and post treatment wise PLSI (p=0.041, p=0.791), PASI (p=0.008, p=0.858), PDI score (p=0.017, p= 0.913) respectively. Similar to our study, Gupta MA et al[14] could not identify any variations in the severity of psoriasis based on age or gender. Patients in the 18 to 29 and 30 to 45 year age groups, regardless of gender, reported more frequent issues related to appearance/socialization and occupation/finances compared to patients in the 46-65 and over-65-year age groups. These differences were statistically significant ($P < \text{or} = 0.05$). No statistically significant gender differences ($P \leq 0.05$) were seen in the frequency of items related to appearance and socialization. However, men reported experiencing higher levels of work-related stress. In contrast to our study, Vora R et al[11] demonstrated that the PDI had a statistically significant correlation with gender.

In the present study we observed metabolic syndrome in 35.3% of patients. PLSI score was inversely correlated with metabolic syndrome at baseline (p=0.989) (t=- 0.13) and after therapy (p=0.778) (t=-0.283). A non-significant association was found between metabolic syndrome and PASI score at baseline (p=0.661), following treatment (p=0.948), and PDI score (p=0.412) and 8 weeks (p=0.399).

CONCLUSION

The study revealed a significant correlation between the severity of psoriasis and both physical disability and psychosocial disability. Additionally, when examining the relationship between psoriasis and metabolic syndrome, no significant correlation was observed. The historical data on alcohol use indicated that there was a statistically significant difference in PSLI, PASI, and PDI at baseline (P=0.017) and after 8 weeks (P=0.015). In this investigation, we identified metabolic syndrome in 35.3% of the patients. The PLSI score shown a negative correlation with metabolic syndrome both at the beginning (p=0.989) (t=-0.13) and after therapy (p=0.778) (t=-0.283). No significant correlation was seen between metabolic syndrome and PASI score at baseline (p=0.661), after treatment (p=0.948), and PDI score (p=0.412) at 8 weeks (p=0.399).

Conflict of Interest: The authors confirm there are no conflicts of interest.
Funding: The study did not receive any financial support.
Consent: Written informed consent was obtained from all participants and securely archived.
Ethical Approval: The study received ethical clearance, adhering to the required institutional protocols.

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