Omentin-1 Level in Psoriatic Patients Treated with Narrow Band Ultraviolet B Phototherapy Versus Acitretin: A Randomized Control Trial

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Abstract

Background: Psoriasis is a chronic inflammatory skin disease that not fully understood till now. Many treatment options has been implicated. Omentin 1 is anew marker implicated in many diseases.

Objectives: To show association betweenserum level of Omentin-1 in psoriatic patients and its correlation with psoriasis area and severity index (PASI) score before and after treatment with narrow band ultraviolet B phototherapy (NBUVB) and Acitretin.

Patients and Methods: This randomized controlled trial was carried out on forty psoriatic cases and twenty normal controls. Patients were randomized into two groups, 1st, NBUVB group:included 20 patients treated with NBUVB. 2nd, acitretin group: included 20 patients treated with acitretin. 3rd group is a control group: included 20 normal healthy individual. Patients were subjected to blood sampling to detect serum levels of omentin-1 by ELISA.

Results: There was a highly significant difference in omentin 1 level ($p<0.001$) between patients and control group. A significance difference in serum levels of omentin-1 before and after treatment in both groups ($p<0.001$). No significant difference was found between both groups after treatment ($p = 0.334$). PASI score was significantly reduced in both groups with ($p < 0.001$) with significant reduction in Acitretin group ($p < 0.001$).

Conclusion: Omentin-1 levels is significantly lowered in psoriasiscompared to the controls. Omentin-1 levels significantly increased after NB-UVB and Acitretin therapy. Omentin-1 may be a future marker for psoriasis help in diagnosis and treatment.

Keywords: Psoriasis, Omentin-1, NB-UVB, Acitretin.

Introduction:

Psoriasis is a chronic inflammatory skin disease with increased proliferation of epidermal cells and infiltration of leukocytes. There is increased awareness that psoriasis is associated with systemic disorders. Numerous studies have demonstrated that psoriasis is significantly associated with metabolic syndrome or its components such as obesity, insulin resistance, hypertension, and atherogenic dyslipidemia [1].

Prevalence of psoriasis in different countries ranges between 0.09% and 11.43%. Psoriasis, on average, affects 2-5% population globally. Though it has spread globally, its prevalence differs among different locations and ethnicities. Generally higher the latitude, the higher is the prevalence [2]. Therefore, Asian and African countries are less prone to psoriasis than the counties away from the equator like Europe and Australia [3]. Psoriasis affects both sexes more or less equally, but in women, the onset of the disease is at a much earlier stage [4]. Studies have shown that the prevalence of the disease has increased many folds over the past years [5].

In psoriasis, adipokines may be implicated in disease onset, progression, severity as well as in the pathogenesis of comorbidities [6]. Omentin is a newly identified secretory protein and omentin-1 has been shown to be the major circulating isoform in human serum [7]. Omentin-1 is expressed in all layers of the epidermis, vascular endothelial cells, hairfollicles, sweat glands, and sebaceous glands of the dermis. Intriguingly, similar to the results of serum omentin-1 levels, omentin-1 expression was significantly decreased in psoriatic lesions compared with normal skin [8].

Phototherapy is a therapeutic method used in several skin diseases such as vitiligo, psoriasis, atopic dermatitis, parapsoriasis, cutaneous T-cell lymphoma (CTCL), scleroderma, graft versus host disease (GVHD) and Idiopathic photodermatoses polymorphic light eruption, solar urticaria, actinic prurigo, chronic actinic dermatitis[9]. Acitretin acts by modulating the proliferation of epidermal keratinocytes. In hyperproliferative tissue, such as psoriasis plaques, acitretin has an antiproliferative effect, whereas in healthy tissues it induces proliferation. In psoriasis, this antiproliferative action reduces desquamation, erythema, and the overall thickness of the lesion [10].

The aim of this study was to To show association betweenserum level of Omentin-1 in psoriatic patients and its correlation with psoriasis area and severity index (PASI) score before and after treatment with narrow band ultraviolet B phototherapy (NBUVB) and Acitretin

Patients and Methods:

This randomized controlled trial included a total of 60 subjects; 40 patients with psoriasis vulgaris and 20 age& sex matched normal persons served as control. They were recruited from patients attending the Dermatology Outpatient Clinic, Aswan University, in the period from November 2018 till June 2021.

Sample size calculation was done using G*power 3 software. A calculated minimum sample of 60 subjects was required to detect size of 0.3 in the correlation between Serum Level of Omentin-1 in Psoriatic Patients Before and After Narrow band Ultraviolet B Phototherapy with an error probability of 0.05 and 80% power on two-tailed test.

Patients were randomly divided into two groups according to randomized coded cards. Randomization was done using tables of random numbers that were arranged in a successive order. First group included 20 patients who were treated with NBUVB phototherapy and the second included 20 patients were treated with acitretin. The third group is the normal control group that included 20 normal healthy subjects.

Patients with malignancies, patients received NB-UVB phototherapy in the last 6 months, patients treated with methotrexate or biologic agents and any systemic treatment of psoriasis, pregnant and lactating females, female in child bearing period planning to conceive in the next 3 years, and patients with debilitating or immunosuppressive diseases have been excluded from this study.

The study was approved by the Aswan Medical College Institutional Review Board with registration number (288/9/18). The study was registered at www.clinicaltrials.com/NCT05203354 with registration number NCT05203354. The study was carried out according to the principles outlined in the Declaration of Helsinki. All participants signed written informed consent before entering the study. Confidentiality was assured for all participants.

Methodology:

At the baseline, all subjects included in the study were subjected to complete history taking, complete general and dermatological examination, and investigation to exclude any other associated systemic disease, body mass index (BMI) and omentin -1 measurement.

Clinical assessment:

All patients were subjected to full medical history and complete general and local examination. PASI score was used to evaluate the patients with psoriasis vulgaris before and after treatment by NB-UVB phototherapy and acitretin therapy. The disease severity was considered as; mild if PASI < 15, moderate if PASI =15–25, and severe if PASI >25. Any adverse effects of treatments were recorded.

Treatment protocol:

Narrowband ultraviolet B treatment:

Twenty patients with psoriasis vulgaris were treated 2 times per week (on nonconsecutive days) for 3 months with NB-UVB (311 nm) phototherapy. The machine used was equipped by eight narrowband UVB lamp (TL01) of Waldmann type F 85/100W-01. These lamps had a radiation spectrum ranging between 310 and 315 nm with a maximum UV-um of 313 nm 100 L. The UVB lamps of type TL01 were marked with one red and one blue colored band. (Waldman, Villingen-Schwenningen, Germany) lighting UVB lamps (TL01lamp) had a physical irradiance value (intensity) 7–10 mW/cm2 and biological effect (erythematous) irradiance 0.4–0.6 mW/cm^2. The initial dose was 0.25 J/cm^2, then the dose was increased at each session by 10–20% with a maximum dose of 5 J/cm2. When erythema, pain, or blistering occurs, the dose was decreased by 20% or the sessions stopped temporarily. At the setting of NB-UVB exposure, patients were instructed to use eye protection 'UV goggles' and male patients to shield genitalia, and also avoided of sunlight exposure during the phototherapy course. Initial NB-UVB was calculated to be 70% of the MED.

Acitretin treatment:

The second group, twenty patients with psoriasis vulgaris were treated with Acitretin in a dose 0.5-1 mg/kg/day for 3 months. Routine laboratory investigations in the form of (ALT, AST, Cholesterol, Triglyceride level) and CBC was done for each patient.

Assessment of serum level of omentin-1:

Patient blood samples (5 cc) were taken from ante cubital veins of the healthy control subjects and psoriatic patients before and after treatment with NB-UVB phototherapy and acitretin therapy. Samples were taken in serum separator tubes. The blood samples were allowed to clot for 30 min at room temperature before centrifugation for 15 min at 1000g. Serum samples were removed and stored at 20 C until assayed. Commercially available enzyme-linked immunosorbent assay (ELISA) kits (using omentin-1 ELISA Kit, RayBiotech, Norcross, GA) (supplied by the R&D Systems, Minneapolis, MN, Catalog no: DC3L10) were used to assess serum levels of omentin-1for the healthy control subjects and psoriatic patients before and after treatment with NB-UVB phototherapy and acitretin .

Statistical analysis:

Data was analyzed using Statistical Package for Social Sciences (SPSS) software program (version 22). Qualitative variable was recorded as frequencies and percentages and was compared by chi-square test.Quantitative measure was presented as means ± standard deviation (SD) and was compared by student t- test. Regression analysis and correlation between different variable will be performed as indicated. P value < 0·05 will be significant.

Results:

There were no significant differences in mean respondents' age (p = 0.067) between groups. On the other hand, treatment groups and control group were matched for age (p = 0.465).Also no significant differences regarding sex, Weight, Hight and BMI between studied groups (Table 1).

Table 1: Baseline Demographic Characteristics and Anthropometric Measures of the Studied Groups

Variable	Control (I) (n = 20)	NB-UB (II) (n = 20)	Acitretin (III) (n = 20)	P-value*
Age/years	42.90 ± 9.5	46.35 ± 14.1	43.35 ± 13.5	= 0.067
P-value**	I vs. II < 0.064	II vs III = 0.465	I vs. III =0.563	
Sex				
Male	10 (50%)	10 (50%)	11 (90)	= 0.06
Female	10 (50%)	10 (50%)	9 (10)	
Weight/Kg	70.80 ± 13.2	76.95 ± 17.6	77.08 ± 16.4	
P-value**	I vs. II = 0.226	II vs III = 0.979	I vs. III = 0.216	= 0.367
Height/cm	167.00 ± 13.1	160.80 ± 8.8	169.70 ± 7.1	= 0.021
P-value**	I vs. II = 0.056	II vs III = 0.007	I vs. III =0.398	
BMI	25.45 ± 3.9	30.18 ± 4.1	26.71 ± 5.3	= 0.064
P-value**	I vs. II = 0.054	II vs III = 0.094	I vs. III = 0.537	
BMI Category				
Normal	9 (45%)	6 (30%)	7 (35)	= 0.180***
Overweight	9 (45%)	7 (35%)	8 (40)	
Obese	2 (10%)	7 (35%)	5 (25)	

*One-way ANOVA test was used to compare means between groups
**Post-hoc test was used for Pairwise Comparisons
***Chi-square test was used to compare the frequency distribution

There was significant difference in the mean serum level of Omentin-1 ($p < 0.001$) between groups. Controls had significantly ($p < 0.001$) higher level of Omentin-1 (1.6 ± 0.2 ng/ml) compared with both treatment groups (0.38 ± 0.02 and 0.4 ± 0.07 ng/ml). Nonetheless, there was no difference ($p = 0.894$) between treatment groups (Table 2).

Table 2: Omentin-1 Serum levels of the Studied Groups

Variable	Control (I) (n = 20)	NB-UB (II) (n = 20)	Acitretin (III) (n = 20)	P-value*
Omentin-1 (ng/ml)	1.60 ± 0.2	0.38 ± 0.02	0.40 ± 0.07	< 0.001
P-value**	I vs. II < 0.001	II vs III = 0.894	I vs. III < 0.001	

*One-way ANOVA test was used to compare means between groups
**Post-hoc test was used for Pairwise Comparisons

In the bivariate analysis, it was found that with one-year increase in age there was 9% increase in the risk of psoriasis ($p = 0.001$). Also, females had 57% less risk of having psoriasis ($p = 0.134$). Likewise, with one-kg increase in weight there was 3% rise in the psoriasis occurrence probability ($p = 0.155$). And, with one cm increase in height there was 1.5% decrease in the possibility of disease ($p = 0.543$). For BMI, there was 10% more risk with every point increase in BMI ($p = 0.107$). Lastly, with one ng/ml increase in the serum Omentin-1 level there was reduction in the disease risk by 99.4% ($p < 0.001$).In the final multivariate regression model, there were four predictors: age, sex, weight, and serum level of Omentin-1. For age, with one-year increase in age there was 5.5% increase in the risk of psoriasis (AOR=1.055, 95% CI: 1.01–1.09) and this was statistically significant ($p = 0.032$). Regarding sex, females were 97% less liable to have psoriasis than males (AOR=0.03, 95% CI: 1.01–1.77, p-value = 0.035). Likewise, with one-kg increase in weight there was 9.5% rise in the psoriasis occurrence probability (AOR=1.095, 95% CI: 1.001–1.2, p-value = 0.049). Likely, with one ng/ml increase in the serum Omentin-1 level there was reduction in the disease risk by 99.9% (AOR=0.001, 95% CI: 0.001–0.09, p-value = 0.002) and this was statistically significant (Table 3).

Table 3: Independent Effect of Psoriasis on the Omentin-1 plasma levels:

Variable	Bivariate		Multivariable	
	OR (95% CI) *	P-value	AOR (95% CI)	P-value
Age/years	1.090 (1.035–1.148)	= 0.001	1.055 (1.012–1.088)	= 0.032
Sex (Female)	0.429 (0.142–1.297)	= 0.134	0.027 (0.001–0.771)	= 0.035

Weight/kg	1.026 (0.990–1.064)	= 0.155	1.095 (1.001–1.200)	= 0.049
Height/cm	0.984 (0.935–1.036)	= 0.543		
BMI	1.090 (0.981–1.211)	= 0.107		
Omentin-1 (ng/ml)	0.006 (0.001–0.088)	< 0.001	0.001 (0.001–0.091)	= 0.002

*OR=Odds Ratio; CI=Confidence Interval

PASI score was 32.3 ± 2.4 at baseline in NB-UB group while it was 34.6 ± 4.5 in Acitretin group with no statistically significant difference (p=0.3). After treatment, it was 7.6 ± 1.3 for NB-UB group and 7.2 ± 1.5 in Acitretin group with non-statistically significant difference (p=0.841). PASI score was significantly reduced in both groups with (p < 0.001).Additionally, there was improvement in PASI score in both groups but more evident in Acitretin group and this was statistically significant (p < 0.05). Also, significant difference was found for the interaction between time and mode type (p = 0.024) (Table 4) (Figures 1,2).

Table 4: Comparison of PASI Score between Groups before vs. after treatment

(Mean ± SD)	NB-UB Group (n=20)	Acitretin Group (n=20)	P-value*
PASI Score			
Before Treatment	32.33 ± 2.4	34.63 ± 2.5	= 0.3
After Treatment	7.62 ± 1.3	7.22 ± 1.5	= 0.841
P-value**	< 0.001	< 0.001	P = 0.024***

*Mean differences between Group Comparison

*Mean differences within Group Comparison

***Two-way Repeated Measure ANOVA was used to compare the mean differences over time

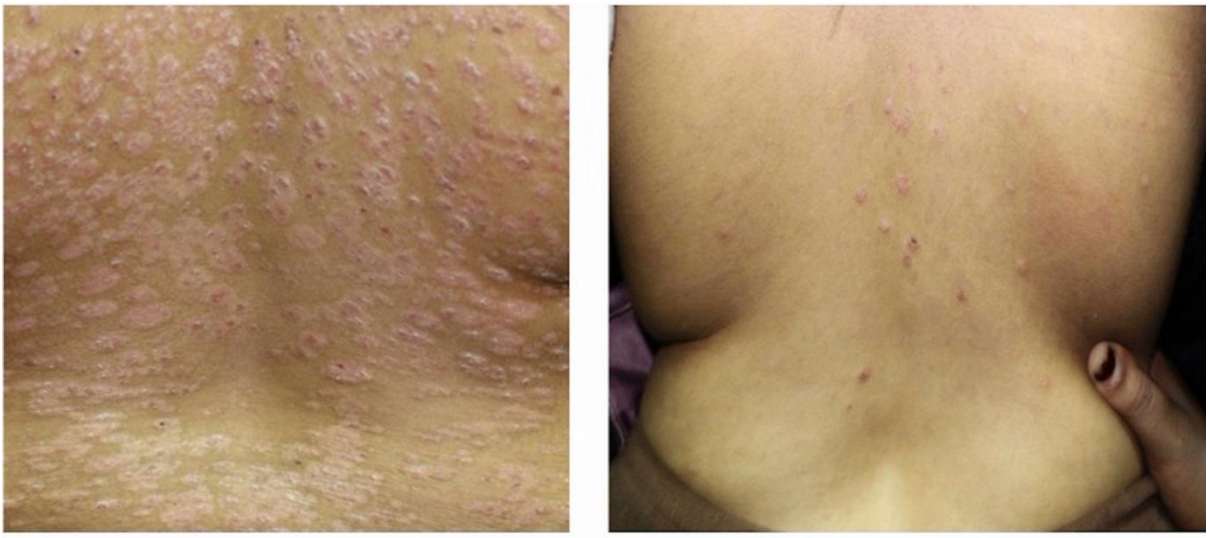

Figure 1: A 40 years old female with plaque psoriasis treated with NBUVB: a)PASI score before treatment was 30 and B) PASI score after treatment was 10.

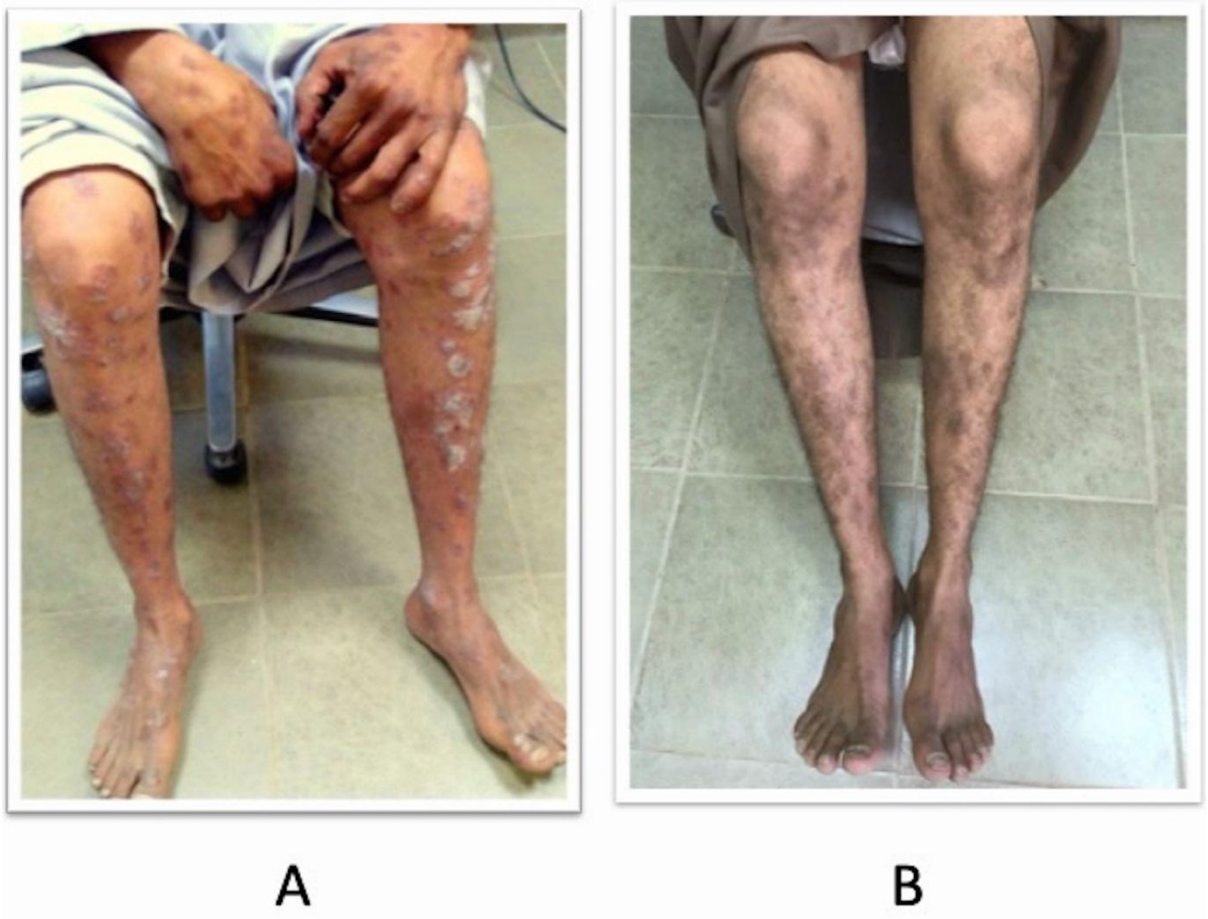

Figure 2: A 50 year-old Male with plaque psoriasis treated with Acitretin: A) PASI score before treatment was 35and B): PASI score after treatment was 10.

Before treatment, the Omentin-1 serum level was insignificantly ($p = 0.770$) higher in in Acitretin group (0.4 ± 0.07 ng/ml) compared with NB-UB group (0.38 ± 0.02 ng/ml).

Likewise, after treatment, it was insignificantly (p = 0.360) higher in NB-UB group (2.96 ± 0.4 ng/ml) than in Acitretin group (2.57 ± 0.2 ng/ml). It was significantly reduced in both groups after treatment (p < 0.001). Additionally, there was improvement in Omentin-1 serum level in both groups with insignificant difference for the interaction between time and mode type (p = 0.334) (Table 5).

Table 5: Comparison of Omentin-1 between Groups before vs. after treatment

(Mean ± SD)	NB-UB Group (n=20)	Acitretin Group (n=20)	P-value*
Omentin-1 plasma levels (ng/ml)			
Before Treatment	0.38 ± 0.02	0.40 ± 0.07	= 0.770
After Treatment	2.96 ± 0.4	2.57 ± 0.2	= 0.360
P-value**	< 0.001	< 0.001	P=0.334***

*Mean differences between Group Comparison

*Mean differences within Group Comparison

***Two-way Repeated Measure ANOVA was used to compare the mean differences over time

In the control group, there was nonsignificant moderate positive correlation between BMI and Omentin-1 (r=0.35, p=0.064). In the NB-UB group, there was nonsignificant mild positive correlation between PASI score and Omentin-1 (r=0.15, p=0.261). Also, there was nonsignificant mild negative correlation between BMI and Omentin-1 (r=-0.15, p=0.064). On the other hand, positive high significant correlation was found between PASI score and BMI (r=0.69, p<0.001) i.e., increase in the BMI was associated with increase in the severity of disease (Table 6).

Table 6: Correlation between Omentin-1, PASI score and BMI in Cases

	Omentin-1	PASI
	r (p-value)	r (p-value)
Control		
PASI	-------	1
BMI	0.352 (p=0.064)	--------
NB-UB		
PASI	0.152 (p=0.261)	1
BMI	-0.150 (p=0.064)	0.692 (p<0.001)
Acitretin		
PASI	-0.495 (p=0.013)	1
BMI	-0.273 (p=0.122)	0.087 (p=0.358)

In the Acitretin group, there was significant high moderate negative correlation between PASI score and Omentin-1 (r=-0.5, p=0.013), in other words, increase in the severity of psoriasis disease was associated with decrease in the serum level of Omentin-1. Also, there was nonsignificant moderate negative correlation between BMI and Omentin-1 (r=-0.27,

p=0.122). On the other hand, positive minimal insignificant correlation was found between PASI score and BMI (r=0.09, p=358) (Table 7) (Figures 3,4).

Table 7: Multiple Linear Regression Analyses of the predictors of Serum Level of Omentin-1 after treatment among Psoriatic Cases

	Estimate	SE	P-value
Intercept	1.149 (0.211 - 2.051)	0.84	= 0.049
Age	-0.014 (-0.048: 0.020)	-0.31	= 0.406
Sex (Female vs. Male)	1.278 (0.166 - 2.390)	0.68	= 0.026
Treatment (NB vs. Acitretin)	-0.395 (-1.259: 0.468)	-0.31	= 0.164
BMI	-1.428 (-3.931: -0.827)	-0.18	= 0.027
PASI Before	-0.031 (-0.062: -0.001)	-0.64	= 0.048
PASI After	0.064 (-0.039: 0.168)	1.05	= 0.215
Omentin-1 Before	-0.056 (-0.087: -0.020)	-0.42	= 0.041

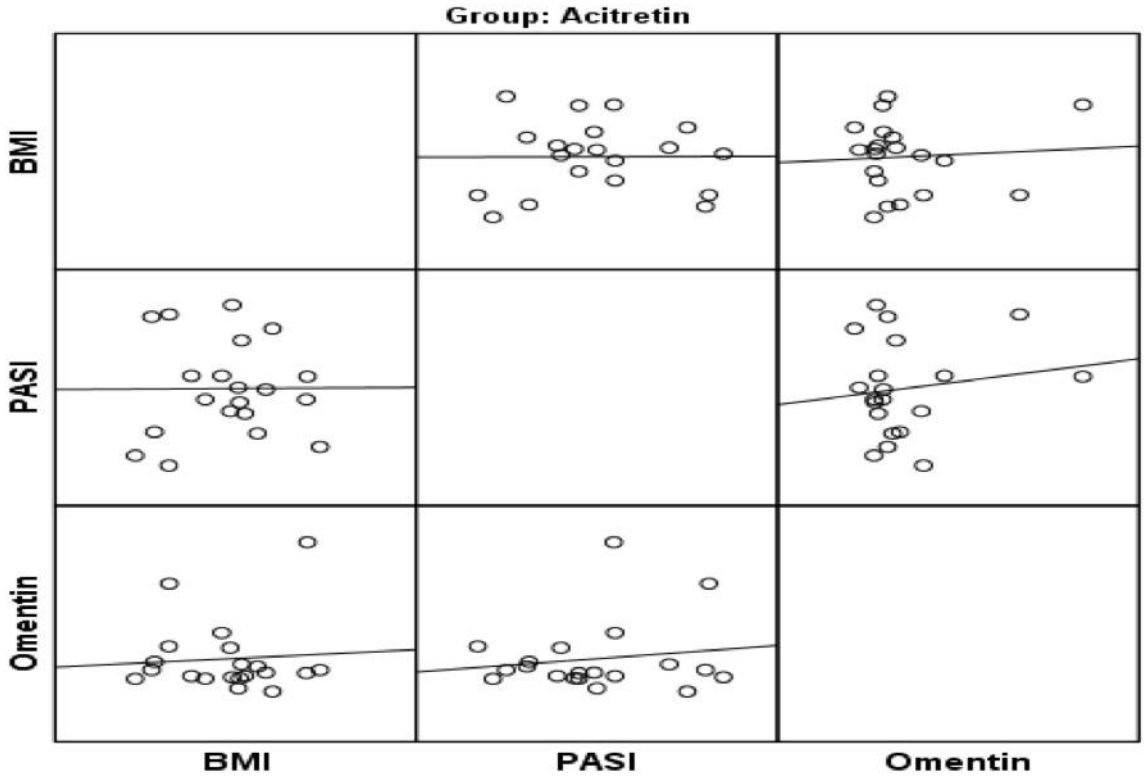

Figure 3: Correlation between Omentin-1, PASI score and BMI in NB-UB Group.

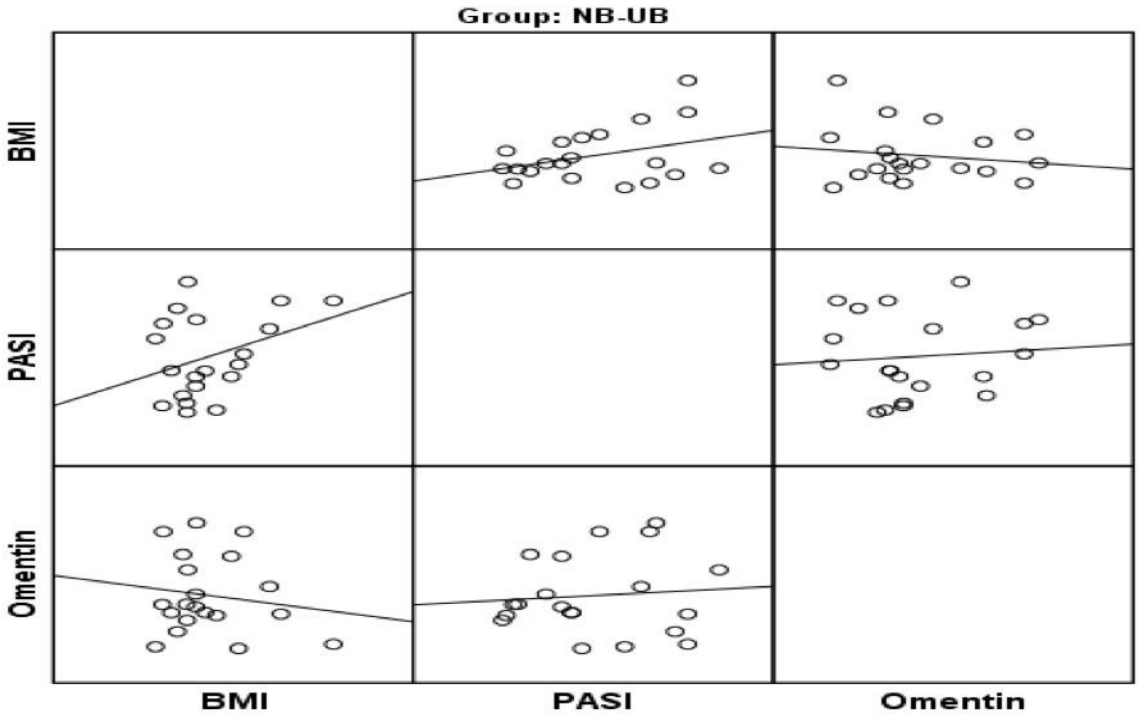

Figure 4: Correlation between Omentin-1, PASI score and BMI in Acitretin Group.

Multivariable linear regression analysis of the significant factors affecting serum Omentin-1 level after treatment among the psoriasis cases has been done. After adjusting for age, the final linear regression model contained three predictors: BMI, PASI before and Omentin-1 before. The intercept (serum Omentin-1 level after treatment) was 1.149 (0.211 – 2.051 ng/ml) after adjusting for all correlates (p = 0.049). Moreover, females had 1.28 ng/ml increase (0.17 - 2.39) and this was statistically significant (p = 0.024). Also, with one-point increase in the BMI there was 1.43 ng/ml (0.83 – 3.93) increase in the Omentin-1 after treatment and this was statistically significant (p = 0.027). Likewise, with one-point increase in the PASI before treatment there was there was 0.03 ng/ml (0.001 – 0.062) increase in the Omentin-1 after treatment and this was statistically significant (p = 0.048). Finally, with one ng/ml decrease in the Omentin serum level before treatment there was there was 0.06 ng/ml (0.02 – 0.09) increase in the Omentin-1 after treatment and this was statistically significant (p = 0.041) (Table 7).

Discussion:

Psoriasis is a common serious, chronic, immune-mediated, hyperproliferative inflammatory skin disease of varying severity, which may induce itchy or painful lesions and negatively impact quality of life. Its prevalence ranges from 0.51% to 11.43% in different countries [11]. White adipose tissue located beneath the skin may contribute to the cutaneous inflammation by secreting adipokines and cytokines. The abnormal cutaneous and systemic expression of adipokines and cytokines could influence the activation, proliferation and differentiation of keratinocytes as well as immune cells contributing to the development of psoriatic lesions [12].

Omentin-1 might be a potential biomarker for the prediction and evaluation of disease severity. Because of functional or anatomical differences between visceral and peripheral fat depots, visceral obesity is more pathogenic in promoting insulin resistance, type 2 diabetes, and cardiovascular disease. Omentin, which is selectively expressed in visceral fat [13].

This studyevaluatedserum omentin-1 level in patients with psoriasis vulgaris and its relationship with PASI score and treatment with NB-UVB phototherapy and acitretin in comparison with control.

In this study, serum of omentin-1 levels were significantly lower in patients with psoriasis vulgaris than healthy control subjects. This finding is in agreement with previous reports found low levels of serum omentin-1 in patients with psoriasis vulgaris compared with healthy control subjects[14,15].**Zhang et al.** [16] measured serum omentin-1 level in 44 patients with psoriasis and 38 healthy controls by using ELISA. They reportedthat serum omentin-1 level was significantly decreased in psoriatic patients compared with controls which matches with the presentstudy. On the contraryto the present study, in a study by **Xue et al.** [17] was done on 41 patients with psoriatic arthritis, serum adipokines (leptin, adiponectin, resistin, chemerin, omentin) were analysed with ELISA. They reported that omentin-1 was significantly increased in patients with psoriatic arthritis compared with both healthy and psoriasis controls, this mightbecause of different sources of samples in their study.

In the present study there was statistically significant increase in the serum omentin-1 level after treatment in both studied groups. In their work, **Takahashi et al.** [18] estimated plasma level of resistin and omentin-1 by ELISA for 62 Psoriaticpatients and 58 healthy controls, patients with psoriasiswere treated with topical steroid, topical vitamin D3, NB-UVB or systemic treatment (etretinate, cyclosporine), reported that the plasma level of omentin-1 was significantly decreased in psoriasis as compared with those of healthy controls ,and reported also that the plasma levels of omentin-1 were significantly increased as compared with those of the pretreatment and this matches also with ourstudy, and suggest that omentin-1 could be a useful biomarker for disease severity or monitoring the response to therapy. Many previous studies reported a high prevalence of metabolic syndrome in patients with psoriasis and increased risk of psoriasis with the increased BMI and obesity [19-21].

Also, **Bakry et al.** [22] reported significantly lower serum level of omentin-1 in patients than control group that negatively correlated with PASI score. On the contrary to our results, some studies reported that no statistically significant correlation could be found between serum omentin-1 and PASI score [23].

In the present work, there was a significant negative correlation between serum level of omentin-1 with BMI in psoratic patients before and after treatment. This is in agreement with many studies which reported that there was a negative correlation of serum omentin-1 with BMI [24].

Conclusion:

This study concluded that the serum level of omentin-1was a significantly loweredin patients with psoriasis vulgaris versus healthy control subjects.There were significant increase in the serum levels of omentin-1 after 3 months of treatment with NB-UVB phototherapy and

acitretin. In addition, there were significant correlations between PASI scores and serum omentin-1 levels before and after treatment with NB-UVB phototherapy and acitretin. Omentin-1 could be considered as an essential biomarker for disease severity, risk ofcomorbidities and treatment success.

Limitations:

This study has some limitations regarding small sample size and lake of follow up.

Financial support and sponsorship: Nil.

Conflict of interest: Nil.

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