Original Article

Efficacy of Intermittent Fasting in the Management of Chronic Plaque Psoriasis: A Phase IIb Clinical Trial

Abstract

Background: Dietary measures have been used as an adjunctive therapy in the management of psoriasis. Intermittent fasting (IF) is an eating pattern in which energy is not consumed for a fixed duration, resulting in metabolic switch from liver-derived glucose to adipose-derived ketones. The data regarding effectiveness of IF in psoriasis are limited. **Aim and Objectives:** The aim of this study was to assess efficacy of IF in patients with chronic plaque psoriasis. The primary outcome of the study was change in psoriasis severity as measured by psoriasis area and severity index (PASI) at 28 weeks. The secondary outcome measures were change in metabolic parameters and biomarkers for atherosclerosis in each group. **Patients and Methods:** The study was designed as a randomized parallel group trial. Clinical parameters, psoriasis severity, fasting and postprandial blood sugar, lipid profile, high sensitivity C-reactive protein (hsCRP), vascular endothelial growth factor (VEGF), and interleukin 6 (IL-6), were measured using standard methods at baseline, 16 weeks, and 28 weeks. Patients were randomized to receive methotrexate in the dose of 0.3 mg/Kg/week with or without intermittent fasting. **Results:** A total of 120 patients were randomized in two groups of 60 each: group 1 (methotrexate) and group 2 (methotrexate and intermittent fasting). The mean age, mean duration of disease, PASI, and dermatology life quality index (DLQI) in group 1 were 45.5 (±12.9) years, 5.06 (±5.5) years, 17.1 (±6.7), and 12.33 (±5), respectively. The mean age, mean duration of disease, PASI, and DLQI in group 2 were and 42.9 (±14.6) years, 6.91 (±6.2) years, 16 (±4.3), and 11.9 (±4.3), respectively. There was no statistically significant difference in baseline parameters in two groups. In both the groups, there was a statistically significant difference in PASI, DLQI, VEGF, and hsCRP from baseline to 16 and 28 weeks. At week 16, 44 (73.3%) patients in group 1 and 47 (78.3%) in group 2 achieved PASI50 (P = 0.8). At week 28, 16 (36%) in group 1 and 27 (54.4%) patients in group 2 maintained PASI50 (P = 0.054). There was a statistically significant weight and waist circumference reduction at 16 weeks and 28 weeks in group 2. There was a statistically significant reduction in VEGF, IL6, and hsCRP at 28 weeks in group 2 as compared to group 1. **Limitations:** The small sample size and loss to follow-up are major limitations of the study. **Conclusion:** Intermittent fasting using 16: 8 protocol is easy to perform and a safe and effective adjuvant for managing severe chronic plaque psoriasis. It helps in maintaining remission and results in improvement in metabolic parameters and markers of vascular inflammation.

Keywords: *Atherosclerosis, intermittent fasting, metabolic syndrome, psoriasis*

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Introduction

Psoriasis is a T-cell-mediated disorder seen in approximately 1–3% of the general population.[1] The prevalence of psoriasis in India varies from 0.44 to 2.8%. Chronic plaque psoriasis is the most common type of psoriasis accounting for almost 90% cases. Other subtypes of psoriasis are erythrodermic psoriasis, guttate psoriasis, and pustular psoriasis. The disease can have exclusive regional involvement such as scalp psoriasis, nail psoriasis, palmoplantar psoriasis, and inverse psoriasis.[2] It is considered a multisystem inflammatory disorder and is associated with psoriatic arthritis, obesity, dyslipidemia, type 2 diabetes mellitus, hypertension, metabolic syndrome, cardiovascular comorbidities, uveitis, and inflammatory bowel disease.[3]

The treatment of psoriasis depends on disease severity, comorbidities, and psychosocial impairment. The treatment options include topical agents; phototherapy; conventional systemic therapies such as methotrexate, cyclosporine, and acitretin; small molecules such as apremilast; and biologics such as TNF α inhibitors (etanercept, infliximab, adalimumab, and

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certolizumab), interleukin (IL) 17 inhibitors (secukinumab, ixekizumab, brodalumab), IL-12/23 inhibitor (ustekinumab), and IL23 inhibitor (tildrakizumab, risankizumab, and guselkumab).[4] Lifestyle measures are very important in the management of psoriasis and should be advised along with pharmacotherapy. Weight reduction, smoking cessation, moderation of alcohol intake, and regular exercise reduce cardiometabolic risks associated with psoriasis.

Dietary measures have been used as adjunctive therapy in the management of psoriasis. Weight loss improves disease control and treatment response. Various diets have been tried in the management of psoriasis, such as Mediterranean diet, ketogenic diet, and gluten-free diet. Other diets that have been used are low carbohydrate/high protein, Palaeolithic diet, and vegetarian diet. Certain food items such as fish oil, fruits, and vegetables have also been reported to improve psoriasis. Intermittent fasting (IF) is an eating pattern in which energy is not consumed for a fixed duration, resulting in metabolic switch from liver-derived glucose to adipose derived ketones. IF improves glucose regulation, suppresses inflammation, and improves stress resistance. These health benefits are not just due to weight loss or reduced free-radical production. The most widely used IF regimens are alternate day fasting, 5:2 IF (fasting 2 days per week), and daily time-restricted feeding. A common type of time-restricted feeding is 16:8 in which 16 hours is fasting time and 8 hours is feeding time. IF improves metabolic parameters and longevity and reduces the incidence of obesity and cancer.[5] The data regarding effectiveness of IF in psoriasis are limited. We conducted this study to assess the efficacy of IF in patients with chronic plaque psoriasis. Atherosclerosis is associated with psoriasis and is chronic vascular inflammation; various biomarkers have been studied to predict the cardiovascular risk. High sensitivity C-reactive protein (hsCRP) is one of the most promising indicators for vascular inflammation, others being IL6 and vascular endothelial growth factor (VEGF). We also assessed the effect of IF on biomarkers of atherosclerosis in these patients.

Patients and Methods

The study was conducted in Department of Dermatology of a tertiary care hospital during the study period from January 2021 to December 2022. The study was approved by the institutional ethical committee vide number IEC/2020/286 dated August 6, 2020 and was registered in the clinical trials registry of India vide CTRI/2020/12/029472 on November 20, 2020.

The study was designed as a randomized parallel group trial.

Patients

The diagnosis of chronic plaque psoriasis was made clinically, and patients with severe chronic plaque psoriasis defined as psoriasis area and severity index (PASI) 10 or more were assessed for inclusion in the study. Patients willing to undertake intermittent fasting for the study duration and aged 18–70 years were included in the study. The exclusion criteria of the study were pregnant and lactating patients, contraindication to methotrexate or intermittent fasting such as uncontrolled diabetes mellitus, and any systemic treatment in the past 6 months.

Sampling and randomization

The study was a preliminary study to assess the efficacy of intermittent fasting in psoriasis, and hence, a feasible sample of 120 patients randomized into two arms with 60 each was included in the study. Block randomization (block of 4) was done using a computer-based randomization protocol, and the results of randomization were concealed and kept in a sealed serially numbered opaque envelope. The severity assessment was done by a blinded assessor.

Data collection

Clinical parameters including age, gender, duration of disease, weight in Kg, waist circumference in cm, and blood pressure were recorded. Severity assessment was done using PASI and dermatology life quality index (DLQI). PASI is an objective score to assess the severity and is calculated using body surface area (BSA), erythema (E), induration (I), and scaling (S). Erythema, induration, and scaling are graded as 0, absent; 1, mild; 2, moderate; 3, severe; and 4, very severe. BSA is assessed separately for four regions of the body – head and neck, upper limbs, trunk, and lower limbs; it is graded as 0, nil; 1, 1–9%; 2, 10–29%; 3, 30–49%; 4, 50–69%; 5, 70–89%; and 6, 90–100%. PASI is finally calculated using the following formula: 0.1 (head and neck) (E + I + S) BSA + 0.2 (upper limb) (E + I + S) BSA + 0.3 (trunk) (E + I + S) BSA + 0.4 (lower limb) (E + I + S) BSA. The maximum score is 72. Blood sugar fasting, post prandial blood sugar, and lipid profiles were measured using standard methods. 3 ml serum was collected and stored at -80^0 C for assessment of hSCRP, VEGF, and IL-6 using ELISA. All the parameters were assessed at baseline, 16 weeks, and 28 weeks.

Protocol

Patients were randomized to receive methotrexate in the dose of 0.3 mg/Kg/week with or without IF. IF was done as time-restricted feeding with 16: 8 hours protocol (16 hours fasting and 8 hours feeding time) 7 days a week. The counseling and support for IF were provided by the dietician. Patients were asked to maintain a diary of meal timings and were assessed every 4 weeks for compliance. Patients maintaining IF schedule 80% of study duration were only assessed in the study.

Methotrexate was given in both the groups and PASI was assessed at 16 weeks. It was stopped in patients who achieved 50% reduction in PASI (PASI50) and observed without systemic treatment for 12 weeks. Patients who

failed to achieve PASI50 were considered as failure, and alternative treatment was started. IF continued in the intervention group for next 12 weeks. Topical emollients were allowed during the study.

Statistical analysis

The data were entered in an excel sheet. The continuous variables were defined as mean and standard deviation, and qualitative variables were defined as frequency and percentage. Paired *t*-test was performed for within group and unpaired *t*-test for intergroup comparison of various parameters. Chi-square test was used for categorical variables. A *P* value of less than 0.05 was taken as statistically significant. The data was analyzed using SPSS 20.

Results

A total of 166 patients were assessed for inclusion; 46 were excluded (16 did not meet age criteria, 18 refused to perform IF, 6 with methotrexate contraindication, 6 with poorly controlled diabetes), and 120 patients were randomized in two groups of 60 each: group 1 (methotrexate) and group 2 (methotrexate and IF). The flow diagram of the study is presented below [Figure 1].

The mean age, mean duration of disease, PASI, and DLQI in group 1 were 45.5 (±12.9) years, 5.06 (±5.5) years, 17.1 (±6.7), and 12.33 (±5), respectively. The mean age, mean duration of disease, PASI, and DLQI in group 2 were 42.9 (±14.6) years, 6.91 (±6.2) years, 16 (±4.3), and 11.9 (±4.3), respectively. There was no statistically significant difference in baseline parameters in the two groups. The rest of the baseline parameters are tabulated in Table 1.

In group 1, 12 patients did not achieve PASI50 and 4 patients were lost to follow-up at 16 weeks. A total of 44 patients achieved PASI50, methotrexate stopped, and were followed up for further 12 weeks [Figure 2]. At 28 weeks, 16 patients maintained PASI50 and 28 patients lost PASI50 response. The mean PASI at baseline, 16 weeks, and 28 weeks was 17.1 (±6.7), 7.47 (±4.6), and 9.3 (±4.1), respectively. The mean DLQI at baseline, 16 weeks, and 28 weeks was 12.33 (±5), 5.21 (±3.2), and 6.76 (±3), respectively. The mean VEGF level at baseline, 16 weeks, and 28 weeks was 236.88 (±245.8), 149 (±159.6), and 163.44 (±183.2) pg/ml, respectively. The mean hsCRP at baseline, 16 weeks, and 28 weeks was 4.56 (±4), 2.35 (±2.7), and 3.41 (±3) mg/L, respectively. There was a statistically significant difference in PASI, DLQI, VEGF, and hsCRP from baseline to 16 and 28 weeks. The rest of the parameters are tabulated in Table 2.

In group 2, 10 patients did not achieve PASI50 and 3 patients were lost to follow-up at 16 weeks. A total of 47 patients achieved PASI50, methotrexate was stopped, and IF was continued for 12 more weeks [Figure 3]. At 28 weeks, 20 patients lost PASI50 response, while 27 patients maintained PASI50 response. The mean PASI at baseline, 16 weeks, and 28 weeks was 16 (±4.3), 6.62 (±3.7), and 7.72 (±2.7), respectively. The mean DLQI at baseline, 16 weeks, and 28 weeks was 11.9 (±4.3),

Table 1: Baseline parameters in the two groups

Parameter	Group 1 (Methotrexate) (mean±SD)	Group 2 (Methotrexate and intermittent fasting) (mean±SD)	*P*
Age (years)	45.5 (±12.9)	42.9 (±14.6)	0.30
Gender	36 M: 24 F	44 M: 16 F	
Duration (years)	5.06 (±5.5)	6.91 (±6.2)	0.12
Weight (Kg)	68.58 (±12)	67.38 (±14.2)	0.62
Waist circumference (cm)	91.93 (±8.7)	93.48 (±11.8)	0.77
PASI	17.1 (±6.7)	16 (±4.3)	0.43
DLQI	12.33 (±5)	11.9 (±4.3)	0.63
SBP (mm Hg)	129.38 (±17.1)	125.8 (±16.5)	0.25
DBP (mm Hg)	84.9 (±13.4)	83.23 (±10.46)	0.44
BSF (mg/dL)	93.5 (±11.9)	97.7 (±21.7)	0.19
BSPP (mg/dL)	111.83 (±18.87)	124.53 (±34.75)	0.01
TC (mg/dL)	187.37 (±37.78)	191.3 (±33.33)	0.48
TG (mg/dL)	134.83 (±71.31)	133.28 (±66.84)	0.92
LDL (mg/dL)	113.58 (±33.6)	124.22 (±29.7)	0.69
HDL (mg/dL)	44.22 (±10)	42.7 (±6.3)	0.32
VEGF (pg/ml)	236.88 (±245.81)	274.14 (±208.86)	0.37
IL6 (pg/ml)	6 (±4.1)	6.55 (±5.6)	0.54
hsCRP (mg/L)	4.56 (±4)	4.39 (±4.13)	0.82

PASI- psoriasis area and severity index; DLQI- Dermatology life quality index: SBP – Systolic Blood pressure; DBP – Diastolic blood pressure; BSF – Blood sugar fasting; BSPP – Blood sugar postprandial; TC – Total cholesterol; TG – Triglyceride; LDL – Low-density lipoprotein; HDL- High-density lipoprotein; VEGF – Vascular endothelial growth factor; IL6 – Interleukin 6; hsCRP – High sensitivity C-reactive protein; SD- Standard deviation

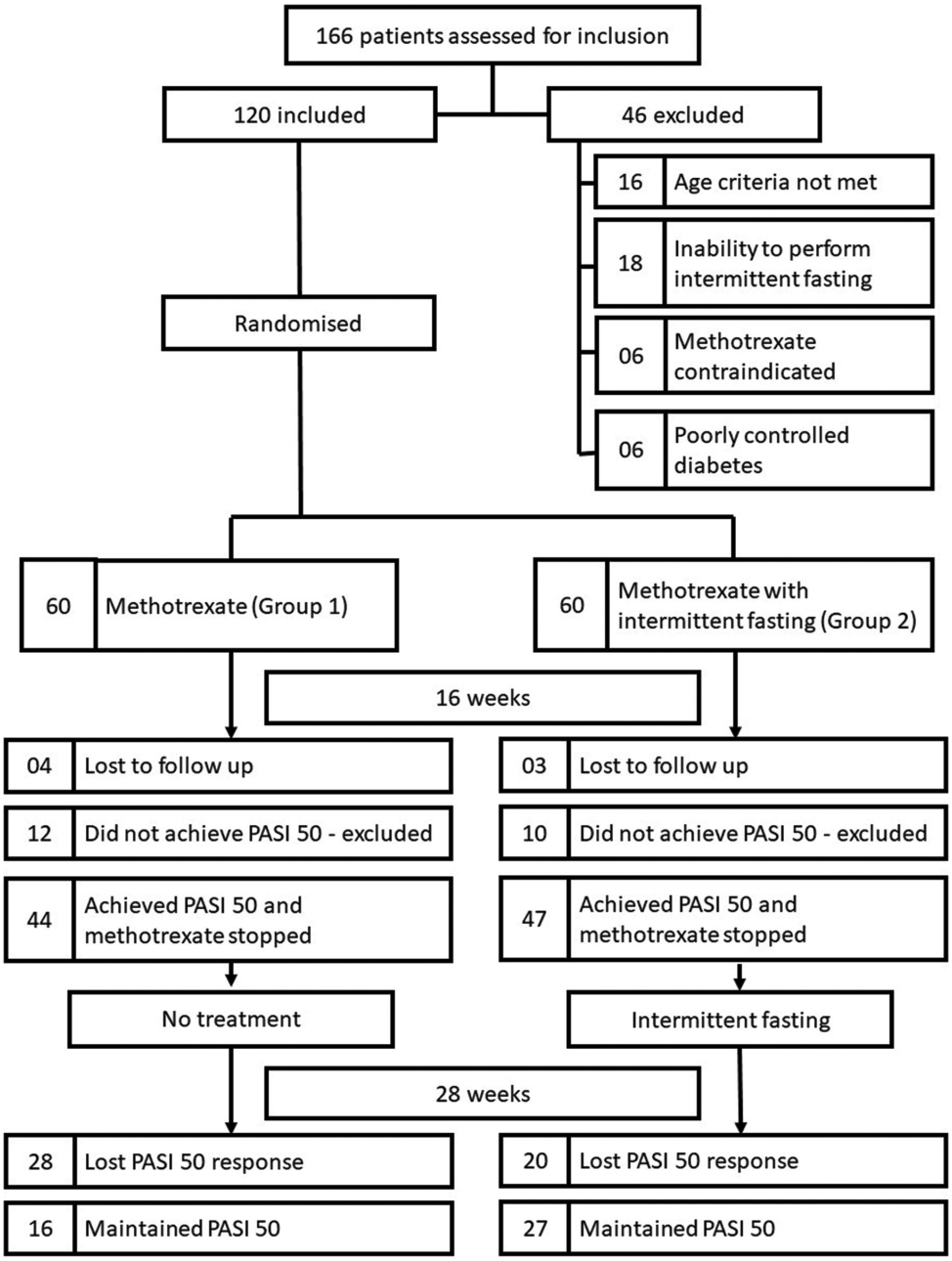

Figure 1: Flow diagram of the study

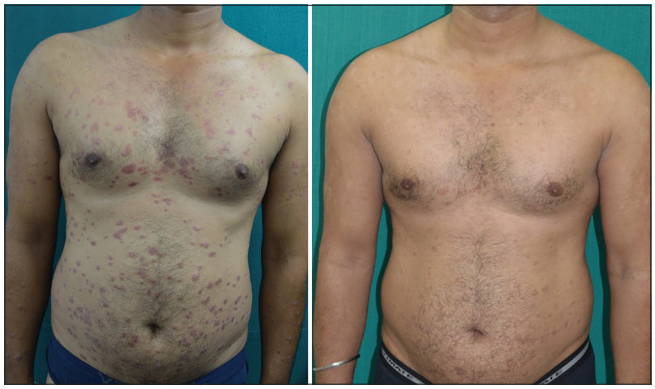

Figure 2: Patient in the methotrexate group before treatment and 28 weeks after treatment

4.89 (±2.3), and 5.14 (±1.3), respectively. The mean VEGF level at baseline, 16 weeks, and 28 weeks was 274.14 (±208.86), 142.33 (±154.8), and 139.77 (±121.1) pg/ml, respectively. The mean IL6 level at baseline, 16 weeks, and 28 weeks was 6.55 (±5.6), 3.63 (±2.8), and 4 (±3.1) pg/ml, respectively. The mean hsCRP level at baseline, 16 weeks, and 28 weeks was 4.39 (±4.13), 2.03 (±2.3), and 2.25 (±2) mg/L, respectively. There was a statistically significant difference in PASI, DLQI, VEGF, IL6, and hsCRP from baseline to 16 and 28 weeks. The rest of the parameters are tabulated in Table 3.

There was a statistically significant reduction in weight and waist circumference at 16 weeks and 28 weeks in the

Table 2: Follow-up of patients in group 1 (methotrexate group)

Parameters	Baseline (*n*=60)	16 weeks (*n*=56)	*P*	28 weeks (*n*=44)	*P*
Weight (Kg)	68.58 (±12)	68.66 (±11.1)	0.96	69.91 (±11.8)	0.67
Waist circumference (cm)	91.93 (±8.7)	92.33 (±8.3)	0.27	93.04 (±8.1)	0.73
PASI	17.1 (±6.7)	7.47 (±4.6)	0.001	9.3 (±4.1)	0.001
DLQI	12.33 (±5)	5.21 (±3.2)	0.001	6.76 (±3)	0.001
SBP (mm Hg)	129.38 (±17.1)	124.75 (±14.1)	0.004	125.82 (±12.6)	0.001
DBP (mm Hg)	84.9 (±13.4)	81.66 (±9.1)	0.016	83 (±8.1)	0.06
BSF (mg/dL)	93.5 (±11.9)	96.46 (±12)	0.042	95.04 (±11.4)	0.75
BSPP (mg/dL)	111.83 (±18.8)	116.55 (±23.8)	0.043	116.47 (±21.7)	0.006
TC (mg/dL)	187.37 (±37.7)	186.32 (±31.9)	0.15	187.96 (±28.1)	0.53
TG (mg/dL)	134.83 (±71.31)	135.48 (±62.4)	0.47	132.58 (±50.4)	0.27
LDL (mg/dL)	113.58 (±33.6)	114.57 (±30.6)	0.99	114.67 (±27.6)	0.18
HDL (mg/dL)	44.22 (±10)	45.2 (±8.4)	0.2	43.84 (±7.1)	0.68
VEGF (pg/ml)	236.88 (±245.8)	149 (±159.6)	0.001	163.44 (±183.2)	0.003
IL6 (pg/ml)	6 (±4.1)	4.1 (±3)	0.001	6.08 (±7.6)	0.8
hsCRP (mg/L)	4.56 (±4)	2.35 (±2.7)	0.001	3.41 (±3)	0.007

VEGF – pg/ml; IL6 – pg/ml; hsCRP – mg/L; PASI- psoriasis area and severity index; DLQI- Dermatology life quality index: SBP – Systolic blood pressure; DBP – Diastolic blood pressure; BSF – Blood sugar fasting; BSPP – Blood sugar postprandial; TC – Total cholesterol; TG – Triglyceride; LDL – Low-density lipoprotein; HDL- High-density lipoprotein; VEGF – Vascular endothelial growth factor; IL6 – Interleukin 6; hsCRP – High sensitivity C-reactive protein

IF group (group 2). There was a statistically significant reduction in VEGF, IL6, and hsCRP at 28 weeks in group 2 as compared to group 1 [Table 4]. At week 16, 44 (73.3%) patients in group 1 and 47 (78.3%) in group 2 achieved PASI50 (P = 0.8). At week 28, 16 (36%) in group 1 and 27 (54.4%) patients in group 2 maintained PASI50 (P = 0.054) [Table 5]. None of the patients reported any serious adverse effects to IF.

Discussion

The main energy sources for cells are glucose and free fatty acids (FFAs). Glucose is used as an energy source in the fed state, while triglycerides are converted to FFA and glycerol in the fasting state. FFA is converted to ketone bodies (acetoacetate and β hydroxybutyrate) by the liver and acts as a source of energy for many tissues. The blood levels of ketones start rising after 8–12 hours of fasting. They also activate transcription factors such as cyclic AMP response elements binding protein and nuclear factor κβ. Decreased availability of glucose results in autophagy and reduced activity of mTOR pathway. This metabolic switch is responsible for health benefits associated with IF.[6,7] IF shows disease modifying effect on chronic diseases such as obesity, diabetes mellitus, cardiovascular diseases, cancers, and neurodegenerative disorders. It has also been shown to improve longevity.[8-11] Many benefits of IF are dissociated from effect on weight loss, such as glucose regulation, blood pressure, endurance training, and abdominal fat loss.[12] IF is found to be a promising dietary intervention for autoimmune diseases such as systemic lupus erythematosus, rheumatoid arthritis, and type 1 diabetes mellitus; it works by changing the cytokine milieu and reducing the proinflammatory cytokines, altering the gut microbiota, modulating the immune response, and improving cellular repair mechanisms. The effect of IF on psoriasis was found to be inconclusive in a review.[13] Time-restricted feeding in the mouse model of psoriasis improved psoriasis-like lesions and reduced inflammatory cytokines in 2 weeks.[14]

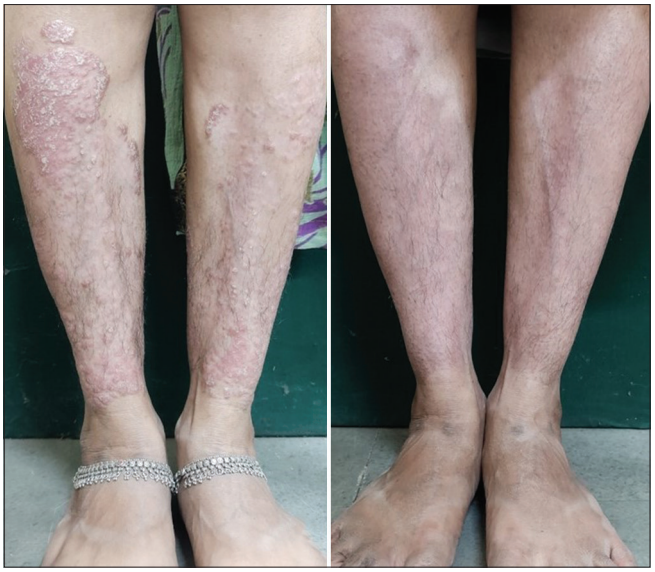

Figure 3: Patient in the methotrexate and intermittent fasting group before and 28 weeks after treatment

Diet has an important role in the management of psoriasis. Low-calorie diet is a useful adjunct in psoriasis treatment and leads to better response in patients on systemic therapy, especially in obese patients.[15] The exact mechanism of beneficial effects of IF on psoriasis is not known; however, it may be due to improvement in cytokine milieu and a decrease in proinflammatory cytokines such as IL1, IL6, and TNFα and immune modulation. Furthermore, IF

Table 3: Follow-up of patients in group 2 (methotrexate with IF group)

Parameters	Baseline (*n*=60)	16 weeks (*n*=56)	*P*	28 weeks (*n*=45)	*P*
Weight (Kg)	67.38 (±14.2)	66.44 (±13.3)	0.001	67.12 (±13.5)	0.001
WC (cm)	93.48 (±11.8)	91.13 (±10.29)	0.001	91 (±10)	0.001
PASI	16 (±4.3)	6.62 (±3.7)	0.002	7.72 (±2.7)	0.001
DLQI	11.9 (±4.3)	4.89 (±2.3)	0.001	5.14 (±1.3)	0.001
SBP (mm Hg)	125.8 (±16.5)	120.77 (±12.8)	0.001	120.77 (±11.4)	0.001
DBP (mm Hg)	83.23 (±10.46)	80.44 (±8.6)	0.025	80.39 (±7.1)	0.1
BSF (mg/dL)	97.7 (±21.7)	97.91 (±18.8)	0.72	97.31 (±17.3)	0.97
BSPP (mg/dL)	124.53 (±34.75)	121.79 (±39.4)	0.22	122.31 (±29.8)	0.06
TC (mg/dL)	191.3 (±33.33)	189.93 (±33.7)	0.057	190.16 (±31.8)	0.38
TG (mg/dL)	133.28 (±66.84)	121.3 (±52.3)	0.013	119.84 (±50.3)	0.011
LDL (mg/dL)	124.22 (±29.7)	122.47 (±30.8)	0.11	121.92 (±28.9)	0.1
HDL (mg/dL)	42.7 (±6.3)	43.21 (±6.5)	0.24	43.73 (±5.4)	0.26
VEGF (pg/ml)	274.14 (±208.86)	142.33 (±154.8)	0.001	139.77 (±121.1)	0.001
IL6 (pg/ml)	6.55 (±5.6)	3.63 (±2.8)	0.001	4 (±3.1)	0.001
hsCRP (mg/L)	4.39 (±4.13)	2.03 (±2.3)	0.001	2.25 (±2)	0.001

WC – Waist circumference; PASI- psoriasis area and severity index; DLQI- Dermatology Quality of life index: SBP – Systolic Blood pressure; DBP – Diastolic blood pressure; BSF – Blood sugar fasting; BSPP – Blood sugar postprandial; TC – total cholesterol; TG – triglyceride; LDL – Low-density lipoprotein; HDL- High-density lipoprotein; VEGF – Vascular endothelial growth factor; IL6 – Interleukin 6; hsCRP – High sensitivity C-reactive protein

Table 4: Comparison between group 1 and group 2 at 16 and 28 weeks

Parameters	16 weeks			28 weeks		
	Group 1	Group 2	*P*	Group 1	Group 2	*P*
Weight (Kg)	68.66 (±11.1)	66.44 (±13.3)	0.039	69.91 (±11.8)	67.12 (±13.5)	0.017
WC (cm)	92.33 (±8.3)	91.13 (±10.29)	0.001	93.04 (±8.1)	91 (±10)	0.001
PASI	7.47 (±4.6)	6.62 (±3.7)	0.13	9.3 (±4.1)	7.72 (±2.7)	0.16
DLQI	5.21 (±3.2)	4.89 (±2.3)	0.9	6.76 (±3)	5.14 (±1.3)	0.1
SBP (mm Hg)	124.75 (±14.1)	120.77 (±12.8)	0.6	125.82 (±12.6)	120.77 (±11.4)	0.68
DBP (mm Hg)	81.66 (±9.1)	80.44 (±8.6)	0.49	83 (±8.1)	80.39 (±7.1)	0.87
BSF (mg/dL)	96.46 (±12)	97.91 (±18.8)	0.17	95.04 (±11.4)	97.31 (±17.3)	0.81
BSPP (mg/dL)	116.55 (±23.8)	121.79 (±39.4)	0.02	116.47 (±21.7)	122.31 (±29.8)	0.001
TC (mg/dL)	186.32 (±31.9)	189.93 (±33.7)	0.96	187.96 (±28.1)	190.16 (±31.8)	0.92
TG (mg/dL)	135.48 (±62.4)	121.3 (±52.3)	0.12	132.58 (±50.4)	119.84 (±50.3)	0.1
LDL (mg/dL)	114.57 (±30.6)	122.47 (±30.8)	0.31	114.67 (±27.6)	121.92 (±28.9)	0.85
HDL (mg/dL)	45.2(±8.4)	43.21 (±6.5)	0.7	43.84 (±7.1)	43.73 (±5.4)	0.12
VEGF (pg/ml)	149 (±159.6)	142.33 (±154.8)	0.058	163.44 (±183.2)	139.77 (±121.1)	0.001
IL6 (pg/ml)	4.1 (±3)	3.63 (±2.8)	0.12	6.08 (±7.6)	4 (±3.1)	0.004
hsCRP (mg/L)	2.35 (±2.7)	2.03 (±2.3)	0.63	3.41 (±3)	2.25 (±2)	0.04

WC – Waist circumference; PASI- psoriasis area and severity index; DLQI- Dermatology Quality of life index: SBP – Systolic Blood pressure; DBP – Diastolic blood pressure; BSF – Blood sugar fasting; BSPP – Blood sugar postprandial; TC – total cholesterol; TG – triglyceride; LDL – Low-density lipoprotein; HDL- High-density lipoprotein; VEGF – Vascular endothelial growth factor; IL6 – Interleukin 6; hsCRP – High sensitivity C-reactive protein

also improves metabolic parameters and cardiovascular biomarkers.

Ramadan fasting is a time-restricted feeding where an individual consumes only two major meals and the fasting period lasts for 10–12 hours. It is done voluntarily, and fasting lasts for a month; hence, it is easy to observe changes in chronic diseases during the fasting period. Damiani *et al.*[16] conducted a real-life multicentric study to see the impact of Ramadan fasting on PASI. There was a statistically significant improvement in PASI after 1 month of Ramadan fasting. The systemic treatment of psoriasis was continued as such in this study. In our study, there was no statistically significant difference in PASI and DLQI in both groups at 16 and 28 weeks; however, a higher proportion of patients maintained PASI50 in the IF group as compared to the control group. This may be due to beneficial effects of IF on psoriasis. Almutairi *et al.*[17] conducted a real-life, multicentric, observational study in plaque psoriasis patients planning Ramadan fasting for a month. The metabolic parameters and PASI were evaluated before and after a fasting period of 4 weeks. Authors found statistically significant improvement in PASI and biochemical parameters such as fasting blood sugar, triglycerides, and HDL.

Table 5: PASI50 response comparison in groups 1 and 2

Timeline	PASI 50	Group 1 (*n*=60)	Group 2 (*n*=60)	*P*
Week 16	PASI 50 achieved	44 (73.3%)	47 (78.3%)	0.8
	PASI 50 not achieved	12 (20%)	10 (16.6%)	
	Lost to follow up	4 (6.6%)	3 (5%)	
Timeline	**PASI 50**	**Group 1 (*n*=44)**	**Group 2 (*n*=47)**	***P***
Week 28	PASI 50 maintained	16 (36 .36%)	27 (57.44%)	0.054
	PASI 50 lost	28 (63.63%)	20 (42.55%)	
	Lost to follow up	0	0	

PASI – psoriasis area and severity index

None of the patients reported weight loss in the study period. In our study, we found a significant reduction in weight and waist circumference in the IF group. This may be because the duration of our study was much longer (28 weeks vs 4 weeks) as compared to the quoted study. Adawi *et al.*[18] conducted a study on the effect of Ramadan fasting on 37 patients with psoriatic arthritis (PsA). The study concluded that IF results in statistically significant improvement in PsA measured using Disease Activity Index for PsA (DAPSA) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), enthesitis, and dactylitis. There was a significant reduction in CRP and PASI. The beneficial effects were not related to weight loss as it remained stable during the study period. Grine *et al.*[19] conducted a randomized controlled trial to assess the effect of modified intermittent fasting in psoriasis (MANGO). The modified fasting regime was 5: 2 regime with 2 nonconsecutive days of fasting with caloric restriction to less than 500 kcal per day. The preliminary result from this pilot study suggested mild improvement in scaling, plaque thickening, and itch after 12 weeks of modified intermittent fasting. The complete analysis of the result from this study is not yet published.[20]

Psoriasis is associated with increased risk of atherosclerosis and coronary artery disease. There was a statistically significant reduction in biomarkers of atherosclerosis such as VEGF, IL6, and hsCRP in both groups 1 and 2 at 16 and 28 weeks from baseline. On comparison of both groups at 16 weeks, there was no statistically significant decrease in IL6 and hsCRP. At 28 weeks, group 2 maintained a statistically significant reduction in VEGF, IL6, and hsCRP as compared to group 1, suggesting ongoing reduction in vascular inflammation resulting from IF.

Limitations

The small sample size and loss to follow-up are major limitations of the study. It is possible that strict entry criteria allow highly motivated patients to join the study and bias may have crept in because of this.

Conclusion

The study aimed to assess the efficacy of IF in the management of severe chronic plaque psoriasis. IF using 16: 8 (16 hours fasting and 8 hours feeding) protocol is easy to perform and a safe and effective adjuvant for the management of severe chronic plaque psoriasis. It helps in maintaining remission after stopping systemic therapy. It also helps in improvement in metabolic parameters and to reduce markers of vascular inflammation associated with atherosclerosis in psoriasis patients.

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Conflicts of interest

There are no conflicts of interest.

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