Dermatology Practical & Conceptual

Elective First-Line Use of Dimethyl Fumarate in Psoriasis: Insights from an Italian Cohort

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ABSTRACT

Introduction: Dimethyl fumarate (DMF) is an approved conventional systemic treatment for psoriasis that does not exhibit any drug–drug interactions or cumulative organ toxicities.

Aim: This retrospective real-world study aimed to analyze the long-term efficacy, safety, and tolerability of DMF in patients with moderate psoriasis.

Methods: Data on safety and efficacy were collected from medical charts. The effect on disease severity was assessed using the Psoriasis Area Severity Index.

Results: Our study included 148 patients over a 48-week treatment period, confirming DMF as an effective option in the treatment of moderate psoriasis. Adverse events were only mild or moderate, principally flushing, epigastralgia, and diarrhea. However, DMF exhibited a delayed onset of action, and the dropout rate was high. These aspects highlight the importance of educating patients about the activity profile of DMF, the potential occurrence of side effects, and their management. However, side effects are self-limiting with discontinuation of treatment and generally occur early, allowing patients to be promptly switched to other therapies if DMF is not tolerated.

Conclusions: Our results confirm that DMF may be offered as a first-line treatment for moderate psoriasis as it demonstrated efficacy even in the long-term, when treatment is tolerated, especially in patients with a disease duration of less than five years. DMF may also be proposed when the patient presents comorbidities, when immunosuppression is undesired, and/or before the initiation of biological therapies.

Introduction

Psoriasis is a chronic inflammatory disease characterized by high prevalence and a relevant physical and psychological burden [1] often requiring systemic treatments, either with conventional or biological agents [2]. The introduction of biologicals targeting tumor necrosis factor-α (TNF-α), interleukin(IL)-12/23, IL-17A, IL-17RA, and IL-23 as well as the small-molecule apremilast has provided new and effective treatment options, partially reducing the use of conventional therapies [3]. However, in many countries, local guidelines recommend a stepwise approach, starting with traditional systemic therapies before initiating biological treatments [4]. The Italian SIDeMAST (Società Italiana di Dermatologia Medica, Chirurgica, Estetica e delle Malattie Sessualmente Trasmesse) guidelines recommend the use of biological therapies for patients with moderate-to-severe plaque psoriasis, defined as Psoriasis Area Severity Index (PASI) >10 or body surface area (BSA) >10, or PASI <10 and BSA <10 with involvement of sensitive areas such as the face, palms, soles, nails, or genital region or in those who have shown inadequate response or intolerance to conventional treatments [2,5]. Although the therapeutic target of new biological therapies is PASI 90 [6], PASI 75 remains an excellent tool for evaluating the efficacy of traditional therapies for psoriasis [7,8]. Traditional systemic treatments, including methotrexate (MTX), cyclosporin, acitretin, and, in Europe, fumaric acid esters (FAEs), have demonstrated moderate efficacy, with a proportion of patients achieving PASI 75 ranging from 15% to 60% [4]. Remarkably, except for FAEs, these drugs exhibit drug–drug interactions and cumulative organ toxicities [9]. Of note, the prescription of systemic drugs for psoriasis in Italy is regulated by the Agenzia Italiana del Farmaco (AIFA) and is influenced not only by the safety profile but also by approved indications and reimbursement policies. MTX is one of the most widely recommended first-line systemic therapies for moderate-to-severe chronic plaque psoriasis and is particularly indicated in patients with psoriatic arthritis or systemic inflammation. With over 50 years of clinical use, it is suitable for long-term management and is supported by solid efficacy evidence [10,11]. MTX's clinical utility is reinforced by established international dosing guidelines and consensus-based laboratory monitoring protocols [12]. However, its use is burdened by several drug interactions and potentially severe adverse events such as hepatotoxicity and myelosuppression [2]. Cyclosporin, on the other hand, is particularly useful for severe and rapidly progressive forms of plaque psoriasis or for cases requiring rapid disease control. It has also been used in non-plaque variants such as pustular or erythrodermic psoriasis. Its fast onset of action makes it valuable as a short-term induction therapy, particularly in adults without renal or cardiovascular contraindications [13]. While effective, its long-term use is limited by nephrotoxicity and other metabolic side effects [12]. Acitretin is mainly indicated for palmoplantar and erythrodermic psoriasis, where its systemic retinoid action provides significant therapeutic benefit. Its oral formulation and efficacy in chronic or treatment-resistant cases further support its role across various psoriasis subtypes [14]. It is contraindicated in women of childbearing potential due to its prolonged teratogenicity [15,16]. Acitretin's longstanding use in Europe underscores its utility in managing difficult-to-treat cases and

keratinization disorders. However, patient selection must account for lipid metabolism and liver function status [12].

Dimethyl fumarate (DMF) is an FAE with anti-inflammatory and immunomodulating effects, approved by the European Medicines Agency (EMA) for the treatment of patients with moderate-to-severe plaque psoriasis since 2017 [17,18]. Regarding DMF efficacy, the DIMESKIN-2 trial reported PASI 75 in 81.1% of patients at week 52 [19], and the BRIDGE Study achieved PASI 75 in 37.5% of patients at week 16 [20]. In a real-world multicenter study, PASI 75 was achieved in 23.3% of patients at week 12, with a further 17.4% reaching it by week 26. Side effects occurred in 61.1% of patients, with the most common being diarrhea, epigastric discomfort, nausea, and flushing. However, DMF does not display major contraindications [21]. Despite these considerations, DMF is still infrequently prescribed for psoriasis treatment, and real-life evidence on its use is scarce. We report the results from an Italian multicenter retrospective study on the use of DMF.

Objectives

The objective of this study was to evaluate the long-term efficacy, safety, and tolerability of DMF in a real-world clinical setting focused on moderate forms of the disease. The study aimed to assess the achievement of disease severity reduction of 50% or 75% (PASI 50 and PASI 75), treatment retention rates, and the occurrence of adverse events over 48 weeks. This work may thus help clarify the role of DMF as first-line systemic therapy, especially for patients with early-stage disease and significant comorbidities.

Patients and Methods

Study Design

This was a retrospective real-world study conducted at the Departments of Dermatology of eight university referral centers in Italy (L'Aquila, Firenze, Roma Tor Vergata, Genova, Roma Cattolica, Roma IFO, Roma Sapienza, Ancona). All subjects enrolled in the study received DMF according to local guidelines and the summary of product characteristics.

Ethical Considerations

The investigation was conducted in accordance with the Helsinki Declaration and later amendments, and patients signed a consent form authorizing the use of their clinical records for scientific purposes. Confidentiality and privacy of patient data are assured by internal data protection regulations as well as by the General Data Protection Regulation (GDPR) (EU) 2016/679. The study did not require ethical approval in accordance with national guidelines.

Patients

Patients aged ≥18 years with a diagnosis of moderate psoriasis who underwent DMF treatment for 48 weeks between June 2022 and December 2023, according to standard clinical practice, were enrolled in the study.

Data Collection

Demographic and disease variables, such as age, sex, weight, body mass index (BMI), psoriasis clinical variant, disease duration, and PASI, were collected alongside information about previous treatments and the presence of comorbidities. Data collection was carried out while ensuring the anonymity of the participants.

Statistycal Analysis

The imputation of missing data was performed using the last observation carried forward (LOCF) analysis. A paired Student t-test was used to compare baseline values with those at each time point (weeks 4, 8, 12, 24, and 48). Data are presented as a percentage of patients who achieved PASI 50 or PASI 75 with a PASI score reduction of 50% and 75% (PASI 50, PASI 75) compared with baseline. To estimate the relationship between variables, a binary logistic regression analysis (binary variables) and a multiple regression analysis (continuous variables) were performed. To account for potential confounders, the logistic regression model included the following variables as independent predictors: age, disease duration, BMI ≥ 30, maximum dosage, and number of comorbidities. Statistical analyses were performed using MedCalc® Statistical Software (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2025).

Results

A total of 148 patients were enrolled in the study, of whom 94 (63.5%) were male. The mean PASI was 8.9 (±4.2). The average age was 53.8 (range 19–88), and 18 (12.2%) patients had a BMI ≥30 (Table 1). The most prevalent variant of psoriasis was the plaque type (141 patients, 95.3%), followed by palmoplantar psoriasis (17 patients, 11.5%), inverse psoriasis (five patients, 3.4%), and psoriatic arthritis (two patients, 1.4%). Most of the population had at least one comorbidity (52.7%). Notably, some patients displayed relevant comorbidities, including various types of anamnestic cancer, hepatitis B virus or hepatitis C virus infections, tuberculosis (TB), or multiple sclerosis. Among the study group, 95 patients (64.2%) had not been previously treated for psoriasis. In contrast, 33.8% had received conventional therapies, including acitretin (16 patients, 10.8%), cyclosporin (31 patients, 20.9%), or MTX (18 patients, 12.2%). A smaller proportion (4.7%) had been treated with biological systemic

Table 1. Patient Baseline Characteristics.

Characteristics	N=148
Sex (Male)	94 (63.5)
Age (years)	53.8 (±16.6, 19–88)
Weight (kg)	75.4 (±13.0, 45.0–123.0)
BMI (kg/m^2)	26.6 (±3.8, 17.6–42.6)
BMI ≥30	18 (22.2)
Psoriasis clinical variants	
• Plaque type	141 (95.3)
• Inverse psoriasis	5 (3.4)
• Palmoplantar psoriasis	17 (11.5)
• Psoriatic arthritis	2 (1.4)
Disease duration (years)	16.9 (±14.3, 1–65)
Mean PASI	8.9 (±4.2)
Comorbidities	
• None	70 (47.3)
• 1	31 (20.9)
• 2	26 (17.6)
• 3	12 (8.1)
• >3	10 (6.8)
Comorbidities of interest	
Neoplasms	9 (6.1%)
• Malignant melanoma	3 (2.0%)
• Non-melanoma skin cancer	2 (1.4%)
• Prostate cancer	1 (0.7%)
• Colorectal cancer	1 (0.7%)
• Thyroid cancer	1 (0.7%)
• Parathyroid cancer	1 (0.7%)
Infections or other relevant comorbidities	
• HBV	6 (4.1%)
• HCV	3 (2.0%)
• IgRA TB positive	5 (3.4%)
• Multiple sclerosis	2 (1.4%)
Previous therapy	
None	95 (64.2%)
Conventional systemic therapies	50 (33.8%)
• Acitretin	16 (10.8%)
• Cyclosporin	31 (20.9%)
• Methotrexate	18 (12.2%)
Biological systemic therapies	7 (4.7%)
• TNF inhibitors	5 (3.4%)
• Ustekinumab	1 (0.7%)
• IL-23 inhibitors	1 (0.7%)
Small molecule (apremilast)	7 (4.7%)

Data are presented as mean (±SD, range) or N (%). Abbreviations: BMI: body mass index; HBV: hepatitis B virus; HCV: hepatitis C virus; PASI: Psoriasis Area Severity Index; IgRA TB: interferon gamma release assay test for tuberculosis; TNF: tumor necrosis factor.

therapies: TNF inhibitors in 3.4% (five patients), ustekinumab in 0.7% (one patient), and IL-23 inhibitors in 0.7% (one patient). Additionally, 4.7% (seven patients) had been treated with apremilast (Table 1).

DMF was effective in reducing the mean PASI from baseline at week 4, with efficacy increasing through week 48 (10.0 vs. 1.8, P<0.001, Table 2). The LOCF analysis also showed a significant effect of DMF throughout the observation period, with mean PASI decreasing from 8.9 to 4.3 (P<0.001, Table 2, Figure 1). At 48 weeks, the percentage of patients who achieved PASI 50 was 56.8%, while 36.5% achieved PASI 75 (Table 3, Figure 2). The mean treatment duration was 6.9 (±4.9) months, ranging from 0 to 12 months, reflecting a dropout rate of 62.8%. The main reasons for discontinuing DMF treatment were the appearance of adverse events (61 patients, 41.2%) and inefficacy (28 patients, 18.9%). Most adverse events occurred within the first 12 weeks of treatment (39/61, 63.9% versus 22/6, 36.1% after 12 weeks, P<0.001).

Interestingly, logistic regression analysis showed that the naïve status of patients as well as prior treatments (experienced) did not influence treatment outcomes with DMF, as observed for the mean PASI and PASI 50 and PASI 75 (Table 4). The analysis also showed that a longer duration of psoriasis was associated with a higher frequency of adverse events upon starting treatment with DMF. DMF treatment was significantly more effective in patients with a disease duration of less than five years after 24 and 48 weeks than in patients with a disease duration of 5–10 or more than 10 years (P=0.04 and P=0.032; Table 5). Furthermore, the treatment with DMF was significantly more effective in patients whose disease onset was less than 10 years at 12 (P=0.041), 24 (P=0.011), and 48 weeks (P=0.009) (Table 5, Figure 3). PASI 50 and PASI 75 responses were comparable between biologic/systemic-naïve and previously treated patients at each time point, with no statistically significant difference observed (all p-values of t-test >0.1; Table 1). Disease duration, BMI ≥30, maximum dosage, and number of comorbidities did not account for significant differences in achieving PASI 50 or 75 at three months in the logistic regression model.

Discussion

Conventional systemic treatment of psoriasis relies on the use of MTX, cyclosporin, and acitretin [7]. DMF is an FAE that has been used as a first-line systemic treatment for psoriasis in recent years because of its good safety profile for long-term therapy [21]. In contrast to cyclosporin, MTX, and acitretin, which are associated with several contraindications, potentially severe adverse events, and cumulative organ toxicity [22–24], DMF predominantly causes non-serious and self-limiting side effects [25]. Mechanistically,

Table 2. Mean PASI Analysis at Each Visit (as observed) and Mean PASI Analyzed using the Last Observation Carried Forward Analysis (LOCF).

PASI analysis	Mean (±SD)		Paired t-test p-value
As observed analysis			
Baseline vs week 4	N=141, 9.0 (±4.2)	N=141, 7.6 (±4.1)	<0.001
Baseline vs week 8	N=82, 9.0 (±4.5)	N=82, 6.4 (±5.0)	<0.001
Baseline vs week 12	N=101, 9.5 (±4.3)	N=101, 5.1 (±4.0)	<0.001
Baseline vs week 24	N=87, 9.6 (±4.2)	N=87, 3.3 (±4.0)	<0.001
Baseline vs week 48	N=54, 10.0 (±4.3)	N=54, 1.8 (±2.3)	<0.001
LOCF analysis			
Baseline vs week 4	8.9 (±4.2)	7.6 (±4.1)	<0.001
Baseline vs week 8	8.9 (±4.2)	6.9 (±4.1)	<0.001
Baseline vs week 12	8.9 (±4.2)	5.7 (±4.1)	<0.001
Baseline vs week 24	8.9 (±4.2)	4.7 (±4.6)	<0.001
Baseline vs week 48	8.9 (±4.2)	4.3 (±4.7)	<0.001

Abbreviations: LOCF: last observation carried forward; PASI: Psoriasis Area Severity Index.

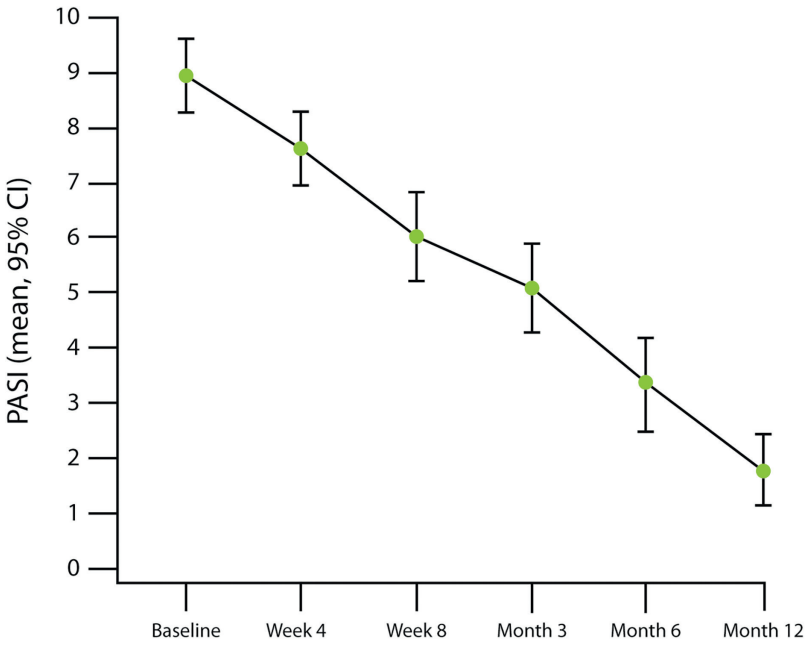

Figure 1. Mean PASI analyzed using the last observation carried forward analysis (LOCF). The figure shows the decline in PASI over follow-up visits.

DMF inhibits NF-kB translocation in fibroblasts and keratinocytes, thereby downregulating the production of inflammatory cytokines and hindering the inflammatory response. Additionally, DMF increases the proportion of regulatory T cells relative to T-helper lymphocytes 17, induces T-cell apoptosis, and inhibits keratinocyte proliferation [18].

Our study showed that DMF is a valid treatment option for patients with moderate psoriasis, as 36.5% of total patients, representing 70.4% of those still on treatment at the timepoint, achieved PASI 75 at week 48. Notably, these results were observed across both treatment-naïve and previously treated individuals, suggesting consistent therapeutic benefit irrespective of prior systemic exposure. Our findings confirmed that DMF is a slow-acting agent that, although starting to reduce PASI by week 4, achieves its full therapeutic effect only after several weeks of treatment. The dropout rate was high (62.8%), with the primary reason for discontinuation being gastrointestinal issues and flushing. Although these adverse events were mild, they were not tolerated by patients. However, it is important to make a distinction between tolerability and safety. While DMF's adverse events are frequent and may lead to early discontinuation due to the patient's low tolerability, they are generally mild, self-limited, and reversible upon treatment cessation. Besides

this, in patients who endured DMF, the drug exerted remarkable and prolonged efficacy in suppressing disease activity, especially in patients with a disease duration of less than five years. Comorbidities, BMI, or dose variations within the studied range did not significantly impact treatment success, underscoring the utility of DMF in diverse patient populations. Furthermore, the analysis showed that the frequency of DMF-induced adverse events was higher in patients with a longer history of psoriasis. This observation supports the postulation that DMF represents a useful first-line therapy option. Moreover, since the adverse events leading to treatment discontinuation mainly occurred during the first 12 weeks, patients could be promptly switched to other therapies if DMF was not well tolerated. Physicians should inform patients about the frequency and types of adverse events as well as of the possibility of slowly titrating the dosage to minimize them. It is crucial that physicians explain to patients that DMF requires time to exert its clinical effects and that most adverse events are manageable or transient. This proactive approach can help identify patients most likely to tolerate and benefit from long-term DMF therapy [26]. Additionally, our real-life study revealed that DMF is predominantly prescribed for moderate psoriasis. This pattern of use aligns with DMF's favorable safety and tolerability profile and with the need for long-term disease control in patients not requiring or not eligible for biologics.

Compared to MTX, cyclosporin, and acitretin, DMF offers a favorable safety profile. MTX is effective in chronic plaque psoriasis and psoriatic arthritis but requires regular monitoring due to risks of hepatotoxicity and myelosuppression [2,27,28]. Cyclosporin acts rapidly and is suitable for severe or non-plaque forms but is limited by nephrotoxicity and metabolic effects and is recommended for intermittent use for up to one year [29]. Acitretin is more effective in palmoplantar and hyperkeratotic psoriasis and safe for patients with a history of malignancy due to its non-immunosuppressive profile, but its use is limited by mucocutaneous side effects, teratogenicity, and potential hepatotoxicity

Table 3. Percentages of Patients Achieving PASI 50 and PASI 75 Analyzed using the Last Observation Carried Forward (LOCF) Analysis.

Visit	N=148, N (%)
PASI 50	
4 weeks	9 (6.1%)
8 weeks	14 (9.5%)
12 weeks	46 (31.1%)
24 weeks	75 (50.7%)
48 weeks	84 (56.8%)
PASI 75	
4 weeks	4 (2.7%)
8 weeks	6 (4.1%)
12 weeks	20 (13.5%)
24 weeks	37 (25.0%)
48 weeks	54 (36.5%)

Abbreviations:PASI: Psoriasis Area Severity Index.

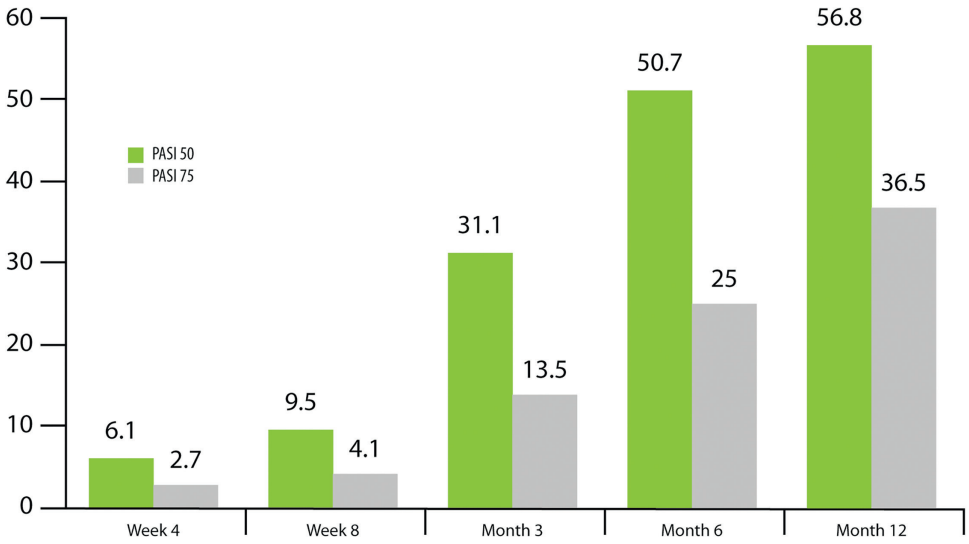

Figure 2. Percentages of patients achieving PASI 50 and PASI 75 analyzed using the last observation carried forward analysis (LOCF). The figure shows the percentages of patients achieving PASI 50 or PASI 75 at different time points during dimethyl fumarate treatment.

Table 4. Mean PASI and Percentages of Patients Achieving PASI 50 and PASI 75 by Visit and Naïve Status Analyzed using the Last Observation Carried Forward Analysis (LOCF).

Visit	Mean PASI (Naïve)	Mean PASI (Exp)	p-value (PASI)	PASI 50 (%) Naïve	PASI 50 (%) Exp	p-value (PASI 50)	PASI 75 (%) Naïve	PASI 75 (%) Exp	p-value (PASI 75)
Baseline	8.6 (±3.9)	9.5 (±4.6)	0.190	–	–	–	–	–	–
4 weeks	7.3 (±3.9)	8.1 (±4.5)	0.228	6.7% (6/89)	5.8% (3/52)	0.820	3.4% (3/89)	1.9% (1/52)	0.619
8 weeks	6.6 (±3.8)	7.4 (±4.5)	0.273	16.3% (8/49)	9.1% (3/33)	0.103	8.2% (4/49)	3.0% (1/33)	0.344
12 weeks	5.4 (±4.0)	6.2 (±4.4)	0.220	41.9% (26/62)	43.6% (17/39)	0.871	22.6% (14/62)	12.8% (5/39)	0.224
24 weeks	4.4 (±4.1)	5.4 (±5.4)	0.209	76.9% (40/52)	77.1% (27/35)	0.981	42.3% (22/52)	34.3% (12/35)	0.455
48 weeks	4.0 (±4.1)	4.7 (±5.6)	0.372	93.9% (31/33)	95.1% (20/21)	0.841	66.7% (22/33)	76.2% (16)	–

Table 5. Mean Psoriasis Area Severity Index by Visit and Disease Duration Analyzed using the Last Observation Carried Forward Analysis (LOCF).

Visit	<5 years (N=33)	5–10 years (N=39)	>10 years (N=76)	p-value (<5/5–10 />10 years)	≤10 years (N=72)	>10 years (N=76)	p-value (≤10 vs >10 years)
Baseline	8.5 (±3.7)	8.7 (±4.6)	9.3 (±4.3)	0.611	8.6 (±4.2)	9.3 (±4.3)	0.336
Week 4	7.0 (±3.5)	7.0 (±4.0)	8.1 (±4.4)	0.314	7.0 (±3.7)	8.1 (±4.4)	0.128
Week 8	6.2 (±3.3)	6.2 (±3.8)	7.5 (±4.5)	0.150	6.2 (±3.6)	7.5 (±4.5)	0.051
Week 12	4.7 (±3.6)	5.2 (±3.8)	6.4 (±4.5)	0.113	5.0 (±3.7)	6.4 (±4.5)	0.041
Week 24	3.6 (±3.7)	3.9 (±3.5)	5.7 (±5.2)	0.040	3.8 (±3.6)	5.7 (±5.2)	0.011
Week 48	3.2 (±3.7)	3.3 (±3.6)	5.3 (±5.4)	0.032	3.3 (±3.6)	5.3 (±5.4)	0.009

[14]. In contrast, DMF lacks cumulative organ toxicity and drug–drug interactions, making it suitable for long-term use, especially in patients with comorbidities or when immunosuppression is contraindicated or unwanted [30]. Table 6 summarizes the efficacy, safety, and target populations of DMF based on real-world data and compares them with other conventional systemic treatments for psoriasis.

The main limitation of this study is its retrospective observational nature, which introduces the potential for selection bias, information bias, and confounding variables and does not allow for a direct comparison between DMF treatment and other conventional or biological therapies. Moreover, although the total number of patients enrolled is relatively high, it should be acknowledged that, considering the multicenter design, the sample size could have been larger to enhance the statistical power and generalizability of the findings.

Conclusions

Our study confirms that, when tolerated, DMF represents a valuable first-line systemic therapeutic option for patients with moderate psoriasis as it can induce long-term disease remission while maintaining a good safety profile. DMF should be offered early in the therapeutic journey as this study shows that it is more efficacious and safer for patients with a disease duration of less than five years. DMF is particularly suitable as first-line therapy in cases where immunosuppression is undesired or when patients are on multi-drug therapy as it does not exhibit any drug–drug interaction or

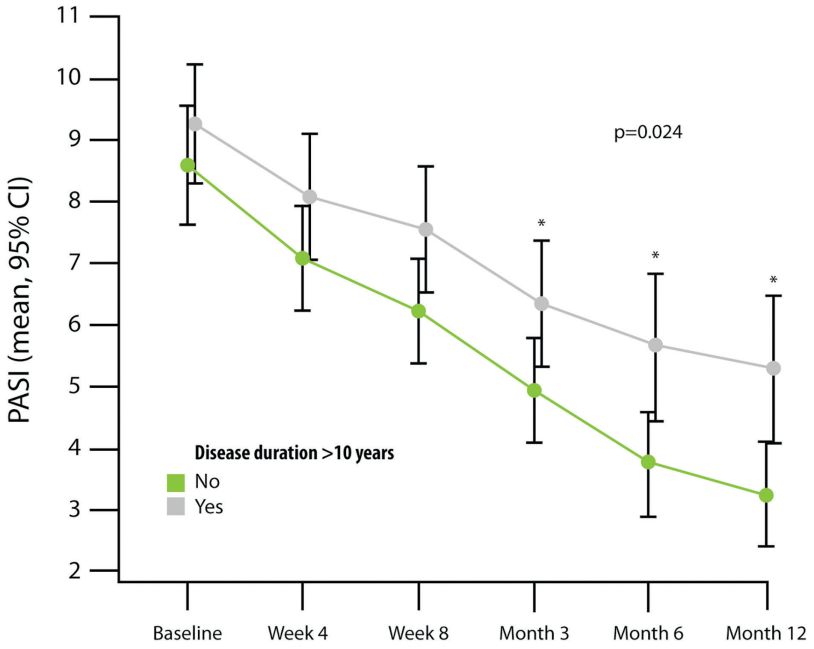

Figure 3. Mean PASI by visit and disease duration analyzed using the last observation carried forward analysis (LOCF).

Table 6. Comparison between these Real-World Data on Dimethyl Fumarate and Efficacy and Safety of other Conventional Systemic Treatments of Psoriasis.

Parameter	Dimethyl fumarate [current study]	Methotrexate [27,28]	Cyclosporin [29]	Acitretin [14]
Efficacy	Moderate efficacy; suitable for long-term management. PASI response lower than methotrexate	Moderate efficacy in chronic plaque psoriasis and PsA	High short-term efficacy; ideal for rapid disease control in severe psoriasis	Moderate efficacy, especially in pustular/ erythrodermic psoriasis; improved with phototherapy
Onset of action	Gradual; improvement over weeks to months	Moderate onset	Rapid onset; ideal for acute flares	Intermediate onset
Tolerability	Generally good; adverse events are mostly early, mild, and reversible (GI upset, flushing); most discontinuations occur early	Requires regular monitoring due to hepatotoxicity, GI effects, and myelosuppression risks	Limited by nephrotoxicity, hypertension, and metabolic issues; requires intermittent short-course use (max ~1 year)	Mucocutaneous AEs common (dryness, cheilitis); lipid/ liver changes require monitoring
Long-term safety	Favorable; lacks cumulative organ toxicity and drug–drug interactions	Risk of liver fibrosis and bone marrow suppression with long-term use	Not recommended beyond 1 year due to renal/metabolic toxicity risks	Teratogenicity (up to 3 years post-therapy), hepatotoxicity, and hyperlipidemia may limit use
Immunosuppressive activity	No	Yes	Yes	No
Best-suited patients	Patients with comorbidities, contraindications to immunosuppressants, or requiring long-term treatment	Patients with extensive plaque psoriasis or joint involvement and no hepatic or hematological contraindications	Patients with rapidly progressive, severe disease requiring fast symptom control	Male or postmenopausal patients with keratinization disorders or pustular/ erythrodermic psoriasis; not for women of childbearing potential

Abbreviations: AE: adverse event; GI: gastrointestinal; PASI: Psoriasis Area Severity Index; PsA: psoriatic arthritis.

cumulative organ toxicities. Further real-world evidence is desiderable to support these findings.

Ethics: The investigation was conducted in accordance with the Helsinki Declaration, and the use of the drug was made according to normal clinical practice and technical data sheet. Patients signed a declaration allowing the use of their clinical records for scientific purposes.

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