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Original research

STUDY ON THE TREATMENT EFFECTIVENESS OF LOW-DOSE METHOTREXATE COMBINED WITH TOPICAL CORTICOSTEROIDS FOR MODERATE TO SEVERE PSORIASIS AT HUE CENTRAL HOSPITAL

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ABSTRACT

Objectives: *To investigate the efficacy of low-dose methotrexate combined with topical corticosteroids and the side effects of low-dose methotrexate in patients with moderate to severe psoriasis.*

Methods: *A descriptive, retrospective study of 31 patients diagnosed with moderate to severe psoriasis treated with a combination of low-dose methotrexate and topical corticosteroids at the Dermatology Department of Hue Central Hospital from January 2019 to June 2022.*

Results: *74.2% of the patients were over 50 years old, with females accounting for 58.1%. 80.6% had a disease duration of over 5 years. Erythematous plaques and scaling were prevalent, distributed across the chest, abdomen, back, and limbs. 77.4% had severe disease, with the psoriasis vulgaris and pustular forms accounting for 32.3%. Obesity and older age were the two highest risk factors. 67.7% used ultra-potent corticosteroids, 90.3% received subcutaneous methotrexate, 58.1% started with a dose of 5 - 10 mg/week, and 74.2% maintained a dose of 10 - 5 mg/week, with 45.2% using folic acid. After 4 weeks, PASI75 was achieved in 38.7%, and 87.1% showed a significant reduction in PASI levels. There was a statistically significant correlation between the rate of achieving PASI75 and age group as well as disease duration (p-values < 0.05). 3.2% experienced abdominal pain, and 6.5% had elevated liver enzymes.*

Conclusions: *The study results indicate that the combination therapy of low-dose methotrexate and topical corticosteroids helps improve clinical status in patients with moderate to severe psoriasis. The adverse effects reported were primarily abdominal pain and mild liver enzyme elevation, which did not impact treatment. However, due to the short follow-up period and low cumulative dose of methotrexate, the study could not fully assess other potential adverse events.*

Keywords: *Psoriasis, methotrexate, corticosteroids.*

I. INTRODUCTION

Psoriasis is a chronic inflammatory skin disease characterized by erythema and scaling, with a global prevalence of approximately 2 - 3% [1,2] and around 1.5% in Vietnam [3]. Several studies have shown no significant difference in prevalence between males and females [1,4]. The pathogenesis of psoriasis involves genetic predisposition and immune dysregulation, with environmental factors playing a triggering role [1,3,4]. Among the clinical variants, psoriasis vulgari is the most common, accounting for about 90% of all cases [4,5].

For mild psoriasis, topical therapies such as corticosteroids, vitamin D analogs, and calcineurin inhibitors are considered the mainstay of treatment. In cases of moderate-to-severe psoriasis, treatment options include phototherapy or systemic therapy (either conventional agents or biologics). Although significant advancements have been made in psoriasis treatment over recent decades-particularly

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with the emergence of biologic agents-high costs and limited availability mean that conventional therapies remain a practical and accessible option for many patients, especially in resource-limited settings. Among these, low-dose methotrexate in combination with topical corticosteroids remains a first-line treatment due to its effectiveness, relatively favorable safety profile, affordability, and ease of use. Topical corticosteroids exert anti-inflammatory, antiproliferative, pro-apoptotic, vasoconstrictive, and immunomodulatory effects [6]. Methotrexate is an antimetabolite that inhibits DNA synthesis and, to a lesser extent, RNA and protein synthesis [7]. Additionally, methotrexate has anti-inflammatory effects, including inhibition of leukocyte oxidative activity, leukocyte chemotaxis, C5a activity, leukotriene B4 activity, and cytokine production [3]. However, prolonged low-dose methotrexate therapy has been associated with adverse effects in up to 61% of patients with psoriasis [8]. Rapidly dividing cells such as hematopoietic progenitors, gastrointestinal epithelial cells, and keratinocytes are particularly susceptible to methotrexate toxicity [8,9]. Therefore, we conducted this study with the following objectives: (1) To describe the clinical characteristics of patients with moderate-to-severe psoriasis indicated for treatment with low-dose methotrexate and topical corticosteroids. (2) To evaluate treatment efficacy and identify risk factors and adverse effects associated with low-dose methotrexate therapy in patients with moderate-to-severe psoriasis.

II. METHODS AND MATERIALS

2.1. Subjects

Inclusion criteria: Patients diagnosed with moderate-to-severe psoriasis based on the Psoriasis Area and Severity Index (PASI) score (moderate: $10 \leq$ PASI < 20; severe: PASI ≥ 20) who were indicated for low-dose methotrexate and topical corticosteroid therapy for a duration of at least 4 weeks. Participants were over 18 years old and had not received systemic treatment, phototherapy, or topical medication within 4 weeks prior to enrollment in the study.

Exclusion criteria: Patients with absolute contraindications to low-dose methotrexate, including alcoholic liver disease or other chronic liver conditions, pregnancy or breastfeeding, alcohol abuse, bone marrow dysfunction, leukopenia, thrombocytopenia, severe anemia, immunodeficiency syndromes, active peptic ulcer disease, severe infections, renal failure, or severe respiratory failure. Patients who declined participation in the study were also excluded.

2.2. Study methods

Study design: Descriptive, retrospective study.

Sample size and sampling method: Convenience sampling of all 31 patients with psoriasis who were hospitalized and treated at the Dermatology Department of Hue Central Hospital from January 2019 to June 2022.

Study procedures: A structured data collection form was created. Patients underwent clinical examination and were screened based on eligibility criteria. Disease severity was assessed using the PASI score. Risk factors were recorded, treatment was administered, and PASI scores were re-evaluated after 4 weeks of therapy. Adverse effects of methotrexate during the treatment course were also documented.

Percentage improvement in PASI:

PASI% = [(PASI before treatment - PASI after treatment) / PASI before treatment] × 100%

Poor response: PASI reduction $< 25\%$, fair response: PASI reduction 25% to $< 50\%$, moderate response: PASI reduction 50% to $< 75\%$, good response: PASI reduction 75% to 99%, very good response: PASI reduction 100%.

2.3. Data processing and analysis

Data were analyzed using SPSS version 20.0. Descriptive statistics were presented as frequencies and percentages. Associations between qualitative variables were assessed using the Chi-square test (χ^2) or Fisher's Exact Test (when expected frequency in any cell was < 5). A 95% confidence interval was used, and p-values < 0.05 were considered statistically significant.

III. RESULTS

3.1. Characteristics of the study population

The age groups 50 - 59 and ≥ 60 years had the highest proportions of patients. Females accounted for 58.1% of the sample. A disease duration of more than 5 years was observed in 80.6% of participants, and none of the patients had a family history of psoriasis (Table 1).

Table 1: Characteristics of the study population

Characteristics		N (%)
Age group	30 - 39 40 - 49 50 - 59 ≥ 60	06 (19.4%) 02 (6.4%) 12 (38.7%) 11 (35.5)%
Sex	Male Female	13 (41.9%) 18 (58.1%)
Disease duration	< 5 years ≥ 5 years	06 (19.4%) 25 (80.6%)
Family history		0 (0%)

In the study, the most common lesions were erythematous plaques and scaling, observed in 96.8% and 100% of patients, respectively (Figure 1). Lesions were most frequently distributed on the chest, abdomen, back, and extremities, and 74.2% of patients had lesions on the scalp (Figure 2).

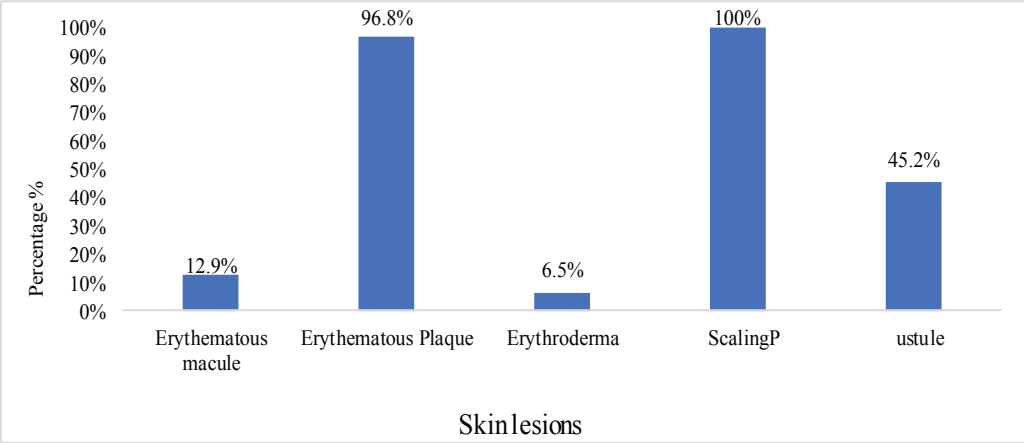

Figure 1: Skin lesions

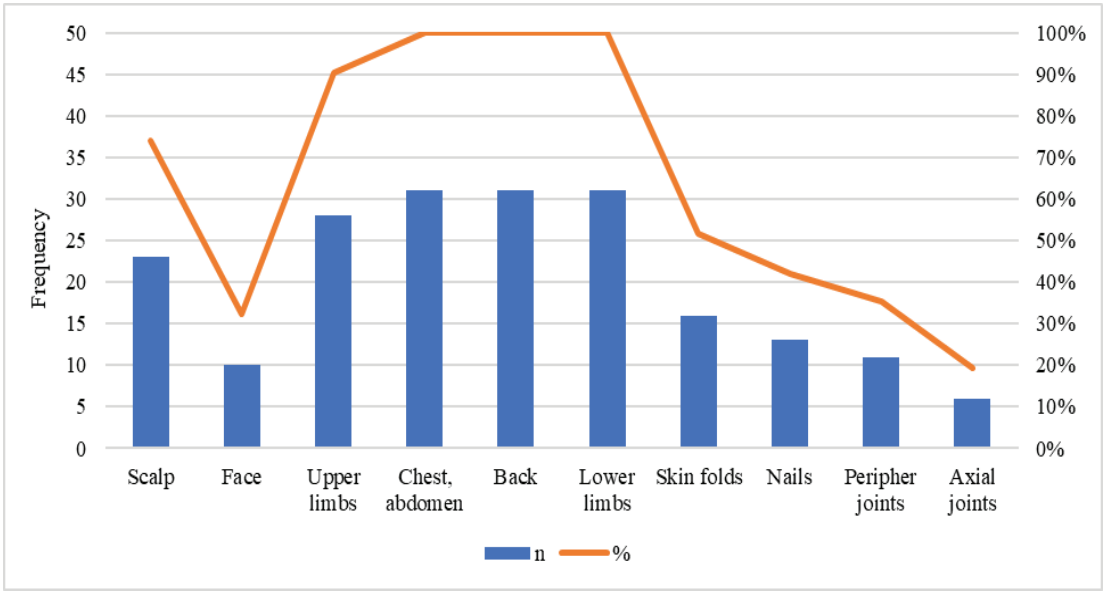

Figure 2: Distribution of psoriatic lesions by body region.

According to the clinical subtypes, plaque psoriasis and pustular psoriasis accounted for an equal proportion of 32.3% (Table 2). Regarding disease severity, 77.4% of patients fell into the severe category, whereas 22.6% were in the mild group (Table 3).

Table 2: Distribution of clinical subtypes

Clinical subtypes	N	%
Vulgaris psoriasis	10	32.3%
Pustular psoriasis	10	32.3%
Psoriatic arthritis	09	29.0%
Erythrodermic psoriasis	02	6.4%
Total	31	100

Regarding disease severity, 77.4% of patients fell into the severe category, whereas 22.6% were in the mild group (Table 3).

Table 3: Classification by disease severity

PASI score	N	%
Moderate	07	22.6
Severe	24	77.4
Total	31	100

3.2. Treatment efficacy of low-dose methotrexate combined with topical corticosteroids in moderate-to-severe psoriasis

As shown in Figure 3, 67.7% of patients used ultra-potent topical corticosteroids. Methotrexate was administered subcutaneously in 90.3% of cases, with initial doses of 5 - 10 mg/week in 58.1% and maintenance doses of 10 - 15 mg/week in 74.2%. Folic acid was supplemented in 45.2% of patients (Figure 3). Treatment outcomes after 4 weeks: 61.3% of patients achieved a mild severity level; the percentage reduction in PASI was highest in the moderate category, while the good response level accounted for 38.7% (Table 4).

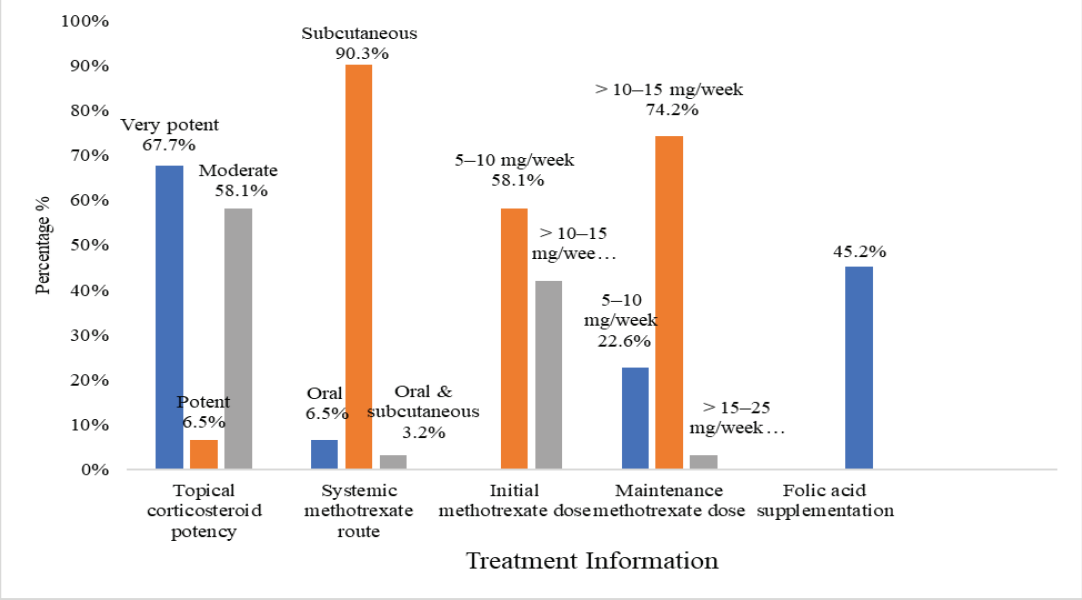

Figure 3: Treatment information

Table 4: Post-treatment follow-up

Post-treatment follow-up		**N (%)**
PASI score after treatment	Mild Moderate Severe	19 (61.3%) 09 (29.0%) 03 (9.7%)
Percentage reduction in PASI	Poor Fair Moderate Good Very good	03 (9.7)% 01 (3.2%) 15 (48.4%) 12 (38.7%) 0 (0)

After 4 weeks of treatment, the proportion of patients achieving PASI75 was 38.7%, while 61.3% did not reach PASI75 (Figure 4). The study found a correlation between the rate of achieving PASI75 and both age group and disease duration. The proportion of patients achieving PASI75 in the group without lesions on the upper limbs was higher than in the group with lesions, and this difference was statistically significant (Table 5).

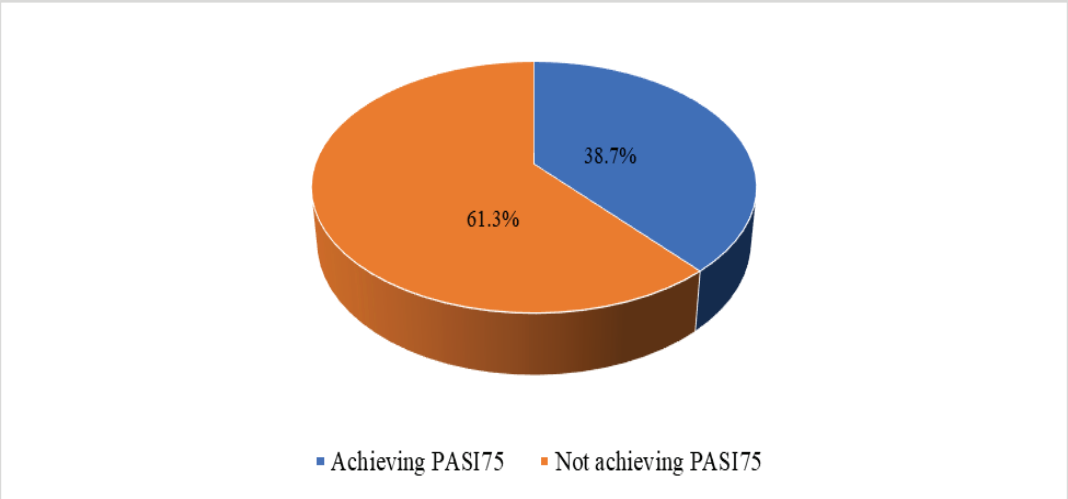

Figure 4: Proportion of patients achieving PASI75 after treatment

Table 5: Some factors associated with treatment outcomes

Associated factors		**Achieved PASI75**		**p**
		n	**%**	
Age group	30 - 39 40 - 49 50 - 59 ≥ 60	6 1 3 3	100 50 25 27.3	0.0026
Sex	Female Male	6 6	33.3 46.2	0.4712
Disease duration	< 5 years ≥ 5 years	5 6	83.3 24.0	0.0086

Associated factors			Achieved PASI75		p
			n	%	
Skin lesions	Erythematous macules	Present Absent	0 12	0 44.4	0.0548
	Erythematous plaques	Present Absent	11 01	36.7 100	0.99
	Erythroderma	Present Absent	02 10	100 34.5	0.1449
	Pustules	Present Absent	03 09	21.4 52.9	0.0935
Location of lesions	Scalp	Present Absent	08 04	34.8 50	0.4598
	Face	Present Absent	03 09	30 42.9	0.702
	Peripheral joints	Present Absent	04 08	36.4 40	0.99
	Axial joints	Present Absent	0 12	0 48	0.206
	Nails	Present Absent	03 09	23.1 50	0.1505
	Skin folds	Present Absent	06 06	37.5 40	0.99
	Upper limbs	Present Absent	09 03	32.1 100	0.0336
Clinical subtypes	Vulgaris psoriasis Pustular psoriasis Psoriatic arthritis Erythroderma		05 02 03 02	50 20 33.3 100	0.0686
Severity	Moderate Severe		02 10	28.6 41.7	0.6841
Phẫu thuật	Very potent	Used Not used	09 03	42.9 30	0.702
	Potent	Used Not used	01 11	50 37.9	0.99
	Moderate	Used Not used	07 05	38.9 38.5	0.99

Associated factors			Achieved PASI75		p
			n	%	
Methotrexate	Route of administration	Oral Subcutaneous inj Oral + inj	0 12 0	0 42.9	0.1469
	Initial dose	5 - 10 mg/ week > 10 - 15mg/week	07 05	38.9 38.5	0.99
	Maintenance dose	5 - 10 mg/ week	04	57.1	0.3965

During the study period, 3.2% of patients experienced abdominal pain, and 6.5% had elevated liver enzymes (Table 6).

Table 6: Adverse effects observed clinically and paraclinically

Adverse effects		N (%)
Clinical	Abdominal pain Others (nausea/vomiting, oral ulcers, skin ulcers, hair loss, pneumonitis)	01 (3.2%) 0 (0)
Paraclinical	Elevated liver enzymes Others (cytopenias including red blood cell, white blood cell, and platelets)	02 (6.5%) 0 (0)

IV. DISCUSSION

According to previous studies, the onset of psoriasis tends to increase from the second decade of life and peaks between the ages of 55 and 60 [1,3,10]. In Table 1, the 50 - 59 and ≥ 60 age groups accounted for 38.7% and 35.5% respectively, similar to the findings by Tran Nguyen Anh Tu, in which patients over 50 years old comprised 49.33% [11], this may be due to the study being conducted on inpatients; younger individuals of working age often prefer outpatient treatment to maintain their daily routines, making older age groups more prevalent among hospitalized patients.

Multiple studies have shown no significant difference in psoriasis prevalence between males and females [1,4], in this study, females accounted for 58.1%, slightly higher than males (Table 1), the difference was not statistically significant and is consistent with the findings of Tran Nguyen Anh Tu [11], this could be explained by the fact that women often have greater aesthetic concerns; visible skin lesions may cause feelings of self-consciousness and thus a stronger motivation to seek treatment. In our study, patients with disease duration longer than 5 years accounted for the highest proportion, consistent with findings from Amador [12], Da Silva M [13], and in accordance with the literature that psoriasis is a chronic disease with a tendency to recur, resulting in prolonged disease duration [1]. Notably, 100% of patients in our study reported no family history of psoriasis (Table 1), a result comparable to that of Tran Nguyen Anh Tu [11], but lower than the 20.84% reported by Phan Huy Thuc [3], this discrepancy may be attributed to the subjective nature of patient self-reporting, potentially underestimating the true prevalence of family history. Nonetheless, psoriasis is widely recognized as a genetically linked disease, with individuals having a family history being at greater risk. Several studies have demonstrated that both disease development and severity are influenced by genetic factors [1].

According to Figure 1, the most common lesions observed were erythematous plaques and scaling, consistent with the literature, which describes typical psoriatic lesions as well-demarcated erythematous plaques covered with thick, silvery-white scales that are easily detached [1,5]. Commonly affected areas include extensor surfaces such as the knees, shins, elbows, trunk, back, and scalp [1,4]. As shown in Figure 2, lesions were frequently distributed on the chest, abdomen, back, and extremities, consistent with findings by Phan Huy Thuc, who reported lesion involvement of the trunk and chest in 90.48% and the limbs in 85.12% of cases, respectively [3]. In our study, 74.2% of patients had scalp involvement-higher than the 62% reported by Dogan [14], but lower than the 80.36% found by Phan Huy Thuc [3]. Nail involvement in our study was comparable to the 23.7% reported by Peng YT [15]. Both scalp and nail lesions are considered special sites of psoriasis due to their significant impact on quality of life and the increased difficulty of treatment at these sites [5,11].

In terms of disease severity, the majority of patients (77.4%) had severe psoriasis (Table 3), aligning with the findings of Amador J, who reported a 62.8% prevalence of severe cases [12]. Clinical variants of psoriasis were diverse in our study (Table 2), with both psoriasis vulgaris and pustular psoriasis accounting for similar proportions. This is likely due to the inpatient setting, where, in addition to the common form of psoriasis, more severe variants such as pustular psoriasis and psoriatic arthritis were also more frequently observed.

Topical corticosteroids are the first-line therapy for mild psoriasis and are also used to treat persistent lesions in more severe cases, as an adjunct to systemic therapy or for localized areas such as the palms, soles, and scalp…[6,16]. According to Figure 3, the most commonly used corticosteroids were of high and very high potency. Patients were instructed on appropriate usage and monitored closely, with step-down or maintenance regimens applied in accordance with current guidelines [1,6,17]. According to the literature, methotrexate is an antimetabolite that inhibits DNA synthesis and, to a lesser extent, protein and RNA synthesis [7]. It also possesses anti-inflammatory properties, inhibiting leukocyte oxidative activity and chemotaxis, reducing C5a activity, suppressing leukotriene B4 activity, and decreasing cytokine production [3]. In our study (Figure 3), most patients received methotrexate via subcutaneous injection, which is generally well tolerated. There were no cases of death, severe infections, malignancies, or cardiovascular events [18], subcutaneous methotrexate may reduce gastrointestinal side effects and improve treatment efficacy [7]. Patients in this study received methotrexate with initial doses of 5-10 mg/week and 10-15 mg/week, consistent with current recommendations [19]. Trial dosing is recommended in patients with relative contraindications, older individuals, or when clinically necessary [7,18]. For elderly patients or those with renal impairment, the starting dose is 7.5 mg/week. In patients with risk factors such as diabetes, obesity, heavy alcohol use, or liver conditions, lower initial doses of 2.5-5 mg/week are advised, followed by blood tests after 7-10 days and dose escalation as appropriate [18]. However, adverse effects from prolonged low-dose methotrexate treatment may occur in 30-80% of patients [9], with an estimated 61% of psoriasis patients affected [8]. Hematopoietic cells, gastrointestinal epithelium, and epidermal cells are especially susceptible to methotrexate toxicity [8,9]. Concomitant folic acid supplementation may improve gastrointestinal tolerance and prevent hematologic toxicity [7-9]. According to Chamorro-Petronacci C, folic acid supplementation reduces mucosal and gastrointestinal side effects by 39% [9]. Folic acid or folinic acid has also been reported to reduce abnormalities in liver function [7,18]. In our study, the proportion of patients receiving folic acid was relatively low (Figure 3), which may be attributed to incomplete documentation in medical records, as folic acid is often not provided during inpatient treatment. Thus, although it may have been prescribed, this information may not have been fully recorded in the clinical charts.

Methotrexate typically shows therapeutic efficacy gradually over the first 4 to 8 weeks of treatment [7]. In clinical practice, however, many psoriasis patients are only hospitalized for approximately 4 weeks to manage acute flares before being discharged. Therefore, a 4-week follow-up was chosen as a key time point to assess early treatment response and guide decisions on outpatient continuation. After 4 weeks, 61.3% of patients had improved to mild disease according to the PASI score. Although three patients with initially severe PASI scores remained in the severe category (Table 4), their PASI scores decreased, indicating a trend toward improvement that could progress with continued treatment. The PASI75 achievement rate was 38.7% (Figure 4), which does not diminish the value of the study, as the primary objective was to evaluate the overall early response to treatment, rather than focus on PASI75, which often requires longer duration. After 4 weeks, 87.1% of patients showed moderate to good PASI reduction, indicating a clear treatment effect, particularly given the use of a low-dose methotrexate regimen that minimizes toxicity risk.

According to Table 5, the PASI75 achievement rate was significantly higher in patients without upper limb lesions. Age group was also associated with treatment response, with younger patients showing better outcomes compared to older ones. Shorter disease duration was another relevant factor. A limitation of this study is the relatively small sample size (n = 31), which may affect statistical power and reliability. Nevertheless, exploratory analysis using appropriate statistical tests was conducted to identify clinical and treatment-related factors associated with PASI75 response. The identification of statistically significant variables suggests that certain characteristics may predict better response to methotrexate. These findings partially align with previous studies, such as that by Menter A, which showed that younger patients with shorter disease duration responded better to systemic therapy [18]. Similarly, Yasmina Behlock found that early treatment in younger patients may result in a faster and more effective therapeutic response [20].

As shown in Table 6, only 3.2% of patients reported abdominal pain, lower than the 73% adverse event rate reported by R.J Van Dooren-Greebe, in which nausea and gastrointestinal complaints were most common [21], Chamorro-Petronacci C also reported common adverse effects including nausea, diarrhea, and abdominal pain, with 11-17% experiencing oral ulcers [9]. Frequently observed side effects include nausea, discomfort, and gastrointestinal ulcers [22]. Carretero G and colleagues found gastrointestinal toxicity in about 60% of patients, including stomatitis, nausea, vomiting, dyspepsia, abdominal pain, diarrhea, anorexia, and weight loss [7]. According to Lewis H, methotrexate-induced skin ulcers in psoriasis are rare [23]. According to A.Nast, pulmonary toxicity is also rare with low-dose methotrexate, especially in short-term use or non-oral routes [22], our study used primarily subcutaneous methotrexate for a short duration with low cumulative doses, and no pulmonary adverse events were observed.

In our study, 6.5% of patients developed mild liver enzyme elevation and continued treatment (Table 6). According to A. Nast, the most common hepatic side effect is elevated transaminases, while fibrosis and cirrhosis are rare [22], liver enzyme elevations typically occur in the initial weeks of treatment and often normalize spontaneously without dose reduction [7]. Risk factors for hepatotoxicity include pre-existing liver disease, family history of inherited liver disorders, hepatotoxic chemical exposure, heavy alcohol use, diabetes, obesity, and hyperlipidemia [18]. No cases of thrombocytopenia, anemia, or leukopenia were observed compared to pre-treatment values. Leukopenia is the most common hematologic manifestation of low-dose methotrexate toxicity and is dose-dependent [8,24]. The limitations of this study include the small sample size, short follow-up duration, and low cumulative methotrexate exposure, which may have limited detection of other potential adverse effects.

V. CONCLUSION

This study demonstrates that combination therapy with low-dose methotrexate and topical corticosteroids is effective in improving clinical outcomes in patients with moderate-to-severe psoriasis. Adverse events were mild and included abdominal discomfort and transient liver enzyme elevations, neither of which required treatment discontinuation. However, due to the short follow-up duration and low cumulative methotrexate exposure, the full spectrum of potential adverse effects could not be assessed.

Conflict of Interest

The authors declare no conflicts of interest.

Ethical Approval

This study was approved by the Scientific and Ethics Committee of Hue Central Hospital.

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