



Dermatology Life Quality Index in Patients with Psoriasis Treated with Biologic Versus Non-biologic Treatment in Malaysia: A Retrospective Cross-Sectional Study

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Abstract

Background Psoriasis imposes a substantial burden on patients' social, emotional, physical, and family life. Although psoriasis has no complete cure, various treatments are available to control its symptoms and improve a patients' quality of life.

Objective We aimed to compare the effectiveness of biologic versus non-biologic treatments on health-related quality of life among patients with psoriasis in Malaysia.

Methods This retrospective cross-sectional study evaluated data of adult patients diagnosed with psoriasis during 2007–18 from the Malaysian Psoriasis Registry. Baseline demographics, disease, and treatment characteristics were described. For a subset of patients treated with biologics and non-biologics who had baseline and 6-month follow-up data available, changes in the mean Dermatology Life Quality Index scores and the proportion of patients with a clinically relevant improvement (≥ 4 points) post-treatment were assessed.

Results Overall, 15,238 adult patients with psoriasis from the Malaysian Psoriasis Registry were included in the analysis. Patients receiving biologics showed a statistically significant reduction in the mean Dermatology Life Quality Index scores after 6 months compared with those receiving non-biologic treatment (-5.7 vs -0.8% ; $p < 0.001$). The proportion of patients who achieved a ≥ 4 -point improvement in Dermatology Life Quality Index scores was approximately two times greater in the biologic-treated group versus the non-biologic-treated group (56.4 vs 27.7%).

Conclusions Biologic treatment showed a greater reduction in the Dermatology Life Quality Index scores of patients with psoriasis versus non-biologic treatment. These results highlight the importance of early treatment with more efficacious treatment options, such as biologic therapies, to improve the overall health-related quality of life of patients with psoriasis.

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Key Points

Psoriasis imposes a substantial burden on patients' social, emotional, physical, and family life. Various treatments are available to control its symptoms and improve patients' quality of life.

Data from the Malaysian Psoriasis Registry were reviewed to assess the effect of biologic and non-biologic treatments on the health-related quality of life of patients with psoriasis.

Treatment with biologics showed a greater reduction in the Dermatology Life Quality Index scores of patients with psoriasis, indicating better health-related quality of life compared with non-biologic treatment.

1 Introduction

Psoriasis is more prevalent in northern Europe than in other geographic regions [1, 2]. In the USA, the prevalence of psoriasis in adults ranges from 0.5% [3] to 3.1% [4], whereas in Europe, it ranges from 1.3% [5] to 11.4% [1]. In Asia, the prevalence ranges from 0.1% [6] to 1.5% [7]. Although there is a lack of population-based epidemiological studies on psoriasis in the Malaysian population, a hospital-based study reported that psoriasis is common in Malaysia, accounting for approximately 9.5% of the dermatological conditions [8].

In both clinical practice and clinical trials, measurements such as body surface area (BSA), Physician's Global Assessment, and the Psoriasis Area and Severity Index (PASI) are used to guide the categorization of psoriasis severity as mild, moderate, and severe [9]. To account for patients with limited cutaneous disease but substantial physical, psychosocial, and functional impairments owing to the involvement of special areas (face, palms, soles, genitalia, and scalp), the International Psoriasis Council redefined psoriasis severity classification to only two categories (candidates requiring topical therapy or those requiring systemic therapy) [10].

Patients with psoriasis experience a substantial emotional, social, physical, and family burden on their lives. In addition to physical discomfort due to the condition, patients also report sleep disturbances, stigmatization, low self-esteem, suicidal thoughts, and negative feelings of shame, embarrassment, worry, and anger [11–14]. Consequently, these patients experience a considerable psychological burden that profoundly influences their personal and social life [15]. Furthermore, the physical and emotional consequences associated with psoriasis frequently interfere with workplace performance, in addition to causing absenteeism [16, 17]. Psoriasis is also associated with a significant burden of comorbid conditions such as cardiometabolic comorbidities (hyperlipidemia, hypertension, type 2 diabetes mellitus, and obesity), cardiovascular diseases (stroke, myocardial infarction, and death), depression, and inflammatory bowel diseases [18–23]. These comorbidities are associated with significant impairments in patients' health-related quality of life (HRQoL) [24, 25].

Although there is no complete cure for psoriasis, various treatments are available to control its symptoms and improve patients' HRQoL. The Dermatology Life Quality Index (DLQI) is a validated tool to measure the impact of psoriasis on patients' HRQoL [26, 27]. Furthermore, changes in the DLQI scores correlate well with variations in patients' clinical status measured using the PASI scores [28]. In clinical practice, DLQI measurement was also found to be useful for assessing patients' concerns that cannot be identified by PASI alone while initiating biologics or switching from other biologics [29].

Therefore, this study aimed to compare the effectiveness of biologic and non-biologic treatments on HRQoL assessed using the DLQI among patients with psoriasis in Malaysia.

2 Methods

2.1 Study Design

This was a retrospective cross-sectional study that evaluated data from the Malaysian Psoriasis Registry (MPR).

2.2 Data Source

The MPR is a prospective ongoing database that collects data on patients with psoriasis from 32 government-funded public hospitals and two private hospitals in Malaysia. The registry has data on patients' demographic characteristics, such as age, sex, and ethnicity; clinical characteristics, such as the type and clinical presentation of psoriasis; comorbidities; disease severity (assessed by BSA); HRQoL (assessed by the DLQI); and type of treatment (biologic vs non-biologic treatment).

2.3 Patient Population

Adult patients (aged ≥ 18 years) diagnosed with psoriasis by a registered dermatologist or a medical practitioner (under the supervision of a dermatologist) during 2007–18 were included in the study.

2.4 Outcomes

The baseline demographic, clinical, and treatment characteristics were described by severity levels (BSA < 5%; BSA 5–10%; BSA > 10–90%; and BSA > 90%). For a subset of patients who had baseline and 6-month follow-up data available, the following outcomes were assessed: change in the mean DLQI scores, proportion of patients reporting a negative impact on DLQI domains, and proportion of patients with a clinically relevant improvement in DLQI scores (defined as minimal clinically important difference of 4 points in the DLQI score) [30]. These outcomes were compared between patients treated with biologic and non-biologic treatments.

2.5 Analysis

Descriptive statistics were prepared, with results presented as frequencies and percentages for the categorical variables

(sex, ethnicity, sites affected, comorbidities, and treatment history) and as mean and standard deviation for the continuous variables (age, psoriasis duration, and DLQI scores). The difference in the mean DLQI scores of patients treated with biologic versus non-biologic therapy was tested using the one-tailed Welch's *t* test. A *p* value of < 0.05 was considered to indicate statistical significance. Statistical analyses were performed using SPSS version 21.0 (IBM Corporation, Armonk, NY, USA) and R software, version 4.1.3.

This study was approved by the Malaysian Research Ethics Committee (NMRR-20-1170-54885) and was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All subjects provided informed consent to participate in the study. No identifying information is included in this article.

3 Results

Table 1 presents the baseline characteristics of the patients identified from the MPR. A total of 15,238 adult patients with psoriasis with complete BSA involvement data from the MPR were included in this analysis. The mean age of the patients was 44.7 years, with a male-to-female ratio of 1:0.8 and an average disease duration of 9.3 years (Table 1). Plaque psoriasis was the most common phenotype (92.7%), followed by guttate (3.1%), erythrodermic (2.6%), and others (1.7%).

The proportion of patients with face, scalp, and nail involvement appeared to increase in tandem with a higher disease severity based on BSA. Obesity (52.4%) was the most frequent comorbidity observed in these patients followed by hypertension (25.3%), hyperlipidemia (17.5%), diabetes (16.9%), and psoriatic arthritis (14.5%). The mean DLQI score for all patients was 9.5, which increased with disease severity. Most patients were being treated with topical agents, either alone or in combination with other therapies (94.0%), whereas a few were receiving phototherapy (2.9%), non-biologic systemic agents (16.2%), and biologics (0.8%; Table 1). Over the last 12 years, the non-biologic systemic agents used included methotrexate, acitretin, corticosteroids, ciclosporin, hydroxyurea, and dapsone, whereas the biologics used were infliximab, etanercept, adalimumab, ustekinumab, certolizumab pegol, efalizumab, and secukinumab.

Overall, 7031 patients with follow-up treatment data at 6 months were included for further analysis. Patients receiving biologic treatment ($n = 78$) had a mean (standard deviation) baseline DLQI score of 13.9 (7.2), whereas patients receiving non-biologic treatment ($n = 6953$) had a score of 8.9 (6.7).

Patients receiving biologic treatment showed a statistically significant reduction in the mean DLQI scores after 6

months compared with those receiving non-biologic treatment (overall patient population: -5.7% vs -0.8% ; nail [all patients with nail involvement with or without concurrent face/scalp involvement]: -5.2 vs -0.8% ; scalp [concurrent nail/face or solely scalp involvement]: -5.5 vs -0.8% ; face [concurrent nail/scalp or solely face involvement]: -5.4 vs -1.0% ; Fig. 1). Similarly, the proportion of patients who achieved a ≥ 4 -point improvement in DLQI scores was approximately two times greater in the biologic-treated group compared with the non-biologic-treated group (56.4 vs 27.7%; Fig. 2).

Figure 3 represents the reduction in the proportion of patients reporting a negative impact on various DLQI domains after 6 months of treatment. The proportion of patients reporting a negative impact on various DLQI domains after 6 months of treatment was lower (for all domains except "leisure activities" and "work and school") for the biologic-treated group compared with the non-biologic-treated group.

4 Discussion

The greater improvement in DLQI scores at 6 months observed in this study for patients treated with biologics compared with those treated with non-biologics corroborated the observations of other studies [31, 32]. More than half of the patients treated with biologics showed a ≥ 4 -point reduction in DLQI scores, whereas only approximately one-quarter of the non-biologic-treated patients achieved this magnitude of DLQI score reduction. In a study conducted in Japan, treatment with biologics led to a marked improvement in DLQI scores compared with any other treatment modality [31]. Another Australian study demonstrated similar results, with biologics showing a significant reduction in DLQI scores at 24 weeks of treatment compared with other systemic and topical treatments [32]. It was interesting to note that biologic treatment conferred a higher magnitude of reduction in all domains of DLQI, except for "leisure activities" and "work and school," compared with non-biologic treatment. This finding may warrant further investigation in our patient population.

In the USA, approximately 37.0% of patients with moderate-to-severe psoriasis received biologics [3]. A survey among the rheumatologists and dermatologists in North America and the European Union 5 countries revealed that 19.6% of patients with moderate-to-severe psoriasis received biologics [33]. Data from the Adelphi 2007 Psoriasis Disease Specific Program demonstrated that the percentages of patients with moderate-to-severe psoriasis receiving biologics were 27.8, 9.7, and 9.3% in Spain, France, and the UK, respectively [34]. Our study revealed a much lower access to biologics (0.8%) among patients

Table 1 Demographic, clinical, and treatment characteristics of 15,238 patients registered in the Malaysian Psoriasis Registry

Characteristic	Overall N = 15,238	BSA < 5% n = 6686	BSA 5–10% n = 4821	BSA > 10–90% n = 3312	BSA > 90% n = 419
Age, mean ± SD	44.7 ± 15.7	44.9 ± 16.4	44.9 ± 15.4	43.7 ± 14.7	45.7 ± 15.4
Female, n (%)	6613 (43.4)	3228 (48.3)	1995 (41.4)	1257 (38.0)	133 (31.7)
Ethnicity, n (%)					
Malay	7993 (52.5)	3589 (53.7)	2515 (52.2)	1671 (50.5)	218 (52.0)
Chinese	3201 (21.0)	1379 (20.6)	1024 (21.2)	698 (21.1)	100 (23.9)
Indian	2547 (16.7)	1194 (17.9)	820 (17.0)	508 (15.3)	25 (6.0)
Other	1497 (9.8)	524 (7.8)	462 (9.6)	435 (13.1)	76 (18.1)
Age at onset, years, mean ± SD	35.4 ± 16.1	36.3 ± 16.5	35.6 ± 15.8	33.3 ± 15.3	33.9 ± 16.1
Disease duration (years), mean ± SD	9.3 ± 9.8	8.6 ± 9.8	9.3 ± 9.7	10.4 ± 9.7	11.6 ± 10.1
Special sites affected by psoriasis ^a , n (%)					
Face	7471 (49.0)	2063 (30.9)	2567 (53.2)	2476 (74.8)	365 (87.1)
Scalp	11,969 (78.5)	4731 (70.8)	3936 (81.6)	2926 (88.3)	376 (89.7)
Nail	8977 (58.9)	3258 (48.7)	2967 (61.5)	2418 (73.0)	334 (79.7)
Comorbidities, n (%)					
Diabetes mellitus	2579 (16.9)	1160 (17.3)	841 (17.4)	524 (15.8)	54 (12.9)
Hypertension	3859 (25.3)	1774 (26.5)	1208 (25.1)	780 (23.5)	97 (23.1)
Obesity	7991 (52.4)	3452 (51.6)	2559 (53.1)	1783 (53.8)	197 (47.0)
Hyperlipidemia	2674 (17.5)	1282 (19.2)	813 (16.9)	519 (15.7)	60 (14.3)
Psoriatic arthritis	2216 (14.5)	899 (13.4)	649 (13.5)	558 (16.8)	110 (26.3)
DLQI, mean ± SD	9.5 ± 6.8	7.7 ± 6.1	9.7 ± 6.5	12.3 ± 7.0	13.9 ± 7.2
DLQI > 10, n (%)	5916 (38.8)	1872 (28)	1934 (40.1)	1840 (55.6)	270 (64.4)
Treatment ^a , n (%)					
Topical treatment	14,320 (94.0)	6185 (92.5)	4581 (95.0)	3159 (95.4)	395 (94.3)
Phototherapy	441 (2.9)	62 (0.9)	133 (2.8)	219 (6.6)	27 (6.4)
Non-biologic systemic agents	2466 (16.2)	728 (10.9)	714 (14.8)	823 (24.8)	201 (48.0)
Biologics	116 (0.8)	28 (0.4)	21 (0.4)	51 (1.5)	16 (3.8)

BSA body surface area, DLQI Dermatology Life Quality Index, SD standard deviation

^aThe total may be more than the number of patients in each category of severity as one patient may have more than one psoriasis site or treatment

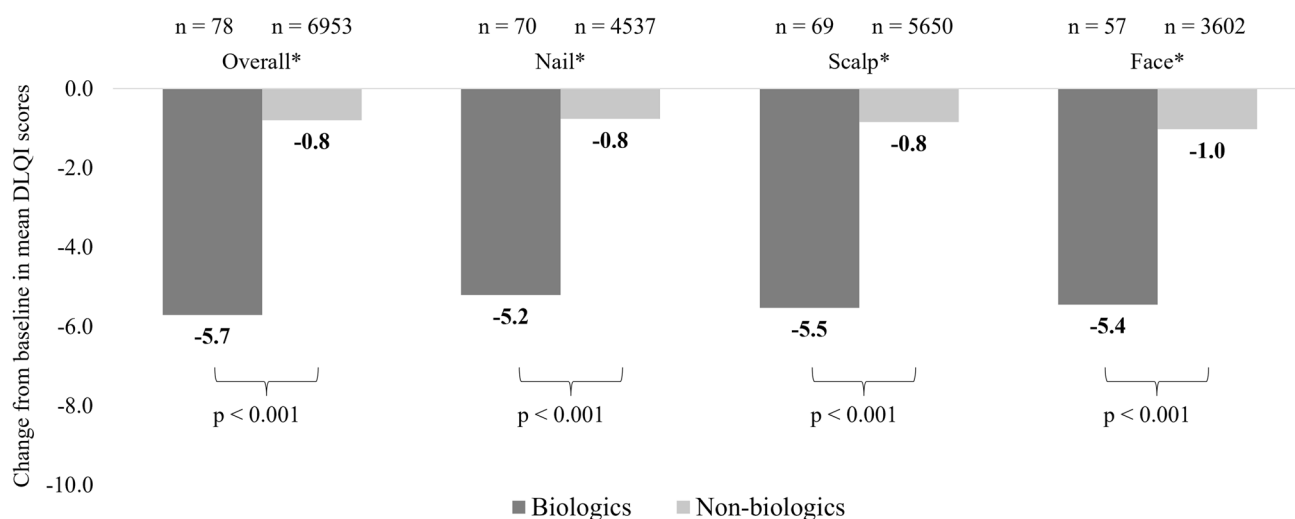


Fig. 1 Change from baseline in mean Dermatology Life Quality Index (DLQI) scores after 6 months of treatment. *Statistically significant difference between biologic and non-biologic treatment groups ($p < 0.05$)

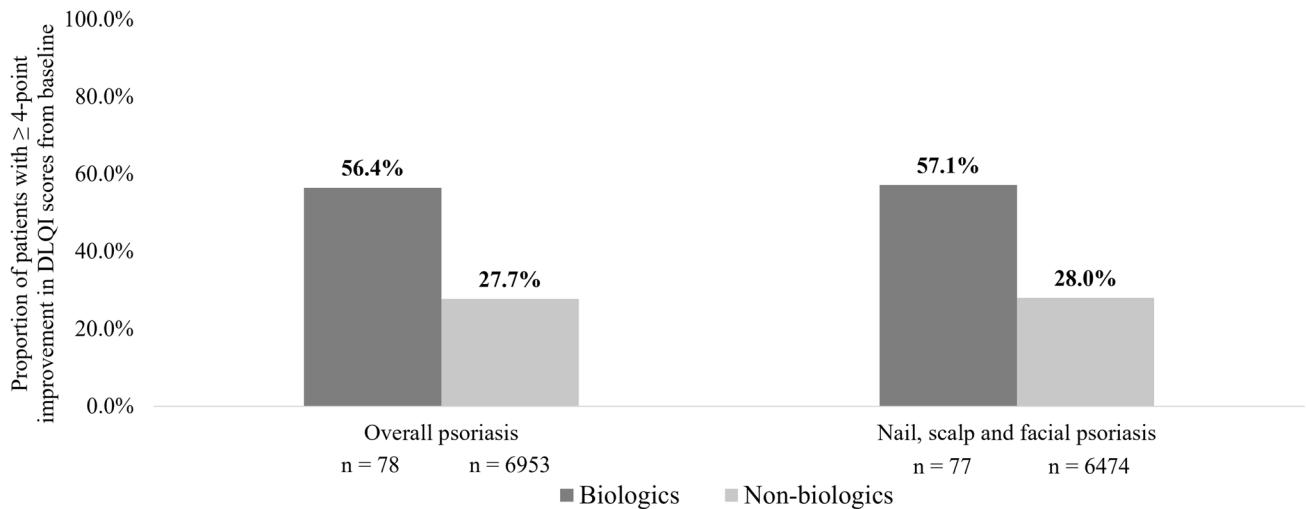


Fig. 2 Proportion of patients with a ≥ 4-point improvement in Dermatology Life Quality Index (DLQI) scores after 6 months of treatment

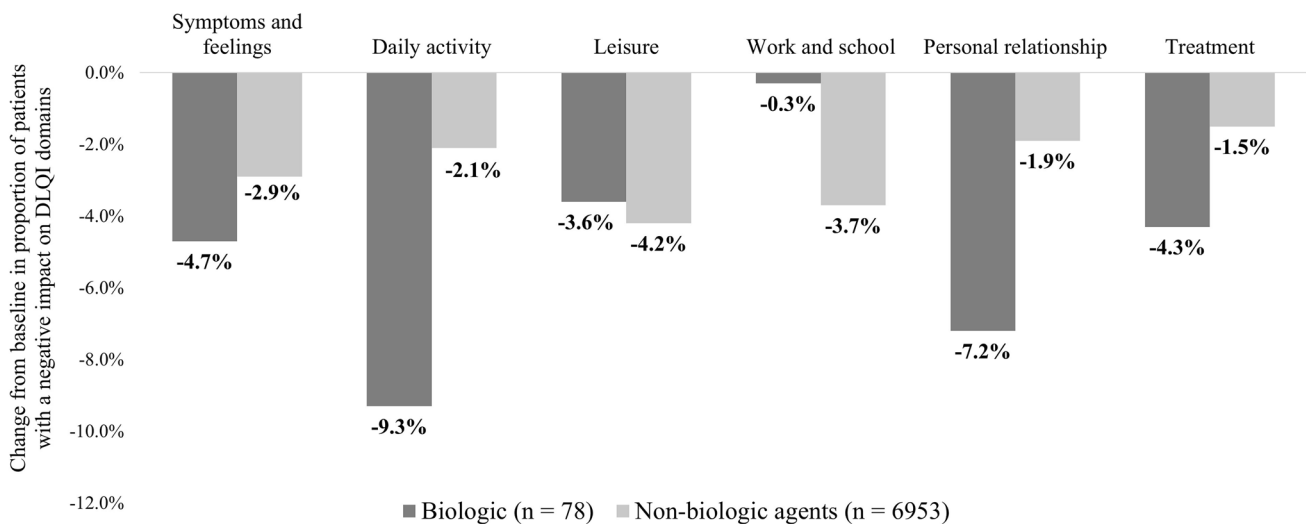


Fig. 3 Change from baseline in the proportion of patients reporting a negative impact on Dermatology Life Quality Index (DLQI) domains after 6 months of treatment

with moderate-to-severe psoriasis in Malaysia compared with these countries. One of the reasons for this might be the more stringent criteria set by the Malaysian Ministry of Health clinical practice guidelines, where only patients with a high disease severity (BSA > 30%, PASI or DLQI > 20) would be considered for biologic treatment. High biologic cost and contraindications in patients with psoriasis with tuberculosis could be other contributing factors for a lower access to biologics in Malaysia [35]. By contrast, the British Association of Dermatologists guidelines consider patients with BSA > 10% and DLQI > 10 as candidates for biologic therapy, which results in a lower hurdle to treatment access. Furthermore, in our study, a substantial proportion of

patients with moderate-to-severe psoriasis had face (49.0%), scalp (78.5%), or nail (58.9%) involvement, which may further impact their quality of life owing to a high visibility of the lesions. As the conventional systemic therapies are known to be less effective and slower acting compared with biologics, in patients with nail and scalp involvement, timely access to biologics is crucial [36].

In this study population, approximately 18.0% of patients with moderate-to-severe psoriasis (BSA > 10%) had psoriatic arthritis. Psoriatic arthritis imposes a considerable additional burden on the HRQoL and functional abilities of these patients [37, 38]. Biologic treatments are more effective in treating psoriatic arthritis compared with conventional

systemic therapies [39–42] and can slow the disease progression when initiated early in the disease course [40, 43, 44]. Therefore, this subgroup of patients can benefit from early treatment initiation with biologics.

Greater skin clearance in patients with moderate-to-severe psoriasis was associated with increased productivity at the workplace and a reduction in annual indirect costs [45]. With a greater improvement in the PASI score, the mean overall work productivity loss decreased correspondingly. Notably, patients with a less than 50.0% improvement from baseline (PASI < 50) lost 429 work hours/year, whereas patients with a 90.0% or more improvement from baseline (PASI ≥ 90) lost only 93 work hours/year. Similarly, the indirect costs associated with PASI ≥ 90 (\$3125) were 74.0% lower than those associated with PASI < 50 (\$11,906) [45]. In addition, improvements in PASI strongly correlated with improvements in HRQoL. For example, the probability of achieving a DLQI score of 0/1 was increased by approximately 50.0% when PASI 75 improved to PASI ≥ 90 [46, 47]. However, a PASI response of ≥ 90 is more likely to be achieved with biologic treatment than with conventional systemic therapies [48]. Therefore, timely treatment escalation to better treatment options, such as biologics, which are the current gold-standard treatment for moderate-to-severe psoriasis, would be beneficial in improving their clinical parameters (reductions in PASI and BSA) and decreasing indirect costs, eventually contributing to the well-being of patients, their families, and society.

The chronic elevation of systemic inflammatory cytokines in patients with psoriasis increases the risk of cardiometabolic comorbidities (diabetes, hyperlipidemia, hypertension, and obesity) [49]. In our study, patients with psoriasis reported a higher prevalence of cardiometabolic comorbidities consistent with the findings from other studies, which implies that the disease manifestations go beyond the skin [50–52]. Therefore, early and effective treatment is crucial for better disease control, which can potentially modify the risk of comorbidities, thereby enhancing HRQoL and life expectancy [53–57].

The limitations of this study include the relatively smaller number of patients in the biologic treatment group compared with the other treatments, as well as the unavailability of PASI scores in the registry data, which prevented a better assessment of the disease severity.

5 Conclusions

Patients treated with biologics had greater reductions in the DLQI scores, indicating better HRQoL compared with those treated with non-biologic treatment. These results highlight the importance of early treatment with more efficacious treatment options, such as biologic therapies, to improve the overall HRQoL of patients with psoriasis.

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Declarations

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Conflict of interest Shu Kee Eng, John Tiong and Harini Chinthapatla are employees of Novartis. Suganthi Robinson, Tang Min Moon, Tan Wooi Chiang, Teh Yeon Chiat, Latha Selvarajah, Tang Jyh Jong, and Suganthi Thevarajah have no conflicts of interest that are directly relevant to the content of this article.

Ethics approval This study was approved by the Malaysian Research Ethics Committee (NMRR-20-1170-54885). This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Consent to participate All subjects provided informed consent to participate in the study. No identifying information is included in this article.

Consent for publication Not applicable.

Availability of data and material The datasets generated and/or analyzed during the current study are not publicly available because of the privacy policies set by the Ministry of Health, Malaysia.

Code availability Not applicable.

Author contributions All authors contributed to the study conception, design, data collection, and analysis. Material preparation and writing were performed by SR and HC. All authors were involved in the review and correction of the manuscript. All named authors meet the International Committee of Medical Journal Editors criteria of authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

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