Comparison of Biologics vs. Methotrexate Treatment on Disease Burden and Treatment Outcome in Malaysian Psoriasis Patients: Data from the Malaysian Psoriasis Registry (MPR)

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INTRODUCTION

- Psoriasis (PsO) is an immune-mediated, chronic inflammatory disease manifesting in the skin, joints or both.[1] The estimated prevalence of PsO in Malaysia is 0.34% with the annual prevalence and incidence increasing steadily from 2010 to 2020.[2]
- According to the Malaysian Psoriasis Registry, the most common clinical subtype of PsO in adult patients is plaque PsO. PsO is associated with multiple comorbidities, especially obesity, cardiovascular disease and metabolic syndrome.[3]
- PsO patients have an increased risk of developing psoriatic arthritis (PsA) which increases with disease duration, disease severity, and family history of psoriasis.[4] Up to 30% of PsO patients may develop PsA.[5,6]
- Systemic agents and biologic therapy are commonly used to treat moderate-to-severe PsO patients. However, there is limited understanding of the impact of these treatments on the development of PsA. Furthermore, there is minimal to no information pertaining to clinical characteristics, treatment outcomes and new incidence of PsA in adult Malaysian PsO patients.
- This study aims to evaluate the patient demographics, clinical characteristics, and treatment outcomes of adult PsO patients in Malaysia who are on biologic and/or methotrexate (MTX) treatment.

METHODS

- This was a multicenter, cross-sectional, observational study utilizing data from the Malaysian Psoriasis Registry (MPR), which, prospectively, collects data of patients with PsO treated at 36 public and 2 private hospitals in Malaysia.
- All adult PsO patients registered between January 2020 to December 2022, who had completed at least 6 months of treatment with MTX or biologic agents [Tumor Necrosis Factor inhibitors (TNFi), Interleukin-17 inhibitor (secukinumab) or Interleukin-12/23inhibitor (ustekinumab)], and remained in the same treatment group till 1 year were included in this study.
- Descriptive analysis for patient demographics, clinical characteristics and treatment outcome (BSA, PASI) was performed at baseline (patient enrolment into registry), 6 months, and 12 months.
- Statistical analysis was performed using the two-sided t test and two proportion z test for continuous and categorical data respectively; p values were calculated against MTX using medcalc® statistical software.
- A sub-analysis compared the risk of new onset of PsA, diagnosed by a rheumatologist after 12 months of treatment, in PsO patients treated with MTX or a biologic agent. PsO patients without a diagnosis of PsA at baseline and who had completed 12 months of treatment were included. Patients with a new onset of PsA within 12 months of treatment initiation were excluded to eliminate potential confounding bias.

RESULTS

- In total, 794 PsO patients, 661 in the MTX group and 133 in the biologic group (secukinumab, ustekinumab or TNFi) were included. At baseline, patients on biologic agents were younger (p<0.05), had longer disease duration (p<0.05), and had more severe disease (p<0.0001) compared to the MTX group (**Table 1 & Figure 1**).
- The female to male ratio was comparable across both groups. A family history of PsO was present in about a quarter of patients in both groups. Higher proportion of patients in the biologic group had fatty liver (NAFLD) disease compared to the patients in the MTX group at baseline (p<0.05) (**Table 1**).
- In the biologic treated group, most were biologic naïve (84.21%). Patients in the IL-17i treated group had the worst disease severity (body surface area (BSA) and psoriasis area and severity index (PASI) scores) (p<0.0001) compared to the IL 12/23i and TNFi groups (**Figure 1**).
- At baseline, about two thirds of patients had nail involvement and one third had concomitant PsA in both the biologic and MTX groups (**Table 1**).
- In the sub analysis of PsO patients without PsA, the risk of new PsA onset was numerically lower among PsO patients on biologic agents vs. MTX after 12-months of treatment [OR, 0.72 (95% CI): 0.24-2.13] (**Table 2**).

Table 1. Baseline demographics and clinical characteristics of adult PsO patients in Malaysia by treatment groups

Demographics and clinical characteristics	Methotrexate N=661	All Biologics (IL-17i, IL-12/23i, TNFi) N=133	IL-17i (Secukinumab) N=79	IL-12/23i (Ustekinumab) N=40	TNFi N=14
Mean age (years) ± SD	48.67±15.15	43.35±14.81*	41.95±14.60*	45.34±15.88	45.51±12.74
Female - n (%)	282 (42.66)	66 (49.62)	44 (55.69)*	17 (42.5)	5 (35.71)
Malay - n (%)	332 (50.22%)	66 (49.62%)	46 (58.22%)	25 (62.5%)	10 (71.42%)
Chinese - n (%)	162 (24.50%)	30 (22.55%)	18 (22.78%)	9 (22.5%)	3 (21.42%)
Indian - n (%)	88 (13.31%)	14 (10.52%)	12 (15.18%)	2 (5%)	0 (0%)
Others - n (%)	79 (11.95%)	8 (6.01%)*	3 (3.7%)*	4 (10%)*	1 (7.14%)
BMI (kg/m^2) ± SD	28.11±5.97	29.54±6.96*	30.09±7.41*	29.10±6.70	27.66±4.63
Mean age of PsO onset ± SD	34.34±14.98	26.47±12.05**	26.48±12.03**	26.73±12.70*	25.64±11.06*
Mean age of PsO diagnosis ± SD	36.24±14.88	27.90±12.43**	27.58±12.08**	28.78±13.60*	27.21±11.58*
Duration of PsO (years, mean) ± SD	14.32±10.35	16.78±10.76*	15.30±11.03	18.59±10.65*	19.86±8.55*
Family history of PsO - n (%)	154 (23.3)	35 (26.31)	20 (25.31)	12 (30)	3 (21.42)
Nail involvement, n/N (%)	426 / 661 (64.45)	88 / 133 (66.16)	56 / 79 (70.88)	28 / 40 (70)	4 / 14 (28.57)
Psoriatic Arthritis (PsA), n/N (%)	209 / 661 (31.6)	42 / 133 (31.57)	31 / 79 (39.24)	2 / 40 (5)**	9 / 14 (64.28)*
Enthesitis/ dactylitis, n/N (%)	23 / 209 (11)	6 / 42 (14.28)	6 / 31 (19.35)	0 / 2 (0)	0 / 9 (0)
Ischemic heart disease – n (%)	33 (4.99)	6 (4.51)	2 (2.53)	3 (7.5)	1 (7.14)
CVD disease (stroke) – n (%)	11 (1.66)	0 (0)	0 (0)	0 (0)	0 (0)
Diabetes mellitus - n (%)	140 (21.18)	33 (24.81)	16 (20.25)	13 (32.5)	4 (28.57)
Hypertension - n (%)	235 (35.5)	48 (36.09)	28 (35.44)	14 (35)	6 (42.85)
Hyperlipidemia - n (%)	194 (29.34)	41 (30.82)	19 (24.05)	16 (40)	6 (42.85)
Fatty liver (NAFLD) – n (%)	40 (6.05)	18 (13.53)*	10 (12.65)	7 (17.5)	1 (7.14)
Biologic naïve - n (%)	-	112 (84.21)	66 (83.54)	35 (87.5)	11 (78.57)
Biologic experienced - n (%)	-	21 (15.79)	13 (16.46)	5 (12.5)	3 (21.43)
Secukinumab dose 300 mg - n (%)	-	-	50 (63.29)	-	-
Secukinumab dose 150 mg - n (%)	-	-	29 (36.71)	-	-

Note: **P<0.0001 vs. methotrexate (non-biologic); *P<0.05 vs. methotrexate (non-biologic)
CVD – Cardiovascular disease, PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor, BSA – Body surface area, PASI – Psoriasis area and severity index, SD – Standard deviation, BMI-body mass index, NAFLD – Non-alcoholic fatty liver disease

Figure 1. Treatment outcome (BSA and PASI) of adult PsO patients in Malaysia on biologic agents and methotrexate therapy at 6 and 12 months

Figure 1a. Body surface area (BSA)

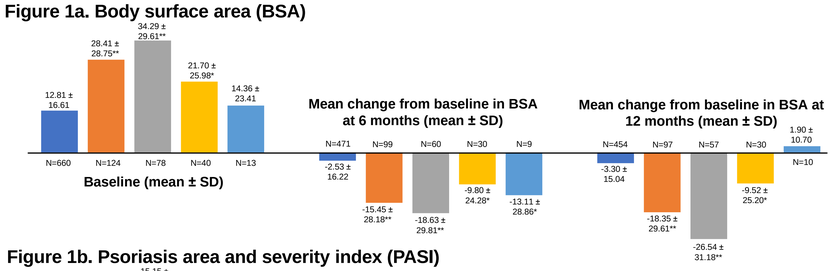
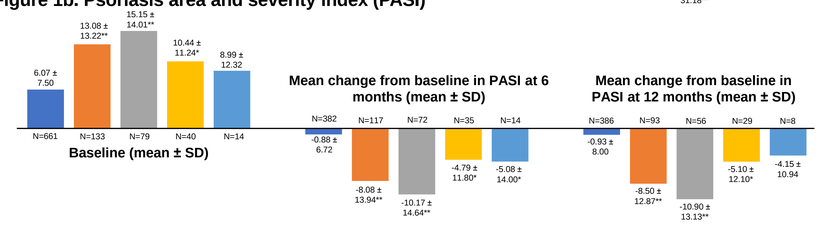


Figure 1b. Psoriasis area and severity index (PASI)



Note: **P<0.0001 vs. methotrexate (non-biologic); *P<0.05 vs. methotrexate (non-biologic)
PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor SD – Standard deviation, PASI – Psoriasis area and severity index

Table 2. PsA incidence rate and odds ratio at 12 months post treatment in adult PsO patients on biologics and methotrexate therapy

Parameter	Methotrexate N=312	All Biologics (IL-17i, IL-12/23i, TNFi) N=56
New onset (incidence) of psoriatic arthritis (PsA) post 12 months treatment, n, %	30 / 312 (9.61)	4 / 56 (7.14)
PsA incidence rates per 1000 patient-years (95% CI)	96.1 (64.87 – 131.27)	71.43 (19.46 – 182.89)
PsA incidence- Odds ratio (95% CI)	1	0.723 (95% CI: 0.244-2.138)

PsO - Psoriasis, IL-17i – Interleukin-17 inhibitor, IL 12/23i – Interleukin 12/23 inhibitor, TNFi – Tumor necrosis factor inhibitor, PsA - Psoriatic arthritis, CI – Confidence interval

CONCLUSION

- PsO patients on biologic treatment had significantly better BSA and PASI improvement, compared to MTX, irrespective of duration and severity of disease at baseline. Among the biologic treated group, patients on IL-17i demonstrated the greatest improvement in disease severity.
- Patients on biologic agents tended to have a numerically lower risk of developing new onset PsA than those on MTX treatment at 1 year, despite higher disease severity and longer disease duration at baseline.
- Early biologic initiation might help to improve treatment outcome in PsO patients.

LIMITATIONS

- Due to the inherent nature of non-interventional, observational registry based studies, it is acknowledged that limitations such as confounding, missing data, inadequate follow-up may affect the accuracy and generalizability of the results.

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