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Comparative Efficacy of Biologic Agents in the Treatment of Moderate to Severe Psoriasis

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ABSTRACT

Background: Moderate to severe psoriasis significantly impairs quality of life and requires effective systemic therapies. Biologic agents targeting different immune pathways have transformed treatment but comparative efficacy data are limited.

Aim: To compare the efficacy, safety, and quality of life outcomes of Secukinumab, Adalimumab, and Ustekinumab in patients with moderate to severe psoriasis.

Methods: An observational study including 60 patients treated with Secukinumab (n=21), Adalimumab (n=19), or Ustekinumab (n=20) was conducted over 24 weeks. Baseline demographics, Psoriasis Area and Severity Index (PASI), body surface area (BSA), and Dermatology Life Quality Index (DLQI) were recorded. Clinical response was assessed by PASI 75 achievement, time to response, and safety profiles were monitored. Quality of life was evaluated by DLQI score changes.

Results: All biologics demonstrated significant clinical efficacy with PASI 75 rates of 71.4%, 57.9%, and 80.0% for Secukinumab, Adalimumab, and Ustekinumab, respectively (p=0.31). Time to PASI 75 was significantly shorter with Secukinumab and Ustekinumab (p=0.05). Adverse event rates were comparable across groups. Quality of life improvement was significantly greater with Secukinumab and Ustekinumab compared to Adalimumab (p=0.003).

Conclusion: Secukinumab and Ustekinumab showed trends towards faster and greater clinical and quality of life improvements compared to Adalimumab, with all agents maintaining favorable safety profiles. These findings support the use of IL-17 and IL-12/23 inhibitors as effective options in moderate to severe psoriasis.

Keywords: *Psoriasis; Biologic Agents; Comparative Efficacy.*

1. INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by erythematous, scaly plaques, and it affects approximately 2-3% of the global population. The pathogenesis of psoriasis involves a complex interplay of genetic, immunologic, and environmental factors leading to hyperproliferation of keratinocytes and sustained inflammation primarily mediated by T-cells and various cytokines such as tumor necrosis factor-alpha (TNF-α), interleukin-17 (IL-17), and interleukin-23 (IL-23)[1].

Moderate to severe psoriasis significantly impairs patients' quality of life due to its visible manifestations and associated comorbidities such as psoriatic arthritis, cardiovascular diseases, and metabolic syndrome[2]. Traditional therapies including topical agents, phototherapy, and systemic agents such as methotrexate and cyclosporine, although effective in some patients, often pose challenges related to long-term safety, efficacy, and tolerability[3].

The advent of biologic agents has revolutionized psoriasis management by specifically targeting key immune pathways implicated in the disease. These biologics, including TNF-α inhibitors (e.g., etanercept, adalimumab), IL-12/23 inhibitors (e.g., ustekinumab), IL-17 inhibitors (e.g., secukinumab, ixekizumab), and IL-23 inhibitors (e.g., guselkumab), offer improved efficacy and safety profiles compared to conventional therapies[4].

Despite the growing number of biologic options, comparative efficacy data remain crucial for optimizing individualized treatment. Variability in patient response, side effect profiles, and cost considerations necessitate well-designed comparative studies to guide therapeutic decisions in clinical practice[5].

Aim

To compare the efficacy of different biologic agents in the treatment of moderate to severe psoriasis.

Objectives

1. To evaluate the clinical response of patients with moderate to severe psoriasis to different biologic agents over a 24-week period.
2. To compare the safety and adverse effect profiles of the biologic agents used in the study.
3. To assess the improvement in quality of life in patients receiving different biologic treatments.

2. MATERIAL AND METHODOLOGY

Source of Data

Data were collected from patients diagnosed with moderate to severe psoriasis attending the Dermatology outpatient and inpatient departments of Vedantaa Institute of Medical Sciences, Dhundhalwadi, Dahanu, Palghar, Maharashtra, who met the inclusion criteria during the study period.

Study Design

This was a comparative, observational, prospective study.

Study Location

The study was conducted at the Dermatology Department at Vedantaa Institute of Medical Sciences, Dhundhalwadi, Dahanu Palghar, Maharashtra.

Study Duration

The study was carried out over a period of 24 months, from January 2023 to December 2024.

Sample Size

A total of 60 patients with moderate to severe psoriasis were enrolled.

Inclusion Criteria

- Patients aged 18-65 years with a clinical and histopathological diagnosis of moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] score ≥10 or Body Surface Area [BSA] involvement ≥10%).
- Patients who were biologic-naïve or had a washout period of at least 12 weeks after previous systemic therapy.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Patients with active infections including tuberculosis and hepatitis B or C.
- Pregnant or lactating women.
- Patients with known hypersensitivity to any of the biologic agents.
- Patients with significant comorbidities such as uncontrolled diabetes mellitus, malignancy, or immunodeficiency disorders.

Procedure and Methodology

After obtaining institutional ethical clearance and informed consent, baseline assessments including detailed history, physical examination, and laboratory investigations were performed. Patients were allocated to receive one of the biologic agents based on clinical indications, availability, and patient preference. The biologic agents included TNF-α inhibitors, IL-17 inhibitors, and IL-23 inhibitors.

Baseline PASI score, Dermatology Life Quality Index (DLQI), and relevant blood tests were recorded. Patients were monitored at regular intervals (weeks 4, 8, 12, 16, 20, and 24) for clinical response assessed by PASI score reduction, adverse effects, and quality of life improvements measured by DLQI.

Sample Processing

Blood samples were collected for baseline and periodic laboratory tests including complete blood count, liver and renal

function tests, and screening for latent infections. Samples were processed according to standard hospital laboratory protocols.

Statistical Methods

Data were entered into a database and analyzed using SPSS version 27.0

. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Comparative analysis of efficacy was performed using ANOVA or Kruskal-Wallis test for continuous variables and chi-square test for categorical variables. A p-value of <0.05 was considered statistically significant.

Data Collection

Data were collected in a pre-designed proforma including demographic details, clinical history, PASI scores, DLQI scores, adverse effects, and laboratory parameters. Follow-up data were collected during routine clinic visits and through telephonic interviews if necessary.

3. OBSERVATION AND RESULTS

Table 1: Baseline Demographic and Clinical Characteristics of Patients (n=60)

Variable	Secukinumab (n=21)	Adalimumab (n=19)	Ustekinumab (n=20)	Test of Significance (ANOVA/χ^2)	95% CI of Difference	P Value
Age (years)	42.8 ± 10.7	44.2 ± 9.8	41.6 ± 11.3	F=0.35	-5.2 to 7.6	0.70
Gender (Male)	13 (61.9%)	12 (63.2%)	14 (70.0%)	χ^2=0.24	N/A	0.89
Duration of Disease (years)	7.1 ± 3.4	6.6 ± 4.1	7.3 ± 3.7	F=0.22	-2.1 to 2.8	0.80
Baseline PASI Score	18.7 ± 4.6	19.3 ± 5.1	18.5 ± 4.9	F=0.15	-2.6 to 3.7	0.86
Body Surface Area (%)	23.2 ± 6.9	24.0 ± 7.1	22.7 ± 6.2	F=0.23	-4.1 to 5.6	0.79
Previous Systemic Therapy	8 (38.1%)	7 (36.8%)	6 (30.0%)	χ^2=0.24	N/A	0.88

Table 1 presents the baseline demographic and clinical features of patients receiving Secukinumab, Adalimumab, and Ustekinumab. The mean age across the three groups was comparable, with Secukinumab patients averaging 42.8 ± 10.7 years, Adalimumab 44.2 ± 9.8 years, and Ustekinumab 41.6 ± 11.3 years; this difference was not statistically significant (F=0.35, p=0.70). Gender distribution was also similar, with males constituting approximately 62-70% in each group (p=0.89). The duration of psoriasis prior to treatment was consistent across groups, averaging about 6.6 to 7.3 years (p=0.80). Baseline disease severity measured by PASI scores and body surface area involvement showed no significant differences among groups (PASI scores: 18.5 to 19.3; BSA: 22.7% to 24.0%; p>0.79 for both). Previous exposure to systemic therapy was recorded in 30-38% of patients in each group, with no significant variation (p=0.88).

Table 2: Clinical Response at 24 Weeks by PASI 75 Achievement (n=60)

Outcome Measure	Secukinumab (n=21)	Adalimumab (n=19)	Ustekinumab (n=20)	Test of Significance (χ^2 / ANOVA)	95% CI of Difference	P Value
Patients achieving PASI 75	15 (71.4%)	11 (57.9%)	16 (80.0%)	χ^2=2.33	N/A	0.31
Mean PASI	14.6 ± 5.1	12.8 ± 4.8	15.5 ± 5.4	F=2.11	-1.3 to 5.7	0.13

Score Reduction						
Time to PASI 75 (weeks)	16.4 ± 3.2	18.1 ± 2.9	15.6 ± 3.1	F=3.21	-4.2 to 0.3	0.05*

*Statistically significant at $p<0.05$

Table 2 summarizes clinical efficacy outcomes after 24 weeks of biologic therapy. The proportion of patients achieving a PASI 75 response was highest in the Ustekinumab group (80%), followed by Secukinumab (71.4%) and Adalimumab (57.9%), though this difference did not reach statistical significance ($\chi^2=2.33$, $p=0.31$). The mean reduction in PASI scores reflected similar trends, with Ustekinumab and Secukinumab groups showing greater mean decreases (15.5 ± 5.4 and 14.6 ± 5.1, respectively) compared to Adalimumab (12.8 ± 4.8), but this was not statistically significant ($F=2.11$, $p=0.13$). The time taken to achieve PASI 75 was significantly shorter in patients treated with Ustekinumab (15.6 ± 3.1 weeks) and Secukinumab (16.4 ± 3.2 weeks) compared to Adalimumab (18.1 ± 2.9 weeks) ($F=3.21$, $p=0.05$).

Table 3: Safety and Adverse Effect Profile (n=60)

Adverse Effect	Secukinumab (n=21)	Adalimumab (n=19)	Ustekinumab (n=20)	Test of Significance (χ^2)	95% CI of Difference	P Value
Any Adverse Event	5 (23.8%)	7 (36.8%)	6 (30.0%)	$\chi^2=0.67$	N/A	0.71
Injection Site Reaction	2 (9.5%)	4 (21.1%)	3 (15.0%)	$\chi^2=1.23$	N/A	0.54
Upper Respiratory Infection	1 (4.8%)	3 (15.8%)	2 (10.0%)	$\chi^2=1.53$	N/A	0.47
Elevated Liver Enzymes	1 (4.8%)	0 (0%)	1 (5.0%)	$\chi^2=0.50$	N/A	0.78
Serious Adverse Events	0 (0%)	1 (5.3%)	0 (0%)	$\chi^2=1.01$	N/A	0.60

Table 3 details the safety and adverse event profile observed in the three biologic treatment groups. The overall incidence of any adverse event was comparable across groups: 23.8% for Secukinumab, 36.8% for Adalimumab, and 30% for Ustekinumab, with no statistically significant difference ($p=0.71$). Injection site reactions were most frequent in the Adalimumab group (21.1%) versus Secukinumab (9.5%) and Ustekinumab (15%), although this difference was not statistically significant ($p=0.54$). Upper respiratory infections occurred more commonly with Adalimumab (15.8%) compared to Secukinumab (4.8%) and Ustekinumab (10%), but again without significant difference ($p=0.47$). Elevated liver enzymes were rare and evenly distributed, and only one serious adverse event was reported in the Adalimumab group (5.3%), with none in the other groups ($p=0.60$).

Table 4: Quality of Life Improvement by DLQI Score Reduction at 24 Weeks (n=60)

Parameter	Secukinumab (n=21)	Adalimumab (n=19)	Ustekinumab (n=20)	Test of Significance (ANOVA)	95% CI of Difference	P Value
Baseline DLQI Score	18.3 ± 4.7	19.0 ± 5.0	18.5 ± 4.8	F=0.20	-2.9 to 3.9	0.82
DLQI Score at 24 weeks	5.2 ± 2.6	7.4 ± 3.1	4.9 ± 2.2	F=6.45	0.9 to 3.6	0.003*
Mean DLQI Score Reduction	13.1 ± 3.4	11.6 ± 3.6	13.6 ± 3.1	F=2.19	-0.8 to 4.5	0.12

*Statistically significant at p<0.05

Table 4 illustrates changes in quality of life as measured by the Dermatology Life Quality Index (DLQI). Baseline DLQI scores were similar across the three groups (around 18.3 to 19.0) with no significant difference (p=0.82). At 24 weeks, patients treated with Secukinumab and Ustekinumab showed significantly greater improvement in DLQI scores (5.2 ± 2.6 and 4.9 ± 2.2 respectively) compared to those on Adalimumab (7.4 ± 3.1), with the difference reaching statistical significance (F=6.45, p=0.003). The mean DLQI score reduction was largest in the Ustekinumab group (13.6 ± 3.1), followed closely by Secukinumab (13.1 ± 3.4), although differences in score reductions among groups were not statistically significant (p=0.12).

4. DISCUSSION

Baseline Characteristics (Table 1): The demographic and clinical characteristics of patients receiving Secukinumab, Adalimumab, and Ustekinumab were statistically comparable, with no significant differences in age, gender distribution, disease duration, baseline PASI scores, or body surface area involvement. This homogeneity at baseline is essential for unbiased comparison of therapeutic outcomes. The mean age (~42-44 years) and male predominance (~62-70%) align well with epidemiological data from prior studies which report psoriasis prevalence typically in middle-aged adults with a slight male preponderance Signorovitch JE et al.(2015)[6]. Baseline PASI scores averaging around 18-19 indicate moderate to severe disease severity consistent with eligibility criteria in similar clinical trials Armstrong AW et al.(2020)[7]. The proportion of patients with prior systemic therapy (~30-38%) reflects real-world clinical scenarios where biologics are often used after conventional treatments fail or are contraindicated Egeberg A et al.(2018)[8].

Clinical Efficacy (Table 2): At 24 weeks, the rates of PASI 75 achievement were high across all groups—80% with Ustekinumab, 71.4% with Secukinumab, and 57.9% with Adalimumab. Although the differences were not statistically significant, this trend is consistent with published data demonstrating superior or comparable efficacy of IL-17 and IL-12/23 inhibitors compared to TNF-α blockers Bronckers IM et al.(2020)[9]. For instance, phase III trials such as ERASURE and FIXTURE showed Secukinumab PASI 75 response rates around 75-80% at 12-16 weeks Mahil SK et al.(2020)[10], while the PHOENIX trials reported Ustekinumab achieving PASI 75 in approximately 77-78% of patients at week 12 Schmitt J et al.(2014)[11]. Adalimumab's PASI 75 rates in this study were slightly lower but within the expected range reported in clinical practice and trials (55-70%). Importantly, time to reach PASI 75 was significantly shorter with Ustekinumab and Secukinumab than with Adalimumab, indicating a faster onset of action for IL-17 and IL-12/23 inhibitors, a finding supported by comparative studies Iskandar IY et al.(2017)[12].

Safety Profile (Table 3): Adverse event rates were comparable among the three biologics, with no statistically significant differences. Injection site reactions and upper respiratory infections were the most commonly reported side effects, which aligns with the known safety profiles of these agents Singh S et al.(2021)[13]. The slightly higher rate of injection site reactions with Adalimumab is consistent with previous reports Sawyer L et al.(2018)[14]. Serious adverse events were rare and only observed in the Adalimumab group, reflecting overall good tolerability. Elevated liver enzymes were infrequent and did not differ significantly, mirroring findings from prior long-term safety studies Ighani A et al.(2019)[15].

Quality of Life (Table 4): Improvements in quality of life as measured by DLQI were substantial in all groups, with mean score reductions exceeding 11 points, indicating clinically meaningful benefit. The statistically significant lower DLQI scores at 24 weeks in the Secukinumab and Ustekinumab groups compared to Adalimumab suggest greater impact on patient-reported outcomes with IL-17 and IL-12/23 blockade. These results are concordant with literature demonstrating that biologics targeting IL pathways often result in superior quality of life improvements compared to TNF inhibitors Loos AM et al.(2018)[16]. The baseline DLQI scores were similar, ensuring comparable initial disease burden.

5. CONCLUSION

In this study comparing Secukinumab, Adalimumab, and Ustekinumab for the treatment of moderate to severe psoriasis, all three biologic agents demonstrated significant clinical efficacy and favorable safety profiles. Secukinumab and Ustekinumab showed a trend towards higher rates of PASI 75 achievement and faster time to clinical response compared to Adalimumab, although differences were not statistically significant for most outcomes. Quality of life improvements, measured by DLQI, were significantly better with Secukinumab and Ustekinumab. Adverse events were generally mild and comparable across the groups. Overall, IL-17 and IL-12/23 inhibitors may offer advantages in speed and extent of clinical response and patient-reported outcomes compared to TNF-α inhibition, making them valuable options in individualized psoriasis management.

6. LIMITATIONS

1. **Sample Size:** The relatively small sample size (n=60) limits the statistical power to detect subtle differences among biologic agents.
2. **Study Design:** As an observational study, potential selection bias and confounding factors may influence outcomes despite comparable baseline characteristics.
3. **Short Duration:** The 24-week follow-up period restricts assessment of long-term efficacy, durability of response,

and safety.

4. **Lack of Randomization:** Treatment allocation was not randomized, which may affect comparability despite efforts to match groups.
5. **Single-Center Study:** Findings may not be generalizable to broader populations due to geographic and demographic constraints.
6. **Missing Data on Comorbidities:** The impact of comorbid conditions on treatment response was not extensively analyzed.

Quality of Life Measurement: Although DLQI was used, other patient-reported outcome measures could have provided a more comprehensive assessment.

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