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Original Article

Short-term Efficacy and Safety of Secukinumab in Pakistani Patients with Ankylosing Spondylitis and Psoriatic Arthritis

Sumera Ghani, Muhammad Ahmed Saeed, Tashia Malik, Zia ud Din*, Sumaira Farman Raja, Nigat Mir Ahmed

Department of Rheumatology, National Hospital & Medical Centre, Lahore Pakistan, *Department of Rheumatology, Lady Reading Hospital, Peshawar Pakistan

ABSTRACT

Objective: To determine the short-term efficacy and safety of Secukinumab in Pakistani patients with ankylosing spondylitis and psoriatic arthritis in regular clinical practice.

Study Design: Case series.

Place and Duration of Study: Department of Rheumatology, National Hospital and Medical Centre, Lahore Pakistan from Aug 2019 to Feb 2021.

Methodology: Patients diagnosed with ankylosing spondylitis according to assessment of spondyloarthritis International Society criteria and psoriatic arthritis according to classification criteria for psoriatic arthritis (CASPAR), who were started on Secukinumab, were enrolled. Disease activity scores and adverse events were recorded in the 12th and 24th weeks. The primary outcomes were remission and low disease activity, and the secondary outcomes were the recording of Adverse events on each visit.

Results: There were 42 patients registered. The mean duration of disease was 11.86±7.31 years for AS and 9.19±4.87 years for PsA patients. At 24 weeks of follow-up, 10% of patients discontinued treatment, 73.7% of AS patients, and 94.7% of PsA patients achieved complete remission or low disease activity. No significant AEs were noted at 24 weeks, except for upper respiratory tract infections. One patient developed a lower respiratory tract infection after 24 weeks of treatment, and one died during treatment (possible myocardial infarction).

Conclusion: Secukinumab was effective and safe in patients with Ankylosing Spondylitis and Psoriatic Arthritis in this study, despite advanced disease with long disease duration.

Keywords: Ankylosing spondylitis, Efficacy, Psoriatic arthritis, Safety, Secukinumab.

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INTRODUCTION

Spondyloarthropathies (SpA) are a group of autoimmune rheumatic diseases that commonly affect the axial spine with or without peripheral joint and extra-articular involvement.[1] The most common type of SpA is Ankylosing Spondylitis (AS), followed by Psoriatic arthritis (PsA).[2] The prevalence of the radiographic Axial SpA has been estimated to be around 1%.[3] There is a lack of data regarding PsA patients in Pakistani populations; however, the prevalence of PsA in the Western population has been reported to be between 0.1%-0.4%.[4]

The first line of treatment recommended for active AS patients is exercise and the use of NSAIDs.[5] The advent of Tissue necrosis factor (TNF) inhibitors has revolutionized the treatment of AS and PsA patients, whose disease remains active despite NSAID use.[6] However, TNF inhibitors show an increased risk of Tuberculosis activation,[7] especially in Tuberculosis endemic countries, & their efficacy wanes off over time.[8]

Correspondence: Dr Sumera Ghani, Department of Rheumatology, National Hospital & Medical Centre, Lahore Pakistan

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Secukinumab is a human monoclonal antibody which selectively inhibits the IL-17 A cytokine. This cytokine is involved in inflammation, hyperimmune responses and pathogenesis of AS and PsA.[8] Secukinumab has shown significant efficacy in treating AS,[9] Plaque Psoriasis 6 and PsA.[10]

Secukinumab has been used in Pakistan since 2018. This study aims to evaluate the efficacy and safety of Secukinumab in our country, where tuberculosis is an endemic disease and the risk of reactivation of TB with anti-TNF usage.

METHODOLOGY

The case series was conducted during regular clinical practices at the Department of Rheumatology, National Hospital and Medical Centre, Lahore Pakistan, from August 2019 to February 2021. The Institutional Review Board has approved this study (IERB: NHMC/1033). Non-probability consecutive sampling was used.

Inclusion Criteria: Patients of either gender and age Group diagnosed with AS or PsA according to ASAS and CASPAR criteria, respectively were included in the study.

Exclusion Criteria: Patients with latent TB, Hepatitis B, Hepatitis C and other infections were excluded from the study.

Informed consent was taken from the patients as per ICH guidelines. Components of disease activity, disease activity scores and outcome measures were recorded at a baseline visit (before starting Secukinumab), at 12 weeks and then at 24 weeks. Any adverse events (AEs) noticed by patients or the treating physicians were documented to assess the safety of Secukinumab. The Primary endpoint of the study was to achieve remission and low disease activity as per ASDAS score for AS and DAPSA for PsA.

In AS-Group, Ankylosing Spondylitis disease activity scores (ASDAS) and Bath ankylosing spondylitis disease activity index (BASDAI) scores were calculated for AS at baseline, 12 weeks and 24 weeks follow-up, depending on examinations findings and patients' reported outcomes, recorded in the predesigned questionnaire by treating rheumatologist.

ASDAS is a valid tool to estimate disease activity in early SpA,[11] comprising of 5 components: Level of Spinal pain, Peripheral joint pain, duration of morning stiffness, global patient assessment of disease activity and Lab value of CRP or ESR. The initial four components are measured on 0-10 cm VAS (Visual analogue score).[12] ASDAS cut-offs for disease activity are <1.3 for remission, <2.1 for low disease activity, ≤3.5 for high disease activity and >3.5 for very high disease activity.[11]

BASDAI is a measure of disease activity for ankylosing spondylitis. It is a composite index consisting of VAS (10cm) in response to 6 questions: Fatigue, Spinal pain, Joint pain/swelling, areas of localized tenderness and duration and severity of morning stiffness.[13,14] The mean of 2 scores related to morning stiffness is taken and added to the remaining score from 0-50, further divided by five to give the final BASDAI Score from 0-10. BASDAI cut-off values of <4 indicate inactive or mild disease, and ≥4 indicate active disease.

In the PSA-Group, Disease activity in psoriatic arthritis (DAPSA) and Psoriasis area and severity index (PASI) scores were addressed in proforma to assess the severity of arthritis and psoriatic rash, respectively.

DAPSA is a validated compound measure to rate disease activity in PsA patients.[15] It is composed of five variables, including two patient-centred items (PtGA-Patient Global Assessment of Disease Activity) and patient's pain on 0-10 VAS Scores, one physician-centred item (66-swollen joints counts), one item dependent on patient and physician (68- Tender joint counts) and laboratory variable (C-Reactive Protein in mg/dl).[16] Cut-off values of ≤4 for remission, >4 and ≤14 for low disease activity. >14 and ≤ for moderate disease activity and >28 for high disease activity.[15]

PASI score is the gold standard for assessing the severity of psoriasis, which combines the assessment of the severity of lesions and the extent of the affected area in a single index score (0 to a theoretical maximum of 72).[17]

Safety of Secukinumab was checked in each patient on three months and 6-month follow-up questionnaires, mentioning adverse events, including Infections (Candida, upper respiratory tract, lower respiratory tract, acute gastroenteritis, urinary tract infections or any other infections), Injection site reaction and Anaphylaxis. The severity of adverse events was recorded based on requiring Outpatient treatment or Hospital care.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were expressed as Mean±SD and qualitative variables were expressed as frequency and percentages. One-way analysis of variance (ANOVA) was applied to gauge the mean differences among the Groups. The *p*-value of 0.05 or less was taken as significant.

RESULTS

A total of 42 patients were included in the study. The Mean age of patients in our series was 33.36±11.29 yrs. The primary disease was ankylosing spondylitis in 21(50%) patients and PsA in 21(50%). The baseline characteristics of patients are summarized in Table-I.

In AS-Group, the mean disease duration of AS was 11.86±7.31years. A history of smoking was positive in 9(42.9%) patients. Involvement of the eye with a history of Uveitis was present in 4(19%) patients. A weekly loading dose for five weeks was given to 2 (9.5%) patients, and all patients received a maintenance dose of 150mg every four weeks. There were 14(66.7%) patients, who were biologic naïve and 7(33.3%) patients, who were non-responders to TNF inhibitors (TNF-IR) and switched to Secukinumab (Table-II).

The mean baseline ASDAS and BASDAI were 3.90±0.66 and 5.11±1.54, respectively. On 12 weeks follow-up, after starting Secukinumab, mean ASDAS and BASDAI were 2.63±0.80 & 2.68±0.94 respectively,

Table-I: Clinico-Demographic Characteristics (n=42)

Characteristics	Ankylosing Spondylitis	Psoriatic Arthritis
Age (years±SD)	31.29±9.08(95%CI 27.19-35.19)	35.45±13.04(95%CI 29.95-40.85)
Male, n(%)	21(100%)	17(81%)
Weight (kg±SD)	79.29±28.68(95%CI 68.63-93.05)	76.29±16.795%CI 68.76-83.04)
BMI	27.31±8.37(95%CI 24.52-31.28)	26.36±6.75(95%CI 23.54-29.30)
Smoking history, n(%)	9(42.9%)	7(33.3%)
Uveitis history, n(%)	4(19%)	
Biologic naïve, n(%)	14(66.7)	18(85.7%)
Disease duration (Years±SD)	11.86±7.31(95%CI 8.9-15.09)	9.19±4.87(95%CI7.21-11.42)
Duration between psoriasis and arthritis (Years±SD)		3.02±2.91(95%CI 1.88-4.44)
Treatment Related Characteristics		
Loading dose of Secukinumab, n(%)	2 (9.5%)	9(42.9%)
Maintenance dose of 300mg/4 weeks Secukinumab, n(%)	0	7(33.3%)
Use of NSAIDs, n(%)	21(100%)	19(90.5%)
Noncompliance	3(14.2%)	3(14.2%)
Secukinumab discontinuation	2(9.5%)	2(9.5%)

Table-II: Disease Activity Scores and its Components in Ankylosing Spondylitis (n=42)

Components	Baseline	12 weeks	24 weeks	*p*-value
Spinal pain	7.16±1.8 (95%CI 6.29-8.03)	4.58±1.89 (95%CI 3.6-5.5)	3.68±2.24 (95%CI 2.6-4.76)	<0.001
Peripheral arthritis	2.74±3.5 (95%CI 1.04-4.42)	0.74±1.48 (95%CI 0.21-1.45)	0.31±0.82 (95%CI 0.079-0.71)	0.005
Patients global assessment. (Pt.GA)	7.53±1.12 (95%CI6.98-8.07)	4.42±1.83 (95%CI3.54-5.30)	2.8±1.26 (95%CI 2.23-3.45)	<0.001
Duration of am stiffness	4.63±2.85 (95%CI3.26-6.01)	2.0±2.05 (95%CI1.01-3)	1.31±1.70 (95%CI0.49-2.136)	<0.001
Intensity of am stiffness	7.16±2.29 (95%CI6.05-8.26)	2.84±1.95 (95%CI1.90-3.78)	1.63±1.89 (95%CI0.72-2.54)	<0.001
Fatigue	7.63±1.34 (95%CI 6.98-8.28)	4.79±1.71 (95%CI3.96-5.61)	2.15±1.80 (95%CI1.29-3.03)	<0.001
Enthesitis	2.05±3.53 (95%CI0.35-3.76)	0.63±1.53 (95%CI-0.011-1.37)	0.31±1.00 (95%CI-0.17-0.79)	0.028
Erythrocyte Sedimentation Rate (ESR)	41.4±17.51 (95%CI 19.65-63.15)	30±19.29 (95% CI 6.05-53.95)	17.8±10.8 (95%CI 4.30-31.29)	0.011
C-Reactive Protein (CRP)	2.8±2.0 (95%CI1.63-3.95)	1.56±1.41 (95%CI0.75-2.38)	0.96±0.84 (95%CI0.48-1.45)	<0.001
Ankylosing Spondylitis disease activity score (ASDAS)	3.90±0.66 (95%CI3.58-4.22)	2.63±0.80 (95%CI 2.25-3.02)	2.01±0.63 (95%CI 1.71-2.32)	<0.001
Bath Ankylosing Spondylitis disease activity index (BASDAI)	5.11±1.53 (95%CI4.37-5.85)	2.7±0.94 (95%CI 2.23-3.14)	1.71±1.15 (95%CI 1.15-2.26)	<0.001

and on 24 weeks follow-up, mean ASDAS & BASDAI were 2.01±0.63 (*p*-value <0.001) and 1.71±1.15 (*p*-value <0.001) respectively. On 24 weeks of follow-up, complete remission was achieved in 5(26.3%) and low disease activity was achieved in 9(47.36%) patients. In the PSA Group, the mean disease duration in years was 9.19±4.87, and the mean duration between psoriasis and arthritis was 3.02±2.91 yrs. In most patients, the psoriatic rash was followed by psoriatic arthritis.

There were 18(85.7%) biologically naive patients. Loading dose for 5 weeks were given to 9(42.9%), rest of patients 12(57.1%) received 4 weekly doses of 150mg S/C. Concomitant DMARDs were already in use by 17(80.95%) patients. Methotrexate was used in 10 (47.6%), Leflunomide in 2(9.5%), Sulfasalazine in 4(19%) and Cyclosporine in 1(4.8%) patients.

Mean baseline DAPSA and PASI Scores were 32.0±9.0 and 19.73±15.69, respectively. On 24 weeks follow-up, DAPSA and PASI scores were 7.0±4.5 (*p*-value<0.001) & 2.19±4.7 (*p*-value<0.001), respectively. The outcome of disease activity at 24 weeks was observed to attain remission in 8(42.1%), Low disease activity in 10(52.6%) and moderate disease activity in 1(5.2%) patient. Disease activity scores and its components in Psoriatic Arthritis are shown in Table-III.

Usage of NSAIDs was observed in 19 patients and discontinued or decreased (dose or frequency) in 14 (70%) after receiving Secukinumab for 24 weeks and

Table III: Disease Activity Scores and its Components in Psoriatic Arthritis (n=42)

Components	Baseline Visit	12th week	24th week	*p*-value
Swollen joint count	5.25±3.04(95%CI3.827-6.67)	2.45±1.46(95%CI1.76-3.14)	0.95±0.88 (95%CI0.53-1.36)	<0.001
Tender joint count	7.05±3.47(95%CI5.38-8.72)	2.74±1.85(95%CI1.84-3.6)	1.21±1.51(95%CI0.48-1.93)	<0.001
Patient pain (PP)	7.4±1.80(95%CI6.5-8.24)	3.4±1.57(95%CI2.66-4.18)	2.0±1.20(95%CI1.42-2.6)	<0.001
Patient's Global Assessment of Disease Activity (Pt.GA)	7.32±1.60(95%CI6.54-8.1)	3.10±1.45(95%CI2.40-3.8)	1.89±1.15(95%CI1.34-2.45)	<0.001
C-Reactive Protein (CRP)	5.00±3.34(95%CI3.39-6.61)	1.39±0.94(95%CI0.94-1.85)	0.89±0.38(0.71-1.08)	0.001
Disease activity score index in Psoriatic Arthritis (DAPSA)	32.0±9.0(95%CI27.6-36.34)	13.0±5.6(95%CI10.36-15.74)	7.0±4.5(95%CI4.87-9.22)	<0.001
Psoriasis area and severity index (PASI)	19.6±16.5795%CI11.67-27.32	3.42±4.6995%CI1.56-5.9	2.19±5.0995%CI0.46-5.07	0.001

remained the same in 6(30%) patients. Adverse events (AEs) in patients receiving Secukinumab were found in 5(23.8%) of patients, including upper respiratory tract infection in 3(14.28%), the flare of psoriasis after the first dose in 1(4.78%) and other AEs were noticed in 1(4.78%) patient, who complained of hypertension and palpitation after three months of starting treatment. Treatment with Secukinumab was discontinued in 2(9.5%) patients before 24 weeks (Death in 1 patient) (Table-IV).

Table-IV: Adverse Events and Adherence to Treatment (n=42)

Adverse Events	Ankylosing Spondylitis	Psoriatic Arthritis
Death	-	1(4.76%)
Lower respiratory tract infection	-	-
Upper respiratory tract infection	3 (14.3%)	3(14.3%)
Urinary tract infection	1(4.76%)	-
Psoriasis flare		1(4.76%)
Injection site reaction, diarrhea, etc.	None	None
Other		
Reasons of Secukinumab Discontinuation/Noncompliance		1(4.76%)
Non affordability	1 (4.76%)	-
In efficacy	1(4.76%)	1(4.76%)
Symptom's improvement	-	-
Adverse events/other	-	1(4.76%)

DISCUSSION

This is the first case series from Pakistan assessing the short-term efficacy and safety of Secukinumab in the treatment of active AS and PsA patients. Although patients in both the AS and PsA Group had the diseases for a relatively long period (11.84±7.31 years and 9.19±4.87years respectively), the target of remission and LDA as per ASDAS and DAPSA were achieved in 73.7% of the patients with AS and almost 94.7% in PsA respectively at 24 weeks. The efficacy data in AS patients in this study show that 47.6% of patients achieved low activity of disease and remission at 12 weeks and 73.7% of patients at 24 weeks. The BASDAI score shows inactive disease in 95% of the patients at 12 weeks and 100% at 24 weeks. A recent study showed ASDAS improvements in 76% of patients, and 90% showed BASDAI 50 improvements in AS patients at 24 weeks.[18]

The Phase-III MEASURE, one extension study, also shows promising results, where ASAS 20/40 responses were 78.6/65.2% and improved BASDAI 50 responses at five years.[19]

The efficacy data of Secukinumab in PsA patients in our study shows promising results, with 61.9% of patients reaching the goal of Remission and Low disease activity at 12 weeks and 94.7% of patients at 24 weeks. The dosage of Secukinumab was 150mg/4 weeks in most patients; the loading dose was not used in most patients due to financial constraints. In our study, the PASI75 response was 82.6% at 12 weeks and 88.8% at 24 weeks compared to the baseline PASI 75 score. A study in India shows that 85% of patients developed Remission and low disease activity by DAS28 ESR in PsA patients.[18]

PASI 75 response is comparable to a recent study in China, where 441 patients of plaque psoriasis were enrolled, and PASI 75 was achieved in 97.7% & 87.2% of patients, with a dosage of 300mg Secukinumab and 150mg Secukinumab respectively.[19]

Regarding the safety of Secukinumab, the most frequent AEs were upper respiratory tract infections during the 24 weeks. One case developed a flare of pustular psoriatic rash after the first injection, which settled with subsequent injections and the addition of methotrexate. None of our patients had injection site reactions, new onset diarrhoea or inflammatory bowel disease features, malignancies, cytopenia or reactivation of TB cases during treatment. Death (Possible Myocardial infarction) of 1 patient was recorded in our study, who received Secukinumab and had a history of renal amyloidosis.

In Summary, Secukinumab was found to be efficacious and safe biologic in Pakistani patients with AS and PsA. However, long-term multi-centric studies are required to focus on the efficacy and safety of Secukinumab. Patients not adhering to treatment were less likely to achieve remission or Low disease activity.

LIMITATIONS OF STUDY

Limitations of the current analysis were the smaller number of patients due to the cost of Secukinumab and the need to include a comparator Group. Axial disease in PsA needs other measures to assess disease activity which was another limitation of this study.

CONCLUSION

Secukinumab was effective and safe in patients with Ankylosing Spondylitis and Psoriatic Arthritis in this study, despite advanced disease with long disease duration.

Conflict of Interest: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

SG & MAS: Data acquisition, data analysis, critical review, approval of the final version to be published.

TM & ZUD: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

SFR & NMA: Concept, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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