Safety and Efficacy of Risankizumab in the Treatment of Chronic Plaque-Type Psoriasis: A Pilot Single-Arm, Single-Center, Prospective Cohort Study

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ABSTRACT

Background: Chronic plaque-type psoriasis is a prevalent autoimmune disease characterized by sharply demarcated erythematous plaques and significantly impacts patients' quality of life (QoL). Conventional treatments often fail, leading to the need for effective alternatives. Risankizumab, a humanized monoclonal antibody, has emerged as a promising treatment option in recent years, demonstrating safety and efficacy.

Objective: This prospective cohort study evaluates the clinical efficacy and safety of Risankizumab in treating moderate to severe chronic plaque-type psoriasis.

Methods: Conducted at Sheikh Jaber Al-Ahmad Armed Forces Hospital in Kuwait from November 2021 to October 2023, this study involved 10 patients of moderate to severe chronic plaque-type psoriasis, excluding pregnant and lactating women and individuals under 18. Data were collected using a structured questionnaire, and clinical follow-ups were done at 3, 6, 12, and 24 months to evaluate efficacy and safety.

Results: The study's participants were predominantly male (90%) with a median age of 34 years. After 24 months of continuous Risankizumab treatment, 70% achieved PASI 90, 20% achieved PASI 75, and 10% achieved PASI 100. Additionally, 90% achieved sPGA 0/1, and 90% achieved DLQI 0/1. The body surface area (BSA) of affected regions saw a significant improvement, with an average decrease of nearly 97% from baseline. Adverse events were infrequent; one patient experienced latent tuberculosis, leading to treatment discontinuation, while another had transient pancytopenia that resolved on follow-up.

Conclusion: Risankizumab is seen as highly effective and safe biologics in the treatment of moderate to severe chronic plaque-type psoriasis, demonstrating substantial improvement in clinical severity and QoL over a 24-month period.

Keywords: Psoriasis area severity index (PASI), Body surface area (BSA), Static Physician Global Assessment (PGA), Dermatology Life Quality Index (DLQI).

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INTRODUCTION

Psoriasis is a chronic inflammatory disease of the skin, in which genetic and environmental factors together play an important role. Strides have been achieved in the fight against psoriasis, with tons of research regarding its cause, genetic involvement, morbidities, and efficacy of immunobiological management.[2] When the topical steroids, various keratolytics, immunosuppressive drugs and phototherapy treatment fail to resolve the skin lesion, biologics are frequently advised for the treatment of moderate to severe plaque psoriasis due to their effectiveness and excellent safety profiles.[1, 3]

Psoriasis mostly presented with characteristic skin lesions of erythematous plaques with silvery white scales usually affect extensor surfaces and the scalp symmetrically.[4] The pathogenesis of plaque psoriasis is an inflammatory process which involve mostly the T-helper cell type 17 (TH17) pathway.[1] Immunobiologics are considered one of the milestones reached in the marathon of developing safe and effective therapeutics to fight psoriasis. The IL-23 inhibitors are a group of biologics that effectively block the p19 subunit of IL-23, and thereby antagonize the TH17 pathway. One of the FDA-approved IL-23 blocker for the treatment of plaque psoriasis in adults is risankizumab.[5] These engineered antibodies are brought from living organisms, in risankizumab's case, it's humanized, which manipulates immune responses once they interact with a specific protein target.[5, 6] Risankizumab antagonize the T cell activities at various level, specifically activation, trafficking into inflammed skin, and effector function under cytokine control.[7]

THE RATIONALE OF THE RESEARCH

Psoriasis is a commonly encountered clinical problem among dermatologic patients. Real-life data are scarce when it comes to this kind of treatment and disease profile. This single-arm, single-center, prospective cohort study aims to investigate the clinical efficacy and safety of Risankizumab as a treatment for moderate to severe chronic plaque-type Psoriasis.

MATERIALS & METHODS

This study was conducted at Sheikh Jaber Al-Ahmad Armed Forces Hospital in Kuwait, spanning from November 1, 2021, to October 30, 2023. A sample of 10 patients with confirmed cases of moderate to severe chronic plaque psoriasis was selected for participation in the study. Patients who were pregnant or lactating, as well as those under 18 years of age, were excluded from the study.

Samples were selected consecutively using a structured questionnaire that included all relevant variables of interest. Safety assessments were conducted by recording adverse events and performing relevant blood tests after one month and subsequently every three months throughout the study.

Data analysis was performed by Statistical Package for Social Science (SPSS), version-29.0.2.0. Data was edited, coded and entered into the computer. t-test and chi-square ($x2$) test were performed. In each case, level of significance (p-value) was set at 0.05 and confidence interval at 95%. Results were presented as text and tables.

RESULTS

Between November 2021 and October 2023, ten patients with psoriasis were recruited from Sheikh Jaber Al-Ahmad Armed Forces Hospital in Kuwait. This study aimed to evaluate the clinical efficacy and safety of Risankizumab, an FDA-approved humanized monoclonal antibody, for treating moderate to severe plaque-type psoriasis.

Table-1 presents the distribution of study participants based on various characteristics.

The majority (58.0%) of patients were aged 30-50 years, with a median age of 34 years (interquartile range [IQR]: 26 to 70). In terms of sex distribution, 90% of the patients were male. The onset of psoriasis was predominantly observed between the ages of 31 and 40 years, with 90% of patients falling within this age range. The mean age at onset was 33.6 ± 3.92 years.

Regarding the duration of illness, 80% of patients had a duration of ≤10 years, with a mean duration of 9.51 ± 1.86 years. Most patients (90%) had a Psoriasis Area and Severity Index (PASI) score of ≤10, as illustrated in Figure 1, with a mean PASI score of 8.01 ± 6.58.

The Dermatology Life Quality Index (DLQI) scores of most patients fell within the range of 10-20, with a mean DLQI score of 14.40 ± 3.86. The static Physician Global Assessment (sPGA) scores for the majority of patients were between 2 and 4, with a median sPGA score of 3 (IQR: 2 to 4). Most patients exhibited body surface area (BSA) involvement of 10-29%, with a mean BSA involvement of 24.31 ± 4.7%. The mean BSA at baseline was 23.8 ± 16.61%.

TABLE-I: Baseline Patient Demographics and Clinical Characteristics enrolled in the study.

Age, Median (IQR)	34 (26, 70)
Sex, N (%)	
Male	8 (80%)
Female	2 (20%)
Total sample	10
Age of onset, Mean ± SD	33.6 ± 3.92
Duration of illness, Mean ± SD	9.51 ± 1.86
PASI, Mean ± SD	8.01 ± 6.58
DLQI, Mean ± SD	14.40 ± 3.86
BSA, Mean ± SD	23.8 ± 16.61
sPGA, Median (IQR)	3 (2, 4)
0	-
1	-
2	4
3	5
4	1
Lab Investigations, (%)	
Normal	10 (100%)

TABLE-II: PASI at different evaluation period (N=10)

Evaluation period	PASI	Patients with Risankizumab (n-10)
03 months	PASI 50	06 (60%)
	PASI 75	03 (30%)
	PASI 90	01 (10%)
	PASI 100	00 (0.0%)
06 months	PASI 50	00 (00%)
	PASI 75	04 (40%)
	PASI 90	06 (60%)
	PASI 100	00 (00%)
01 year	PASI 50	00 (0.0%)
	PASI 75	03 (30%)
	PASI 90	06 (60%)
	PASI 100	01 (10%)
02 years	PASI 50	00 (00%)
	PASI 75	02 (00%)
	PASI 90	07 (80%)
	PASI 100	01 (10%)

It was observed that 01(10%) patients achieved PASI 90 after 03 months of treatment. 06 (60%) patients achieved PASI 90 after 06 months, 06 (60%) patients achieved PASI 90 after 01 years. 07(70%) patients achieved PASI 90 and 01(10%) patients achieved PASI 100 after 02 years (Table-II).

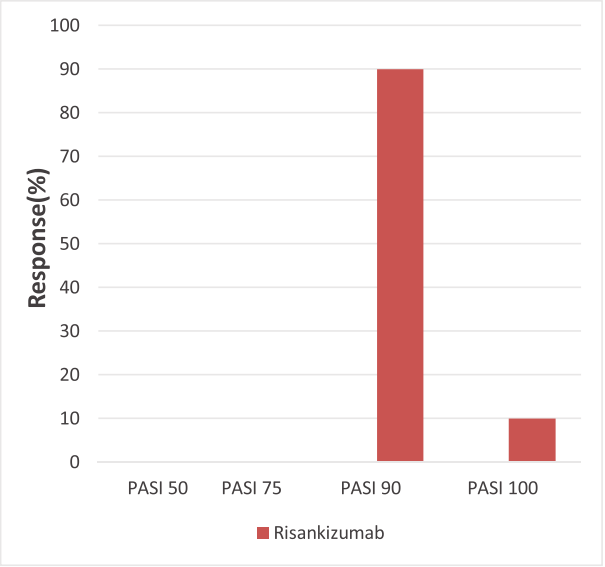

Figure-1 shows PASI after continuous treatment with risankizumab at the end of 02 years

TABLE-III: sPGA Score (Static Physician global assessment) at different evaluation period (N=10)

Evaluation period	sPGA Score	Patients with Risankizumab (n-10)
03 months	0 (Clear) 1 (Almost clear) 2 (Mild) 3 (Moderate) 4 (Severe)	00 (00%) 03 (30%) 06(60%) 01(10%) 00(00%)
06 months	0 (Clear) 1 (Almost clear) 2 (Mild) 3 (Moderate) 4 (Severe)	07 (70%) 02 (20%) 01(10%) 00 (00%) 00 (00%)
01 year	0 (Clear) 1 (Almost clear) 2 (Mild) 3 (Moderate) 4 (Severe)	09 (90%) 01 (10%) 00 (00%) 00 (00%) 00 (00%
02 years	0 (Clear) 1 (Almost clear) 2 (Mild) 3 (Moderate) 4 (Severe)	09 (90%) 01 (10%) 00 (00%) 00 (00%) 00 (00%)

It was observed that 09(90%) patients achieved sPGA score 0 after 02 years of treatment. (Table-III).

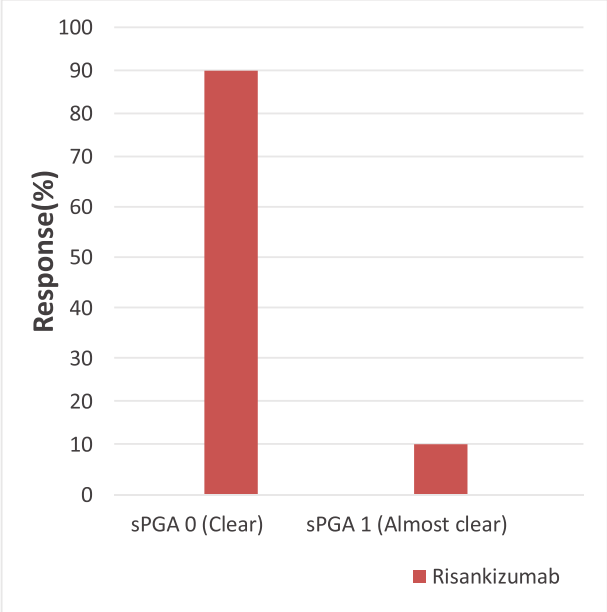

Figure-2: Shows sPGA after continuous treatment with risankizumab at the end of 02 years

TABLE-IV: DLQI Score at different evaluation period (N=10)

Evaluation period	DLQI Score	Patients with Risankizumab (n-10)
03 months	1-1 = No effect on patient's life 2-5 = Mild 6-10 = Moderate 11-20 = Severe ≥20 = Extremely severe	00(00%) 02 (20%) 06(60%) 02(20%) 00(00%)
06 months	0-1 = No effect on patient's life 2-5 = Mild 6-10 = Moderate 11-20 = Severe ≥20 = Extremely severe	04 (40%) 05 (50%) 01 (10%) 00(00%) 00(00%)
01 year	0-1 = No effect on patient's life 2-5 = Mild 6-10 = Moderate 11-20 = Severe ≥20 = Extremely severe	08 (80%) 02 (20%) 00 (00%) 00 (00%) 00 (00%)
02 years	0-1 = No effect on patient's life 2-5 = Mild 6-10 = Moderate 11-20 = Severe ≥20 = Extremely severe	09 (90%) 01 (10%) 00 (00%) 00 (00%) 00 (00%)

It was observed that 09(90%) patients achieved DLQI Score 0-1 after 02 years of treatment (Table-IV).

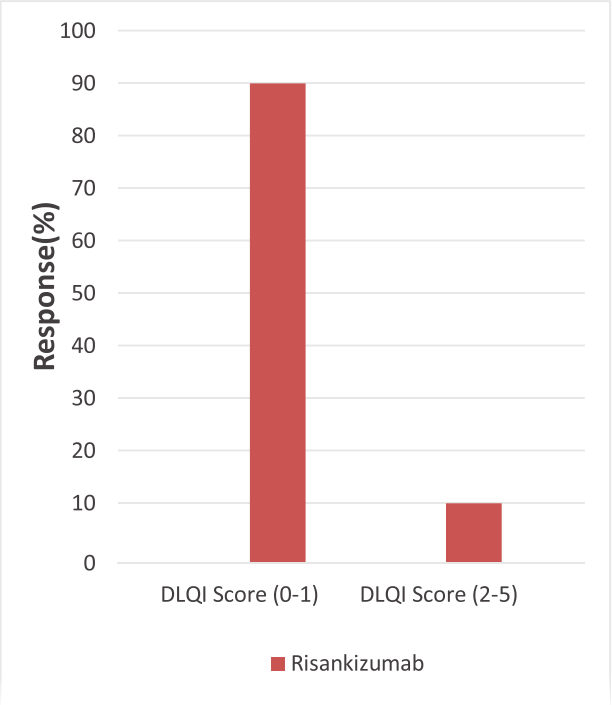

Figure-3: showing DLQI Score after continuous treatment with risankizumab at the end of 02 years

TABLE-V: BSA (Body surface area) at different evaluation period (n=10)

Evaluation period	BSA	Patients with Risankizumab (n-10)
03 months	≤ 03% = Mild 03-10% = Moderate >10% = Severe	01 (10%) 07(70%) 02 (20%)
06 months	≤ 03% = Mild 03-10% = Moderate >10% = Severe	06 (60%) 03 (30%) 01 (10%)
01 year	≤ 03% = Mild 03-10% = Moderate >10% = Severe	08 (80%) 02 (20%) 00 (00%)
02 years	≤ 03% = Mild 03-10% = Moderate >10% = Severe	09 (90%) 01 (10%) 00 (00%)

It was observed that 09(90%) patients were having only ≤ 03% body surface involvement at the end of 02 years of treatment. (Table-V).

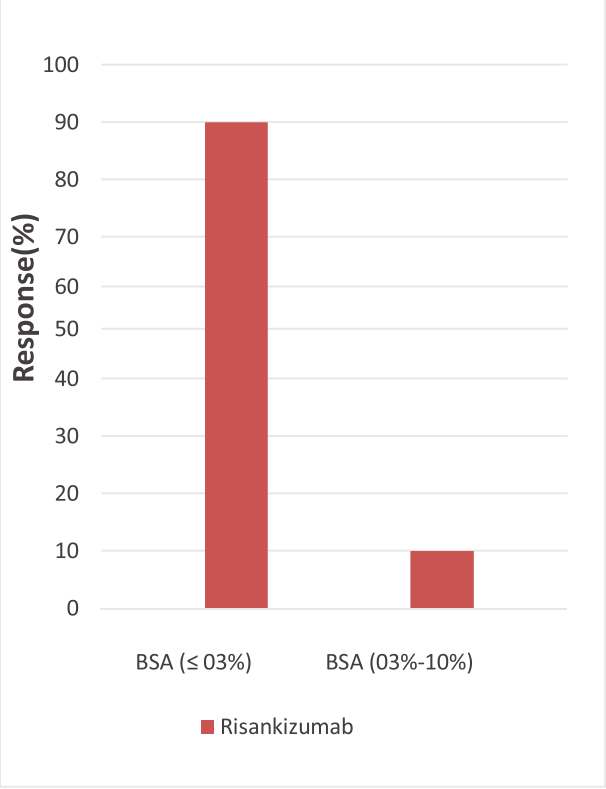

Figure-4: showing BSA (Body surface area) involvement after continuous treatment with risankizumab at the end of 02 years

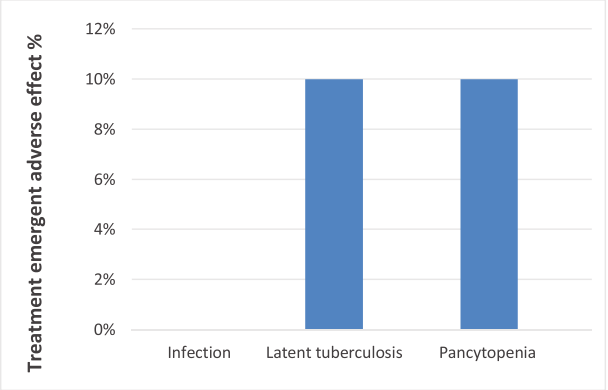

Figure-5: Shows 01 patient (10%) was found to have latent tuberculosis leading to discontinuation of treatment and 01 patient (10%) was found to have pancytopenia which became normal at next follow up.

DISCUSSION

The present study demonstrated the clinical outcomes regarding PASI, DLQI, sPGA, and body surface area involvement status and treatment-emergent adverse effects as safety margin throughout the follow-up period (3, 6,12, 15, 18, 21, and 24 months).

The findings align with those of Reich and Gordon, who reported positive responses in PASI and sPGA at 6, 12, and 48 months following treatment with Risankizumab.[8, 9] Hawkes's results also validate these results, which showed 93.77% of patients achieved PASI 90 for Risankizumab at 24 months of follow-up.[7] Regarding the sPGA, this study indicated that 60% of patients had mild, and 10% of patients had moderate involvement after three months of treatment at the first follow-up. At the end of 2 years of continuous treatment, 90% of patients showed full clearance, and 10% of patients showed an almost clear response, which was statistically highly significant (p=<0.001).

Kim A. Papp et al. conducted a similar study on 110 enrolled patients where 99 (90.0%)

completed the phase 2 open-label extension trial, which revealed no major side effects. At week 48, 74.1% of patients achieved PASI 90 and sPGA 0/1, respectively. No new safety findings were noted. Papp et al. also have similar study which focused on results beyond three years of follow-up. The analysis of PASI, sPGA, and DLQI responses after 172 weeks supported our findings in the long-term use of Risankizumab.[10]

Additionally, The result of the present study was per the findings of Iskandar IYK et al., which noted 100% full clearance of skin lesions for Risankizumab at the end of 24 months.[11] Data synthesized in a meta-analysis by Yu et al. suggest the enhancement of the clinical status of patients receiving Risankizumab, which came in line with our study results.[12] Thaci et al. found that DLQI scores improved significantly in moderate to severe plaque-type psoriasis patients; thus, this means Risankizumab could yield a better health-related QoL.[13] The improvement rate of Risankizumab for DLQI was considerable at the first follow-up, three months away from the baseline, and after two years of continuous treatment, which is parallel to previous reports on the quality of life in psoriatic cases receiving an anti-IL23 inhibitor.[8, 9, 13] It was documented that mild impairment of quality of daily life was seen in 2 patients, moderate impairment of quality of daily life was seen in 6 patients, and severe impairment of quality of daily life was seen in 2 patients (20%) at the end of 3 months of treatment. After two years of continuous treatment, nine patients had no impairment of quality of daily life, and one patient had mild impairment of quality of daily life, which was statistically highly significant (p=<0.001). Mark G. Lebwohl et al. conducted a post hoc analysis of four phase 3 studies, the analysis results align with our results as well as having similar demographics to ours. Lebwohl reported a significant clinical success rate of Risankizumab.[14] The study was done on 2101 patients, with a mean age of 47.5 years; 70% were males, and the mean duration since psoriasis diagnosis was 18.6 years. They concluded that 87% of patients treated with Risankizumab only throughout the study period achieved PASI 90 and DLQI 0/1 after one year of continuous treatment.

These findings validate our results. In addition, Lebwohl's AUC analysis showed that patients who received Risankizumab only had the longest PASI 90 and DLQI 0/1 duration.[14] In the assessment of body surface area involvement, the present study showed an excellent response, which was statistically significant (p=<0.001). After three months of treatment, mild ($\leq$ 3%) involvement was seen in 10% of patients, and moderate (3-10%) involvement was seen in 70% of patients. At the end of two years of treatment, 90% of patients had mild body surface involvement, and only 10% of patients were found to have moderate body surface involvement. Abdulmajeed Alajlan et al. conducted the same study on Erythrodermic psoriasis (>90% body surface involvement) patients with Risankizumab (150 mg on day 0, week 4, and then every 12 weeks). During treatment, the patients complained of deterioration of muscle and joint pain at very beginning but these were not appeared with the subsequent doses. By the third dose, all patients exhibited a complete resolution of their skin lesions and symptoms of pruritus, myalgia, and arthralgia.[15]

Regarding the safety margin throughout the study period, one of the patients was identified to have latent tuberculosis, leading to discontinuation of treatment, and another patient was identified to have pancytopenia, which became normal after the next follow-up. K.B. Gordon et al. had done multiple similar

studies which recruited 1306 patients treated with Risankizumab 150 mg and 300 patients took placebo. They also had done long-term study which recruited 3072 Risankizumab-treated patients. The median treatment duration was 2.9 years (range two days to 5.9 years). With long-term Risankizumab treatment, it was revealed that severe side effects were 7.8 per 100 PY, severe infections cases 1.2 per 100 PY, nonmelanoma skin cancer (NMSC) 0.7 per 100 PY, malignant tumors without NMSC 0.5 per 100 PY, and major side effect in cardiovascular system 0.3 per 100 PY, without any significant risks.[16]

Limitations

This study, like any cohort study, has several limitations. However, it is important to recognize its strengths, particularly regarding the ethical advantages of Pilot- single-arm cohort studies. These studies are often easier to conduct ethically and typically require smaller sample sizes. Furthermore, the absence of a control group allows all patients to benefit from the study treatment, which is a significant ethical consideration.

CONCLUSION

Psoriasis has laid a huge burden on patients suffering from chronic psoriasis. New medications, like IL-23 Inhibitors, have brought hope for better health and enhanced quality of life. Risankizumab showed significantly greater efficacy in providing skin clearance in patients with moderate-to-severe plaque psoriasis. Moreover, treatment with Risankizumab injections provides an excellent safety margin in the long-term treatment of psoriasis.

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