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Research Article

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Real Clinical Experience with Great Outcome in Guselkumab Injection (Tremfya) Treatment in Psoriatic patients, A retrospective Study

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Abstract

Introduction

Psoriasis is a chronic inflammatory disease. Current time many biologicals are available which gives a wide range of therapeutic options for psoriatic patients. Guselkumab is one of the earliest IL-23p19 inhibitors approved for psoriasis treatment with high efficacy and proven safety.

Material and Methods

This retrospective study analyzed data from the electronic medical record system of As'ad Al-Hamad Dermatology Center Sabah hospital Kuwait. We collected relevant demographic data and clinical features of all patients on Guselkumab injection from January 2022 to December 2024.

Results

This study ultimately included a total 43 patients with psoriasis on Guselkumab therapy. The median age was 45.0 years (IQR 40.0-56.5), with 46.5% (n=20) male patients. Treatment effectiveness was very high as PASI90 and PASI100 were achieved in 97.7% (n=42) and 76.7% (n=33) of patients, respectively. PASI90 was typically reached early median dose 1, while PASI100 was achieved by a median of dose 2. It showed no significant baseline differences between patients with and without prior biologic exposure, except for higher baseline PASI in biologic-naïve patients (43.3 ± 12.6 vs 26.9 ± 8.8, $p < 0.001$) and PASI100 achievement was significantly lower in biologic-experienced patients. Regard safety the adverse events were reported in 25.6% (n=11) of patients, predominantly mild injection-site pain in 16.3% (n=7). Infection-related events were infrequent, occurring in 9.3% (n=4), with isolated cases of urinary tract infection (2.3%, n=1), cellulitis (2.3%, n=1), impetigo (2.3%, n=1), and upper respiratory infection (2.3%, n=1).

Conclusions

Interleukin (IL)-23p19 inhibitors guselkumab demonstrated a significant maintained effectiveness for psoriasis treatment. In addition, a high safety profile regardless comorbidities, and treatment was not discontinued due to any adverse effects complications.

Keywords: Psoriasis, Patients, Biologicals, Interleukin (Il)-23p19 Inhibitors Guselkumab

Abbreviations: **IL:** Interleukin, **TH17:** T Helper 17, **Tc17:** Cytotoxic 17, **IL-23R:** Interleukin 23 Receptor, Psoriasis Area and Severity Index [PASI]

1. Introduction

Psoriasis is fairly common chronic disease. The etiopathogenesis of psoriasis assumed to many factors causing modification in skin immune response in genetically predisposed individuals. Expanded knowledge and deepen immensely studies has led to the development of new therapies that target key cytokines such as IL-12, IL-23, and IL-17, which are central to the inflammatory process in psoriasis and provide good results in terms of their safety and efficacy [1]. IL-23 antagonist is one of emerged therapies in psoriasis treatment that has shown vital role in controlling psoriasis through targeting T helper 17 (TH17) and T cytotoxic 17 (Tc17) cell differentiation, expansion, and maintenance [2]. Selective interleukin 23 blockade suppresses keratinocytes proliferation and IL-23-driven inflammation in psoriatic skin lesions [3,4]. There are many skin cells producing IL-23 including dermal myeloid DCs, macrophages and epidermal Langerhans cells [5]. The IL-23 receptor (IL-23R) is expressed on memory T cells, natural killer cells, neutrophils, mast cells, ILCs and macrophages [6]. It is clearer that dysregulation of the IL-23/IL-17 axis mediates inflammation and affect different immune cells especially resident memory cell to maintain chronicity in psoriasis [7-9]. Guselkumab is one of the earliest IL-23p19 inhibitors approved for the treatment of moderate-to-severe plaque psoriasis and according to countless studies has shown a strong effectiveness and favorable safety across both settings in the short- and especially in the long term, accompanied by an improvement in health-related quality of life and reduction of the main symptoms [10-12].

2. Material and Methods

This is cohort retrospective study was conducted in tertiary dermatology center from electronic medical record system of As'ad Al-Hamad Dermatology Center Sabah hospital Kuwait from January 2022 to December 2024. Total 43 patients were included who are complaint and complete adherent to guselkumab therapy (Dosage of guselkumab, was 100 at weeks 0, 4, and every 8 weeks). Full demographic history and Psoriasis Area and Severity Index [PASI], PASI90and 100 achieving, comorbidities for each patient were collected in 3 years duration. Special sites psoriasis involvement and smoking was documented.

3. Results

A total of 43 patients were included **(Table 1)**. The median age was 45.0 years (IQR 40.0-56.5), with 46.5% (n=20) male patients. The cohort demonstrated a high burden of metabolic risk factors, with 48.8% (n=21) classified as obese and 46.5% (n=20) current smokers. Comorbidities were present in 39.5% (n=17) of patients, most commonly diabetes mellitus in 18.6% (n=8). Disease severity at baseline was high (mean PASI 38.0 ± 13.8), with frequent involvement of special areas in 86.0% (n=37). Most patients were treatment-naïve (65.1%, n=28), while 32.6% (n=14) had prior biologic exposure. Medical Comorbidities were found in 17 (39.5%) cardiovascular disorder in 3 patients (one of them is open heart surgery) and one patient was epilepsy on treatment.

Treatment effectiveness was high **(Table 2)**, PASI90 and PASI100 were achieved in 97.7% (n=42) and 76.7% (n=33) of patients, respectively. Among responders, PASI90 was typically reached early by median dose 1, while PASI100 was achieved by a median of dose 2. Relapse occurred in 23.2% (n=10) of patients during follow-up. Adverse events were reported in 25.6% (n=11) of patients **(Table 3)**, predominantly mild injection-site pain in 16.3% (n=7). Infection-related events were infrequent, occurring in 9.3% (n=4), with isolated cases of urinary tract infection (2.3%, n=1), cellulitis (2.3%, n=1), impetigo (2.3%, n=1), and upper respiratory infection (2.3%, n=1).Exploratory subgroup analysis **(Table 4)** showed no significant baseline differences between patients with and without prior biologic exposure, except for higher baseline PASI in biologic-naïve patients (43.3 ± 12.6 vs 26.9 ± 8.8, $p < 0.001$). PASI100 achievement was significantly lower in biologic-experienced patients (50.0%, n=7) compared with biologic-naïve patients (89.7%, n=26; OR=8.67, p=0.007). In regression analysis **(Tables 5-6)**, increasing age (aOR 0.904, p=0.027) and number of prior biologics (aOR 0.117, p=0.004) were independently associated with lower odds of achieving PASI100.

10/43 (23.2%)

Characteristic	Overall (N=43)
Demographic Characteristics	
Age, years	45.0 (40.0-56.5)
Sex, male	20 (46.5%)
Weight, kg	80.0 (75.0-94.0)
Height, m	1.68 (1.60-1.70)
BMI, kg/m²	29.76 (26.47-33.84)
Obesity (BMI ≥30 kg/m²)	21 (48.8%)
Current smoker	20 (46.5%)
Medical Comorbidities	17 (39.5%)
Hypertension	4 (9.3%)
Diabetes mellitus	8 (18.6%)
Cardiovascular disease	3 (7.0%)
Other	2 (4.7%)
Family history of psoriasis	10 (23.3%)

Disease Characteristics	
Disease duration, years	7.0 (4.0-11.0)
Baseline PASI	38.0 ± 13.8
Special-area involvement	37 (86.0%)
Scalp involvement	24 (55.8%)
Nail involvement	20 (46.5%)
Ear involvement	18 (41.9%)
Groin involvement	9 (20.9%)
Psoriatic arthritis	6 (14.0%)
Treatment-naïve	28 (65.1%)
Prior non-biologic only	1 (2.3%)
Biologic therapy exposure	14 (32.6%)
One prior biologic therapy drug	10 (23.3%)
Two prior biologic therapy drugs	4 (9.3%)
Prior anti-TNF exposure	9 (20.9%)
Prior anti-IL-17 exposure	7 (16.3%)
Prior IL-12/23 exposure	2 (4.7%)
*Values are presented as n (%), median (interquartile range [IQR]), or mean ± standard deviation (SD) according to distribution assessed by Shapiro-Wilk testing. **Abbreviations**: BMI, body mass index; PASI, Psoriasis Area and Severity Index; TNF, tumor necrosis factor; and IL, interleukin.*	

Table 1: Baseline Demographic and Clinical Characteristics

Outcome	**Value**	**95% CI (%)**
PASI90 achieved	42/43 (97.7%)	87.7-99.9
PASI100 achieved	33/43 (76.7%)	61.4-88.2
Dose number to first PASI90 among responders	1.0 (1.0-2.0)	—
Responders to reach PASI90 by dose 1	26/42 (61.9%)	45.6-76.4
Responders to reach PASI90 by dose 2	16/42 (38.1%)	23.6-54.4
Dose number to first PASI100 among responders	2.0 (2.0-3.0)	—
Responders to reach PASI90 by dose 2	21/33 (63.6%)	45.1-79.6
Responders to reach PASI90 by dose 3	10/33 (30.3%)	15.6-48.7
Responders to reach PASI90 by dose 4	2/33 (6.1%)	0.7-20.2
Relapse during follow-up	10/43 (23.2%)	13.5-41.2
*Binary outcomes are shown as n/N (%) with exact (Clopper-Pearson) 95% confidence intervals. Timing variables are shown as median (IQR) among responders only. Dose number refers to the first follow-up dose at which the response threshold was achieved. PASI90 = at least 90% improvement from baseline PASI; PASI100 = complete skin clearance. **Abbreviations:** PASI, Psoriasis Area and Severity Index.*		

Table 2: Effectiveness Outcomes and Response Timing

Safety outcome	**Overall (N=43)**
Any adverse event	11 (25.6%)
Injection site pain	7 (16.3%)
Any infection-related adverse event	4 (9.3%)
Urinary tract infection	1 (2.3%)
Cellulitis	1 (2.3%)
Impetigo	1 (2.3%)

Upper respiratory infection	1 (2.3%)
Values are presented as n (%).	

Table 3: Safety Profile During Follow-Up

Variable	No prior biologic therapy (n=29)	Prior biologic therapy (n=14)	Statistic	Effect size	df	P
Age, years	45.0 (40.0-56.0)	46.0 (40.5-59.0)	U=192.0	r_{rb}=0.054	—	0.785†
BMI, kg/m²	30.1 (26.3-32.4)	28.9 (26.7-36.6)	U=202.0	r_{rb}=0.005	—	0.990†
Disease duration, years	7.0 (4.0-11.0)	7.5 (5.0-9.0)	U=192.5	r_{rb}=0.052	—	0.795†
Baseline PASI	43.3 ± 12.6	26.9 ± 8.8	t=4.960	g=1.398	35.54	**<0.001**††
Male sex	13 (44.8%)	7 (50.0%)	—	OR=0.81	—	1.000†††
Current smoker	15 (51.7%)	5 (35.7%)	—	OR=1.93	—	0.353†††
Medical comorbidities	12 (41.4%)	5 (35.7%)	—	OR=1.27	—	1.000†††
Psoriatic arthritis	3 (10.3%)	3 (21.4%)	—	OR=0.42	—	0.373†††
Special-area involvement	25 (86.2%)	12 (85.7%)	—	OR=1.04	—	1.000†††
PASI90 achieved	29 (100.0%)	13 (92.9%)	—	—	—	0.326†††
PASI100 achieved	26 (89.7%)	7 (50.0%)	—	OR=8.67	—	0.007†††
Relapse	9 (31.0%)	2 (14.3%)	—	OR=2.70	—	0.291†††
Any adverse event	10 (34.5%)	1 (7.1%)	—	OR=6.84	—	**0.071**†††

†Mann-Whitney U test.
††Welch t-test.
†††Fisher's exact test.
Values are presented as median (IQR), mean ± SD, or n (%), according to variable type and distribution. Effect sizes are reported as rank-biserial correlation (r_{rb}) for Mann-Whitney U, Hedges' g for Welch's t-test, and odds ratio (OR) for Fisher's exact test. The OR for PASI90 is infinite because there were no PASI90 non-responders in the no-prior-biologic group. All P values are two-sided and exploratory. p-value < 0.05 was considered statistically significant.

Table 4: Exploratory Comparison by Prior Biologic Exposure

Predictor	β	SE	OR	95% CI for OR	P value
Age, years	-0.066	0.033	0.936	0.878 to 0.998	**0.043**
Male sex	-0.182	0.723	0.833	0.202 to 3.435	0.801
BMI, kg/m²	-0.017	0.036	0.983	0.916 to 1.055	0.644
Current smoker	0.345	0.733	1.412	0.335 to 5.944	0.638
Disease duration, years	0.005	0.066	1.005	0.882 to 1.144	0.943
Medical comorbidities	-1.099	0.744	0.333	0.078 to 1.432	0.140
Number of prior biologics	-1.666	0.603	0.189	0.058 to 0.617	**0.006**
Psoriatic arthritis	-2.335	0.974	0.097	0.014 to 0.653	0.017
Baseline PASI	0.014	0.027	1.014	0.962 to 1.069	0.609
Results are reported as β coefficients, standard errors, odds ratios (ORs), 95% confidence intervals, and two-sided P values					

Table 5: Univariable Logistic Regression for Pasi100 Achievement

Predictor	β	SE	Adjusted OR	95% CI for ad-justed OR	P value
Age, years	-0.101	0.046	0.904	0.827 to 0.989	0.027
Number of prior biologics	-2.149	0.756	0.117	0.026 to 0.513	0.004
Predictor count was restricted to variables significant in the univariate analysis because of the small number of non-events.					

Table 6: Multivariable Logistic Regression for Pasi100 Achievement

4. Discussion

Psoriasis is chronic long-standing inflammatory dermatosis and considered one of metabolic disorders. This is realized in our results as studied psoriasis patients have shown a high burden of metabolic risk factors, 48.8% of them in the frame of obesity (BMI ≥30 kg/m²), this finding agrees with many previous studies and even reflect severity of psoriasis [12-14]. Associated comorbidities were present in 39.5% of studied patients which presentable to metabolic syndrome in psoriasis patients [15]. likewise, cigarette smoking was found in 46.5% of studied cases, smoking is recognized as a risk factor in psoriasis as a part of metabolic comorbidities [16]. Psoriasis patients have achieved PASI90 and PASI100 in 97.7% and 76.7% of patients, respectively over 3 years regardless durations of psoriasis and associated comorbidities. Psoriasis patients have shown super response to Guselkumab injection as 97.7% achieved PASI90 after one median dose and 76.7% achieved PASI100 after two median doses. These results were superior to previous studies show high effectiveness of Guselkumab injection in psoriasis patients [17-18]. Our results are explained by those patients without prior biologic exposure, except for higher baseline PASI (biologic-naïve patients) ($p < 0.001$) had achieved PASI90.They achieved PASI100 was as well significantly lower in biologic-experienced patients compared with biologic-naïve patients (89.7%, n=26; OR=8.67, p=0.007). This agrees with previous study shown that biologically naïve were positively associated with achieving PASI90 response, and especially IL23, appeared to provide a better therapeutic response [19].There is significant negative correlation, whenever the higher number of prior biological therapy the more resistant to achieve super response for treatment (P= 0.006).In the other hand BMI dose not corelate with super response in our patients (P= 0.644) which is controversy to previous studies that showed high BMI negatively affect response to Guselkumab injection in psoriatic patients [20-22].Special site involvement was not significantly affect response ,except for psoriatic arthritis (P=0.017),although special sites affection (especial scalp, retroarticular) delays response to PASI 90/100 .Regard relapse about quarter(25.6) of patients had relapsed during follow up during treatment and according them they were not adherent to treatment rather than ineffective of Guselkumab therapy. The Safety profile during follow-up was minor adverse effects with no serious reactions and was recorded in 11(25.6%) patients totally inform of site pain to Guselkumab injection in7 patient (16.3%) and any minor infection in 4 (9.3%) which controlled on antibiotic without continuation of treatment. Our results showed higher safety profit more than some previous study had showed infections in 65.9%, but it is comparable to another study which showed mild AEs like pharyngitis, headache and flu-like illness without requiring treatment discontinuation [23,24].

5. Conclusion

Interleukin (IL)-23p19 inhibitors guselkumab demonstrated the high drug survival and efficacy in psoriasis. Early disease intervention is favorable for getting this result. Some factors affect the efficacy of treatment including severity of psoriasis before starting treatment, and prior biological therapy before guselkumab injection. High BMI in Kuwaiti patients does not affect efficacy and to achieve PASI 100 after guselkumab injection. High safety profile of therapy as patient with open heart surgery, epilepsy on treatment or other comorbidities were continue on treatment without any complications.

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