Dermatology Practical & Conceptual

Effectiveness of Ixekizumab in Elderly Patients for the Treatment of Moderate-to-Severe Psoriasis: Results From a Multicenter, Retrospective Real-Life Study in the Lazio Region

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ABSTRACT

Introduction: This was an observational, retrospective, multicenter study, enrolling elderly patients (>65 years old) treated with ixekizumab with a diagnosis of psoriasis (PsO) and/or psoriatic arthritis (PsA) during the period 2020 to 2023.

Objectives: Efficacy of ixekizumab in elderly patients in the treatment of moderate to severe psoriasis.

Methods: We included 73 patients with psoriasis (32.9%), psoriatic arthritis (1.4%) and both of them (PsO-PsA 65.8%), attending the outpatient clinics of seven Italian referral center for psoriasis in Lazio region: Policlinico Umberto I Università Roma La Sapienza, Sant'Andrea Università di Roma La Sapienza, Polo Pontino Università Roma La Sapienza, Fondazione Policlinico Universitario A. Gemelli, Università Campus Biomedico Roma, Istituto Dermopatico dell'Immacolata – IDI and Policlinico Tor Vergata. We collected data related to the characteristics of the patients (age, sex, body mass index) and of the disease (age at onset, duration of psoriasis, previous treatments). The severity of psoriasis was measured with the Psoriasis Area and Severity Index (PASI) score at baseline and after 16, 24, 52, 104 and 156 weeks of treatment.

Results: PASI90 was achieved by all the patients in week 16 and remained stable until the end of the study. PASI100 has been achieved by 55.1% of patients at weeks 16 and by 81.3% at week 104. A statistically significant difference has been showed between baseline and all the other time points ($P < 0.0001$) for PASI score. A similar trend was observed for Visual Analogue Scale score and Dermatology Life Quality Index score.

Conclusions: Ixekizumab was effective and with a good safety profile in psoriatic patients over 65 years. No significant adverse events were reported.

Introduction

Psoriasis is a chronic inflammatory dermatosis with a multifactorial pathogenesis and a relapsing trend [1]. It is currently estimated that around 120 million individuals are affected worldwide, with a prevalence around 2%-3% of the adult population and 0.5%-1% of children. Psoriasis shows a bi-modal distribution with a main onset peak around 20-30 years and a second peak after 50-60 years, with a worse prognosis if the onset occurs at a young age compared to a development in adulthood [2]. Skin lesions and the chronic and relapsing course of the disease deeply and negatively undermine the quality of life of patients. Furthermore, these patients have an increased risk of developing other serious comorbidities, such as psoriatic arthritis, metabolic syndrome, cardiovascular diseases, Crohn disease, psychiatric disorders, such as anxiety and depression [3-5]. The pathogenesis of psoriasis involves antimicrobial peptides (AMPs), dendritic cells (DCs), tumor necrosis factor (TNF)α, interleukin (IL) 23, Th17, IL17, IL22, and signal transducer and activator of transcription (STAT)3. The IL-23/TH17 immune axis is now thought to be central to the pathogenesis of psoriasis. The main cytokines involved in psoriasis pathogenesis, IL-23, TNF and IL-17, can be subdivided into regulatory and effector cytokines based on their mode of action. IL-23 exerts regulatory effects on the maintenance of TH17 cells, whereas IL-17 and TNF mediate effector functions of innate (TNF) and adaptive (TNF, IL-17) immune cells. IL-23 was identified in 2000 as a heterodimer composed of the IL-12/23p40 subunit and a newly discovered p19 subunit that is exclusive to IL-23 [6] IL-23 signals through a heterodimeric receptor complex composed of two subunits, IL-23R and IL-12Rb1. This complex predominantly activates signal transducer and activator of transcription 3 (STAT3), leading to IL-23–dependent gene expression. IL-23 is an upstream regulatory cytokine that acts early in the inflammatory cascade in psoriasis to maintain the TH17 cell phenotype and is critical in the production of downstream effector cytokines, such as IL-17A, IL-17F and TNF. The IL-17 cytokine family consists of six isoforms termed IL-17 A–F. IL-17A shows similarities with IL-17F and both cytokines bind to the same receptor IL-17RA. The biologically active form of IL-17A comprises either an IL-17A homodimer or an IL-17A-IL-17F heterodimer, although the first one has greater biological activity Increased expression of IL-17A, E and F in psoriatic lesions has been described [7]. TH17 (CD4+) cells are a major source of IL-17A, although this cytokine can also be produced by CD8+ T cells and cd T cells, natural killer T cells, mast cells and neutrophils. IL-17 is an effector cytokine downstream of IL-23 that mediates psoriatic inflammation. IL-17 induces IL-17 receptor–dependent proliferation of keratinocytes and production of pro-inflammatory cytokines, including IL-1b, IL-6 and TNF, and antimicrobial peptides, including b-defensin and matrix metalloproteinase 9.82–85,87. Blockade of either IL-17A or the IL-17 receptor has been shown to be an effective therapy in plaque psoriasis [8]. Anti-IL17 biologics drugs (including secukinumab, ixekizumab, brodalumab and bimekizumab) are effectice in

the treatment of psoriasis that act by neutralizing IL-17A, a key cytokine in the pathogenesis of the disease. There are three large prospective, double-blind, multicenter, phase III studies (UNCOVER-1, -2 and -3) that evaluated ixekizumab efficacy and safety [9].

Objectives

Our study was designed to evaluate, in a real-world setting, the effectiveness and safety of ixekizumab in elderly patients (>65 years old) with psoriasis (PsO) and/or psoriatic arthritis (PsA) [10]. The main objective was to evaluate the effectiveness and safety of ixekizumab in a cohort of real-life psoriasis patients.

Methods

We performed a multicenter, retrospective, observational analysis in patients with chronic plaque psoriasis and psoriatic arthritis in real life of elderly patients treated with ixekizumab. We included males and females attending the outpatient clinics of seven Italian referral center for psoriasis in Lazio Region: Policlinico Umberto I Università Roma La Sapienza, Sant'Andrea Università di Roma La Sapienza, Polo Pontino Università Roma La Sapienza, Fondazione Policlinico Universitario A. Gemelli, Università Campus Biomedico Roma; Istituto Dermopatico dell'Immacolata – IDI; Policlinico Tor Vergata. All patients were treated with ixekizumab at the European Medical Agency (EMA) approved dosage (80 mg x2 administered by subcutaneous injection at week 0, and 80 mg at weeks 2, 4, 8, 12, and every 4 weeks thereafter). We collected data related to the characteristics of the patients (age, sex, BMI) and of disease (age at onset, severity and duration of psoriasis, previous treatments). The severity of psoriasis was measured with the Psoriasis Area and Severity Index (PASI) score at baseline and after 16, 24, 52, 104 and 156 weeks of treatment.

Study Design and Patients

This was an observational, retrospective, multicenter study performed in seven centers in Italy in Lazio region, enrolling elderly patients with a diagnosis PsO and/or PsA during the period from 2020 to 2023.

Inclusion Criteria

Patients over 65 years old, affected by PsO and/or PsA and currently treated with ixekizumab were included in the study.

Procedures

Baseline clinical and demographic characteristics of the patients have been collected from hospital records. Results from the PASI and Visual Analogue Scale (VAS) have been collected for 6 time points: baseline, 16, 24, 52, 104 and 156 weeks. Results from Dermatology Life Quality Index (DLQI) have been collected at baseline and at 52 weeks. Patients have been diagnosed with PsO, PsA, or both (PsO-PsA). Concerning the body areas affected by the disease, PsO presentation has been classified in "Difficult areas" (head, nails, hands, feet, genital area) and "Widespread" (all the remaining areas not included in the first group).

Statistics

The sample has been described in its clinical and demographic characteristics applying descriptive statistics techniques. Qualitative variables have been described with absolute frequencies and percentage; quantitative variables have been summarized with mean and standard deviation. Comparisons between groups of patients have been performed applying the Chi square test (or the Fisher Exact Test) for categorical variables; for continuous, not normally distributed, variables the Mann Whitney test have been applied.

To evaluate the effectiveness of ixekizumab PASI score, VAS and DLQI have been considered. Results from the three questionnaires have been described for each time points, applying the already mentioned descriptive statistics techniques. Moreover, the percentages of patients achieving PASI90 and PASI100 improvement have been calculated at each time point not considering the loss to follow-up patients. To evaluate the changes over times a one-way repeated measures ANOVA has been performed for PASI and VAS over a total of 6 time points. A Wilcoxon signed rank test has been performed for the evaluation of changes in DLQI over two timepoints (baseline and week 52).

A subgroup analysis (male vs female; bio naive vs not bio naive; PsO-PsA versus PsO; BMI<25 vs BMI ≥25) for PASI, VAS (100 points score) and DLQI data, has been performed applying an ANOVA mixed model for repeated measures. Due to subgroup dimension, only PsO-PsA and PsO patients have been considered (in the sample there was only one PsA patient). Before performing the ANOVA mixed model for repeated measures, some preliminary tests were carried out to verify that groups were not significantly different at the baseline in relation to some selected variables that could influence the results. Ixekizumab safety has been evaluated investigating the frequency and the severity of adverse events.

A P -value <0.05 has been considered as significant. All the statistical analyses were performed using R (4.3.0).

Results

A total of 73 patients, 56.2% males and 43.8% females, with mean age of 71.5 years (SD = 6.4), have been included in the study. The diagnosis was PsO for 24 patients (32.9%),

PsA for 1 patient (1.4%) and both of them (PsO-PsA) for 48 patients (65.8%). The mean disease duration was 25.3 years (SD = 16.0), with a minimum of 1 year and a maximum of 63 years.

Most patients (N = 62; 84.9%) had undergone a traditional systemic therapy and 15 patients (20.5%) were bio naive. The most frequently prescribed traditional therapy before treatment with ixekizumab was methotrexate (47 patients) and the most frequently prescribed biologic was an anti TNF-α agent. Most patients (N = 60; 82.2%) had comorbidities and the most frequent were the cardiovascular diseases. See Table 1 for clinical and demographic details about the sample. Concerning the safety of ixekizumab, during the study only 2 mild adverse events have been recorded (oral candidiasis and pain at the injection site). In order to evaluate the effectiveness of the ixekizumab, detailed analyses of the score trend for the PASI, VAS and DLQI were performed.

PASI Score

At baseline the mean PASI score was 14.6 (SD=8.7), with a minimum of 1 and a maximum of 60 points. After only 16 weeks of treatment, PASI scores had improved, reaching a mean value of 1.4 (SD=2.4), with a minimum of 0 and a maximum score of 10 points. This trend remained stable until the end of the study (Table 2 and Figure 1). The one-way ANOVA model presented a significant effect of time on PASI score ($P < 0.0001$); pairwise comparisons highlighted a significant difference only between baseline and all the other time points ($P < 0.0001$).

PASI90 has been achieved by all the patients in week 16 and remained stable until the end of the study. PASI100 has been achieved by 55.1% of patients on weeks 16 and by 81.3% on week 104 (Table 3 and Figure 2).

The proportions of patients achieving PASI 90 and PASI 100, in the Bio-Naïve group and in the Bio-experienced group, are displayed in Table 4. PASI 90 was achieved by all the patients in both the groups in week 16 and the result was maintained until week 156. PASI 100, for all the Bio-Naïve patients, is achieved in week 24 and maintained in week 52 and 104. In week 156 the proportion of patient achieving PASI 100 decreased to 83.3%. For the Bio-experienced group, the proportion of patients achieving PASI 100 is constantly increased from 52.7% of week 16 to 80.0% of week 156.

VAS Score

At baseline the mean pain VAS score was 16.5 points (SD=23.3), with a minimum of 0 and a maximum of 80. Mean VAS score decreased with time reaching its minimum of 1.7 points at week 52 and maintained at week 104. At week 156 mean VAS score presented a light increase (2.3). Similarly, with what was seen for PASI score, the one-way ANOVA model presented a significant effect of time on VAS score ($P < 0.0001$) and pairwise comparisons showed a significant difference between baseline and all the other time points ($P < 0.0001$). See Table 5 for details.

DLQI Score

As presented in Table 6, DLQI score decreased significantly from baseline to week 52. Mean and median changed from 15.9 and 16.0 to 0.5 and 0, respectively. The Wilcoxon signed rank test highlighted a significant difference between the two considered time points, $P < 0.0001$.

See Figure 3 for a graphical representation of mean VAS and DLQI score.

Subgroups Analyses

The results of a preliminary, comparative test indicated that the proposed subgroups are not significantly different in term of age, PASI, VAS and DLQI score at baseline. There was only a statistically significant difference between mean PASI score at baseline for BMI < 25 patients and BMI ≥ 25 ones; 10.9 (SD = 6.7) and 16.1 (SD = 9.1) respectively (Table 7).

Sex

For PASI score, the ANOVA mixed model showed a statistically significant difference between sex ($P = 0.037$) and, as already reported, between timepoints ($P < 0.0001$). Pairwise comparisons showed that all timepoints are significantly different from the baseline ($P < 0.0001$) but there are no significant differences between the remaining pairs of timepoints. See Figure 4 for details.

ANOVA mixed model also revealed a statistically significant difference in VAS scores between time points ($P < 0.0001$) but no significant difference in VAS score between males and females ($P = 0.247$).

Concerning DLQI index, no statistically significant differences have been highlighted between males and females, $P = 0.829$.

PsO Versus PsO-PsA

For PASI score, the ANOVA mixed model highlighted a statistically significant difference between time points ($P < 0.0001$) and no significant difference between the groups ($P = 0.647$). Pairwise comparisons showed that all times are significantly different from the baseline ($P < 0.0001$) but there are no significant differences between the remaining pairs of timepoints.

For VAS score, the ANOVA mixed model showed a statistically significant difference between time points ($P = 0.011$) and no significant difference between the groups ($P = 0.239$).

For DLQI index, the ANOVA mixed model revealed a statistically significant difference between time points

Table 1. Clinical and demographic characteristics of the sample (N = 73)

Characteristics			
Sex (N;%)	Male	41	56.2
	Female	32	43.8
Diagnosis (N;%)	PsO-PsA	48	65.8
	PsO	24	32.9
	PsA	1	1.4
Age (mean; SD)		71.5	6.4
BMI (mean; SD)		27.3	4.1
Disease duration (mean; SD)		25.3	16.0
PsO locations (N;%)	Difficult areas	30	41.1
	Widespread	23	31.5
	missing	19	26.4
PsA subtype (N;%)	Polyarticular	27	37.0
	Oligoarticular	21	28.8
	missing	1	2.0
Traditional therapy (N;%)	Yes	62	84.9
	No	11	15.1
Traditional therapy drug details (Frequency of patients that underwent a certain traditional therapy. The same patient could have undergone more than one type of traditional medicine)	acitretin	10	
	cyclosporine	25	
	oral steroids	5	
	phototherapy	7	
	methotrexate	47	
	salazopyrine	3	
Bio-Naive (N;%)	No	58	79.5
	Yes	15	20.5
Bio-experienced (N %)	anti TNF-Alpha	43	58.9
	anti TNF-Alpha, anti IL-17	4	5.5
	anti TNF-Alpha, anti IL-17, anti IL-23	3	4.1
	anti TNF-Alpha, anti IL-23	3	4.1
	anti IL-23	2	2.7
	APREMILAST	2	2.7
	anti IL-17	1	1.4
Comorbidities (N;%)	Yes (	60	82.2
	No	13	17.8
Comorbidities details (Frequency of patients that presents the same comorbidity. The same patient could have more than one comorbidity)	Cardiovascular	42	
	Other	18	
	Diabetes	11	
	Dyslipidemia	10	
	Thyroid gland disorders	7	
	Depression	3	
	Obesity	3	
	Fibromyalgia	2	
	Bipolar disorder	1	
	Tuberculosis	1	

BMI = body mass index; PsA = psoriatic arthritis; PsO = psoriasis; SD standard deviation.

Table 2. Descriptive statistics for PASI score at each timepoints and pairwise comparisons P-value.

	Baseline	Week 16	Week 24	Week 52	Week 104	Week 156
N	72	69	68	64	48	40
Mean	14.58	1.43	0.55	0.59	0.47	0.81
Std. Dev.	8.71	2.39	1.23	1.54	1.15	1.82
Median	15	0	0	0	0	0
Min	1	0	0	0	0	0
Max	60	10	6	8	5	7
Pairwise comparisons (timepoints)						
Baseline versus other timepoints (P-value)		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

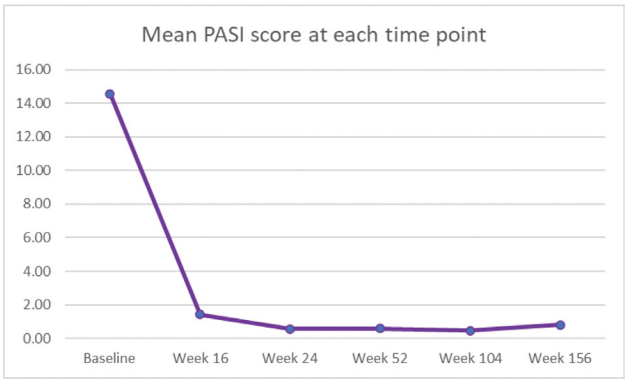

Figure 1. Trend in mean Psoriasis Area and Severity Index (PASI) score at each time point.

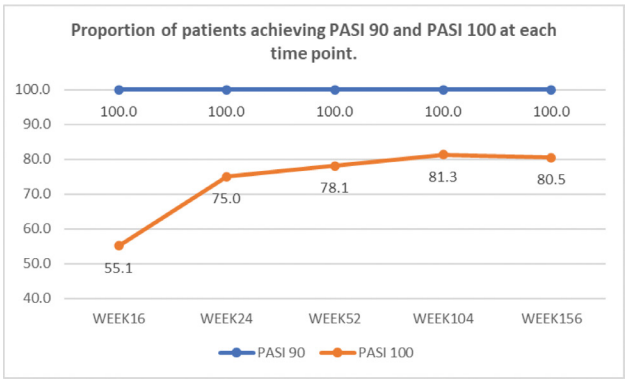

Figure 2. Proportion of patients achieving Psoriasis Area and Severity Index (PASI)90 and PASI 100 at each time point.

Table 3. Proportion of patients achieving Psoriasis Area and Severity Index (PASI) 90 and PASI 100 at each time point

	Week 16	Week 24	Week 52	Week 104	Week 156
Patients achieving PASI 90	69/69	68/68	64/64	48/48	40/40
PASI 90	100%	100%	100%	100%	100%
Patients achieving PASI 100	38/69	51/68	50/64	39/48	33/41
PASI 100	55.1%	75.0%	78.1%	81.3%	80.5%

Table 4. Proportions of patients achieving Psoriasis Area and Severity Index (PASI) 90 and PASI 100 at each time point. Bio-Naive vs Not Bio-Naive

	Week 16	Week 24	Week 52	Week 104	Week 156
Bio-Naïve patients achieving PASI 90	14/14	13/13	12/12	7/7	5/5
PASI 90 (Bio-Naïve)	100.0%	100.0%	100.0%	100.0%	100.0%
Bio-Naïve patients achieving PASI 100	9/14	13/13	12/12	7/7	5/6
PASI 100 (Bio-Naïve)	64.3%	100.0%	100.0%	100.0%	83.3%
Bio-experienced patients achieving PASI 90	55/55	55/55	52/52	41/41	35/35
PASI 90 (Bio-experienced)	100.0%	100.0%	100.0%	100.0%	100.0%
Bio-experienced patients achieving PASI 100	29/55	38/55	38/52	32/41	28/35
PASI 100 (Bio-experienced)	52.7%	69.1%	73.1%	78.0%	80.0%

Table 5. Descriptive statistics for Visual Analogue Scale score at each timepoints and pairwise comparisons P-value

	Baseline	Week 16	Week 24	Week 52	Week 104	Week 156
N	56	53	53	50	43	38
Mean	16.5	4.8	2.9	1.7	1.7	2.3
Standard deviation	23.3	9.8	6.2	4.4	5.0	4.4
Median	7.5	0.0	0.0	0.0	0.0	0.0
Min	0	0	0	0	0	0
Max	80	50	30	20	30	20
Pairwise comparisons (timepoints)						
Baseline versus other timepoints (P-value)		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

Table 6. Descriptive statistics for Dermatology Life Quality Index (DLQI) at each time point

	DLQI_ BASALE	DLQI_ WEEK52	P-value
N	73	65	
Mean	15.9	0.5	<0.0001
SD	6.2	1.6	
Median	16.0	0.0	
Min	1	0	
Max	29	10	

SD = standard deviation.

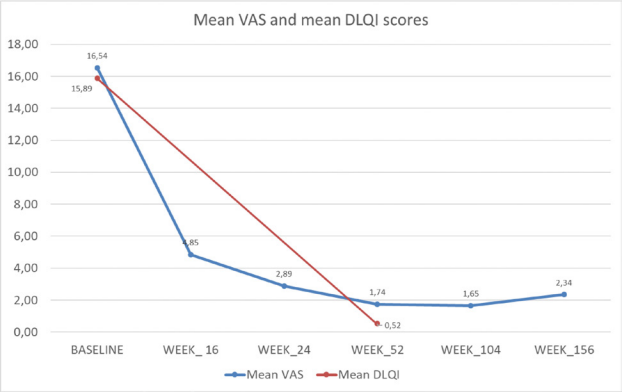

Figure 3. Mean Visual Analogue Scale (VAS) and Dermatology Life Quality Index (DLQI) score at each timepoints.

(P < 0.0001) and no significant difference between the groups (P = 0.291).

Bio-naive Versus Bio-experienced

For PASI score, the ANOVA mixed model highlighted a statistically significant difference between time points (P < 0.0001) and no significant difference between the groups (P = 0.99). Pairwise comparisons showed that all times are significantly different from the baseline (P < 0.0001) but there are no significant differences between the remaining pairs of times.

For VAS score, the ANOVA mixed model showed a statistically significant difference between time points (P < 0.0001) and no significant difference between the groups (P = 0.259). Pairwise comparisons showed that all times are significantly different from the baseline but there are no significant differences between the remaining pairs of times.

For DLQI index, the ANOVA mixed model revealed a statistically significant difference between time points (P < 0.0001) and no significant difference between the groups (P = 0.265).

BMI < 25 Versus BMI ≥ 25

As seen in Table 5, there was a statistically significant difference between mean PASI score at baseline for BMI < 25 patients and BMI ≥ 25 ones; 10.9 (SD=6.7) and 16.1 (SD=9.1) respectively. For PASI score, the ANOVA mixed model highlighted a statistically significant difference between time points (P < 0.0001) and no significant difference between the groups (P = 0.374). Pairwise comparisons showed that all times are significantly different from the baseline (P < 0.0001) but there are no significant differences between the remaining pairs of times.

For VAS score, the ANOVA mixed model showed a statistically significant difference between time points (P < 0.0001). No significant difference between the groups (P = 0.970) was observed. Pairwise comparisons showed that all times are significantly different from the baseline but there are no significant differences between the remaining pairs of times.

For DLQI index, the ANOVA mixed model highlighted a statistically significant difference between time points (P < 0.0001) and no significant difference between the groups (P = 0.668).

For a fully detailed description of subgroups comparison see Table 8.

Table 7. Subgroups comparison on a selected list of variables

	Female		Male		
	mean	SD	mean	SD	P
PASI (baseline)	12.2	6.5	16.5	9.8	0.07
VAS (baseline)	17.0	25.2	16.2	22.3	0.54
DLQI (baseline)	15.7	6.8	16.1	5.9	0.79
Age	72.0	5.9	71.2	6.7	0.45
	PsO		PsO-PsA		
	mean	SD	mean	SD	P
PASI (baseline)	15.4	6.5	14.2	9.7	0.47
VAS (baseline)	6.0	1.4	16.8	23.1	0.07
DLQI (baseline)	18.3	3.8	14.6	6.9	0.07
Age	71.0	6.4	71.4	6.0	0.21
	Bio-naive		Not Bio-naive		
	mean	SD	mean	SD	P
PASI (baseline)	14.2	8.9	16.0	8.1	0.55
VAS (baseline)	16.3	23.5	18.6	23.2	0.19
DLQI (baseline)	15.3	6.6	18.0	4.1	0.23
Age	71.2	6.1	72.9	7.2	0.51
	BMI <25		BMI≥25		
	mean	SD	mean	SD	P
PASI (baseline)	10.9	6.7	16.1	9.1	0.02
VAS (baseline)	21.1	28.3	14.6	20.8	0.65
DLQI (baseline)	15.1	6.7	16.2	6.1	0.41
Age, years	71.8	7.4	71.4	5.9	0.89

BMI = body mass index; DLQI = Dermatology Life Quality Index PsA = psoriatic arthritis; PsO = psoriasis; SD standard deviation. PASI = Psoriasis Area and Severity Index; SD = standard deviation; VAS = Visual Analogue Scale.

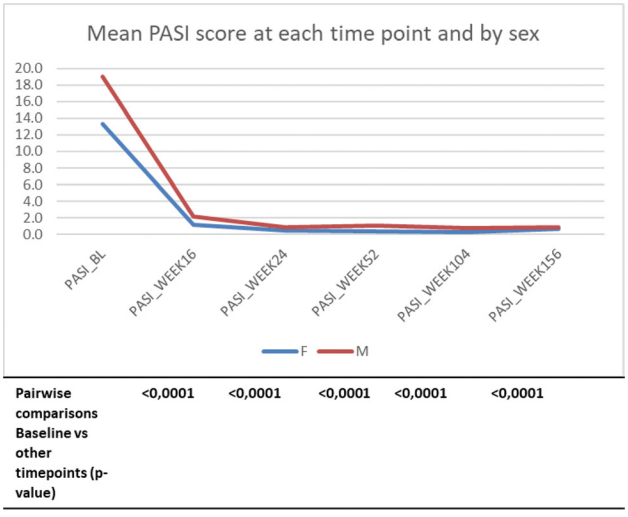

Figure 4. Trend in mean Psoriasis Area and Severity Index (PASI) score by sex at each time point.

Conclusions

As we know, psoriasis is a chronic and relapsing dermatosis. Approximately 15-20% of affected patients are over 65 years of age and are affected by many comorbidities (cardiovascular, metabolic, renal, intestinal, etc) [11-12]. Therefore, in this category of patients, when considering treatment of psoriasis, it is very important to take into account not only the clinical presentation and severity of skin disease but also all the associated pathologies. Data on the efficacy and safety of other biological drugs in the treatment of patients with psoriasis treated with biological drugs have been presented in the literature. In particular, for example, in the work presented by Ruggiero and collaborators, the authors focus their attention on the elderly patient being treated with guselkumab, risankizumab and tildrakizumab over the age of 65, but there are no data in clinical practice on the efficacy of ixekizumab in the elderly patients [13]. However, most of the reported relevant clinical studies on biologics in elderly patients have focused on the efficacy and safety of anti-TNFα drugs, owing to their longer market availability [11,12-14]. Regarding anti-IL-17 inhibitors, a recent study including 114 elderly patients showed that these drugs were an effective and safe therapeutic option for patients with psoriasis aged ≥ 65 years, with low rates of only mild adverse events; however, the discontinuation rate was 28.9%, mostly related to psoriasis relapses. A post hoc analysis of three phase III secukinumab trials (ERASURE, FIXTURE and CLEAR) showed comparable efficacy profiles between elderly and younger patients; however, the rates of serious AEs and discontinuation were higher in older participants [15,16]. For ixekizumab, a retrospective observational study showed optimal efficacy and safety in elderly patients throughout a 1-year treatment period, confirming the results highlighted in the drug product information, reporting that the response in elderly patients seems to be higher than that in younger patients [17]. We performed a multicenter, retrospective, observational analysis in real life in patients with chronic plaque psoriasis and psoriatic arthritis of elderly patients (>65 years) treated with ixekizumab. We included male and female patients attending the outpatient clinics of seven Italian referral center for psoriasis in Lazio Region: Policlinico Umberto I Università Roma La Sapienza, Sant'Andrea Università di Roma La Sapienza, Polo Pontino Università Roma La Sapienza, Fondazione Policlinico Universitario A. Gemelli, Università Campus Biomedico Roma; Istituto Dermopatico dell'Immacolata – IDI; Policlinico Tor Vergata. Our results show that ixekizumab was found to be effective and safe in the whole sample of enrolled patients, every parameter taken into consideration has already significantly improved at week 16, maintaining the results. Subgroup analyzes confirmed that time is significant

Table 8. Subgroups comparisons

Sex	PASI score	P-value		PASI score	P-value
	M vs F	0.037	Naive, Bio-experienced	Naive vs Bio-experienced	0.99
	BL vs week 16	<0.0001		BL vs week 16	<0.0001
	BL vs week 24	<0.0001		BL vs week 24	<0.0001
	BL vs week 52	<.,0001		BL vs week 52	<0.0001
	BL vs week 104	<0.0001		BL vs week 104	<0.0001
	BL vs week 156	<0.0001		BL vs week 156	<0.0001
	VAS score	P-value		VAS score	P-value
	M vs F	0.247		Naive vs Bio-experienced	0.259
	BL vs week 16	0.004		BL vs week 16	<0.0001
	BL vs week 24	0.005		BL vs week 24	<0.0001
	BL vs week 52	0.006		BL vs week 52	<0.0001
	BL vs week 104	0		BL vs week 104	<0.0001
	BL vs week 156	0.015		BL vs week 156	<0.0001
	DLQI score	P-value		DLQI score	P-value
	M vs F	0.829		Naive vs Bio-experienced	0.265
	BL vs week 52	<0.0001		BL vs week 52	<0.0001
BMI<25, BMI≥25	PASI score	P-value	PsO, Pso-PsA	PASI score	P-value
	BMI<25 vs BMI≥25	0.374		PsO vs PsO-PsA	0.647
	BL vs week 16	<0,0001		BL vs week 16	<0.0001
	BL vs week 24	<0.0001		BL vs week 24	<0.0001
	BL vs week 52	<0.0001		BL vs week 52	<0.0001
	BL vs week 104	<0.0001		BL vs week 104	<0.0001
	BL vs week 156	<0.0001		BL vs week 156	<0.0001
	VAS score	P-value		VAS score	P-value
	BMI<25 vs BMI≥25	0.97		PsO vs PsO-PsA	0.239
	BL vs week 16	<0.0001		BL vs week 16	<0.0001
	BL vs week 24	<0.0001		DLQI score	p-value
	BL vs week 52	<0.0001		PsO vs PsO-PsA	0.291
	BL vs week 104	<0.0001		BL vs week 52	<0.0001
	BL vs week 156	<0.0001			
	DLQI score	P-value			
	BMI<25 vs BMI≥25	0.668			
	BL vs week 52	<0.0001			

BL = Baseline ;BMI = body mass index; DLQI = Dermatology Life Quality Index; PsO = Psoriasis PsA = Psoriatic Arthritis ; PASI Psoriasis Area and Severity Index; VAS =Visual Analogue Scale; vs = versus.

but that, among subgroups, only gender for PASI is significant. In detail, females report lower PASI than males. The limitations of our study included its retrospective nature, relatively small sample size.

We found that ixekizumab was a good option in elderly patients. However, more data, both from dedicated trials and real-life reports, are needed to confirm our results, our limitations is that the population comes from Lazio Region and it is not representative of the Italian population. We consider this data a useful tool for the physician in clinical practice because no data from real life have been published regarding elderly patients and ixekizumab treatment.

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