

Efficacy and safety of risankizumab in patients with moderate-to-severe plaque psoriasis: a real-life retrospective study

Magdalena Kręgiel-Prylińska, Magdalena Ciążyńska, Igor A. Bednarski, Marcin Noweta^{ORCID},
Joanna Narbutt^{ORCID}, Aleksandra Lesiak^{ORCID}

Department of Dermatology, Paediatric Dermatology and Oncology Clinic, Medical University of Lodz, Poland

ABSTRACT

Introduction: In recent years psoriasis treatment underwent a true revolution. Synthesis of monoclonal antibodies and increased knowledge about immunological disturbances driving psoriasis resulted in the development of several therapies targeting different signalling pathways of psoriasis. In 2019 risankizumab (Skyrizi®) was introduced in the treatment of moderate-to-severe plaque psoriasis and showed high clinical effectiveness, but despite existing clinical trials, there is still the need to evaluate its safety profile, efficiency and tolerability among different groups of patients. This study aims to evaluate the effectiveness and safety of risankizumab in a Polish group of patients with moderate-to-severe plaque psoriasis.

Material and methods: A longitudinal retrospective 2-year study was performed in which 48 adults with plaque psoriasis were enrolled. The patients received at least 1 dose of risankizumab during 2 years of observation. The response to treatment was assessed using the Psoriasis Area and Severity Index (PASI), body surface area (BSA) and Dermatology Life Quality Index (DLQI) at baseline, in the 4th, 16th, 28th, 40th, 52nd and 96th week of treatment. Additionally, the safety profile using patients' medical histories was evaluated.

Results: A statistically significant reduction of PASI was noted (from 20.54 points to 0.16 points), BSA (from 18.77% to 0.20%) and DLQI (from 19.96 points to 0.00 point) after 96 weeks of treatment. No side effects were observed at any time during the treatment.

Conclusions: Risankizumab seems to be another effective monoclonal antibody in psoriasis treatment, however, more studies are urgently needed to compare its effectiveness with other existing therapies.

Forum Derm. 2023; 9, 2: 43–49

Key words: psoriasis, risankizumab, IL-23, biological treatment, monoclonal antibody

INTRODUCTION

Psoriasis is a chronic inflammatory skin disease characterized by the presence of well-defined erythematous plaques and scaling [1]. Being one of the most prevalent dermatological disorders, psoriasis affects about 2% of the population worldwide [2]. While in most cases psoriasis is not a life-threatening disease, its comorbidities including autoimmune and metabolic disorders are associated with cardiovascular events and reduced lifespan implying the need for effective and well-tolerated treatment [3]. In addition, psoriasis decreases patients' quality of life, which could result in depression, cognitive impairment and sleep disturbances [3, 4].

Regardless of many studies, the exact pathogenesis of psoriasis remains unclear, but some of its paradigms have been revealed. It is known that immune dysregulation present in psoriasis starts with the activation of dendritic cells by keratinocytes, which release interleukin-12 (IL-12) and interleukin-23 (IL-23) [5]. In the next step, IL-12 and IL-23

stimulate the maturation of T helper type 1 (Th1), T helper type 17 (Th17) and T helper type 22 (Th22) lymphocytes, which results in the production of pro-inflammatory cytokines including tumour necrosis factor- α (TNF- α), interferon- γ (IFN- γ), interleukin-17 (IL-17) and interleukin-22 (IL-22) [1, 4, 6]. IL-17 and IL-22 promote keratinocyte hyperproliferation, while IL-17 and TNF- α stimulate dendritic cells in an autocrine manner to produce IL-23 thus forming a vicious inflammatory cycle disrupting keratinocyte proliferation and differentiation [7, 8]. It is hypothesized that this interaction network is the core of psoriatic inflammation and is known as IL-23/IL-17 axis [5, 8]. The validity of the IL-23/IL-17 axis in the development of psoriasis has been already proven in the last several years by multiple studies in which its constituents have been pharmacologically targeted using monoclonal antibodies [8]. While anti-TNF- α , anti-IL-17 and anti-IL-22 antibodies are considered the mainstays in the therapy of psoriasis, the IL-23 inhibitors are now emerging as safer and more efficacious forms of biological treatment [9].

Address for correspondence:

Magdalena Kręgiel-Prylińska MD, Dermatology, Paediatric Dermatology and Dermatological Oncology Clinic, Medical University of Lodz, Kniaziewiczza 1/5, 91–347 Lodz, Poland; e-mail: magda.kregiel@interia.pl

Received: 8.03.2023

Accepted: 29.04.2023

Early publication date: 19.05.2023

One of the IL-23 inhibitors is risankizumab (Skyrizi®), a humanized monoclonal antibody directed against the p19 subunit of IL-23 thereby disrupting IL-23-dependent inflammation [10]. In 2019 risankizumab received its first global approval in Japan, followed by Canada, USA and the EU in the same year [10]. Two-phase III clinical trials (UltIMMa-1 and UltIMMa-2) already demonstrated the effectiveness of risankizumab in psoriasis by showing a high frequency of PASI-90 (75% of patients in UltIMMa-1 in week 16.) and PASI-100 (59% of patients in UltIMMa-2) among treated individuals [11, 12], but since its introduction to therapy, many questions have arisen. Considering that most registration clinical trials have strict inclusion criteria or long wash-out periods for previously used treatments, a real-life study could provide some evidence about the effectiveness and therapy response in different patients.

MATERIAL AND METHODS

We performed a single-centre retrospective observational study based on real clinical practice in patients with moderate-to-severe plaque psoriasis treated with risankizumab from March 2020 to February 2023. All patients were qualified for risankizumab treatment according to requirements of The Polish Drug Program B.47, "Treatment of moderate to severe form of plaque psoriasis (ICD-10 L40.0)". All patients provided informed consent for the use of their anonymized data for research purposes. Finally, 48 patients were included (34 males, 14 females). For the analysis were considered patients who received at ≥ 1 dose of risankizumab. At the baseline visit demographic data, psoriasis treatment history, psoriasis type and comorbidities were obtained. Data on PASI, BSA, DLQI and adverse events were acquired at baseline and in the 4th, 16th, 28th, 40th, 52nd and 96th week of observation. The treatment regimen included subcutaneous administration of 150 mg of risankizumab in weeks 0. and 4., followed by a maintenance dose once every 12 weeks. Treatment response was assessed using Psoriasis Area Severity Index (PASI), Body Surface Area (BSA) and Dermatology Life Quality Index (DLQI). The safety of treatment was evaluated during every visit. All evaluations were performed in the Department of Dermatology, Paediatric Dermatology and Dermatological Oncology at the Medical University of Lodz, Poland.

Statistical analysis

Statistical analysis was performed using Statistica 13 software. Characteristics of participants including demographic data and clinical assessments were presented as means with standard deviations or cumulative incidence (N) with percentages. The distribution of continuous variables was evaluated using the Shapiro–Wilk test. Student t-tests or non-parametrical counterparts were used to compare

the 2 groups. For comparison of more than 2 groups Friedman ANOVA was employed. A p-value < 0.05 was deemed significant.

RESULTS

The baseline characteristics of the study group are shown in Table 1. The mean age of the study group was in mean age 41.77 ± 14.05 with a mean body mass index (BMI) of 28.29 ± 6.03 kg/m². The mean duration of psoriasis was 16.28 ± 9.86 years. Most of the patients included had a familial history of psoriasis (52.08%). Active smoking was present in 20.83% of cases and was more frequent in males than females (26.47% vs. 7.14%). The most common comorbidities were cardiovascular, psychiatric and metabolic disorders (16.67%, 16.67% and 10.42%, respectively). In relation to sex, cardiovascular, psychiatric and metabolic disorders (20.59%, 14.71% and 11.76%, respectively) dominated among males, while in females psychiatric disturbances were the most commonly reported (21.43%). Considering other forms of psoriasis, 22.92% of the study population were having psoriatic arthritis, 18.75% had nail psoriasis and 8.33% had inverse psoriasis. Regarding systemic therapies of psoriasis methotrexate, cyclosporin A and retinoids were the most frequent treatments used in the past (91.67%, 66.67% and 50%, respectively). The majority of the study group had a history of using biological treatment (52.08%).

Assessment of treatment response revealed that PASI, BSA and DLQI scores significantly decreased between baseline and 96. week (Fig. 1, Tab. 2). In weeks 4th, 16th, 28th, 40th, 52nd and 96th, a significantly decreased PASI, BSA and DLQI were observed in comparison to the baseline values ($p < 0.01$) (Fig. 1). It was observed that PASI score changed from 20.49 ± 7.65 (N = 48) at baseline to 9.12 ± 6.63 in the 4th week (N = 45), 2.30 ± 3.25 in the 16th week (N = 39), 0.66 ± 1.10 in the 28th week (N = 32), 0.36 ± 0.62 (N = 28) in the 40th week, 0.49 ± 0.87 (N = 23) in the 52nd week and 0.16 ± 0.36 in the 96th week (N = 5). The decrease in PASI was statistically significant ($p = 0.0054$). It was also noted that BSA significantly ($p = 0.0034$) changed from 18.63 ± 10.82 at baseline, to 10.15 ± 10.98 in the 4th week, 2.65 ± 4.13 in the 16th week, 0.64 ± 0.87 in the 28th week, 0.36 ± 0.74 in the 40th week, 0.30 ± 0.58 in the 52nd week and 0.20 ± 0.45 in the 96th week. Regarding DLQI a significant decrease was observed ($p = 0.0012$) from 19.79 ± 4.40 at baseline to 10.13 ± 7.23 in the 4th week, 2.85 ± 4.28 in the 16th week, 1.22 ± 2.12 in the 28th week, 0.50 ± 1.17 in the 40th week, 0.43 ± 1.04 in the 52nd week and 0.00 ± 0.00 in the 96th week. Detailed results were presented in Table 2.

No significant difference regarding PASI was observed between patients previously receiving methotrexate, cyclosporin A, retinoids and phototherapy and patients without these forms of systemic therapy. Previous treatment with biologics was associated with lower PASI in the 16th week

Table 1. Baseline characteristics of study participants

	Study group (N = 48)	Males (N = 34)	Females (N = 14)
Demography			
Age	41.77 ± 14.05	40.74 ± 13.93	44.29 ± 14.54
BMI	28.29 ± 6.03	28.74 ± 6.17	27.22 ± 5.77
Psoriasis duration	16.28 ± 9.86	15.18 ± 9.89	18.86 ± 9.65
Family history of psoriasis	52.08% (25)	55.88% (19)	42.86% (6)
Active nicotine	20.83% (10)	26.47% (9)	7.14% (1)
Comorbidities			
Cardiovascular	16.67% (8)	20.59% (7)	7.14% (1)
Metabolic	10.42% (5)	11.76% (4)	7.14% (1)
Endocrine	2.08% (1)	0.00% (0)	7.14% (1)
Liver disease	6.25% (3)	5.88% (2)	7.14% (1)
Neurological	0.00% (0)	0.00% (0)	0.00% (0)
Psychiatric	16.67% (8)	14.71% (5)	21.43% (3)
Gastrointestinal	4.17% (2)	5.88% (2)	0.00% (0)
Other forms of psoriasis			
Psoriatic arthritis	22.92% (11)	23.53% (8)	21.43% (3)
Nail psoriasis	18.75% (9)	17.65% (6)	21.43% (3)
Inverse psoriasis	8.33% (4)	8.82% (3)	7.14% (1)
Previous systemic therapies			
Methotrexate	91.67% (44)	88.24% (30)	100.00% (14)
Cyclosporine A	66.67% (32)	58.82% (20)	85.71% (12)
Retinoids	50.00% (24)	58.82% (20)	28.57% (4)
Phototherapy	22.92% (11)	17.65% (6)	35.71% (5)
Previous biological treatment			
Anti-TNF-α	22.92% (11)	20.59% (7)	28.57% (4)
Anti-IL-17	16.67% (8)	11.76% (4)	28.57% (4)
Anti-IL-12/IL-23	10.42% (5)	11.76% (4)	7.14% (1)
Anti-IL-23	4.17% (2)	0.00% (0)	14.29% (2)

of treatment in comparison to naïve patients. Detailed results are shown in Table 3. Also, it was not observed that BMI significantly influences PASI at all time points (Tab. 4). None of the patients reported adverse events of any kind.

DISCUSSION

Despite proving risankizumab effectiveness in the treatment of psoriasis in several phase III trials (UltIMMa-1, IMMvent and UltIMMa-2) [10], there is still limited evidence about long-term clinical outcomes and real-life efficacy of this recently introduced drug. The first real-life study on risankizumab was performed by Hansel et al. [13] and included 57 Italian patients, of whom 16 were receiving risanki-

zumab as the first biological treatment. The results of the investigation were documented twice, after 16 weeks [13] and after 52 weeks [14]. After 52 weeks of observation PASI-75, -90 and -100 were achieved in 96%, 86% and 60% of patients, respectively [14]. Interestingly, in the 52nd week, females had a better response rate, compared to males (PASI-100 83% vs. 49%, PASI 90 100% vs. 78% respectively) [14]. Authors hypothesized that this effect was associated with obesity- only 29% of the males were having normal BMI, while in females BMI values within normal limits were present in 68% of cases [13, 14]. Additionally, the efficacy of treatment was associated with the severity of psoriasis [13, 14]. A significant difference in the frequency of PASI-100 was observed

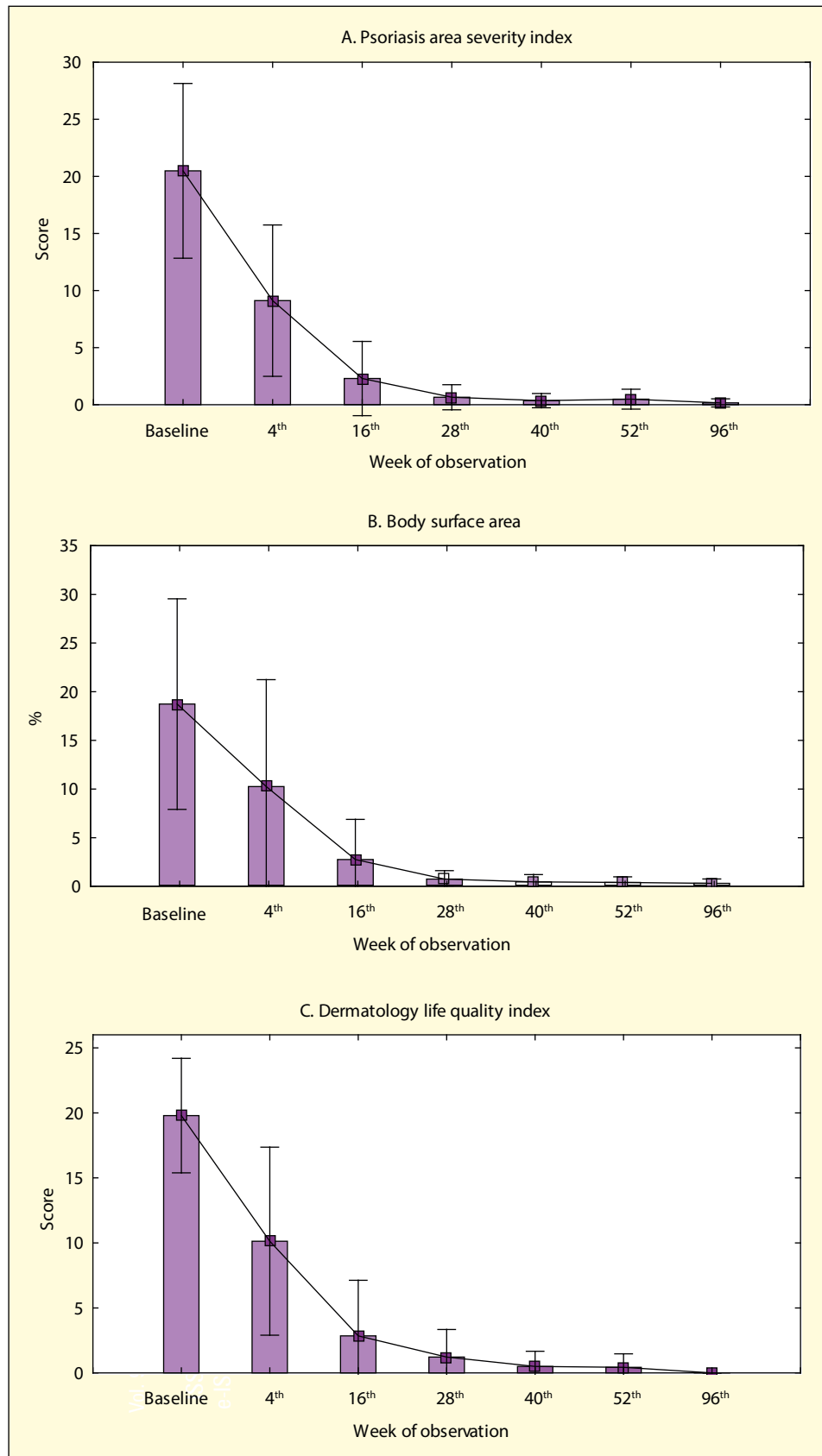


Figure 1. Assessment of treatment response

Table 2. Changes in PASI, BSA and DLQI during the study

Week	0 (N = 48)	4 th (N = 45)	16 th (N = 39)	28 th (N = 32)	40 th (N = 28)	52 th (N = 23)	96 th (N = 5)	p-value
PASI	20.49 ± 7.65	9.12 ± 6.63	2.30 ± 3.25	0.66 ± 1.10	0.36 ± 0.62	0.49 ± 0.87	0.16 ± 0.36	0.0054
BSA	18.63 ± 10.82	10.15 ± 10.98	2.65 ± 4.13	0.64 ± 0.87	0.36 ± 0.74	0.30 ± 0.58	0.20 ± 0.45	0.0034
DLQI	19.79 ± 4.40	10.13 ± 7.23	2.85 ± 4.28	1.22 ± 2.12	0.50 ± 1.17	0.43 ± 1.04	0.00 ± 0.00	0.0012

BSA — body surface area; DLQI — Dermatology Life Quality Index; PASI — Psoriasis Area and Severity Index

Table 3. Comparative reduction of PASI in regard to previous treatment

Week	0	4 th	16 th	28 th	40 th	52 nd	96 th
Biologics							
Yes	18.84 ± 8.70	7.37 ± 6.40	2.98 ± 3.13	0.97 ± 1.37	0.60 ± 0.77	0.66 ± 1.24	0.27 ± 0.46
No	22.28 ± 6.01	10.95 ± 6.51	1.65 ± 3.30	0.38 ± 0.72	0.18 ± 0.42	0.42 ± 0.69	0.00 ± 0.00
p-value	0.0045	0.0387	0.0581	0.0594	0.0876	0.9673	0.6831
Methotrexate							
Yes	20.35 ± 7.93	9.01 ± 6.42	2.13 ± 3.08	0.65 ± 1.12	0.39 ± 0.64	0.45 ± 0.85	0.20 ± 0.40
No	21.98 ± 3.73	10.20 ± 9.66	4.33 ± 5.22	0.70 ± 0.99	0.00 ± 0.00	0.90 ± 1.27	–
p-value	0.4441	0.8575	0.2324	0.7999	0.3603	0.4611	–
Cyclosporin A							
Yes	20.27 ± 8.46	8.85 ± 6.57	1.95 ± 2.75	0.65 ± 1.27	0.29 ± 0.66	0.48 ± 0.95	0.00 ± 0.00
No	20.93 ± 5.95	9.73 ± 6.96	3.08 ± 4.19	0.67 ± 0.79	0.46 ± 0.58	0.51 ± 0.78	0.40 ± 0.57
p-value	0.9738	0.7313	0.6272	0.4346	0.2563	0.8165	0.4142
Retinoids							
Yes	21.11 ± 7.16	10.07 ± 7.03	3.24 ± 3.95	0.75 ± 0.92	0.52 ± 0.79	0.75 ± 1.12	0.00 ± 0.00
No	19.87 ± 8.23	8.12 ± 6.19	1.41 ± 2.14	0.55 ± 1.30	0.23 ± 0.42	0.26 ± 0.49	0.27 ± 0.46
p-value	0.3478	0.2856	0.1083	0.1575	0.3447	0.3448	0.6831
Phototherapy							
Yes	22.86 ± 9.24	8.46 ± 5.59	2.60 ± 2.73	0.48 ± 0.57	0.53 ± 0.60	1.15 ± 1.52	–
No	19.78 ± 7.11	9.33 ± 7.00	2.21 ± 3.42	0.72 ± 1.23	0.31 ± 0.63	0.35 ± 0.65	0.00 ± 0.00
p-value	0.6497	0.7612	0.2796	0.7232	0.3273	0.2732	–

PASI — Psoriasis Area and Severity Index

Table 4. Comparative reduction of PASI according to patients' BMI

Week	0	4 th	16 th	28 th	40 th	52 nd	96 th
BMI							
≥ 30	21.45 ± 7.22	7.37 ± 6.40	2.98 ± 3.13	0.97 ± 1.37	0.60 ± 0.77	0.66 ± 1.24	0.27 ± 0.46
< 30	17.92 ± 8.12	7.76 ± 6.72	2.59 ± 4.22	0.58 ± 0.02	0.50 ± 0.02	0.92 ± 1.02	–
p-value	0.0879	0.4880	0.7116	0.9623	0.3273	0.4924	–

PASI — Psoriasis Area and Severity Index; BMI — body mass index

between the patients with PASI < 20 and with PASI ≥ 20 (64% vs. 56% respectively) [14]. Moreover, the patients who were previously receiving biological treatment reached PASI-100 in weeks 36th and 52nd more frequently than their naïve counterparts [14]. Only one adverse event was reported, a relapse of ulcerative colitis in one patient which forced investigators to cease the treatment in this patient [14]. Since the study was

performed during the coronavirus disease 2019 (COVID-19) pandemic, all of the participants were continuously screened for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Three patients who developed the disease recovered without the need to terminate the therapy [14].

The high efficacy of risankizumab was also reported by Mastorino et al. [15] who retrospectively analysed 166

Italian patients in the 52 weeks. In the 52nd week, PASI-100 and PASI-90 were achieved in 73% and 82% of the patients, respectively, while crude PASI change went from a mean of 12.5 at baseline to 0.5 at the end of the observation [15]. In contradiction to results reported by Hansel et al. [14] higher efficacy of treatment with risankizumab was more frequently observed in naïve patients compared to those previously treated with biologics (PASI-100 in week 40 95% vs. 82% of patients, respectively) [15]. In the current study patients previously treated with biologics had lower PASI scores in the 16th week of treatment compared to the naïve patients, however, no significant differences were found in later parts of the observation. A retrospective study by Gkalpakiotis et al. [16] on 154 Bohemian patients also demonstrated the high effectiveness of risankizumab treatment by showing that PASI-90 and PASI-100 in 52nd week of treatment were achieved by 82% and 68% of patients, respectively [16]. Moreover, the authors reported that abnormal BMI or previous biologic therapy was not associated with worse treatment response [16]. Likewise, Ruiz-Villaverde et al. [17] in a real-life 52-week multicentre study on 78 Spanish patients confirmed the clinical effectiveness of risankizumab. In this study, 79% of patients achieved PASI-100 and 93% of patients PASI-90 in the 52nd week [17]. What is important, 8 patients in this study had a history of solid tumours and no reactivation of neoplasia was noted after the introduction of risankizumab [17]. The authors also did not observe that previous treatment with biologics was associated with better therapy outcomes with risankizumab at any point of treatment [17]. To date, the largest (185 Polish patients) real-life study was presented by Adamczyk et al. [18] who also reported high PASI-90 and PASI-100 frequencies in the 56th and 96th week of risankizumab therapy (89% and 71% of patients in the 56th week, 82% and 68% in the 96th week, respectively) [18]. Similarly to the majority of reported results, the authors did not observe that BMI or previous exposure to biological drugs influenced the outcomes of the therapy [18].

As for possible predictors of response, there is still limited evidence that tobacco smoking, sex or BMI substantially influences the treatment efficacy. Taking into account that risankizumab is a fairly novel drug, more studies are needed to elucidate all the contradictory observations. Considering the safety profile of risankizumab, both clinical trials and real-life studies show a low frequency of adverse events (AE). Most commonly reported AEs include upper respiratory tract infections, headaches and arthralgias [19–21]. The present study confirms the results reported in other studies. Despite this, the present study is limited by the retrospective acquisition of data, small sample size and subjective safety evaluation. Due to the lack of information

about long-term outcomes, more studies evaluating the effectiveness of risankizumab are needed.

CONCLUSIONS

The results of this study confirm previously reported clinical efficacy and safety of risankizumab.

Conflict of interest

The Authors declare no conflict of interest.

Funding

The study was funded by the Medical University of Lodz (project No. 503/5-064-01/503-1).

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