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ORIGINAL RESEARCH

Real-world experience with brodalumab in a Portuguese cohort of patients with moderate-to-severe psoriasis

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Abstract

Background: Brodalumab is a monoclonal antibody directed to the IL-17 receptor A, approved for the treatment of moderate-to-severe psoriasis. In phase III clinical trials, brodalumab showed clinical efficacy and a favourable safety profile. However, real-world data on brodalumab treatment are still limited. This study aimed to evaluate the real-world efficacy and safety of brodalumab treatment in a Portuguese population.

Methods: This is a retrospective, observational, multicentre study of patients with moderate-to-severe plaque-type psoriasis treated with brodalumab between January 2019 and August 2022. The follow-up period was 74 weeks. Brodalumab efficacy was accessed by the percentage of patients reaching the Psoriasis Area Severity Index (PASI) 75, 90 and 100 responses and by improvement in absolute PASI and Dermatology Life Quality Index (DLQI) scores. Drug survival of brodalumab treatment, causes of treatment discontinuation and adverse events were also reported.

Results: A total of 126 patients were included. Four weeks after treatment initiation, 83%, 57% and 29% of patients reached PASI 75, 90 and 100, respectively. These values increased to 96%, 93% and 66% at 74 weeks. A significant reduction in PASI score was observed after 4 weeks of brodalumab treatment and until week 74 ($p<0.001$). Quality of life measured by DLQI score significantly increased during the treatment period ($p<0.001$). Drug survival of brodalumab treatment was 82.5%, and secondary failure (8.5%) was the main reason for treatment discontinuation. The occurrence of adverse events was low and restricted to non-severe infectious.

Conclusion: This real-world data show that brodalumab is effective and safe for the treatment of moderate-to-severe psoriasis.

Keywords: biologics, brodalumab, IL-17 inhibitors, psoriasis, real-world data.

Citation

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Introduction

Psoriasis is a chronic, immune-mediated inflammatory disease that affects more than 40.8 million people worldwide, with an incidence of 4.6 new million cases in 2019.[1,2] In Portugal, studies indicate a prevalence rate of 4.4%, with a similar prevalence between both sexes.[3] Psoriasis can manifest in different phenotypes, with plaque-type psoriasis being the most common, and is associated with several comorbid diseases, including rheumatological, metabolic, cardiovascular and psychiatric conditions.[2] Furthermore, patients with psoriasis have a significant decrease in quality of life due to the physical and psychological burden of the disease.[4]

The pathogenesis of psoriasis involves chronic activation of both innate and adaptive immune systems and an increased release of pro-inflammatory cytokines by immune cells.[5] Amongst them, IL-17 is a key mediator of

psoriasis pathogenesis. IL-17 family includes six related cytokines, IL-17A to IL-17F, mainly produced by T helper type 17 (T_H17) cells, that act in its target cells through its corresponding receptor, the IL-17 receptor A (IL-17RA).[6] IL-17 promotes keratinocyte proliferation and the production of cytokines, chemokines and antimicrobial peptides leading to a positive feedback loop by stimulating the production of additional inflammatory cells and IL-17-producing cells.[7]

The understanding of the pathophysiology of psoriasis allowed the development of biological agents with promising results and favourable safe profiles.[6] Brodalumab is a recombinant, fully human, monoclonal antibody that blocks IL-17RA, preventing the signalling of diverse IL-17 cytokines.[8] Brodalumab was approved for the treatment of moderate-to-severe plaque psoriasis based on the results from pivotal clinical trials AMAGINE 1/2/3.[9,10] These were multicentre, randomized, double-blind phase III trials that established the efficacy and safety of brodalumab, including in patients who received previous biological therapy.[9,10]

The evaluation of real-world efficacy is of extreme importance, especially for chronic diseases that require a long period of treatment and for populations that are underrepresented in clinical trials. In Portugal, brodalumab has been available for clinical use since 2018 but real-world data about its efficacy and safety is lacking.[11] Therefore, this study aims to evaluate the efficacy and safety of brodalumab in a Portuguese real-world setting.

Methods

Participants and inclusion and exclusion criteria

This is a retrospective, observational, multicentric study involving five mainland Portuguese centres. Patients diagnosed with moderate-to-severe psoriasis and treated with brodalumab were identified from outpatient medical records or patient charts that support usual routine clinical practice from January 2019 to August 2022. Data were collected until the last follow-up or January 2023. The minimum follow-up period was 74 weeks. Data collection and handling complied with applicable laws, regulations and guidance regarding patient protection, including patient privacy. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Collected variables

The following variables were collected: demographic information, comorbidities, past therapies, Psoriasis Area Severity Index (PASI), Dermatology Life Quality Index (DLQI), adverse events and reasons for discontinuation.

Outcomes

To determine the therapeutic effectiveness of brodalumab in a real-world setting, the following outcomes were analysed: absolute PASI, DLQI, proportion of patients achieving PASI 75, PASI 90 and PASI 100 over 74 weeks of brodalumab treatment, and drug survival. The safety of brodalumab in a real-world setting was evaluated by collecting data regarding the adverse events registered during treatment, including those leading to drug discontinuation.

Statistical analysis

All categorical variables were expressed as numbers or percentages. All continuous variables were expressed using median and interquartile range (IQR) or mean and 95% CI. Between-group analysis was performed using the Mann–Whitney U test or the χ^2 test for continuous and discrete variables, respectively. Within-group analysis was performed using the related samples Wilcoxon test or the Friedman test with correction for multiplicity when appropriate. The log-rank test was used to compare Kaplan–Meier curves. Tests were considered significant at α=0.05 significance level (two-sided). SPSS v23 was used for statistical analyses.

Results

Participant characterization

A total of 126 patients from five Portuguese centres were included in this study. Table 1 describes the baseline characteristics of the total cohort. The mean age at baseline was 46 years, 64.3% of patients were men and the mean body max index (BMI) was 27.1. Disease duration was, on average, 17.8 years, ranging from 1 to 76 years. The mean PASI score was 18.6, body surface area was 24.2 and DLQI score was 16.9. At the beginning of brodalumab treatment, 24.6% of patients had psoriatic arthritis, 33.3% showed nail involvement and 47.4% scalp involvement. In terms of comorbidities, 30 (24.8%) patients had obesity (defined as a BMI ≥30), eight (6.3%) had diabetes and 26 (20.6%) had hypertension.

As shown in Table 1, six (4.8%) patients were naive to any systemic therapy, and 74 (58.7%) initiated brodalumab as the first biological treatment. The most frequent previous biological treatment was anti-TNF (23.8%), followed by anti-IL-12/IL-13 (22.2%) and anti-IL-17A (16.6%).

Efficacy outcomes

Brodalumab showed early clinical effectiveness, with 83% of patients achieving PASI 75, 57% PASI 90 and 29% PASI 100 at week 4 after treatment initiation. By week 12, 89% of patients achieved a PASI 75 response, 83% a PASI

Table 1. Baseline characteristics of the study population.

Characteristics	Patients (*n*=126)
Age	
Mean, years	46
95% CI	43.5–48.6
Sex	
Female (%)	45 (35.7)
Male (%)	81 (64.3)
BMI	
Mean	27.1
95% CI	26.1–28.1
Disease duration	
Mean, years	17.8
95% CI	15.5–20.1
PASI score	
Mean	18.6
95% CI	16.7–20.4
BSA (%)	
Mean	24.2
95% CI	20.7–27.7
DLQI	
Mean	16.9
95% CI	15.7–18.1
PsA (%)	31 (24.6)
Nail involvement (%)	39 (33.3)
Scalp involvement	55 (47.4)
Comorbidities (%)	
Obesity	30 (24.8)
Hypertension	26 (20.6)
Diabetes	8 (6.3)
Dyslipidaemia	30 (23.8)
Previous retinoids (%)	41 (32.5)
Previous phototherapy (%)	26 (20.6)
Previous systemic therapy	
Systemic therapy naive (%)	6 (4.8)
Methotrexate (%)	79 (62.7)
Previous biologic treatment	
Biologic naive (%)	74 (58.7)
Anti-TNF (%)	
Adalimumab	14 (11.1)
Etanercept	11 (8.7)
Infliximab	5 (4.0)
Anti-IL-12/IL-23 (%)	
Ustekinumab	28 (22.2)
Anti-IL-23 (%)	
Guselkumab	4 (3.2)
Risankizumab	2 (1.6)
Anti-IL-17A (%)	
Ixekizumab	8 (6.3)
Secukinumab	13 (10.3)

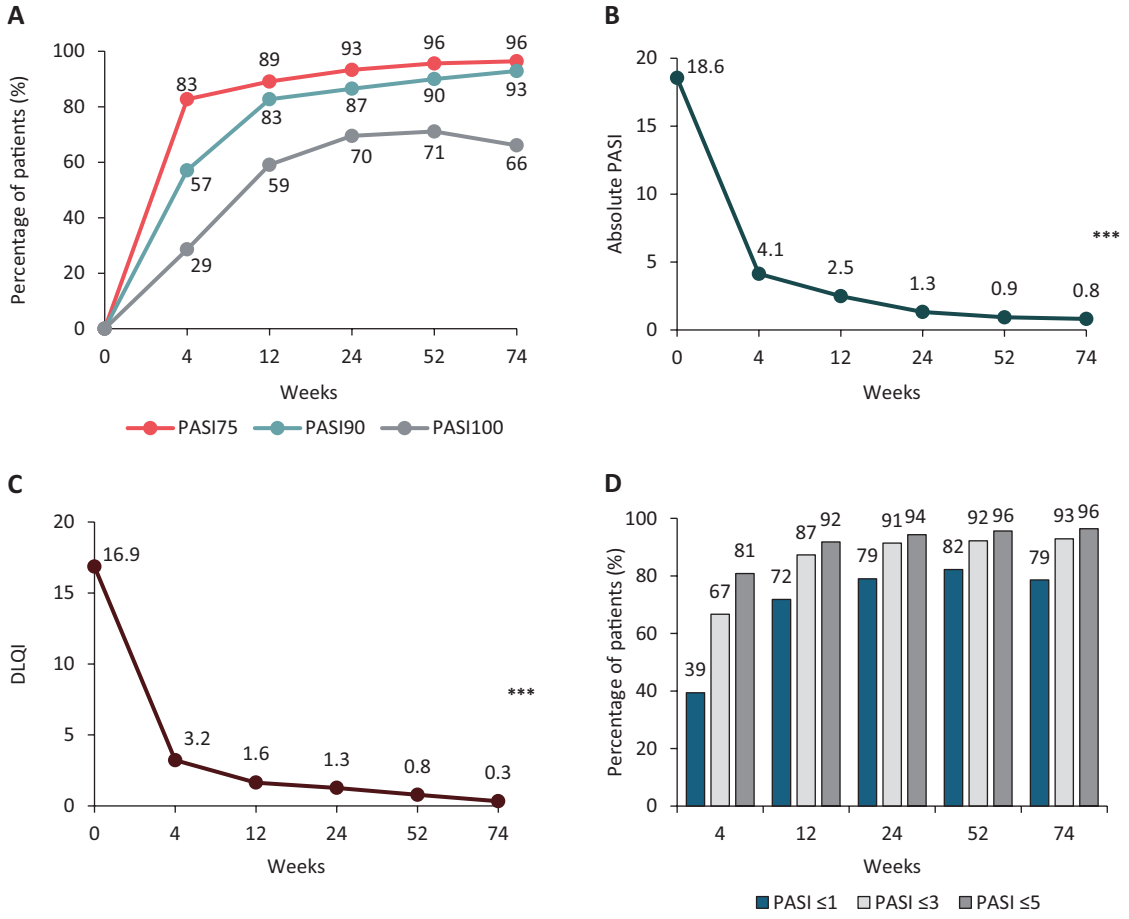
BMI, body max index; BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index; PsA, psoriatic arthritis.

90 and 59% a PASI 100 (Figure 1A). An absolute PASI ≤1 was achieved by 72% of patients at this time point (Figure 1D). At week 74, at 96%, 93% and 66% achieved a PASI 75, 90 and 100 responses, respectively, and 79%, 93% and 96% of patients achieved an absolute PASI ≤1, ≤3 and ≤5, respectively (Figure 1A,D).

A significant decrease in PASI score was observed over time from week 4 until week 74 ($p<0.001$). Mean PASI was reduced from 18.6 at baseline to 4.1 at 4 weeks, 1.3 at 12 weeks and 0.8 at 74 weeks (Figure 1B). The mean PASI score was significantly higher in patients who received previous biological treatment when compared with biological-naive patients at weeks 4 (4.5 *versus* 3.9; $p=0.008$) and 52 (1.3 *versus* 0.7; $p=0.037$) after treatment initiation (Supplementary Figure 1A; available at: https://www.drugsincontext.com/wp-content/uploads/2025/03/dic.2024-11-4-Suppl.pdf). Mean PASI was also superior in patients with obesity compared with patients without obesity at baseline (21.8 *versus* 17.6; $p=0.033$) and at weeks four (9.1 *versus* 2.4; $p=0.034$) and 12 (7.8 *versus* 1.4; $p=0.016$) after beginning of brodalumab treatment (Supplementary Figure 1B). No significant differences in mean PASI score were found between patients with difficult-site involvement (nails and scalp) and those without such lesions (Supplementary Figure 1E).

Four weeks after treatment initiation with brodalumab, mean DLQI showed a significant reduction from 16.9 (baseline) to 3.2 ($p<0.001$). DLQI remained consistently low over the study period (Figure 1C). Additionally, 78.7% of patients reached a DLQI of either 0 or 1 during the study period. Mean DLQI was significantly lower in biological-naive patients when compared with patients who

Figure 1. Clinical efficacy of brodalumab treatment throughout 74 weeks. A. Percentage of patients that achieved PASI 75, PASI 90 and PASI 100 responses during study time. B. Improvement in PASI score over time. A statistically significant improvement in PASI score was observed at all time points (4, 12, 24, 52 and 74 weeks) when compared with baseline PASI (*$p<0.001$, related samples Friedman's two-way test). C. Changes in DLQI score during the study period. A statistically significant improvement in DLQI was observed at all time points (4, 12, 24, 52 and 74 weeks) when compared with baseline DLQI (***$p<0.001$, related samples Friedman's two-way test). D. Percentage of patients achieving an absolute PASI score of ≤1, ≤3 and ≤5 at studied time points (4, 12, 24, 52 and 74 weeks). Statistically significant differences were observed for the percentage of patients achieving PASI ≤1, PASI ≤3 and PASI ≤5 across different time points ($p<0.001$, $p<0.001$ and **$p=0.002$, respectively, related samples Cochran's Q test). DLQI, Dermatology Life Quality Index. PASI, Psoriasis Area Severity Index.**



received previous biological therapy (2.4 *versus* 4.5; $p=0.018$) at 4 weeks of treatment (Supplementary Figure 1C). DLQI was also significantly different between patients with or without obesity at weeks 4 (2.1 *versus* 3.9; $p=0.015$) and 12 (1.2 *versus* 3.7; $p=0.005$) of brodalumab treatment (Supplementary Figure 1D).

Drug survival

Drug survival of brodalumab treatment was 82.5% at week 74 with 17.5% of patients having discontinued treatment (Figure 2). No significant differences were found between biologic-naive and biologic-experienced patients nor between patients with or without obesity (Supplementary Figure 2). Secondary failure (8.5%) was the main reason for treatment discontinuation, followed by primary failure (4.8%), patient decision (4.4%) and safety events (0.8%) (Table 2). At the end of follow-up, 97 patients remained on brodalumab treatment.

Lower values of body surface area and DLQI at baseline were significantly associated with increased discontinuation of brodalumab ($p=0.046$ and $p=0.016$, respectively). Regarding previous therapy, only treatment with anti-IL-23 (including both anti-IL-12/IL-23 and anti-IL-23) was significantly associated with treatment discontinuation ($p=0.033$; Table 3).

Safety outcomes

During the 74 weeks of the study, the occurrence of adverse events was low. The incidence of infections was 7.9%, including four cases of candida infection (3.2%) and one case of herpes zoster (0.8%) (Table 4). None

Figure 2. Kaplan–Mayer of brodalumab overall drug survival. Drug survival was 82.5% at week 74. All causes for treatment discontinuation were included.

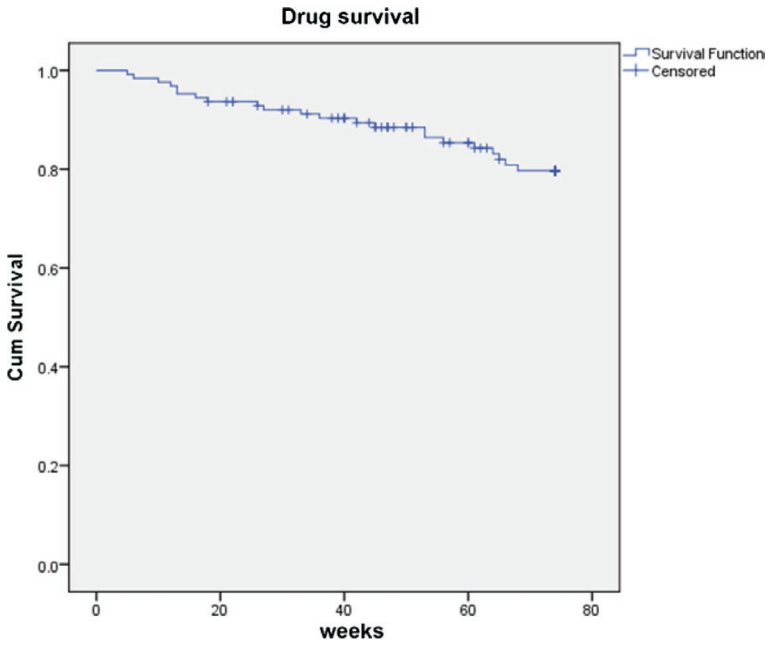


Table 2. Reasons for brodalumab treatment discontinuation.

Reasons for discontinuation	Patients (*n*=126)
Primary failure, *n* (%)	6 (4.8)
Secondary failure, *n* (%)	9 (8.5)
Patient decision, *n* (%)	2 (4.4)
Safety, *n* (%)	1 (0.8)

Table 3. Association of previous therapy with discontinuation of brodalumab treatment.

Previous therapy		Patients (*n*=126)	Statistics[a]
Systemic therapy naive	Yes	6	1.000
	No	120	
Biologic naive	Yes	74	0.081
	No	52	
Previous anti-TNF therapy	Yes	27	0.567
	No	99	
Previous anti-IL-23 therapy	Yes	33	0.033*
	No	93	
Previous IL-17A therapy	Yes	17	0.078
	No	109	

For previous therapy, only one biological in each class was considered. For anti-IL-23 therapy, both anti-IL-12/23 and anti-IL-23 were considered.
[a]Statistical analysis for categorical variables was performed using χ^2 test.
*p<0.05.

of these infections resulted in hospitalization of the patients. Only two cases of eczema were registered during the study period. No cases of cancer, major adverse cardiovascular events, inflammatory bowel disease, depression or suicide/suicidal ideation were registered in this cohort.

Discussion

In this study, brodalumab showed a rapid and sustained effect in the treatment of psoriasis. The time required to reach a significant response and improvement in psoriasis disease is of extreme importance.[12] Four weeks after treatment initiation, PASI 75, PASI 90 and PASI 100 response rates were 83%, 57% and 29%, and increased up to 89%, 83% and 59% at week 12. Our results are in accordance with AMAGINE 1/2/3 clinical trials that reported a PASI 75 response rate between 83% and 86% at 12 weeks after treatment initiation.[9,10] Nevertheless, our results indicated

Table 4. Safety summary of brodalumab treatment.

Adverse event	Patients (*n*=126)
Infection	10 (7.9)
Candida	4 (3.2)
Herpes Zoster	1 (0.8)
Serious	0
Cancer	0
Major adverse cardiovascular event	0
Inflammatory bowel disease	0
Depression	0

Values are expressed as number of adverse events and its percentage in parentheses.

higher rates of PASI 100 responses, with 59% of patients reaching this endpoint at week 12, compared with 37–44% reported in AMAGINE trials.[9,10] However, there are differences in baseline characteristics between the mentioned clinical trials and our cohort that could have influenced these results. The baseline PASI score was higher in clinical trials, and the percentage of patients with no previous systemic therapy and no previous biological treatment was also superior in AMAGINE trials.[9,10] These results were supported by the absolute PASI score, which significantly decreased from an average of 18.6 at baseline to 4.1 in only 4 weeks after treatment initiation and to 2.5 after 12 weeks of treatment. The rapid efficacy of brodalumab can be attributed to its mechanism of action that targets multiple IL-17 isoforms, in contrast to other anti-IL-17 biologicals that target only a specific isoform (IL-17A).[13]

Our results show superior responses to brodalumab treatment compared to other retrospective real-world data studies.[14–16] In an Italian multicentre retrospective cohort, 83% of patients reached PASI 75, 64% PASI 90 and 49% PASI 100 after 12 weeks of brodalumab treatment.[15] In a retrospective study from Greece, at the same time point, 62% of patients achieved PASI 75, 34% PASI 90, and 23% PASI 100.[16] These differences can be in part due to the different percentages of biological-naive patients enrolled in each study, with ours having a higher percentage. Nevertheless, results more similar to ours were obtained by other studies, with comparable or even lower percentages of biological-naive patients.[17,18] For instance, a single-centre study from Denmark reported that 58% of patients reached PASI 100 and 74% PASI 90 after 12–17 weeks of treatment, in a population of only 9.6% of biological-naive patients.[17] More recently, Kojanova et al. also showed that 95%, 87% and 70% of patients reached PASI 75, PASI 90 and PASI 100, respectively, 1 year after brodalumab treatment initiation.[18]

Achieving an absolute PASI ≤1 was previously considered an ideal treatment goal, whilst achieving an absolute PASI ≤3 is a realistic treatment goal.[19] In our study, at the end of follow-up, 79% of patients achieved an absolute PASI ≤1, whilst 93% and 96% achieved a PASI ≤3 and ≤5, respectively. Similar findings were reported in a recent real-world data study from the Czech Republic, with 95% of patients achieving an absolute PASI ≤3 at 18 months of follow-up.[18]

The long-term efficacy of psoriatic drugs is an important consideration that may have a positive impact on patients' quality of life.[20] Regarding sustained skin clearance over time, our results show that brodalumab effectiveness remained consistent up to week 74. The highest percentage of patients achieving PASI 100 was at 52 weeks after treatment initiation, with 71% of patients experiencing complete skin clearance. At the end of the follow-up period, 66% of patients maintained PASI 100. In AMAGINE trials, brodalumab responses were sustained in most patients up to week 52 and, in extension trials, PASI responses remained stable until week 120.[9,10,20,21] The long-term efficacy of brodalumab can be related to its immunogenicity profile since the production of neutralizing antibodies is one mechanism that contributes to the loss of efficacy of biologicals.[13] Accordingly, in our study, drug survival was 82.5% at 74 weeks of treatment. Drug survival is considered an indicator of a good and durable response and a good safety profile.[22] Previous real-world data studies reported a shorter drug survival of brodalumab.[12] Nevertheless, higher drug survival rates were found in previous real-world data studies, including 78.8% at 96 weeks[16] and 66.2% at 156 weeks[23] of brodalumab treatment.

Switching between biologicals is a frequent scenario in the treatment of patients with moderate-to-severe psoriasis due to an inadequate primary response, secondary failure or adverse events.[24] In our cohort, the mean PASI score was significantly higher in patients who received previous biological therapies compared with patients with no prior exposure. Better responses to brodalumab treatment were also found in biological-naive patients in previous studies.[15,16] Furthermore, increased treatment suspension was associated with prior anti-IL-23 therapies but not with previous anti-IL-17 or anti-TNF. This might indicate that patients who received previous anti-IL-23 therapy may have a lower response to brodalumab. Data regarding interclass switching to anti-IL-17 after anti-IL-23 are still very limited. However, in a small study of seven patients who switched to anti-IL-17 after anti-IL-23 failure,

five patients achieved PASI 100 after 16 weeks of treatment.[25] Recently, Papp et al. reported high responses to brodalumab in patients with a previous failure to another biological agent.[26] Patients who switched from IL-23 inhibitors showed similar response rates to those who switched from another class of biological.[26] Furthermore, in a pooled analysis from AMAGINE 2/3 trials, patients who switched to brodalumab after an inadequate response to ustekinumab (anti-IL-12/IL-23) showed high rates of PASI 90 and PASI 100 and were superior to those who switch to guselkumab (anti-IL-23).[27] Therefore, future studies are important to determine the efficacy of brodalumab treatment after switching from previous biologicals.

In our study, mean PASI was also superior in patients with obesity at baseline and until week 12 after treatment initiation. Obesity is known to increase the risk of developing psoriasis and can influence response to therapy.[28] Our results support that patients with obesity have worse disease control before initiating brodalumab treatment and that this difference is only annulled at 24 weeks of brodalumab treatment. Although previous studies reported similar outcomes,[15,28] the efficacy of brodalumab did not differ in patients within other cohorts.[28] Psoriatic lesions can occur in areas of the body that are classified as difficult to treat, such as nails, palms, soles, scalp and genitalia, negatively affecting patients' quality of life.[29] In our cohort, brodalumab showed efficacy regardless of difficult-to-treat area involvement. This is particularly relevant since lesions in these areas are challenging to treat and usually resistant to topical therapies, requiring systemic drugs.[29] Previous studies showed the efficacy of brodalumab in patients with difficult-to-treat lesions, including post hoc analysis from the AMAGINE 1 clinical trial.[15,30] Accordingly, in a 52-week observational study, Cacciapuoti et al. found a significant reduction in PASI, psoriasis scalp severity index, palmoplantar PASI and DLQI from baseline since week 24 in patients with difficult area involvement.[31]

The reduction in PASI score was accompanied by significant reductions in DLQI. Psoriasis has a negative impact on the health-related quality of life of patients,[32] which is supported by our data, with a mean baseline DLQI score of 16.9. Therefore, the ability of biologics to improve the self-reported quality of life, as measured by DLQI, is of extreme importance in this context.[33] Improvement in DLQI scores was also observed in other retrospective studies and polled data analysis from AMAGINE trials.[16,33] According to our results, the reduction of DLQI scores was slower in patients who received previous biological therapy and in those with obesity. Nevertheless, in this sub-group analysis, patients still achieved a significant reduction in DLQI score.

Our results show that brodalumab has a good safety profile. Only ten cases of infection were registered, including four due to candida and one to herpes zoster. In fact, infection is one of the main causes of biologic treatment discontinuation and a commonly reported adverse event of brodalumab treatment.[21,34,35] The fact that brodalumab targets IL-17, which is involved in protective immunity, namely in preventing and controlling *Candida* spp. infections, justifies these observations.[36] Eczema is one of the most common cutaneous adverse events of IL-17 pathway inhibition, including brodalumab.[37] A recent study found a numerically highest incidence of eczema in patients exposed to IL-17 inhibitors compared with exposure to IL-12/IL-23, IL-23 and TNF inhibitors, with no statistical significance.[38] In our study, only two cases of eczema were registered and none led to treatment discontinuation. No cases of depression or suicide/suicidal ideation were registered in our study. During phase III clinical trials of brodalumab, three cases of suicide were listed, and brodalumab treatment was associated with depression and increased risk of suicide.[39] However, later studies did not find casual associations between brodalumab treatment and increased risk of suicide.[21,40]

Our study has limitations, namely the retrospective design did not allow the retrieval of data for all patients, namely PASI and DLQI scores for all time points. Furthermore, this study included a relatively small number of patients with a follow-up until 74 weeks. Further real-world data studies with larger patient cohorts and a longer follow-up period would be important to definitively assess the efficiency and safety of brodalumab, namely in certain populations.

Conclusion

In this study, we conducted a retrospective multicentre analysis of real-world data on the efficacy and safety of brodalumab in a cohort of 126 Portuguese patients with psoriasis. Brodalumab treatment demonstrated rapid clinical responses and maintained long-term efficacy over 74 weeks. The results were supported by a high rate of drug survival that was not influenced by patient characteristics. The efficacy of brodalumab was also reflected in patient-reported quality of life, with significant reductions in DLQI score observed as early as 4 weeks after treatment initiation. Furthermore, only a few adverse events were registered and restricted to non-severe infections during the follow-up period, suggesting that brodalumab treatment is a tolerable and safe biological therapy.

Supplementary material available at: https://www.drugsincontext.com/wp-content/uploads/2025/03/dic.2024-11-4-Suppl.pdf

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