Correspondence

Brodalumab: short-term effectiveness and safety in real clinical practice

Dear Editor,

Psoriasis is a chronic and recurrent inflammatory skin disease that affects 2.3% of the population in Spain.[1] The last drug regarding anti-IL17 family to join our therapeutic arsenal has been Brodalumab. Brodalumab is a recombinant monoclonal antibody (IgG2) that binds with high affinity to human IL-17 receptor A and blocks the biological activity of IL-17A, IL-17F, and IL-25 proinflammatory cytokines. It has been approved in the European Union (EU)[2] for the treatment of moderate to severe psoriasis in adults who are candidates for systemic treatment. Its mechanism of action is focused on the inhibition of the A receptor of IL-17 as opposed to the other anti-IL17 drugs. Discontinuation of treatment should be considered if no response has been demonstrated after 12–16 weeks of treatment, although some patients with a partial response at baseline may subsequently improve with continued treatment beyond 16 weeks.

Table 1 Sociodemographic Data

Age (years)	53 (35–75)
Sex	
Male	11 (78.6%)
Female	3 (21.4%)
Time onset (years)	17.8 (7–35)
Weight (kg)	89.8 (64–113)
Height (cm)	169.8 (155–183)
BMI (kg/m^2)	31.6 (21.4–47)
Comorbidities	
Psoriatic arthritis (5)	35.7%
Diabetes (3)	21.4%
Hypertension (2)	14.3%
Dyslipidemia (4)	28.6%
Depression (2)	14.3%
Nonalcoholic fatty liver (1)	7.1%
Previous biological treatments	
Naïve	3 (21.4%)
1 line	4 (28.6%)
2 lines	5 (35.7%)
4 lines	2 (14.3%)

A total of 14 patients were included, 11 men (78.6%) and three women (21.4%), with an average age of 53 years and average time of evolution of their psoriasis of 17.8 years. Our study population had a high body mass index (BMI = 31.6 kg/m^2). Among the comorbidities, the presence of psoriatic arthropathy was highlighted (35.7%), although they also showed dyslipidemia (28.6%), diabetes (21.4%), arterial hypertension (14.3%), depression (14.3%), and nonalcoholic fatty liver (7.1%). Table 1 summarizes the demographic characteristics of our patients.

Regarding PASI values, our patient series showed a mean baseline PASI of 14.3, which evolved to an average PASI = 7.2 at week 4, PASI = 3.4 at week 8, and PASI = 0.6 at 12 weeks (n = 14), with 85.3% of patients presenting with an absolute PASI $\leq$ 2 in week 12, with all patients being clear (absolute PASI 0) in week 24 (n = 7). In parallel, an improvement in body surface area (BSA) was observed, starting from an average of 16.57%, which was 1% at week 12, to be completely clean in week 24. In addition, we could observe an improvement in the quality of life, measured by Dermatology life quality index (DLQI), with a

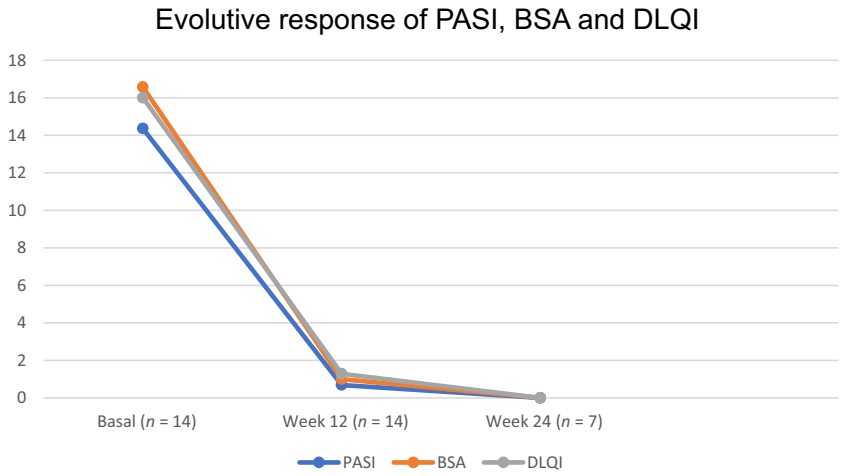

Figure 1 Evolutive response of PASI, BSA, and DLQI

decrease in the score from 16 at baseline to 1.29 in week 12 and 0 in week 24. Figure 1 shows the evolution of the values of PASI, BSA, and DLQI of our series. No neutropenia, candidiasis, inflammatory bowel disease, flu-like symptoms, or behavioral disturbances could be stated till date.

Efficacy and safety of brodalumab was evaluated in three phase III, multicenter, randomized, double-blind, placebo-controlled clinical trials (AMAGINE-1, AMAGINE-2, and AMAGINE-3).[3,4]

Brodalumab showed a PASI 75 response at 12 weeks of 83–86%, higher than that achieved with placebo (3–7%). About 76–79% of patients achieved a response of 0 or 1 (whitening or minimal involvement) in the sPGA compared to 1–4% with placebo. Brodalumab 210 mg was higher than ustekinumab in the percentage of patients who reached PASI 100 at week 12 (AMAGINE-2: 44 vs. 22% $P \leq 0.001$).

From the safety point of view, the most commonly reported adverse effects were arthralgia, (4.6%), headache (4.3%), fatigue (2.6%), diarrhea (2.2%), and oropharyngeal discomfort (2.1%) without serious adverse effects in comparison with other therapeutic lines.

Recent meta-analyses[5] show that IL-17, IL-12/23, and IL-23 inhibitors had high efficacy in the achievement of PASI 75, PASI 100, and sPGA 0/1 after 12 or 16 weeks of treatment. IL-17 inhibitors showed superior efficacy. However, its clinical safety has been considered poor. We have not found this safety data in short-term follow-up in our patient series.

Brodalumab shows excellent results in the control of psoriasis in the short term with a good safety profile. It remains pending to assess whether it maintains the results of efficacy and safety in real clinical practice in the medium and long term, with statistically significant differences in relation to other anti-IL17 drugs because of its different mechanism of action.

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