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A cohort study of obese patients with moderate-to-severe psoriasis using biological medicines in Catalonia, Spain

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Conflict of interest: the authors declare that they have no competing interests.

Ethics approval and consent to participate: this study was approved by the Comité de Ética de la Investigación con medicamentos (CEIm) of the Vall d'Hebron University Hospital in Barcelona on November 11, 2022. It has been carried out in accordance with the principles of the Declaration of Helsinki and according to current legal regulations (Real Decreto 957/2020). All information obtained in the study has been treated confidentially, in compliance with the *Ley Orgánica de Protección de Datos de Carácter Personal* LOPD 3/2018. Patient consent was waived.

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Abstract

Obesity impacts both the clinical management and therapeutic strategies for psoriasis. This study aims to describe the use of biological medicines in treating obese patients with moderate-to-severe psoriasis. We conducted a retrospective cohort study (2007-2022) of obese patients who initiated biological treatments for moderate-severe psoriasis. The primary outcome was the number of biological treatment lines required to achieve an optimal or adequate Psoriasis Area and Severity Index (PASI) score reduction. Secondary outcomes included the duration of biological use and reasons for discontinuation. We included 58 patients (mean age 50 years, body mass index [BMI] 35.9 kg/m^2, psoriasis duration 16.5 years). Biological treatments enabled 77.6% (45) of patients to achieve an optimal response, and 87.9% (51) achieved an adequate response. The median time-to-response was 2-7 months, with the greatest improvements seen with adalimumab, etanercept, and ustekinumab. The primary reason for discontinuation was lack of effectiveness (50% of first-line treatments). This study suggests that systemic biologics are effective for obese psoriasis patients and emphasizes the need for close monitoring of reasons that lead to discontinuation. As biologics evolve, refining guidelines will be essential for optimizing psoriasis management in obese patients.

Introduction

Psoriasis is a chronic inflammatory skin disease managed by reducing the affected body surface, controlling symptoms, and improving quality of life.[1] Treatment response has traditionally been established as Psoriasis Area Severity Index (PASI) <5, although current guidelines recommend a target of <3.[2] Moderate-to-severe psoriasis is characterized by a PASI, body surface area (BSA), or Dermatology Life Quality Index (DLQI) score exceeding 10. In patients who fail to achieve adequate disease control with, or are intolerant to, topical or conventional first-line therapies, biologic treatments are recommended.[3] By 2022, 12 biological agents indicated for psoriasis were authorized in Spain, with no specific preferences or recommendations for their use due to a lack of comparative evidence (*Supplementary Table 1*).[2,4]

Psoriasis is frequently associated with metabolic disorders, including obesity, potentially due to increased systemic inflammation induced by adipose tissue. However, the direction of this association remains unclear.[5,6] Obesity may predispose individuals to psoriasis and worsen disease severity, increasing the risk by up to 2.7-fold compared with lean individuals.[3,5] It has also been associated with poorer treatment responses. Conversely, psoriasis itself may contribute to the development of obesity, a condition that affects 21.6% of the Spanish population.[1,6-8] Additionally, obesity is further associated with higher treatment costs and discontinuation rates due to perceived decreased efficacy.[5,9]

In our setting, 21% of psoriasis patients treated with biological drugs are obese,[6] yet evidence in this subpopulation is limited.[9,10] For instance, obese patients are 36% less likely to receive biological treatments compared to those with a body mass index (BMI) of 25-30.[9] Therefore, we aim to describe the use, effectiveness, and reasons for discontinuation of biological medicines in obese patients with moderate-to-severe psoriasis.

Materials and Methods

Study design and population

A retrospective cohort study from July 15, 2007, to December 31, 2022, was conducted. We included adult obese patients with moderate-to-severe psoriasis at Vall d'Hebron University Hospital (VHUH), a tertiary-level hospital in Catalonia, receiving patients from its area of influence to initiate systemic medication for psoriasis. Patients had to be naïve to biological therapy with a BMI ≥30 kg/m^2, who had progressed to conventional systemic treatments without contraindications to starting a biological medicine. Cases were excluded if either the PASI or BMI was missing at the cohort entry date. The index date was defined as the start date of the first biological treatment. Follow-up continued until the earliest occurrence of loss to follow-up, death, or the end of the study period.

Exposures of interest were biological medicines commercialized in Spain and approved for psoriasis (*Supplementary Table 1*). The start of a new active principle meant a new treatment line/episode. We did not consider any overlap, washout, or grace period.

Main and secondary endpoints

Main endpoints were to describe the number of biological treatment lines needed to achieve a PASI <3 (optimal clinical response) and PASI <5 (adequate response), and to detail the reduction of the initial PASI for each active principle at weeks 12±4, 24±4 and at discontinuation for each treatment line. Secondary endpoints included general characteristics of the patients, the duration of use of each biological drug, the number of lines of treatment, and the reasons for discontinuation, categorized as lack of effectiveness (primary non-response or secondary loss of effectiveness over time after an initial response), psoriasis improvement, adverse events, loss to follow-up, patients' decision, death, intercurrent disease preventing biological use, and other reasons.

Covariates

Age, sex (defined as the gender assigned at birth), weight, height, and BMI were collected at the index date visit and during follow-up. Comorbidities were selected at baseline because of their known associations with obesity, psoriasis disease, or biological medication use.[8] We also recorded years of

evolution of psoriasis disease, and conventional systemic therapies used before starting the biological treatment. Lastly, the concomitant use of methotrexate during the biological treatment was assessed.

Data source

Patients were identified from the registry of those with psoriasis treated in the Outpatient Clinics of the Dermatology Department of VHUH. A record is triggered by having a medical visit in the Dermatology Department and is hosted inside the medical charts system. A RedCap® form was developed to systematically extract study information.

Statistical analysis and data management

Standard descriptive statistics were calculated. PASI was reported as absolute numbers and differences between various follow-up time points. Outcomes were stratified by sex, treatment line, and medicine. Patients without at least one follow-up PASI were excluded from the calculation. All analyses were carried out with RStudio (v4.3.1). Data completeness, reliability, and clinical plausibility were assessed before analysis. Missing data were addressed by consulting treating dermatologists; if unavailable, no imputation was performed, and missingness was assumed.

Results

General characteristics

We included 58 patients contributing 390.1 person-years. Each patient had received at least two conventional systemic therapies before starting biological treatment, including methotrexate (84.5%), acitretin (36.4%), and phototherapy (36.4%), among others. Nearly 45% had hypertension and dyslipidemia, and women were twice as likely as men to experience anxiety or depression (Table 1). Weight change during follow-up ranged from −18 to +10 kg for males using tumor necrosis factor (TNF)α inhibitors and −13 to +26 kg for interleukin (IL) antagonists; for females, it was −13 to +39 kg and −42 to +9 kg for TNFα inhibitors and IL antagonists, respectively.

Treatment lines and duration of exposure

The median number of treatment lines was 2 [range: 1-5]. Only 15.5% (9 patients) required over three treatment lines (*Supplementary Figure 1*). The median time of exposure to any biological treatment was 80 months [range: 1-194], which was slightly higher for subjects who achieved a PASI <3 (88 months [range: 12-194]). Notably, 77.6% (45 patients) achieved an optimal clinical response, and 91.1% (51 patients) achieved an adequate response (Table 2).

Biological medicines

Regardless of the treatment line, the most commonly used biological medicines were ustekinumab (32, 26.0%), adalimumab (31, 25.2%), secukinumab (18, 14.6%), and etanercept (17, 13.8%) (*Supplementary Table 2*). Only five patients received concomitant methotrexate. Adalimumab emerged as the most common first-line therapy, followed by etanercept and ustekinumab. For second-line therapy, adalimumab and ustekinumab remained, while etanercept was replaced by secukinumab. Nevertheless, IL-12/23 and IL-17 inhibitors persisted more across lines compared to TNFα inhibitors (*Supplementary Table 2* and *Supplementary Figure 1*). It should be noted that patients did not necessarily switch to a biological one with a different mechanism of action than the previous one.

Treatment response: PASI score

Supplementary Figures 2-4 illustrate the PASI evolution overall, by biological medicine, treatment line, and therapeutic target. The most significant drops were observed with etanercept (-15 mean points) and adalimumab (−17 points) as fourth-line, secukinumab (−12.5 points) as first-line, and infliximab (−12 points) as second-line treatment during the early weeks of treatment. Generally, most treatments showed consistent improvement during the early weeks of use, but psoriasis worsened for some treatments between weeks 12 and 24, particularly in the second and fourth lines. Notably, no intensification strategies (increased dose or shortening of dosing intervals) were employed to enhance therapeutic outcomes.

Reasons for discontinuation

Most first-line biological medicines were discontinued (39/58;67.2%) due to lack of secondary (24/39;61.5%) or primary (5/39;12.8%) effectiveness. This trend continued throughout the treatment lines. Unrelated to the medication, one patient died while receiving etanercept (Table 3). Of the 4 treatments withdrawn or changed due to intercurrent disease, one case was due to melanoma, one case to pustular psoriasis, and two cases to neoplastic disease.

Discussion

Biological drugs helped 77.6% of patients with moderate-to-severe psoriasis and obesity to achieve an optimal clinical response and 87.9% an adequate response. The median time to response was 2-7 months, with the greatest PASI reductions observed by week 12±4 for etanercept and adalimumab. Discontinuation was mainly due to a lack of secondary effectiveness. These findings provide further insight into treatment options for this subpopulation and suggest that patients with obesity may respond to biologicals similarly to the general population.[2]

Demographic characteristics were consistent with prior studies regarding depression, psoriatic arthritis, and sex distribution.[1,2,11] However, higher rates of cardiovascular comorbidities and increased BMI were observed, likely reflecting the hospital-based nature of the obese cohort.[11,12] Latent tuberculosis prevalence (~25%) aligned with Spanish epidemiology.[13] All patients had failed at least two conventional therapies before starting biological treatments, reflecting local guidelines,[2,4] resulting in a higher prior exposure to methotrexate, cyclosporin, or acitretin compared to previous literature.[11]

Biological medicines have broadened options for patients with psoriasis and are considered safer long-term options.[12,14] Despite concerns about reduced efficacy in obesity,[10,15] our study found that ustekinumab and secukinumab showed the greatest PASI reductions, consistent with earlier publications.[9,16,17] IL-12/23 antagonists and TNFα inhibitors, particularly adalimumab, were most commonly used, while infliximab use was limited, as it has to be administered at the hospital.[16] We showed 3-fold higher use of ustekinumab and 2-fold of etanercept. This might be explained by etanercept being one of the earliest commercialized biologicals, and ustekinumab offering weight-based dosing[9,17] and lower risk of discontinuation.[18]

Newer agents (guselkumab, ixekizumab, risankizumab) were typically used in later treatment lines,[4,16] reflecting increasing availability of new alternatives and the commercialization of biosimilars.[4] But we cannot generalize about which biological treatment is preferred, since secukinumab was not marketed until 2015, and more recent treatments may prove to be more effective.[9,12] Recently, successful therapy with tildrakizumab has been reported in an obese patient.[19] Similar outcomes have been observed in other studies involving the general population,[16,20] albeit with the use of intensified posology.[21] No consistent switching pattern between biologicals was identified, and patients could progress to an active principle either of the same or a different mechanism of action, highlighting the need for clearer guidance as long-term data become available.[14]

We assessed treatment response at 12 and 24 weeks, following the Catalan Harmonization Program (PHF).[2] While initial PASI scores aligned with previous findings, infliximab showed a higher PASI at week 12 compared to previous literature (10 *vs.* 3 PASI),[20] likely owing to greater disease severity or its use as a second-line treatment. Medications typically used first-line showed the most significant PASI improvement because of a higher starting score. Notably, response rates exceeded the Catalan PHF's reported ranges (28.8-91.0% and 10.7-75.3%, respectively),[2] supporting biological treatments' effectiveness in obese patients despite head-to-head studies being lacking.[9,17]

The primary reason for discontinuation was lack of secondary effectiveness (61.5% in first-line treatments); this corresponds with findings in the general population in our setting (67.2%).[2] Adverse events led to discontinuation in <7% of patients despite exposure for up to more than 7 years, and so

did similar studies.[14,16]

Strengths and limitations

One of the key strengths of our study is its specific focus on the use of biological medicines in obese patients with psoriasis, a population often addressed only in sub-analyses.[9,14] Generating evidence in this group is essential to support clinical decision-making, particularly given the risk of poorer treatment outcomes described in previous studies.[5,6] Furthermore, the use of in-hospital electronic medical records, updated on a daily basis by healthcare professionals, provides reliable real-world data. As a tertiary reference center for psoriasis requiring systemic therapies, we offer an extensive follow-up period of over 10 years, which exceeds that of current publications,[13] allowing a comprehensive assessment of patient outcomes and discontinuation patterns. Lastly, our findings are derived from routine clinical practice and direct patient information, eliminating the need for imputation or other statistical adjustments.

This study has some limitations. First, it is a single-center study with a limited sample size, although conducted in a reference tertiary-level hospital. Second, medication dosages and biosimilars were not differentiated. However, their effectiveness and safety are expected to be comparable, holding the same active principle. Third, weight changes varied widely and could not be attributed to biologics, as multiple confounders (*e.g.*, smoking cessation, bariatric surgery, glucagon-like peptide-1 inhibitors) were present, warranting cautious interpretation.[17,22] Fourth, missing follow-up PASI scores required consultation with treating dermatologists to enhance completeness. Fifth, PASI might not be the best evolution estimator for certain types of psoriasis, such as pustular psoriasis, although only one case was included. Finally, long-standing cases close to the electronic medical record implementation (in 2008) may have incomplete data due to prior manual records.

Conclusions

Our study highlights the effectiveness of systemic biological medicines in obese patients with moderate-to-severe psoriasis who have exhausted conventional treatments. It found that these patients can achieve optimal clinical responses, similar to the general population, within 2 to 7 months. The primary reason for discontinuation was the lack of secondary effectiveness, underscoring the importance of close monitoring.[14] The study also emphasizes the diversity in biological therapy choices and suggests that therapy should be individualized. As more data become available, it will be crucial to refine treatment guidelines and strategies to optimize the management of psoriasis, considering weight.

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Table 1. Demographic characteristics at baseline overall and stratified by sex assigned at birth.

	Total	Male	Female
General demographic information (median [range])			
Gender, n (%)	58 (100)	34 (58.6)	24 (41.4)
Age (years)	50 [20-79]	47 [20-75]	55.5 [21-79]
Weight (kg)	100 [69-130]	105 [90-130]	90 [69-130]
Height (cm)	169.5 [143-183]	173.5 [160-183]	157.5 [143-180]
BMI (kg/m^2)	35.9 [30.5-47.8]	35.64 [30.8-45.0]	36.24 [30.5-47.8]
Characteristics relating to psoriasis disease (median [range])			
PASI score at start	15 [3-50]	15 [4-35]	13 [3-50]
Years of psoriasis	16.5 [2-65]	17.5 [4-55]	15.5 [2-65]
Comorbidities (n, %)			
Anxiety/depression	12 (20.7)	5 (14.7)	7 (29.1)
Arterial hypertension	26 (44.9)	13 (38.2)	13 (54.2)
Autoimmune disease*	4 (6.9)	1 (2.9)	3 (12.5)
Diabetes mellitus type 2	18 (31.0)	9 (26.5)	9 (37.5)
Dyslipaemia	25 (43.1)	12 (35.3)	13 (54.2)
Hepatic B virus	2 (3.5)	2 (5.9)	0 (0)
Hepatic C virus	0 (0)	0 (0)	0 (0)
Human immunodeficiency virus	0 (0)	0 (0)	0 (0)
Psoriasic arthritis	10 (17.2)	4 (11.8)	6 (25.0)
Tuberculosis (latent)	14 (24.1)	9 (26.5)	5 (20.8)

BMI, body mass index; PASI, Psoriasis Area and Severity Index; *autoimmune diseases included amyloidosis, autoimmune thyroiditis, and systemic lupus.

Table 2. Number and proportion of patients achieving PASI <3 and PASI <5 for the first time during follow-up, and median time (months) to achievement, according to treatment line, regardless of the biologic therapy used.

	Number of patients meeting PASI <3, n (%)	**Time to PASI <3 (median months [range])**	**Number of patients meeting PASI <5, n (%)**	**Time to PASI <5 (median months [range])**
First line	33 (73.3)	5 [1-42]	43 (84.3)	3 [1-35]
Second line	5 (11.1)	2 [1-7]	4 (7.8)	3 [1-4]
Third line	5 (11.1)	4 [1-7]	3 (5.9)	3 [3-4]
Fourth line	2 (4.5)	4.5 [2-7]	1 (2)	7 [7]
Total	45 (100)	0 [0]	51 (100)	0 [0]

PASI, Psoriasis Area and Severity Index.

Table 3. Number and proportion of reasons for discontinuation or change of biological medicine by line.

		First line n (%)	**Second line n (%)**	**Third line n (%)**	**Fourth line n (%)**
Discontinue	Lack of primary effectiveness	5 (8.6)	4 (11.4)	3 (15.0)	1 (11.1)
	Lack of secondary effectiveness	24 (41.4)	15 (42.9)	7 (35.0)	1 (11.1)
	Adverse events	3 (5.2)	0 (0)	0 (0)	0 (0)
	Loss of follow-up	2 (3.4)	2 (5.7)	0 (0)	0 (0)
	Patient decision	0 (0)	0 (0)	0 (0)	0 (0)
	Intercurrent disease	2 (3.4)	1 (2.9)	1 (5.0)	0 (0)
	Significant improvement in psoriasis	1 (1.7)	0 (0)	0 (0)	0 (0)
	Death	1 (1.7)	0 (0)	0 (0)	0 (0)
	Others*	1 (1.7)	1 (2.9)	0 (0)	0 (0)
Not discontinue		19 (32.8)	12 (34.3)	9 (45.0)	7 (77.8)
Total		**58 (100)**	**35 (100)**	**20 (100)**	**9 (100)**

*Reasons for discontinuation not specified.

Online supplementary material:

Supplementary Figure 1. *Switching patient pathways by biological medicine and treatment line.*

Supplementary Figure 2. *PASI score evolution overall by biological.*

Supplementary Figure 3. *PASI score evolution by biological medicine and line of treatment.*

Supplementary Figure 4. *PASI score evolution by biological, stratified by therapeutic target.*

Supplementary Table 1. *Anatomical Therapeutic Chemical code classification of biological medicines with the first year of marketing in Spain and the year of approval for psoriasis by the European Medicines Agency.*

Supplementary Table 2. *Number and proportion of patients who receive each type of biological medicine used by line and total.*