





Retrospective study of apremilast drug survival in psoriasis patients in a daily practice setting: A long-term experience

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Abstract

There is limited evidence about the real-world survival of apremilast in patients with psoriasis, especially over the long term. To evaluate the long-term survival of apremilast and its predictive factors when used to treat psoriasis. A retrospective hospital-based study, including data collected from 104 patients. Survival curves were estimated using the Kaplan–Meier estimator. Proportional hazard Cox regression models were used for multivariate analysis. The average duration of the treatment before discontinuation was 28.82 months (95% CI, 22.08–35.57 months) and the median was 12 months (95% CI, 2.68–21.31 months). The retention rates were 51% (1 year), and 33% (5 years). The survival study revealed statistically significant differences between patients with PASI < 10 and those in the PASI ≥ 10 group (log-rank test, $p < 0.001$). The 5-year prevalences were 64% for patients with a PASI of < 10 and 5% for those with an index ≥ 10. In the PASI < 10-patient group, the retention rates were 77% (1 year) and 64% (5 years). Furthermore, 66% of patients who continued apremilast treatment for more than 2 years were receiving off-label doses (30 mg/day). Apremilast may be a suitable and efficient alternative for the treatment of psoriasis patients in the PASI < 10 group.

KEYWORDS

apremilast, drug survival, PASI, psoriasis

1 | INTRODUCTION

Apremilast, an oral phosphodiesterase-4 inhibitor, has immunomodulatory activity which partially blocks the expression of proinflammatory cytokines and induces the expression of anti-inflammatory cytokines that have a pathogenic role in psoriasis.¹ It is especially useful for patients in whom the use of biologic drugs it to be avoided (e.g., those with cancer, latent tuberculosis infection, or infective hepatitis). However, little is known about the drug survival associated with apremilast, in the real world, especially in the long term.^{2–19} Moreover, there is also a variability in the term survival of Apremilast (APR) and its predictive factors for the treatment of psoriasis. The objectives of this retrospective study were to determine survival of the APR and to study the

factors that predict discontinuation in patients diagnosed with plaque psoriasis.

2 | MATERIALS AND METHODS

2.1 | Study design, patients, and data collection

We retrospectively reviewed medical records of patients who were treated with apremilast at the Department of Dermatology in Hospital Universitario Central de Asturias from March 1, 2016 to November 30, 2021. Drug efficacy was evaluated on November 30, 2021.

A total of 104 patients who were prescribed with at least one dose of apremilast and had at least one follow-up visit were included.

We previously reported the experience of 48 patients¹⁵ and this report includes these 44 patients. Patients included received non-concomitant systemic therapy or phototherapy. Three patients who received a combination of apremilast and phototherapy are excluded. Data were obtained from each patient's clinical history. Apremilast was administered at labeled dosage for psoriasis and psoriatic arthritis (induction phase followed by 30 mg twice daily). After 2 years in patients with stabilized disease we try to deintensify the treatment to 30 mg daily. The study was approved by the Ethics and Research Committee of the Principality of Asturias, Spain (Number 2021-568).

Statistical analyses were performed with IBM SPSS version 27.0 (IBM, Armonk, NY, USA). Data are presented as mean \pm standard

deviation for continuous variables, and number and percentage for categorical variables. The chi-square test was used for qualitative variables. Survival curves were approximated through the Kaplan–Meier estimator and compared using the long-rank test. Proportional hazard Cox regression models were used for multivariate analyses while both unadjusted and adjusted hazard ratios (HR) were used for summarizing the studied differences. 95% confidence intervals (95%CI) are also provided. The proportionality of the risks was previously checked through the Schoenfeld residual.

We selected the following variables as possible predictors: sex, age of onset of psoriasis, family history, obesity, arthritis, previous use of biologics, arterial hypertension, and dyslipidemia. Group differences were considered to be statistically significant for values of $p < 0.05$.

Final sample size allows to declare significant (Type I error of 0.05) with a probability of 0.2 (Type II error) those hazard ratio above 1.75, difference in proportions above 25% and standardized differences of means above 0.5.

TABLE 1 Baseline characteristics of patients ($n = 104$)

Patient characteristic	Value
Sex (male), n (%)	62 (59.6%)
Mean age (years) at start of biologic treatment \pm mean (SD)	56.21 \pm 13.58
Positive family history of psoriasis (yes), n (%)	60 (57.7%)
Onset before 40 years of age (%)	39 (37.5%)
Duration of treatment (months); mean \pm SD; median	28.82 \pm (6.75); 12
Mean initial PASI score \pm SD	11.57 \pm 5.69
Age < 40 years at start of therapy	10 (9.6%)
Comorbidities, n (%)	
Obesity (BMI \geq 30)	42 (40.4%)
Diabetes mellitus	27 (26.0%)
Arterial hypertension	40 (38.5%)
Dyslipidemia	61 (58.7%)
Arthritis	47(45.2%)
Number of previous biologic treatments (%)	
One	7 (6.7%)
Two	8 (7.7%)
Three	4 (3.8%)
Four	2 (1.9%)
Five	1 (1.0%)

3 | RESULTS

3.1 | Patients' characteristics

The study included 104 patients (Table 1). The sample comprised equal numbers of men and women, a predominance of psoriasis patients with a family history, and early psoriasis onset. A considerable proportion had concomitant arthritis and comorbidities.

3.2 | Drug survival

Overall, 46.2% (48/104), and 42 of 56 patients with a Psoriasis Area and Severity Index (PASI) of <10, remained on apremilast, their treatment durations ranging from 60 to 2085 days. At the end of the study 32 of 48 patients (66%) were off-label dosage (30 mg daily).

In our cohort, the retention rates were 51% (1 year), 36% (2 years), and 33% (5 years), and the mean survival was 28.82 months (95% CI, 22.08 to 35.57 months) and the median was 12 months (95% CI, 2.68 to 21.31 months) (Figure 1A). Log-rank tests revealed no

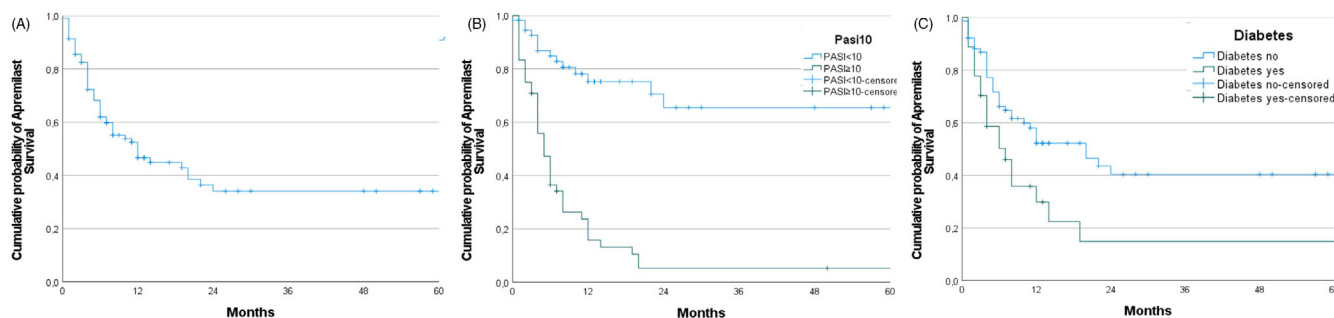


FIGURE 1 (A) Kaplan–Meier curve of apremilast survival. (B) Kaplan–Meier curves of apremilast survival according to PASI < 10 ($p < 0.001$). (C) Kaplan–Meier curves of apremilast survival according to diabetes status ($p = 0.014$)

significant differences in drug survival in relation to the presence of arterial hypertension ($p = 0.186$), dyslipidemia ($p = 0.208$), member of family with history of psoriasis ($p = 0.737$), age of onset of psoriasis of 40 or more years ($p = 0.159$), obesity ($p = 0.074$), arthritis ($p = 0.906$), previous treatment with biologics ($p = 0.263$), or sex ($p = 0.536$). There were significant differences between the two PASI groups ($p < 0.001$) (Figure 1B) and between the presence or absence of diabetes ($p = 0.014$) (Figure 1C). The probability of remaining on the treatment after 5 years of follow-up was significantly higher in patients with PASI < 10 (64% vs. 5%; $p < 0.001$). In the PASI < 10 group the mean duration was 48.8 months (95% CI, 39.7–58.0 months), and in the PASI ≥ 10 group was 9.3 months (95% CI, 5.2–13.5 months) (Figure 1B). In our cohort, the retention rates were 24% (1 year), 5% (2 years), and 5% (5 years) in the PASI ≥ 10 patient group and 77% (1 year), 69% (2 years), and 64% (5 years) in the PASI < 10 group. We

also observed that 66% of patients who continued apremilast treatment after 2 years were receiving off-label doses (30 mg/day).

3.3 | Univariate and multivariate analysis

Univariate analyses revealed statistically significant differences in the hazard ratios of the risk of apremilast discontinuation between groups with respect to the presence of diabetes and the two PASI groups, and a positive correlation between the risk and PASI when treated as a continuous variable (Table 2). The univariate analysis of factors related to apremilast survival showed it to be greater in the PASI ≥ 10 than in the PASI < 10 group (HR 5.993, 95% CI 3.227–11.130; $p < 0.001$), and in those with, rather than without, diabetes (HR 1.945, 95% CI 1.113–3.397; $p = 0.019$). In the multivariate model, only the PASI group retained its statistical significance.

TABLE 2 Cox regression analysis

Univariate analyses	p	HR (95% CI)
Psoriasis onset at ≥ 40 years	0.174	0.677 (0.385–1.189)
Sex (male)	0.550	0.847 (0.493–1.458)
Obesity (BMI ≥ 30)	0.087	1.590 (0.935–2.702)
Arthritis: yes	0.909	0.970 (0.571–1.646)
Arterial hypertension: yes	0.203	1.415 (0.830–2.412)
Dyslipidemia: yes	0.225	1.404 (0.811–2.427)
Family history: yes	0.745	1.093 (0.641–1.862)
Non-naïve patients	0.280	1.400 (0.761–2.576)
PASI (continuous variable)	<0.001	1.114 (1.075–1.155)
Diabetes: yes	0.019	1.945 (1.113–3.397)
PASI ≥ 10	<0.001	5.993 (3.227–11.130)
<i>Multivariate analysis</i>		
PASI ≥ 10	<0.001	5.631 (3.006–10.548)
Diabetes: yes	0.263	1.380 (0.785–2.426)

Note: Hazard ratios of risk of apremilast discontinuation. Bold indicates statistically significant differences.

3.4 | Characteristics of PASI < 10 and PASI ≥ 10 patient groups

Compared with patients in the PASI ≥ 10 group, the PASI < 10 patients were older (mean age 59.79 ± 12.75 years vs. 52.04 ± 13.45 years; $p = 0.003$), were more likely to have no family history of psoriasis (51.8% vs. 31.3%; $p = 0.035$), and to have late onset of psoriasis (50.0% vs. 22.9%; $p = 0.004$). There were no differences between the two patient groups with respect to any of the other variables (Table 3).

3.5 | Patients who discontinue treatment

At the end of the study, 48 of the 104 patients in the study (46.2%) were still pursuing their treatment (Table 4). The reasons for the other 56 patients not continuing with their treatment were primary failure (13.5%), secondary failure (12.5%), adverse events (17.3%), psoriatic arthritis inefficacy (4.8%), and others (5.4%). Analyzing the reason for

TABLE 3 Characteristics of patients regarding PASI ≥ 10

	PASI < 10 (56)	≥ 10 (48)	p
Age	59.79 ± 12.75	52.04 ± 13.45	0.003
Male/Female, n (%)	32 (57.1)/24 (42.9)	30 (62.5)/18 (37.5)	0.579
Family history, no/yes, n (%)	29 (51.8)/27 (48.2)	15 (31.3)/33 (68.8)	0.035
Early/late onset, n (%)	28(50)/28 (50)	37 (77.1)/11 (22.9)	0.004
Evolution time \pm SD	19.3 ± 15.0	23.5 ± 15.7	0.349
Naïve Yes/No, n (%)	47 (83.9)/9 (16.1)	35 (72.9)/13 (27.1)	0.170
Obesity (BMI ≥ 30 , no/yes, n (%))	34 (60.7)/22 (39.3)	28 (58.3)/42 (40.4)	0.805
BMI mean \pm SD	28.09 ± 5.38	28.68 ± 4.63	0.146
Dyslipidaemia, no/yes, n (%)	23 (41.1)/33 (58.9)	20 (41.7)/28 (58.3)	0.951
Diabetes mellitus, no/yes, n (%)	43 (76.8)/13 (23.2)	34 (70.8)/14 (29.2)	=0.490
Arterial hypertension, no/yes, n (%)	35 (62.5)/21 (37.5)	29 (60.4)/19 (39.6)	=0.828
Arthritis, no/yes, n (%)	28 (50)/28 (50)	29 (60.4)/19 (39.6)	=0.287

Bold indicates statistically significant differences.

TABLE 4 Patients who discontinued and reasons for apremilast discontinuation

Discontinuations	56 (100%)	PASI < 10 (13)	PASI ≥ 10 (43)	p
Adverse events	18 (32.1%)	6	12	0.054
Primary failure	14 (25%)	1	13	<0.001
Secondary loss of efficacy	13 (23.2%)	1	12	<0.001
Arthritis inefficacy or joint pain	5 (8.9%)	1	4	0.119
Pancreas adenocarcinoma	1 (1.8%)	1		
Spleen lymphoma	1(1.8%)	1		
Death (progression of esophagus and tongue carcinoma)	2(3.6%)	0	2	
Dermatomyositis	1(1.8%)	1		
Patient request (complete remission)	1(1.8%)	1		

Note: The number of patients's group PASI<10 are 56 and patient's group PASI≥10 are 48.

treatment discontinuation by PASI group revealed differences in the proportions of discontinuation due to primary failure, and secondary loss of efficacy. The magnitude of the differences in the proportions of adverse events between the groups was not significant ($p = 0.054$) because of the small number of patients.

4 | DISCUSSION

Survival data provide valuable information and can influence our choice of therapeutic regimen.¹⁸

The mean age of our cohort (56.2 years) was similar to that in other apremilast studies,^{10,12,14,16} but older than in our ustekinumab,²⁰ adalimumab,²¹ and secukinumab series,²²

One-year survival in our study (51%) was toward the higher end of the range of other studies, being surpassed by retrospective observational studies from Austria (57.3%),² Spain (54.9%),¹² and Japan (53.4%).¹² Our present results are quite different from our previous results with apremilast.¹⁵ This difference may be ascribed to the fact that in our cohort the PASI≥10 group comprised 29 out of the 48 patients (60.4%) and since April 2018, the PASI≥10 patient group comprised 19 of the 56 patients included (33.9%) (chi-square = 7.29, $p = 0.007$).

Our analysis indicates that apremilast is not influenced by most patient- or disease-related factors. We found that patients in the PASI≥10 group had a higher risk of discontinuing apremilast than those in the corresponding group. These differences have not been noted in previous studies^{6,8,10,18} but may have become evident because our study had a high percentage of patients in the PASI<10 group (53.8%). When considered as a continuous variable, PASI increased by a factor of 1.1 per unit probability of a patient discontinuing treatment.

The main reasons for drug discontinuation in our analysis were side effects (32.1%), primary treatment failure (25%), secondary loss of efficacy (23.2%). While the observed rates of primary and secondary treatment failure are in the range of previously published results, the range of drug discontinuation due to side effects is similar to Graier results² and higher to other studies (5.1%–26.9%).^{6,10,12,14,16,18,23–25}

Primary treatment failure and secondary loss of efficacy were more frequent in baseline PASI ≥ 10 group. Adverse events are more frequent

in baseline PASI ≥ 10 group but did not reach a statistically significant ($p = 0.054$) probably due to a small sample size (beta-type error).

Our results underlined a good profile of efficacy and safety of apremilast, it is also stated in elderly patients requiring systemic treatment for moderate-to-severe psoriasis.²⁶

A recent study showed that 39% of patients who began treatment with biologics had a PASI of <10 at initiation.²⁷ In our cohort, the retention rates in the PASI<10 patient group were the highest in the literature, and 66% of patients were receiving off-label doses (30 mg/day) after 2 years, with the reduction in dose having no effect on patients' clinical response. Dose-adjustment strategy in real-world dermatological practice is not deleterious to the efficacy outcomes of long-term responder patients.^{21,28} Although its degree of efficacy is not comparable to that of biologics, apremilast can be a safe choice for the patients with a PASI of <10. This is supported by Del Alcazar et al, who concluded that apremilast may be an alternative for treating moderate psoriasis, with a PASI score of around 10.¹⁰

5 | LIMITATIONS OF THE STUDY

The study has several limitations: it is observational in nature; the selection of treatment for each patient was not randomized; patients were still receiving their treatment on the lock date, which might have altered the frequency of drug survival; and concomitant topical treatment was not considered.

AUTHOR CONTRIBUTIONS

Cristina Galache-Osuna, Francisco Vázquez-López, and Jorge Santos-Juanes contributed to study conception, design, writing and editing. Sebastián Reyes-García contributed to material preparation and review the text. Esther Salgueiro, Javier Bordallo-Landa and Ana Lozano contributed to formal analysis and investigation. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

Jorge Santos-Juanes has been member of board committee and have received speaker's fee from Abbvie, Janssen, Amgen, Novartis, Lilly and Sanofi. Cristina Galache-Osuna has received speaker's fee from Sanofi.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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