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THERAPEUTIC FAILURE IN MODERATE AND SEVERE PSORIASIS PATIENTS IN A HEALTH INSTITUTION – A TRANSVERSAL STUDY OF PREVALENCE AND DEMOGRAPHIC DETERMINANTS

Therapeutic Failure in moderate and severe psoriasis patients

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ABSTRACT

Background: Psoriasis is a chronic disease that seriously impacts quality of life. There are known genetic and environmental factors that influence its onset and progression. Even though there is no cure for it, there are a variety of treatments available today to control its symptoms, although many of them fail to do so substantially.

Objective: to identify the association of multiple sociodemographic, clinical, and pharmacological factors with therapeutic failure.

Methods: observational, descriptive, cross-sectional, retrospective, and analytical study of therapeutic failure in patients with moderate or severe psoriasis between 2020 and 2021 was performed.

Results: In total 1051 patients with moderate or severe psoriasis were evaluated. Gender (ORa: 0.579 CI95%: 0.382 – 0.878), type of therapy (biologic or non-biologic; ORa: 1.939 CI95%: 1.242 – 3.027), age (ORa: 1.018 CI95%: 1.003 – 1.034), days of treatment (ORa: 1 CI95%: 0.999 - 1) and DLQI (ORa: 1.212 CI95%: 1.172 – 1.253) are significantly associated with therapeutic failure.

Conclusion: Being male and receiving biologic therapy are associated with a higher incidence of therapeutic failure in the treatment of moderate or severe psoriasis. The increase in DLQI increase in the probability of failure, and mayor age or days of treatment decrease in the probability of failure.

KEYWORDS: psoriasis, therapeutic failure, Dermatology Life Quality Index, Psoriasis Area and Severity Index, treatment.

INTRODUCTION

According to the World Health Organization, psoriasis is a chronic, non-transmissible, painful, disfiguring, and disabling disease, for which there is no cure, and which generates enormous negative impacts on the quality of life of patients who suffer from it (1).

It is characterized by the excessive proliferation of keratinocytes, which are the main cells that compose the epidermis, the outermost layer of the skin (1). The reason why this occurs is still uncertain, although there is evidence of genetic predisposition to the pathology (2,3). It is also hypothesized that there is an autoimmune component, implying that the proliferation of keratinocytes could be a response to the activation of the immune system by T lymphocytes in focal cutaneous regions. However, no single auto-antigen has yet been confirmed to be responsible for such activation (3). External and internal triggers, such as mild trauma, sunburn, infections, systemic use of some medications, and stress, are also believed to exist (4).

Psoriasis can occur at any age and is most common in the age group between 50 and 69 years (5). The reported prevalence of psoriasis by country ranges from 0.1% to 11.4% (6,7). In Colombia, although whole population data is not available, studies have estimated a prevalence of 3.0% among patients who consult for dermatology, making it quite a serious problem for the country's health systems and the different entities involved (8).

The treatment of psoriasis is still based on symptom control. There are topical and systemic therapies available for this, which in practice are usually applied in combination. Such treatment is usually lifelong, and the goal (therapeutic success)

is remission, not cure. Despite their proven effectiveness, skin clearance using only these "conventional" treatments is difficult to achieve and requires the combination of multiple targeted therapies and systemic agents, with a significant risk of cumulative toxicity (9).

Currently, among the treatments available are also biologic therapies, which include monoclonal antibodies such as Adalimumab (10). Their effectiveness for the treatment of psoriasis has been widely demonstrated, as well as the advantages they have over other treatments, achieving a high proportion of patients with excellent control of symptoms.

However, their costs are high, and it has been found that more than 50.0% of patients receiving biologic treatment need dose optimization during therapy and that 20.0% to 50.0% of patients experience disease relapse and require a switch to another drug, or even discontinue therapy altogether (11,12). The reasons for this are complex and varied, but among the risk factors suspected of this type of therapeutic failure to occur are the female gender, obesity, and history of use of other biologic therapies (1). However, the individual predictive power of each of these factors proved to be low in a cross-sectional study (13).

In this same study, a series of machine learning-based predictive models were also built to measure the probability of treatment failure for moderate and severe psoriasis, some of which achieved up to 82.0% accuracy. To create them, a small number of variables were used, including measurements such as the Dermatology Life Quality Index (DLQI) and Psoriasis Area Severity Index (PASI), as well as sociodemographic and clinical variables. Through an input optimization analysis, it was established that the profile of a patient with the best probabilities of long-term

biologic treatment success corresponds to one with no history of biologic therapy use, younger than 49 years, weighting less than 100 kg, with an early-onset plaque psoriasis phenotype and no psoriatic arthritis (13).

In another longitudinal study focused exclusively on biologic therapies, eight factors associated with reduced odds of achieving ≥ 90% improvement in PASI (PASI 90) at 6 months were identified (described as odds ratio and 95% confidence intervals): demographic (female sex, ORa: 0.78, CI95%: 0.66 - 0.93); social (unemployment, ORa: 0.67, CI95%: 0.45 - 0.99); unemployment due to ill health (ORa: 0.62, CI95%: 0.48 -0.82); smoking (ORa: 0.79, CI95%: 0.63 - 0.99); previous history of smoking (ORa: 0.81, CI95%: 0.66 - 0.99); clinical factors (high weight, ORa: 0.99, CI95%: 0.99 - 0.99); psoriasis of the palms and/or soles (ORa: 0.75, CI95%: 0 61 - 0 91); and presence of only small plaques, compared with presence of small and large plaques (ORa: 0.78, CI95%: 0.62-0.96). White ethnicity (ORa: 1.48, CI95%: 1.12-1.97) and higher baseline PASI (ORa: 1.04, CI95%: 1.03-1.04) were associated with higher odds of achieving PASI 90 (14). The findings were largely consistent at 12 months. There was little evidence that differential treatment (including the use of biologic therapies) was an important predictor of success.

Therapeutic decision making for patients undergoing psoriasis therapy, either non-biologic or biologic, is still largely based on trial and error. Likewise, intervention is usually limited to reinforcing adherence to the treatment by conventional means of patient monitoring such as telephone alerts, failing many times to address the main cause of non-adherence.

In this study, the aim is to obtain a deeper insight into psoriasis and the factors associated with therapeutic failure, which could hopefully guide health providers and physicians in their decision-making process to effectively treat this disease, improving patient Quality of Life.

METHODS

Type of study

Cross-sectional; since failure was determined from the most recent PASI available for each patient, observational; given that in terms of cause-effect relationship, the researchers were limited to observing the occurrence of the outcome given an exposure, without intervention in the causal pathway, retrospective; since the outcome was extracted from available data, and analytical; given the statistical scope and epidemiological measures calculated.

This study addresses the causal principles of biologic plausibility: through the determination of variables that explain therapeutic failure adjusted for confounders; and of consistency: given that the study can be performed with data or patients with similar exposure profiles. Since the object of study does not allow for experimentation, the causal principles of dose-response relationship, specificity and experimental evidence were not addressed (15).

Study population

The study population consists of 1051 records of moderate or severe psoriasis patients from the CLIPSO (Integral Psoriasis Clinic) of the Colombian health provider institution +helPharma, representing the universe from 2018 onwards.

Inclusion and exclusion criteria

From the total of 2280 patients, all records presenting moderate or severe psoriasis and at least two PASI measurements were included, representing about half of the initial population (n=1051).

Sample design

Considering that a census of the patients was carried out, it is not necessary to describe the type of sampling, type of sample selection, or calculation of the sample size.

Dependent variable

Therapeutic outcome was used as the dependent variable or response, which was obtained from the PASI quantitative response, with a scale from 0 to 100. The two PASI measurements available for each patient were used. Therapeutic success was considered when the value of the second measurement was less than 5, or when there was a reduction of at least 50% compared to the first measurement (PASI50); and failure when neither of these two conditions was met. Similar criteria based on PASI have been used before to establish therapeutic failure (14).

Independent variables

The initial dashboard had a total of 231 variables. The information was extensively cleaned and filtered; discarding variables with no relevance (such as some fields used exclusively for internal management by the health provider), no predictive power (i.e. categorical variables with only 1 category), or with excess missing data (>30%), leaving a total of 27 independent variables, excluding dates.

The remaining variables were: treatment adherence, gender, marital status, region, age, depression, anxiety, psoriatic arthritis, diabetes, dyslipidaemia, hypertension, current medication, current therapy, number of medications, DLQI (first and second measurement), effect of DLQI on patient's life (first and second measurement), change in DLQI between measurements, HRQoL (Health-Related Quality of Life; first and second measurement), range of last HRQoL, waist circumference, waist circumference range, CVR (cardiovascular risk) for excess weight, and risk associated with waist circumference.

Sources of information

The information was extracted from the CLIPSO program's skin immune-mediated diseases dashboard.

Information gathering process

A request was made to the information analyst at +helPharma for all the available information in the CLIPSO dashboard; once all the data was provided, the database was extracted, cleaned, and consolidated for subsequent analyses. The consolidation of the information was carried out with the assistance of the thematic expert and the information analyst.

Control of selection and information biases

The study did not incur selection biases, since 100% of the available records were included. Information bias was controlled through a multivariate analysis of the available data, from which adjusted Odds-ratios and coefficients were extracted.

Imputation

Some of the missing data (when <30%) was imputed to prevent issues in the analyses. For this procedure, a K nearest neighbours approach (KNNImpute) with

k=5 was used (16). The data was checked afterwards, and hypothesis testing confirmed that its distribution hadn't changed significantly due to the imputation process (17,18).

Analysis plan

The analysis plan was divided in three main steps: univariate analyses, bivariate analyses against therapeutic outcome, and multivariate analyses. These three steps were conducted using the scikit-learn and stats models Python libraries (19,20). An alpha of 0.05 was selected to determine statistical significance.

For the univariate analyses, absolute and relative category counts were performed for each of the qualitative variables, and measures of central tendency were obtained for the quantitative ones.

For the bivariate analyses the reference category (r) was chosen for each qualitative variable, based on previous clinical knowledge. Chi-square tests were performed, and crude Odds Ratios (ORc) corresponding to each category against r were obtained, with their respective p-values, degrees of freedom, and confidence intervals. To study the association of quantitative variables with therapeutic failure, a series of simple logistic regression models were constructed (incorporating only one independent and one dependent variable), from which the z-statistic and crude Odds ratios were obtained, with their respective p-values and confidence intervals.

Variables (either quantitative or qualitative) that had a p-value lower than 0.25 in the bivariate tests were included in a multivariate logistic regression model, from which adjusted Odds Ratios (ORa) were obtained.

Ethical approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and local research ethics guidelines. The study was approved by the health provider institution scientific and research committee.

RESULTS

Univariate analyses

In the table 1 shows analyses of categorical variables, the prevalence of failure was 16.6% (n= 174), 48.5% (n= 510) of the patients were women, and 83.77% (n= 967) lived in the Aburrá Valley.

Regarding clinical and pharmacological variables, 47.6% (n= 551) of the patients reported having at least one of the following comorbidities: psoriatic arthritis, hypertension, dyslipidaemia, diabetes, anxiety, and depression; 6.5% (n= 68) of patients were found to be nonadherent to therapy, while 79.5% (n= 836) were adherent. Around 39.9% (n= 419) of patients were receiving some type of biologic therapy for the disease, while 60.1% (n= 601) are receiving non-biologic ones.

The mean age was 51 years with a variation above and below 16 years. The minimum age was 6 years, and the maximum age was 90 years. The mean score of the first PASI measurement was 6.39 ±7.36, and of the second was 3.04 ± 4.36. For the DLQI, which ranges from 0 to 30, the mean score was 4.44 ± 5.69. Measures of central tendency for other quantitative variables can be found in table 2.

Bivariate analyses for categorical variables

According to the bivariate statistics presented in table 3 and table 4, a higher (albeit non-significant) proportion of patients exhibiting failure were female than male. Being male decreased the odds of presenting the outcome by 33%, compared to the probability of females (ORc: 0.67 CI95%: 0.48 - 0.93).

The region in which the patients were located showed a statistically significant association with failure: about 12% of the patients with therapeutic failure lived outside the Aburrá Valley, whereas 92% of the successful patients lived there. Living outside the Aburrá Valley increased the odds of presenting therapeutic failure by 77% (ORc: 1.77 CI95%: 1.05 - 2.99), without considering other variables.

In terms of comorbidities, 43.7% of the patients with therapeutic failure had some comorbidity, compared to 54.2% of those with success.Having a comorbidity acted as a protective factor against failure, reducing its odds by 34% (ORc: 0.66 CI95%: 0.47 - 0.91). Regarding clinical and pharmacological variables, non-adherence acted as a risk factor for therapeutic failure, increasing its odds by 56% (ORc: 1.56 CI95%: 0.88 - 2.75), although such association is not statistically significant.

Lastly, biologic therapy acted as a risk factor that significantly increased the odds of failure compared to non-biologic therapies (ORc: 2.65 CI95%: 1.81 - 3.87).

Bivariate analyses for quantitative variables

The number of medications, DLQI and days between start of treatment and therapeutic outcome showed a statistically significant association with outcome. Increases in DLQI meant an increase in the odds of failure. On the other hand, an increase in the number of medications seemed to decrease them. The number of

days between treatment and outcome, although showing a significant association, represented only a marginal increase in the odds of failure per day.

Multivariate analyses

The findings in the adjusted model (pseudo-R-squared = 0.2468) show that the factors that influence the probability of presenting therapeutic failure are gender, type of therapy, age, days between start of treatment and outcome, and DLQI. All these associations were statistically significant.

When adjusting these variables for the other confounders, it becomes clear that the crude (i.e., bivariate) models underestimated the association of therapeutic failure with gender, and very slightly of the days of treatment and of DLQI.

The direction of association changed for age, meaning that the bivariate models, by not considering other confounding factors, were giving a misleading picture of their contribution to failure. In this model, unlike the bivariate model, it is evident that an increase in age also involves an increase in the odds of failure (table 5).

DISCUSSION

In the present population, an incidence of failure of 16.6% was observed. It is important to consider that the therapeutic goal PASI50 selected for this study is not a main measure used to establish therapeutic success or failure; in fact, expert panels have recently suggested that stricter thresholds can be used to assess treatment success (21). However, the thresholds selected for this study allow objective realistic goals to treatment decisions/modifications and assessment of patient improvement after treatment with association between treatment success and quality-of-life metrics such as DLQI.

For the literature review, reports of instances of failure in heterogenous populations were considered, as no previous reports of therapeutic failure observing different psoriasis treatments were found.

The obtained multivariate logistic regression model successfully explains 24.68% of the variation found in the data. The determinants of therapeutic failure incorporated into the model, from most to least significant, were: DLQI, type of therapy, gender, and days between start of treatment and outcome.

DLQI seems to have the most straightforward association with therapeutic failure, with an increase on it representing a corresponding increase in the odds of failure. This is to be expected, as similarly to the dependent variable PASI, it measures the quality of life of the patient in terms of the impact that the disease has on it, with a bigger score indicating a higher affectation (22).

Undergoing biologic therapy as opposed to non-biologic (topical, systemic, etc.) increases the odds of therapeutic failure, although biologic therapy seems generally to be much more effective in treating this disease (10,13,23). This could be, however, because biologic therapy is usually one of the last options of treatment given to a patient, after other more conventional means have proven ineffective at addressing psoriasis. It would therefore be no surprise if the most aggressive cases of psoriasis, and therefore those most likely to fail, are the ones that are being treated with biologics.

Being female has previously been reported as a factor associated with therapeutic failure for biologic therapies (14), and this study seems to corroborate these findings. The reason why this happens cannot be established only from the

analyses presented here, but previous studies have attributed treatment discontinuation in this group mainly to adverse events (24).

Lastly, and perhaps unsurprisingly, length of treatment duration seems to be negatively associated with therapeutic failure. The longer the treatment lasts, the easier it seemingly is to keep psoriasis symptoms under control, to the extent that quality of life is improved on the patient.

This study achieved only a moderate fit to the available data. Further studies are necessary to achieve a higher fit, incorporating recommendations for the information capture systems based on both the most important factors found in this model, as well as the ones reported in the literature. Perhaps the most important of these is the weight and height information which, due to the low quality of the records used, could not be incorporated into the model. This is crucial given that obesity is recognized as one of the major risk factors for psoriasis therapeutic failure, and previous studies mention that an "ideal" patient for therapy development weighs 100 kg or less (13).

Another variable that is partially captured is phenotype. Very few patients had their psoriasis properly classified into one of the commonly occurring phenotypes. While classification may represent a challenge, it is important to capture it in a larger number of patients as not only the probability of failure depends on it, but also the decision making on what type of therapy to use, which is currently recognized to be less than ideal (11).

Despite these shortcomings, this study presents a comprehensive analysis of the sociodemographic and clinical factors that determine therapeutic failure in patients

across different treatment types, laying the groundwork for future research to be done around psoriasis treatment.

In conclusion, the factors that explain therapeutic failure (given by the difference between two PASI tests to evaluate the severity of involvement at different points in time) in the population of patients with moderate or severe psoriasis are: gender, type of therapy (biologic or non-biologic), age, days between the start of treatment and outcome, and DLQI.

CONFLICT OF INTEREST

None declared.

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Table 1. Univariate analyses of categorical variables

Variable	Categories	n	%
Outcome			
Therapeutic outcome	Success	877	83.4
	Failure	174	16.6
Sociodemographic factors			
Gender	Male	541	51.5
	Female	510	48.5
Region	Aburrá Valley	967	92
	Outside of Aburrá Valley	84	8
Clinical and pharmacological factors			
Adherence	Adherent	836	79.5
	Non-adherent	68	6.5
	(Missing data)	147	14.0
Comorbidities	No	551	52.4
	Yes	500	47.6
Type of therapy	Biologic	419	39.9
	Non-biologic	601	57.2
	(Missing data)	31	2.9

Table 2. Univariate analyses of quantitative variables

Variable	n	mean	std	25%	50%	75%
Age	1051	50.48	15.51	39	51	61
Last DLQI	1051	4.44	5.69	0	2	6
Waist perimeter	889	93.29	12.44	85	93	101.2
Number of medicines taken	1051	5.42	4.17	2	4	7
Days between start of treatment and outcome	1051	830.3	1036	129.5	490	1106

Table 3. Bivariate analyses of categorical variable

Variable	Failure		Success		χ^2	p value	DF	ORc	IC 95%	
	N	%	N	%					LL	UL
Gender										
Female (r)	70	40.23	440	50.17	5.35	0.02 *	1	1	-	-
Male	104	59.77	437	49.8				0.67	0.48	0.93
Region										
Aburrá Valley (r)	153	87.93	814	92.82	4.07	0.04 *	1	1	-	-
Outside of Aburrá Valley	21	12.07	63	7.18				1.77	1.05	2.99
Adherence										
Adherent (r)	157	90.23	820	93.50	1.9	0.17	1	1	-	-
Non-adherent	17	9.77	57	6.50				1.56	0.88	2.75
Comorbidities										
No (r)	98	56.32	402	45.84	5.98	0.01 *	1	1	-	-
Yes	76	43.68	475	54.16				0.66	0.47	0.91
Type of therapy										
Non-biologic (r)	135	21.36	497	78.64	25.63	<0.01 **	1	1	-	-
Biologic	39	9.31	380	90.69				2.65	1.81	3.87

Table 4. Bivariate analyses of quantitative variables

Variable	z	p-value	ORc	IC 95% LL	UL
Age	-1.370	0.171	0.9927	0.9824	1.0032
Number of medicines taken	-2.333	0.020*	0.95	0.91	0.9918
Last DLQI	12.090	<0.001***	1.2131	1.1757	1.2517
Waist perimeter	1.353	0.176	1.0095	0.9958	1.0235
Days between start of treatment and outcome	-4.417	<0.001***	0.9995	0.9992	0.9997

Table 5. Results of the multivariate logistic regression model

Variable (reference category)	Crude Odds-ratio (IC95%)	Adjusted Odds-ratio (IC95%)	Z	p value
Adherence (Adherent)	1.56 (0.88 – 2.75)	1.338 (0.687 – 2.606)	0.858	0.391
Gender (Male)	0.67 (0.48 – 0.93)	0.579 (0.382 – 0.878)	-2.571	0.01**
Region (Aburrá Valley)	1.77 (1.05 – 2.99)	1.809 (0.958 – 3.417)	1.827	0.068
Comorbidities (No)	0.66 (0.47 – 0.91)	0.856 (0.565 – 1.297)	-0.734	0.463
Type of therapy (non-biologic)	2.65 (1.81 – 3.87)	1.939 (1.242 – 3.027)	2.915	0.004**
Waist perimeter (N/A, quantitative)	1.01 (1 – 1.02)	1.001 (0.983 – 1.019)	0.081	0.936
Age (N/A, quantitative)	0.99 (0.98 – 1)	1.018 (1.003 – 1.034)	2.286	0.022*
Number of medicines taken (N/A, quantitative)	0.95 (0.91 – 0.99)	0.962 (0.909 – 1.019)	-1.319	0.187
Days between start of treatment and outcome (N/A, quantitative)	1 (1 – 1)	1 (0.999 – 1)	-2.432	0.015*
Last DLQI (N/A, quantitative)	1.21 (1.18 – 1.25)	1.212 (1.172 – 1.253)	11.329	<0.001***