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Effectiveness and Safety of Ustekinumab 90 mg in Patients Weighing 100 kg or less: A Retrospective, Observational, Multicenter Study

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ABSTRACT

Background: Scant information from clinical practice is available on the effectiveness and safety of ustekinumab (UST) 90mg in patients with psoriasis weighing 100kg or less.

Objectives: To assess the effectiveness and safety at weeks 16 and 24 of UST 90 mg in patients with psoriasis weighing ≤ 100 kg, and to study the impact on clinical outcomes of body mass index and prior exposure to UST 45mg.

Methods: A retrospective, observational, multicenter study of 74 adult patients who were treated with UST 90mg at least 24 weeks.

Results: Mean (SD) score on PASI was 7.9 (4.8) at baseline, 3.3 (3.5) at week 16, and 2.2 (2.4) at week 24, when 69.7% of the patients had a PASI under 3. Overweight and obese patients achieved a mean PASI of 2.2 by week 24 ($P = 0.995$). In patients who had previously been treated with UST 45mg (52/74) with insufficient response, mean (SD) absolute PASI score was 2.7 (2.6) at week 24. No serious adverse events were reported.

Conclusion: In patients who weigh 100kg or less but are overweight or obese and do not present an adequate response with UST 45mg, increasing the dose to UST 90mg could be an alternative option.

Introduction

Ustekinumab (UST), a fully human IL-12/23p40 monoclonal antibody, was approved in 2009 by the European and US health agencies for the treatment of moderate-to-severe plaque psoriasis in adult patients [1,2].

The efficacy of UST was demonstrated in two Phase III randomized clinical trials (RCT) (PHOENIX 1 and PHOENIX 2) in which patients were randomized to receive either UST (45 mg or 90 mg) at weeks 0 and 4 and then every 12 weeks or to placebo with crossover to UST (45mg or 90 mg) at week 12 [3,4]. After analyzing the impact of patient weight on the efficacy, safety and pharmacokinetics of UST, Lebwohl et al. concluded that, in patients with a baseline body weight greater than 100 kg, the PASI 75 response was 20% higher in the group receiving 90 mg than in the group receiving 45 mg (74.2% vs. 54.6%; $P < 0.0001$)[5]. By contrast, in the group of patients whose baseline body weight was 100 kg or less, no significant dose-related differences were observed in response (PASI 75 in 80.8% for 90 mg and 76.9% for 45 mg; $P = 0.1823$). As a result, the Summary of Product Characteristics (SmPC) for UST specifies a 45 mg dose for patients with body weight of 100 kg or less and 90 mg for patients weighing more than 100 kg [6].

In Spain, due to pricing and reimbursement conditions (the cost of the UST 90 mg dose was twice that of the 45 mg vial), prescription has been restricted. However, owing to a change in pricing policy in July 2017, the price of UST for subcutaneous administration is now the same for both doses. This change not only favors the application of the SmPC dose recommendation, but also opens the possibility of prescribing UST 90 mg in patients who have experienced primary or secondary failure with UST 45 mg, irrespective of body weight or previous treatment with other biologic agents.

The primary aim of this Spanish study was to evaluate the effectiveness and safety of UST 90 mg at weeks 16 and 24 in a group of patients whose weight did not exceed 100 kg but who were treated with UST 90 mg for moderate-to-severe plaque psoriasis. The secondary objective was to study the relationship of clinical response with body mass index (BMI) and prior exposure to UST 45 mg and other biologic agents.

Material and Methods

Study Design, Patients and Data Collected

This was an observational, retrospective study of patients treated in 7 hospitals. The inclusion criteria were age greater than 18 years, maximum weight at baseline of 100 kg, and a diagnosis of moderate-to-severe plaque psoriasis treated with UST 90 mg for at least 24 weeks. To assure a minimum follow-up of 24 weeks, all observations were censored at May 31th, 2018.

The following patient data were extracted from anonymized electronic medical records: age, gender, weight, BMI (normal, 18.5 to < 25; overweight, 25 to < 30; and obesity ≥ 30), comorbidities (hypertension, dyslipidemia, diabetes mellitus, psoriatic arthritis), disease duration, induction period, previous treatment for psoriasis, including systemic and biologic therapies.

The response regarding prior exposure to biological agents was divided into naïve and non-naïve patients. However, an additional subanalysis was performed considering naïve patients and those who had previously received only 1 biologic - “naïve or near naïve” compared with those who had previously been treated with more than 1 biologic agent as “biologic experienced patients”. In the patients whose response to UST 45 mg had been classified by their dermatologist as primary or secondary

treatment failure, this prior treatment was considered to represent “previous treatment with a biologic” for the purposes of this classification. Nonetheless, outcomes in this group were also considered separately.

Treatment Protocol

There was no wash-out period before patients started treatment with UST 90 mg. When the regimen included an induction dose, patients received subcutaneous injections of UST 90 mg at weeks 0 and 4 and every 12 weeks thereafter. Those who did not receive an induction dose were treated at baseline and every 12 weeks.

Response Assessment

The PASI scores of patients with UST 90 were assessed at baseline, week 16 and week 24. The primary endpoints were improvement in mean absolute PASI and the percentage of patients achieving a PASI score under 3 at weeks 16 and 24. Secondary outcomes were PASI 75 and PASI 90.

Safety

Data was collected on any serious adverse events that might indicate dose adjustment or lead to withdrawal or interruption of therapy and on adverse events of particular interest, such as cardiovascular events, infections and tumors. Motives for withdrawal of therapy were also collected and classified as follows: lack or loss of efficacy, serious adverse events, and others (moving to another reference hospital, lost to follow-up, skin clearance, etc.).

The present study was conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and was approved by the local clinical research ethics committee at Hospital Universitari

Statistical Analysis

Descriptive statistics were calculated for each variable: frequencies and percentages for categorical variables and mean and standard deviation (SD) for quantitative variables, which were normally distributed (Shapiro-Wilk test). For between-group comparisons, the Pearson χ^2 test was used for categorical variables and Student's *t*-test for quantitative variables. Differences between the subgroups in clinical response were compared using the Pearson χ^2 test. Analysis of variance (ANOVA) of one factor was used to compare the means of the continuous variables. No substitution methods were used for missing data (as observed).

The statistical analysis was performed using the SPSS software package (version 22.0 for Windows). In all cases a *P* value less than 0.05 was considered statistically significant.

Results

Demographic and Clinical Characteristics

During the study period, 113 patients were treated with UST 90 mg in the 7 hospitals participating in the study. Of these, 39 were excluded from the analysis because they weighed over 100 kg at baseline and were, therefore, being treated according to the SmPC recommendation. Data from the other 74 patients, who were being treated off label, was included in the analysis. The demographic and clinical characteristics of the study population are shown in Table 1. The mean (SD) age of the 74 patients (44 men and 30 women) was 54.1 (14.3), mean weight was 86.4 (10.7) kg, mean BMI was 30.1 (3.9) and mean PASI was 7.9 (4.8). Of the 74 patients, 63 (85.1%) had been treated previously with a biologic agent and 12 (16.2 %) received concomitant

systemic treatment, such as methotrexate (n = 9) and acitretin (n = 3). Only 17 (23%) of the patients received an induction dose: 7 naive and 10 non-naive.

Status of UST 90 mg Use During the Follow-Up Period

At the end of the follow-up period (week 24), 66 of the 74 patients (89.2%) were still receiving treatment with UST 90 mg. Treatment was discontinued between weeks 16 and 24 in 8 patients (10.8 %) after a mean (SD) duration of 4.8 (0.5) months. The reasons for withdrawal of treatment were as follows: clearance (n = 1), lost to follow-up (n = 1), and loss of response or lack of efficacy (n = 6).

The mean (SD) baseline PASI score for the study population was 7.9 (4.8). This fell to 3.3 (3.5) at week 16 and 2.2 (2.4) at week 24. Therefore, the mean reduction over baseline PASI was 58.2% at week 16 and 72.2% at week 24, when 69.7% (46/66) of the patients achieved a PASI under 3. In terms of relative PASI response, the percentage of patients achieving PASI 75 and PASI 90 responses, respectively, was 43.2% (32/74) and 20.3% (15/74) at week 16 and 56.1% (37/66) and 31.8% (21/66) at week 24.

Improvement in mean PASI by BMI is shown in Figure 1. At week 24, both groups (overweight and obese) achieved a mean absolute PASI of 2.2 ($P = 0.995$). PASI ≤ 3 response rate according to BMI is shown in Figure 2. In the comparison according to BMI, patients whose weight was in the normal range were not included because of the small size of the subgroup (4 at week 16 and 3 by week 24). The mean (SD) PASI score for this group was 6.2 (1.0) at baseline and 1.9 (1.7) at week 24; all of them had previously received treatment with UST 45 mg. Treatment with UST 90 was discontinued in 1 of these patients before week 24 due to a lack of response (PASI 6.5).

There were no significant differences in mean (SD) baseline PASI between the patients classified as naive (n = 11) and non-naive (n = 63): 9.2 (4.4) and 7.7 (4.9), respectively ($P = 0.326$). At week 24, mean (SD) PASI in the naive group was 1.2 (1.6) compared to 2.3 (2.4) in the non-naive group ($P = 0.152$). At week 24, 80% (8/10) of the patients in the naive group and 67,9 % (38/56) of those in the non-naive group achieved a PASI score under 3 and there was no significant difference between the 2 groups ($P = 0.711$). In the subanalysis according to “naive or near naive” and “biologic experienced group”, there were no significant differences in the reduction of the mean PASI and the proportion of patients who achieved PASI <3 at week 16 and 24.

One of the objectives of the present study was to evaluate outcomes in patients who weighed 100 kg or less at baseline and who had previously failed to respond to treatment with UST 45 (n=52). This group, which had a mean (SD) baseline PASI of 6.5 (3.2), achieved a mean of 3.7 (3.7) and 2.7 (2.6) at weeks 16 and 24, respectively. By week 24, 63% (29/46) had a PASI under 3. It is important to note that the induction dose recommended in the SmPc was given to only 5.8% (3/52) of the patients in the UST 45 mg group. No significant differences in mean PASI or in the percentage of patients who achieved a PASI under 3 at weeks 16 and 24 were observed between the group who received UST 45 mg, the naive group, and the patients who had been switched from treatment with tumour necrosis factor inhibitors or conventional systemic treatment (Table 2).

No serious adverse events were reported during the follow-up period. Of the 74 patients, 1 developed a human papilloma virus (genital warts) that did not lead to withdrawal of treatment.

Discussion

In this case series, patients treated with UST 90 mg achieved a mean absolute PASI score under 3 at week 24 irrespective of BMI and prior treatment with biologic therapy. Interestingly, this result was maintained in the group of patients with a history of partial response treatment failure with UST 45 mg.

It is difficult to compare the outcomes in our group with data from the follow-up period of the Phase III RCTs [3,4]. In the PHOENIX 1 and 2 trials, the group of patients weighing 100 kg or less who were treated with UST 90 mg had a mean (SD) baseline PASI of 19.5 (7.3) (5), whereas in our series mean (SD) baseline PASI was 7.9 (4.8), mainly because of prior biologic treatment and the lack of a wash-out period. Furthermore, unlike the study population in the RCTs, more than 80% of our patients had previously received biologic therapy. Consequently, the percentages for relative PASI responses were considerably lower in our study (at week 24) than in the RCTs (at week 28) for both PASI 75 (56.1% vs. 80.8%) and PASI 90 (31.8% vs. 61.4%) [5]. However, in routine clinical practice, the use of the absolute PASI score is much more common and it can be a better indicator of effectiveness in patients with lower baseline PASI scores, as was the case in our series. Indeed, in some consensus documents, such as that published by the Spanish Psoriasis Group, absolute PASI is included as a treatment objective and a PASI score under 5 is considered to be an acceptable response to treatment (7).

It is known that obesity limits response to treatment [7]. Several studies have shown the importance of dose adjustment according to weight in patients treated with biologic agents to ensure that they achieve concentrations that will obtain the optimum effect. Naldi et al.(9) found that BMI was a prognostic factor in the response to

systemic treatment. However, there is not always a good correlation between obesity and weight, a circumstance to consider in populations of moderate height, such as that of the Mediterranean region.

In the RCTs, it was observed that better outcomes were achieved with 90 mg than with 45 mg, independently of patient weight: 78.6% vs. 71.2% , respectively, achieved a PASI 75 response in PHOENIX 1 and 78.5% vs. 69.5% in PHOENIX 2 (week 28) [3,4]. One might ask why UST 90 mg was not recommended in all patients with dose adjustment according to weight. One answer is that the context of the approval of UST, 9 years ago, was quite different from the current situation. At that time, with PASI 75 as a gold standard and with tumor necrosis factor inhibitors as comparators [8], there was no need to achieve the drug's maximum potential. Since then—with the advent of anti-IL17 agents—PASI 90 has become the primary end point in clinical trials [9,10], favoring the optimization of the possibilities of all biologic agents. It is, therefore, logical to suggest that patients who weigh 100 kg or less but who are overweight or obese may also benefit from the 90 mg dose. In fact, 45% (31/69) of our patients weighing 100 kg or less were overweight and almost 50% (34/69) were obese. In our series, 70.3% (52/74) had been previously treated with UST 45 mg with a clinical response considered insufficient.

One of the most notable findings in this case series was the positive response in patients weighing 100 kg or less previously treated without success with UST 45 mg. At week 24, mean PASI in this subgroup was 2.7 and over 60% of these patients had achieved a PASI score less than 3 and almost 90% a score under 5. These results suggest that in patients whose response to UST 45 mg is inadequate, UST 90 mg could be considered before making a switch to another therapeutic target. While it could be argued that raising the dose could increase the risk of adverse events, the good safety

profile of UST has been demonstrated in the RCTs, extension studies, diverse registries, and in clinical series [11,12]. A recent meta-analysis positioned UST as one of the treatments offering the best trade-off between efficacy and acceptability [13]. In our case series no serious adverse events were reported and no adverse events led to withdrawal of treatment.

This study has certain limitations. Due to its retrospective design, some data may be missing or incomplete, in particular relating to adverse events that did not affect the continuation of therapy. Moreover, the number of patients in the series is small. The “as observed” evaluation may have led to overestimation of results, even though very few patients stopped treatment. As the study was based on data from clinical settings, there could be no clear definition of and “adequate” or “inadequate” responses since these could vary depending on the opinion of the dermatologist and the patient. Finally, we could reach no conclusions about the results for the normal weight subgroup because of the small number of patients ($n = 4$).

In summary, our investigation showed that UST 90 mg could be an alternative option for overweight or obese patients weighing 100 kg or less who do not achieve complete clearance with UST 45 mg or other biologic therapies.

Conflicts of interest:

E del Alcazar has perceived speakers honoraria from Abbvie, Almirall, Janssen, Novartis, Leo Pharma, UCB and Lilly and participated in clinical trials sponsored by Novartis. M Ferran and F Gallardo have participated in clinical trials and/or received honoraria as a consultant or speaker from AbbVie, Celgene, Janssen, Lilly, Leo Pharma, MSD, Novartis, and Pfizer. A López-Ferrer has received speaking fees and consultancies from Abbvie, Celgene, Almirall, Janssen, MSD, LeoPharma, UCB, Pfizer, Lilly and Novartis. J Notario has perceived consultancy/speakers honoraria and/or participated in clinical trials sponsored by AbbVie, Almirall, Celgene, Gebro, Janssen, Leo Pharma, Lilly, MSD, Novartis and Pfizer. D Vidal D Vidal has participated in clinical trials and received honoraria as speaker from Abbvie, Janssen, Novartis and Lilly. J Riera and M Alsina have no conflicts of interest to declare. G Aparicio has received consultancy/speakers' honoraria and participated in clinical trials sponsored by Abbvie, Cellgene, Janssen, Leo-Pharma, Lilly, Novartis and Pfizer. E Vilarrasa has received consultancy/speakers' honoraria and participated in clinical trials sponsored by Abbvie, Almirall, Boheringer, Celgene, Janssen, LeoPharma, Lilly, MSD, MSD, Novartis, and Pfizer. JM Carrascosa has received institutional grants/research support from AbbVie, Novartis, honoraria or consultation fees from Abbvie, Almirall, Amgen, Biogen, Celgene, Gebro, Janssen, Leo-Pharma, Lilly, Novartis, Pfizer and has served as a speaker for Celgene, Lilly, Janssen, Novartis, Abbvie, Gebro, Biogen, and Pfizer. L Puig has received institutional grants/research support and/or received honoraria as a consultant, investigator, speaker from Abbvie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Gebro, Janssen, Leo-Pharma, Lilly, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Sandoz, Sanofi, UCB. C Ferrándiz has participated in clinical trials and/or received honoraria as a consultant, investigator, speaker from AbbVie,

Celgene, Janssen, Lilly, Leo Pharma, MSD, Novartis, Pfizer, Almirall, Amgen. None of the aforementioned has relation to the present work.

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Table I. Baseline Characteristics of the Study Population

Characteristic		≤ 100 kg (n = 74)
Male		44 (59.5%)
Mean age, <i>years</i>		54.1 ± 14.3
Comorbidities	Diabetes mellitus	18 (24.3%)
	Dyslipidaemia	32 (43.2%)
	Hypertension	20 (27.0%)
Weight, <i>kg</i>		86.4 ± 10.7
Height, <i>cm</i>		169,6 (n = 69)
Body Mass Index, <i>Kg/m²</i>		30.1 ± 3.9 (n = 69)
Body Mass Index	18.5-24.9	4 (5.7%)
	25.0-29.9	31 (45.0%)
	≥ 30	34 (49.3%)
Baseline PASI score		7.9 ± 4.8
Psoriatic arthritis		22 (29.7%)
Psoriasis duration, <i>years</i>		21.9 ± 14.6 (n = 71)
Induction dose		17 (23%)
Previous conventional systemic therapy	Methotrexate	61 (82.4%)
	Ciclosporin	35 (47.3%)
	Acitretin	35 (47.3%)
	Phototherapy	43 (58.1%)
	Apremilast	1 (1.4%)
Previous biologic therapy	Previous biologic	63 (85.1%)
	1 biologic	25 (33.8%)
	2 biologics	15 (20.2%)
	3 biologics	18 (24.3%)
	≥ 4 biologics	2 (2.7%)
Biologic therapy immediately before UST 90 mg	UST 45 mg	52 (70.3%)
	Secukinumab	0 (0%)
	Etanercept	2 (2.7%)
	Adalimumab	5 (6.8%)
	Infliximab	0 (0%)

Table 2. Response by Treatment Received Immediately Before Ustekinumab 90 mg.

	UST 45 mg	Naive	TNFi	Other*	P value
No of patients	52	11	7	4	
Baseline PASI, mean (SD)	6.5 (3.2)	9.2 (4.4)	12.4 (7.5)	14.2 (9)	< 0.001**
Week 16					
No of patients	52	11	7	4	
PASI, mean (SD)	3.7 (3.7)	2.5 (2.3)	1.9 (1.6)	1.1 (1.3)	0.212
PASI ≤ 3	25 (48.1%)	7 (63.6%)	6 (85.7%)	4 (100%)	0.064
PASI ≤ 5	40 (76.9%)	10 (90.9%)	7 (100%)	4 (100%)	0.264
Week 24					
No of patients	46	10	6	4	
PASI, mean (SD)	2.7 (2.6)	1.2 (1.6)	1.2 (1.6)	0.5 (0.6)	0.076
PASI ≤ 3	29 (63%)	8 (80%)	5 (83.3%)	4 (100%)	0.292
PASI ≤ 5	41 (89.1%)	10 (100%)	6 (100%)	4 (100%)	0.503

Abbreviations: PASI, Psoriasis Area and Severity Index; TNFi, tumour necrosis factor inhibitor; UST, ustekinumab.

*Non-naïve patients who switched from systemic treatment.

** Statistically significant differences in baseline PASI were observed between UST 45 mg and tumour necrosis factor inhibitors and between UST 45 mg and non-naïve patients who had switched from systemic treatments (Others).

FIGURE LEGENDS

Figure 1. Improvement in mean (PASI) according to BMI.

Figure 2. PASI ≤ 3 response rate according to BMI.