1.0 Abstract

Title

Evaluation of Humira Retention Rate in Psoriasis in Daily Practice and Assessment of Work Productivity and Quality of Life

Keywords

Psoriasis – Adalimumab – Observational – PASI – Quality of Life – Work impairment

Rationale and Background

Humira therapy in moderate-to-severe psoriasis patients should be taken in a continuous manner. However in daily clinical practice physicians or patients might interrupt or permanently discontinue this therapy for a variety of reasons. Since data are lacking to describe and clarify real-life treatment patterns, this study was designed to follow psoriasis patients newly initiated on Humira, during 2 years, irrespective of further therapeutic management.

Research Question and Objectives

The primary study objective was to document to what extent in daily clinical practice Humira therapy is continued, interrupted or permanently discontinued during a two year follow-up.

Study Design

Inclusion/Exclusion criteria

All of the following criteria were to be fulfilled to make the patient eligible for the study:
- Inclusion criteria:
  o Age $\geq$ 18 years
  o Patient with chonic plaque psoriasis
  o Patient newly initiated on Humira
  o Patient compliant with Humira SmPC
  o Patient compliant with belgian reimbursement criteria of Humira in plaque psoriasis
  o Patient has signed the Informed Consent Form.
- Exclusion criteria:

      o   Patients having any of the contraindications mentioned in the SmPC Humira

      o   Patients not willing to sign the Informed Consent Form.

Patient was withdrawn from the study if he/she withdrew consent or if the investigator found it no longer appropriate to keep the patient in the study.

Setting

As this study is observational in nature, the follow-up of patients was not prescriptive in nature and left up to the judgment of the investigator. Visits were to take place according to the usual practice of the investigator. Failure to observe the intervals of patient visits mentioned above did not constitute a breach or violation of the protocol.

Due to the nature of this study AbbVie did not supply any product. The physicians prescribed the medication for the participants of the study as regulated by Belgian legislation.

Subjects and Study Size, Including Dropouts

The study population consisted of patients with chronic plaque psoriasis in whom Humira treatment was recently initiated. All medications were prescribed in the usual manner in accordance with the terms of the marketing authorization and in line with the Belgian reimbursement criteria. The patients provided written authorization to the investigator to use and/or disclose personal and/or health data before entry into this observational study.

200 patients were to be enrolled in 35 investigational sites in Belgium. Each site was to recruit between 5 and 15 patients. The recruitment period was 31 months. Sites were selected based on the investigator's experience in psoriasis patient care. University Hospitals as well as regional hospitals and private dermatology practices with experience in psoriasis patient care were asked to participate. The number of psoriasis patients in follow-up was a determining factor as well as the previous experience of the investigator in clinical studies and adequate availability of clinical research staff.

Variables and Data Sources

Age, study duration, treatment duration, demographics, weight, height, waist circumference, smoking status, alcohol consumption, blood pressure, previous and current psoriasis treatments, PASI, BSA, PGA scores, laboratory parameters, concomitant medication, DLQI, WPAI psoriasis, serious adverse events.

Results

191 patients constitute the ITT Set.

On average the patients were 44.9 years of age (SD=12.1 years), ranging from 18.9 to 78.9 years. The sex ratio was 69.6% male to 30.4% female.

Topical treatment was used previously by 99.0%, phototherapy by 94.8%, a, systemic treatment 99.5%, and biological treatments 33.0%.

The most frequent previously used systemic treatments were methotrexate (94.7%) and ciclosporine (85.3%).

The most frequent previously used biological was etanercept (82.5%), infliximab had been used by 7.9%, efalizumab by 1.6%, and other biologics by 20.6%.

Treatment and Efficacy Data

Adalimumab retention status

Continuous treatment was recorded for 84 patients (44.0%). The early intermittent group consisted of 5 patients (2.6%), the late intermittent group of 16 patients (8.4%), and the permanently discontinued group of 74 patients (38.7%). The group 'other', which consisted of patients impossible to classify, consisted of 12 patients (6.3%).

Adalimumab treatment

In total 106 patients (55.5%) were still on adalimumab treatment at the end of the study. Two third of the patients (66.2%) that permanently discontinued had a treatment duration of 12 months or less.

For 121 patients (63.4%) a change in adalimumab treatment (interruption, stopped permanently, restart, or other) was recorded at any visit. The most frequently given reasons for temporarily stopping adalimumab were 'other' (24 patients, 12.6%), request of the patient (16 patients, 8.4%) and side effect (8 patients, 4.2%).

For permanently stopping adalimumab the most frequently mentioned reasons were lack of efficacy (36 patients, 48.6%), request of patient (14 patients, 18.9%), side effect (12 patients, 16.2%)

PASI

The average PASI score was 17.9 at baseline. This decreased to 3.4 in Time-Window Month 24. The differences between baseline and each time-window were all statistically significant.

A tendency is observed of more improvement in PASI score in the continuous group than in the permanently discontinued group.

PASI 75 and PASI 90 were obtained by 72.1% and 49% of patients at time-window 24 months, respectively. At last observation, 65.2% and 41.3% of patients had a PASI score decreased by at least 75% and 90%, respectively.

DLQI Questionnaire

The average total DLQI score was 12.7 at baseline. This decreased to 3.2 in Time-Window Month 24.

The change from baseline in total DLQI score at each time-window was all statistically significant. A tendency is observed of more improvement in total DLQI score in the continuous group than in the permanently discontinued group.

Treatment goals

In the continuous group, higher frequencies of reaching the treatment goal are observed than in the other groups.

WPAI Questionnaire

At baseline 69.9% of the patients were employed and 30.1% unemployed. For 4 of the unemployed patients (8.0%) this was considered to be due to psoriasis.

For presenteeism, total work productivity impairment (TWPI), and activity impairment due to psoriasis the differences between baseline and each time-window were all statistically significant.

No notable differences were observed between the adalimumab retention groups.

Metabolic syndrome

At baseline 57 patients (41.6%) suffered from metabolic syndrome. The frequency of metabolic syndrome fluctuated during the study. At Time-Window Month 24 45.9% patients suffered from metabolic syndrome.

No significant difference in the frequency of metabolic syndrome was found for any of the post-baseline timepoints

Discussion

More than half of the patients were still on adalimumab treatment at the end of the study. Continuous treatment was recorded for 44% of the patients. The most frequent reasons for permanent discontinuation of the treatment were lack of efficacy, request of patient and side effect. Higher improvements in PASI, DLQI score and

achievement of treatment goals were observed in the continuously treated group compared to the permanently discontinued group. The differences between baseline and each time-window were all statistically significant for presenteism, TWPI, and activity impairment, however no notable differences were observed between the adalimumab retention groups.

Marketing Authorisation Holder(s)

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Names and Affiliations of Principal Investigators

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