1.0 Abstract

Title

PMOS: P13-990. Observational study in Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA) patients to evaluate work productivity before and after the start of adalimumab therapy in daily practice in Belgium (SPACTIVE)

Keywords

Ankylosing Spondylitis/Psoriatic Arthritis, adalimumab therapy, employment status, work productivity, disease activity.

Rationale and Background

Ankylosing spondylitis (AS) and psoriatic arthritis (PsA) are the major subtypes of rheumatic diseases named as spondyloarthritides (SpAs). The most important clinical features of this group are inflammatory back pain, asymmetric peripheral oligoarthritis, predominantly of the lower limbs, enthesitis, and specific organ involvement such as anterior uveitis and chronic inflammatory bowel disease. As a consequence both diseases imply a significant economic burden, arising from both medical and disability direct costs. Health economics data become increasingly important to justify the costs of medicines.

The aim of this study is to analyze the employment status and work productivity of patients with AS and PsA before and after the start of adalimumab and to look at the relationship between employment status, work productivity, disease activity and clinical evaluations.

Research Question and Objectives

The main objective of this study is to observe in daily practice the evolution of work productivity over 18 months in AS and PsA patients after the start of adalimumab treatment.

Secondary objectives are to investigate:

- A possible difference in evolution of employment status and work productivity between AS and PsA patients throughout the study
- The relationship between disease activity and employment status and between clinical evaluations and employment situation at baseline and after 18 months
- Possible correlations between work productivity and disease activity/clinical evaluations

Study Design

This is a multicenter, observational, prospective, single arm study of AS/PsA diagnosed patients in whom adalimumab treatment is initiated. The total observation period is approximately 18 months, with routine visits at baseline and afterwards preferably after 3, 6, 12 and 18 months.

Setting

Two hundred (200) patients were to be enrolled in 20 investigational sites in Belgium during a recruitment period of 12 months and with an average of 8 patients per center. Investigators had experience in observational studies, sufficient patient potential, required availability and resources, and acceptance of the study protocol.

Patient data were collected during routine visits at baseline and afterwards preferentially after 3, 6, 12, and 18 months.

Subjects and Study Size, Including Dropouts

One hundred eighty-three (183) patients were enrolled between 05 June 2013 and 23 December 2015. The last study completion or withdrawal date was 23 June 2017.

Variables and Data Sources

- Demographic data and medical history.
- Disease activity.
- Work productivity.
- Health-Related Quality of Life.
- Clinical evaluations.
- Adverse events.

Results

One hundred eighty-three (183) patients were enrolled between 05 June 2013 and 23 December 2015. The last study completion or withdrawal date was 23 June 2017.

Five patients did not receive any dose of adalimumab and another 5 patients had no follow-up data available. These patients were not considered in the statistical analysis. All 173 remaining patients were considered in the analysis, and constitute the ITT Set and the PPS. Among these patients 117 had AS (67.6%) and 56 PsA (32.4%). The subgroup of patients considered for an additional statistical analysis of the WPAI questionnaire (patients aged ≥ 18 and ≤ 50 years), consists of 146 patients, 106 with AS and 40 with PsA.

In total, 121 patients (69.9%) completed the study. One patient (0.6%) discontinued because of consent withdrawal, 12 patients (6.9%) were lost to follow-up, 4 patients (2.3%) discontinued because of administrative reasons, 4 patients (2.3%) due to a serious adverse event, and 33 patients (19.1%) because of other reasons. Similar results were observed for the two patient groups.

The average study duration was 15.2 months (SD: 5.4), ranging between 2 and 24 months. The average adalimumab treatment duration was 14.9 months (SD: 5.6), ranging between 1 and 23 months.

Onset Data

On average, the patients in the PP population were 39.5 years of age.
Eighty-six (86) patients (49.7%) were male and 87 (50.3%) female.

In total, 70 patients had psoriasis (40.5%), 16 patients had inflammatory bowel disease (9.2%), and 18 patients had uveitis (10.4%).

Analgesics were used by 105 patients (60.7%), NSAIDs by 158 patients (91.3%), DMARDs by 85 patients (49.1%), and steroids by 53 patients (30.6%).

WPAI

In the PPS, 127 patients (76.0%) [AS: 76.8%, PsA: 74.5%] were professionally active at baseline and 129 patients at the last observation after baseline [AS patients: 80.6%, PsA patients: 76.4%].

Absenteeism (percentage work time missed due to the disease) decreased with 7.9% between baseline and the last observation.

Presenteeism (percentage impairment while working due to the disease) decreased with 27.2% between baseline and Month 3 and with 23.8% between baseline and the last observation.

TWPI (total work productivity impairment due to the disease) improved with 29.8% between baseline and Month 3 and with 26.2% between baseline and the last observation.

The impairment in daily activities due to the disease improved with 23.1% between baseline and Month 3 and with 26.2% between baseline and the last observation.

The improvement in all 4 WPAI variables was observed in both the AS and PsA groups.

The analysis of the WPAI questionnaire on the basis of the subgroup of patients satisfying Inclusion Criterion 1 (age ≥ 18 and ≤ 50 years) showed similar results as for the entire PP population.

BASDAI and HAQ-S (AS Group)

The mean change in BASDAI score between baseline and the last observation was –3.10. Active axial disease (BASDAI total score > 4) was present in 99.1% of the AS patients at baseline and 45.5% at the last observation. Axial disease remained stable in 46.4% of the patients and improved for 53.6%.

The mean change in HAQ-S score between baseline and the last observation was –0.53.

A significant effect of the work status on the HAQ-S score was observed both at baseline and at the last observation with a lower HAQ-S score in professionally active patients.

Significant positive correlations were found for the change between baseline and the last observation between the variables presenteeism, total work productivity impairment (TWPI), and percentage activity impairment, of the WPAI questionnaire, and both the BASDAI total score and the HAQ-S score.

DAS28 and HAQ-DI (PsA Group)

The mean change in DAS28 score between baseline and the last observation was –2.1. The mean change in HAQ-DI score between baseline and the last observation was –0.66.

Significant (positive) correlations were found for the change between baseline and the last observation between the variables presenteeism, TWPI, and percentage activity impairment, and both the DAS28 score and the HAQ-DI.

Adverse Events

A total of 9 adverse events (AEs) were reported for 8 patients. In the AS group, 6 AEs were reported for 5 patients and in the PsA group 3 events were reported for 3 patients. Serious adverse events (SAEs) were reported for 6 patients, 4 in the AS and 2 in the PsA group. No new safety signals were observed.

Discussion

The main objective of this study was to observe in daily practice the evolution of work productivity over 18 months in Belgian AS and PsA patients treated with adalimumab.

The results showed a marked improvement of the disease activity and health-related quality of life parameters associated with AS (BASDAI, HAQ-S) and PsA (DAS 28, HAQ-DI). The study demonstrated as well a substantial improvement in all 4 WPAI variables in both AS and PsA patients treated with adalimumab. Most of the improvement was already observed after 3 months. A correlation was found between AS and PsA disease activity measures and work productivity variables. Both in AS and PsA patients who were professionally active and treated with adalimumab decreasing disease activity was associated with marked improvements in work productivity and daily activities. These results are consistent with previously published data in As and psA patients from other countries (Australia, UK, Italy, The Netherlands, Norway, Sweden).

Marketing Authorisation Holder(s)

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