1.0 Abstract

Title

Impact of adalimumab (Humira®) therapy on selected health care resource utilization and sick leave in patients with ankylosing spondylitis in clinical practice

IDEA - Multi-country, Multi-center, Post-marketing Observational Study in Routine Clinical Use in Central and Eastern Europe

Keywords

Humira®, adalimumab, ankylosing spondylitis, effectiveness, observational study

Rationale and Background

Ankylosing spondylitis (AS) is a disease that represents a considerable economic burden to the health care system as well as the whole society. The treatment of AS with anti-tumor necrosis factor-a agents (anti-TNF) has been proven to provide significant improvements in clinical symptoms, physical function, patients' health related quality of life and work productivity outcomes. The high cost of biologic agents has increased the need for pharmacoeconomical evaluations in the field of AS.

Due to differences in the health care systems, health insurance and general country settings, health economic data cannot be generalized across countries. Such data is generally lacking in Central and Eastern European countries, especially in the field of rheumatology. This study evaluated selected health care resource utilization and productivity loss in patients with AS before and during the treatment with adalimumab in clinical practice. The impact of adalimumab therapy on the extent of outpatient attendance, hospitalizations and sick leave, which could be influenced by adalimumab therapy, was taken into account in relation to treatment response.

Research Question and Objectives

The primary objective of this study was to assess the proportion of AS patients achieving treatment response to adalimumab therapy.

Secondary objectives were:

- to evaluate the impact of adalimumab therapy in relation to treatment response on selected health care resource utilization: hospitalizations and outpatient attendance;

- to evaluate the impact of adalimumab therapy in relation to treatment response on sick leave;
- to evaluate changes in AS disease activity during treatment with adalimumab;
- to evaluate changes in physical function during treatment with adalimumab.

Study Design

This post-marketing observational study (PMOS) was performed in a multi-country, multi-center, single-arm format. Data were collected prospectively and retrospectively. There were five target visits: one at baseline, and four follow-up visits 3, 6, 9 and 12 months after baseline.

Setting

Participating countries were Croatia, Czech Republic, Hungary, Romania and Russia.

Subjects and Study Size, Including Dropouts

A baseline visit (V0) was documented for 452 patients. Of these patients, 148 (32.7%) were enrolled in Hungary, 121 (26.8%) in Romania, 90 (19.9%) in Russia, 62 (13.7%) in the Czech Republic and 31 (6.9%) in Croatia.

For 2 patients, adalimumab (Humira®) treatment was not documented in this study. These patients were excluded from the main analysis set (MAS) which comprised 450 patients.

In total, 109 patients dropped out of the study before the end of the study. For 87 dropped out patients, reason for study discontinuation of treatment with adalimumab was documented in the electronic case report form. The remaining 22 patients were lost to follow-up without recording the reason.

Variables and Data Sources

The following questionnaires were applied to assess disease activity:

- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
- Ankylosing Spondylitis Disease Activity Index (ASDAS)

The following questionnaire was applied to assess functionality:

- Bath Ankylosing Spondylitis Functional Index (BASFI)

For measuring utilization of health care resources, the following parameters were recorded:

- number of admissions to hospital,
- corresponding inpatient days and number of visits at different health care providers,
- number and length of sick leaves.

Patient questionnaires have only been recorded if they were part of the routine clinical practice.

Results

The majority (72.3%) of the patients achieved a 50% reduction in disease activity as assessed by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) from baseline to V4-LOCF (primary endpoint of the study). According to the Ankylosing Spondylitis Disease Activity Score (ASDAS), the responder rate at V4-LOCF was 58.9%, i.e. more than half of patients responded to therapy. The mean Bath Ankylosing Spondylitis Functional Index (BASFI) score decreased continuously from 6.2 at V0 to 2.3 at V4 (2.6 at V4-LOCF), corresponding to an increase in functionality. Results showed as well that numbers of visits at health care providers and number of sick leaves decreased.

19 patients (4.2%) had at least one SAE. Overall, 29 serious adverse events occurred, the majority of which were classified as moderately severe (20 events, 69.0%). 17 events (58.6%) were assessed to be related to adalimumab with reasonable possibility; the remaining events were assessed to be not related to adalimumab. 12 patients (2.7%) had SAEs which led to the discontinuation of adalimumab treatment. All SAEs with the causality “related with reasonable possibility” were in the scope of the known safety profile of adalimumab.

Discussion

Treatment of AS with adalimumab was effective and well-tolerated. Characteristics of the study population were in line with real-world population in terms of age, prevalence of comorbidities, as well as the male preponderance. Data of IDEA are in accordance with previous large clinical and observational trials on the effectiveness and safety of adalimumab in AS.

Marketing Authorisation Holder(s)

AbbVie Croatia

AbbVie Czech Republic

AbbVie Hungary

AbbVie Romania

AbbVie Russia

Names and Affiliations of Principal Investigators

[redacted]