

1.0 Abstract

Title

An Observational Study of the Effectiveness of Adalimumab on Health and Disability Outcomes in New Zealand Patients with Immune-Mediated Inflammatory Diseases (VITALITY)

Date of Abstract

18 October 2018

Keywords

Adalimumab, World Health Organisation Disability Assessment Schedule (WHODAS), psoriasis (PsO), Crohn's disease (CD), rheumatoid arthritis (RA).

Rationale and Background

Disability has been defined as impairments, activity limitations and participation restrictions due to personal and environmental factors. There are few data on the effectiveness of adalimumab on disability outcomes in patients with Immune-Mediated Inflammatory Diseases (IMIDs), particularly in the "real world" clinical practice setting. There are no data available for New Zealand patients in this setting.

Research Question and Objectives

The objective of this Post-Marketing Observational Study (PMOS) was to assess the effect of adalimumab (Humira®) on health and disability outcomes in New Zealand patients with the IMIDs of RA, CD and PsO.

Study Design

The study was a Phase IV, observational, multicentre study designed to investigate the effectiveness of adalimumab on health and disability outcomes in New Zealand patients diagnosed with, RA, CD and PsO.

All patients received at least 3 months of treatment with adalimumab. Adalimumab was prescribed by the physician under usual and customary practice and according to the approved adalimumab New Zealand Datasheet. Adalimumab is subsidized by the New Zealand Government for the above conditions, according to "Special Authority" criteria, which relate to disease severity. Almost all patients in New Zealand access adalimumab via this pathway. Continuation of adalimumab was dependent upon the patient meeting "Special Authority" response criteria between 3 and 6 months.

To assess health and disability outcomes, the WHODAS 2.0 score and other patient reported outcomes (PROs) of work activity and well-being were assessed at baseline, 2 months, 4 months and 6 months after treatment initiation with adalimumab.

Setting

The investigational sites were centres with a high level of experience in the treatment of RA, CD and PsO. All study sites were in New Zealand. A total of 24 investigators, at 14 centres, participated in the study. The study population comprised of male and/or female patients clinically diagnosed with RA, CD and PsO who had made a decision, with their physician, to commence treatment with adalimumab in accordance with routine medical practice.

Subjects and Study Size, Including Dropouts

A total of 168 patients were recruited in the study, 72 of these had CD, 37 had PsO and 59 had RA.

Of the 168 recruited patients, 4 patients withdrew or were withdrawn prior to baseline measures being completed (i.e., 164 patients had baseline WHODAS data recorded), and a further 50 patients withdrew or were withdrawn prior to the 6-month WHODAS data being recorded (i.e., 114 patients had 6-month WHODAS data recorded).

Variables and Data Sources

The primary outcome variable for the study was change in WHODAS 2.0 response score at 6 months compared to Baseline.

The secondary outcome variables included: WHODAS 2.0 response score at 2 months and 4 months compared to baseline; PRO scores of work activity and well-being at all study time points compared to baseline (Work Productivity and Activity Impairment Questionnaire: General Health [WPAI:GH], Kessler Psychological Distress Scale [K10], Flourishing Scale and Subjective Vitality Scales); disease-specific PROs (Health Assessment Questionnaire-Disability Index [HAQ-DI] for RA, Short Inflammatory Bowel Disease Questionnaire [SIBDQ] for CD and Dermatology Life Quality Index [DLQI]) for PsO.

Results

Primary outcome measure: Following 6 months' treatment with adalimumab, an improvement in patients' health and disability outcomes was observed. A significant reduction in mean total WHODAS 2.0 scores was observed compared with baseline for all indications and in each indication (RA, CD and PsO). Significant improvements in WHODAS scores occurred as early as 2 months after adalimumab initiation.

Secondary outcome measures: Patients (all indications combined) achieved improvements that were statistically significant across the four measures of the WPAI:GH at 6 months post treatment compared to baseline, indicating that adalimumab decreased the impact on their ability to work and perform regular activities.

Statistically significant reductions in mean K10 scores in patient (all indications combined) indicate that distress levels (anxiety and depressive symptoms) decreased following treatment with adalimumab after 6 months.

An improvement that was statistically significant was observed for the Flourishing Scale at 6 months post treatment compared to baseline, demonstrating an improvement in human functioning (positive relationships, feelings of competence, having meaning and purpose in life) across all indications combined.

Statistically significant improvements from baseline for the Subjective Vitality Scale (state of feeling alive and alert to having energy available to the self) were observed following 6 months of treatment with adalimumab (all indications combined).

Disease-specific patient reported outcome questionnaires: There were significant improvements following 6 months of treatment with adalimumab in all of the disease-specific PRO questionnaires. Questionnaires included: the HAQ-DI (measures functional status in patients with RA); the SIBDQ (quality of life [QoL] for CD); and the DLQI (QoL for PsO).

Safety: The adverse event (AE) profile observed in this study was consistent with other reports of adalimumab in patients with RA, CD and PsO. A total of 130 AEs were reported by 65 individuals (40% of the study population), and 19 serious adverse events (SAE) were reported by 18 individuals (11% of the study population) during the study period. The majority of AEs were mild in intensity (63/130 events), with 54/130 events classified as moderate and 13/130 events Severe in intensity. One SAE was considered related to adalimumab. A patient experienced pneumonitis, 48 days from the start of treatment and was withdrawn from the study. The event was considered severe in intensity and required hospitalisation/prolongation of hospitalisation. One patient died (cause of death unknown) during the study period. The investigator considered this event not related to adalimumab. No other information on this patient is available.

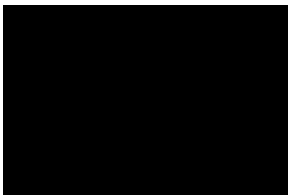
Discussion

Patients with conditions such as RA, CD and PsO can experience joint damage, hospital admissions and decreased quality of life. Adalimumab (Humira®) was found to significantly improve health and disability outcomes in New Zealand patients with the IMIDs of RA, CD and PsO. This was reflected by statistically significant improvements in WHODAS 2.0 scores, and other PROs of work activity and well-being at 6 months after adalimumab treatment compared with baseline.

Results from this observational study demonstrate the effectiveness of adalimumab (Humira®) in adult patients with severe inflammatory disease in routine clinical practice in New Zealand. The results of this PMOS may be more applicable to the general population than randomised control trials.

Marketing Authorisation Holder

AbbVie Limited



Names and Affiliations of Principal Investigator

