1.0 Abstract

Title

IDEA Study: Improvement of Work Productivity and Quality of Life with anti-TNF Therapies Used in Crohn's Disease in Routine Clinical Practice in Turkey

Keywords

Anti-TNF, Quality of life, Crohn's Disease, WPAI

Rationale and Background

Crohn's Disease (CD) is one of the major forms of inflammatory bowel diseases manifested by focal asymmetric, transmural, and granulomatous inflammation affecting any segment of the gastrointestinal tract. Current therapy for moderate to severe CD is based on 'step-up' algorithms, which initiate treatment with corticosteroids followed by immunomodulatory agents, and defer therapy with biological agents until patients become refractory to conventional medications. This study was designed to demonstrate long-term effects of anti-TNF agents on Work Productivity and Impairment (WPAI) scales in patients with moderate to severe CD under routine conditions.

Research Question and Objectives

The primary objective of this PMOS was to demonstrate long-term (12 months) effects of anti-TNF agents on Work Productivity and Impairment (WPAI) scales in patients with CD under routine conditions. Secondary objectives of this study were long-term improvement of Quality of Life (QoL), evaluation of improvement of extra-intestinal symptoms and comorbidities, and evaluation of safety.

Study Design

This is study was designed as a multicenter, prospective post marketing observational study (PMOS) to be conducted in Turkey.

Setting

Crohn's Disease patients who were identified by treating physicians and whose treatment regimens were recently initiated with an anti-TNF agent in compliance with the regulations of the Turkish Ministry of Health were enrolled in this observational study and observed for one year.

Subjects and Study Size, Including Dropouts

A total of 106 patients were enrolled to the study. During the study 33 patients were lost to follow up or dropped out of the study, therefore data of 73 patients who continued to receive any anti-TNF treatment for CD at 12th month visit were included in the statistical analysis.

Variables and Data Sources

Demographic data, medical history and information on CD were collected from enrolled patients in a prospective manner.

Results

Patients for whom the physician has recently initiated Crohn's disease treatment with anti-TNFs in accordance with Turkish Ministry of Health regulations were included in this study. Results of this study revealed that patients with moderate to severe CD experience significant improvements in their work productivity after long term treatment with anti-TNF agents compared to baseline. The pronounced improvement was detected in activity impairment score at 12th month comparing to the baseline visit (47.0% at baseline vs. 30.0% at 12th month; $p < 0.001$).

As the secondary objective, patient QoL was measured with two other tools: Inflammatory Bowel Disease Questionnaire (IBDQ) and Short Form (36) Health Survey (SF-36). Similar to the primary endpoint results, results revealed that patients under long-term treatment of anti-TNF agents significantly improve their QoL in

terms of IBDQ (for all 4 measures; $p < 0.001$) and SF-36 (for all 8 measures; $p < 0.005$) when compared to baseline.

A total of 2 serious adverse events (SAEs) (1.9%) were observed during this study and both were reported in the system organ class (SOC) of Infections and Infestations which included an abdominal abscess and an anal abscess. No deaths were reported and observed SAEs did not indicate any new safety signal for administered anti-TNF treatments such as adalimumab or infliximab.

Discussion

Parallel to the published literature, our study results showed that patients on long term anti-TNF treatment have significantly better work productivity and QoL when compared to baseline. However, limitations of our study should also be taken into consideration, including the lack of a control group in this observational study.

Marketing Authorisation Holder(s)

AbbVie Tıbbi İlaçlar Sanayi ve Ticaret Limited Şirketi

Names and Affiliations of Principal Investigators

Names and affiliations of the principal investigators are as follows:

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