

## **1.0 Abstract**

### **Title**

Assessment of Pain Management in Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis Patients Who Are About to Be Treated with Adalimumab

### **Keywords**

Rheumatology, Pain treatment

### **Rationale and Background**

Aim was to assess if treatment with adalimumab in real world settings is associated with changes in pain medication in rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) patients with or without co-morbidities, which do not constitute a contraindication for adalimumab as stated in the released summary of product characteristics.

### **Research Question and Objectives**

Main objective was to assess if adalimumab can influence pain medication in RA, PsA and AS patients with or without co-morbidities, which do not constitute a contraindication for adalimumab as stated in the released SPC. Assessment on present pain severity and on average pain severity within visit periods was recorded by patients and physicians using VAS and Likert Scale.

Secondary objectives were assessments of SF-36 and HAQ-DI questionnaire, and RADA, BASFI and BASDAI scales.

### **Study Design**

Post-marketing observational study (PMOS)

## **Setting**

15 rheumatology specialist centers in Austria

## **Subjects and Study Size, Including Dropouts**

155 subjects with rheumatoid arthritis (RA), psoriasis arthritis (PsA), or ankylosing spondylitis (AS), aged 18 years were included. Patients should fulfill the international and national guidelines for the use of a BDMARD in RA, PsA, AS, and should have had:

unsatisfactory DMARD response defined as failure to treatment with at least two DMARDs including methotrexate: RA or PsA patients;  
unsatisfactory NSAID response: AS patients  
and optional unsatisfactory response to prior BDMARDs: all patients.

## **Variables and Data Sources**

Assessment at baseline and Months 3, 6, 9, 12 of:

Pain intensity (patient and physician) at present and past 3 months, using VAS and Likert scale  
Pain medication  
RADAI, BASFI, BASDAI,  
HAQ, SF36  
ESR, CRP  
Adverse events.

## **Results**

One hundred fifty-five (155) patients from 15 Austrian centers (RA: 78, PsA: 30, AS: 47) were included and received adalimumab treatment. Mean age was  $49 \pm 13.6$  years. Sixty-one percent (61%) were female.

Twenty-three (23) patients (14.8%) had co-morbidities, and with 6 patients (3.9%) an influence of the co-morbidity on pain management was stated. One hundred twelve (112) patients (72.3 %) received additional pain medication.

Median pain intensity assessed by all patients by VAS at baseline was 60 (range, 0 – 100), and 58.5 (range, 0 – 100) as assessed by physicians. After 1 year of adalimumab therapy for those patients who remained in the study, median pain intensity was 10 (assessed by patients) and 7 (assessed by physicians). Pain intensity measured by Likert scale at baseline was: 2.6% with 'no pain,' 14.2% with 'mild pain,' 39.4% with 'moderate pain,' 40.6 % with 'severe pain,' and 3.1% were not assessed. After 1 year of treatment 31.6% stated 'no pain,' 25.8% 'mild pain,' 9.0 % 'moderate pain,' 1.9 % severe pain,' and 32.4 % were not assessed.

Median score values of RADAI, BASFI, BASDAI, and HAQ-DI decreased between baseline and 12 months.

Of the 112 patients (72.3 %) receiving additional pain medication, for 90 patients (58% of all patients) an influence of adalimumab on use of pain drugs was stated. For these patients, a substantial reduction of number of pain drugs (83 out of 90 patients), switch to a less potent pain drug (50%) and dose reduction of pain drugs (76%), was stated by the investigator.

### **Conclusion**

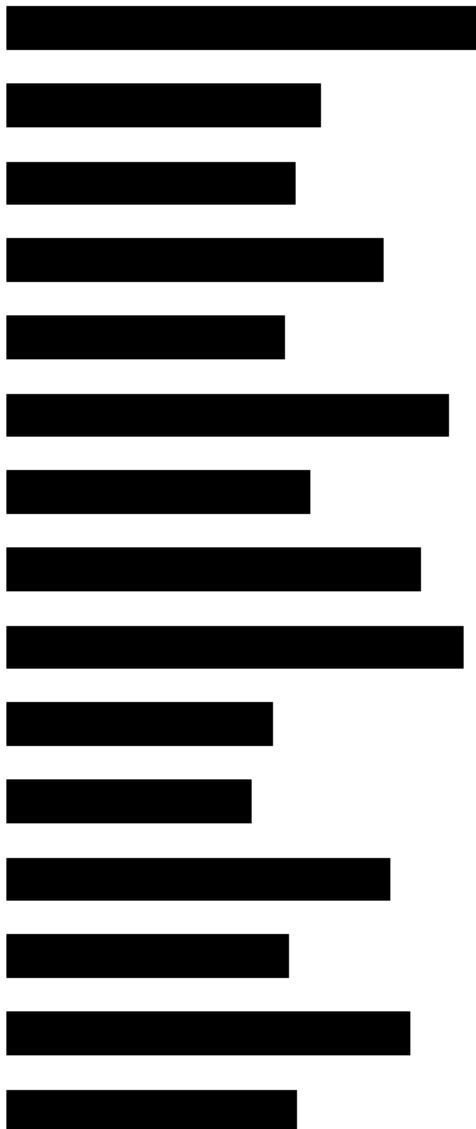
These real life data clearly have revealed a pain reduction and improvement in physical function as well as patient's quality of life during 12 months therapy with adalimumab. Concomitant pain medication was reduced or omitted in 80% (90 out of 112) patients who remained in the study for 1 year, which has a clinical impact.

**Marketing Authorisation Holder(s)**

AbbVie GmbH



**Names and Affiliations of Principal Investigators**



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