

Conclusions: During the 5-year follow-up period, patients with SpA responded well to TNFi and the response rate increased over time. Tuberculosis was the most common SAE in this registry therefore surveillance of TB should be done.

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AB0701 THE REAL-LIFE USE OF GOLIMUMAB IN PATIENTS WITH IMMUNE-MEDIATED RHEUMATIC DISEASES: ONE YEAR RESULTS OF THE GO-PRACTICE STUDY

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Background: The GO-PRACTICE study was initiated to describe the use of Golimumab (GLM), a human anti-TNF α monoclonal antibody, in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in French clinical practice.

Objectives: The primary objective of this interim analysis was to assess the persistence of GLM at 1-year.

Methods: Observational, multicenter, prospective, national study. Adult patients with RA, PsA and AS were included consecutively at GLM after the decision for GLM therapy has been taken or at least after GLM initiation, and followed-up for 2 years. We present here baseline characteristics for overall population (n=754) and interim results for patients with 1-year follow-up (n=228 patients with available data regarding persistence of GLM)

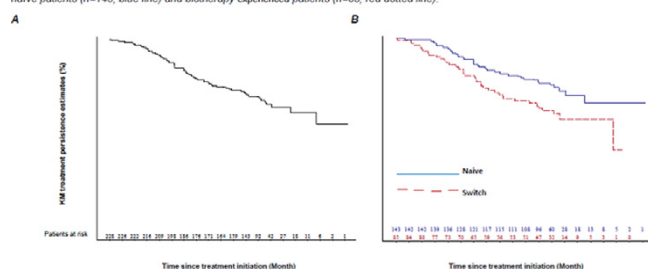
Results: A total of 754 patients (134 sites) were included between January 2015 and March 2016. Most of them had AS (64%), and 22% and 13% had RA and PsA, respectively. Mean age was 46 \pm 13 years and 61% were female. Almost 37% had received prior biotherapy.

Nearly all patients (99%) were prescribed GLM as 50 mg-monthly injections. GLM was mostly co-prescribed with other antirheumatic treatments (84%).

Of the 163 patients with available data at strictly 1-year, 56.4% were still treated with GLM; (61.9% in biotherapy-naïve patients); the persistence rate was similar across the three groups. The Kaplan-Meier duration curves of GLM are presented in figure 1. The main reason for GLM discontinuation was primary non-response, reported in 42% of patients.

Among patients who continued GLM treatment, a meaningful improvement in disease activity was observed at 1-year in 71.9% of RA, 63.2% of PsA and 68.0% of AS patients. Patients-reported outcomes, including pain and functional disability, also showed improvement

Figure 1: Kaplan-Meier duration curve of treatment with golimumab for A) the global population (n=228) and B) by prior biotherapy: biotherapy naïve patients (n=143, blue line) and biotherapy experienced patients (n=85, red dotted line).



Conclusions: In real-life practice in France, GLM was prescribed according to recommendations in terms of dosage and therapeutic strategy. One-year interim analysis, performed in one third of the cohort, suggests that GLM treatment is associated with clinical improvements leading to persistence of treatment. These results need to be confirmed in the final overall analysis planned in 2018.

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AB0702 IMPROVEMENT OF FATIGUE IN PATIENTS WITH SPONDYLOARTHRITIS TREATED WITH ANTI-TNF THERAPY: A PROSPECTIVE STUDY IN A REAL-LIFE SETTING

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Background: Besides randomized controlled trials evaluating biologic agents on

fatigue, the impact of anti-TNF therapy on this crucial symptom has been poorly assessed in a real-life setting (1).

Objectives: To assess the early effect of etanercept (ETN) on fatigue-related outcomes in spondyloarthritis (SpA) patients in a real-life setting.

Methods: This prospective study included patients with active SpA fulfilling ASAS 2009 axial or peripheral criteria requiring an anti-TNF. All patients were treated with ETN 50mg weekly. BASDAI, BASFI, functional assessment of chronic illness therapy-fatigue (FACIT-F) (0 maximum and 52 the minimum of fatigue) and visual analogic scale of fatigue (VAS-F) (0 the minimum -100 maximum of fatigue) were assessed at inclusion at the time of ETN beginning (M0) and 4 \pm 1 months later (M4).

The primary outcome was the M0-M4 change of VAS-F. The secondary outcomes were i) the M0-M4 change of FACIT-F ii) the frequency of patients who met improvement according to FACIT-F (defined as the minimal clinically important difference of FACIT-F corresponding to a 4-points decrease (FACIT-F responders)). To determine whether fatigue change was related to disease activity improvement, a correlation between M0-M4 changes of BASDAI and VAS-F or FACIT-F was determined.

Results: 30 SpA patients were enrolled (60% women, mean age \pm standard deviation 39 \pm 8 years-old, axial SpA 83%, mean BMI 26 \pm 4, 80% ETN as a 1st line). Mean BASDAI improved at M4 (M0 48 \pm 20 versus M4 36.5 \pm 22; p=0.04) as well as VAS-F (M0 69 \pm 18 vs M4 52 \pm 24; p=0.01). The frequency of patients having VAS-F >50/100 was 86% at M0 and decreased at 36% at M4. Conversely, no significant change was observed concerning FACIT-F (M0 24.5 \pm 24 versus M4 28.8 \pm 11; p=0.36). At M4, 64% patients were FACIT-F responders. FACIT-F and VAS-F M0-M4 changes were highly correlated (r=0.78, p<0.0001).

Despite no correlation between BASDAI and FACIT-F M0-M4 changes (r=0.36, p=0.1), a trend was observed for BASDAI and VAS-F M0-M4 changes in the same fashion (r=0.36, p=0.07). Interestingly, there was no baseline clinical characteristic associated with subsequent better fatigue improvement.

Conclusions: This real-life study investigating the early effect of etanercept therapy on fatigue in SpA patients showed that fatigue (according to VAS-F) significantly improved while effect on FACIT-F was less pronounced. This improvement was explained, only in part, by disease activity improvement.

References:

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AB0703 IMPACT OF ANTI-TNF AGENTS ON PATIENT-REPORTED OUTCOMES IN SPONDYLOARTHRITIS: A SYSTEMATIC REVIEW OF THE LITERATURE AND META-ANALYSIS

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Background: Disability, alteration in quality of life and fatigue are frequently reported in spondyloarthritis (SpA). Anti-TNF demonstrated clinical efficacy in SpA. However efficacy on patient-reported outcomes (PROs) may differ from medical assessment.

Objectives: To assess the impact of anti-TNF on quality of life, disability and fatigue reported by SpA patients.

Methods: Design: systematic review and meta-analysis of the literature. Data sources: two authors (SL and YD) independently screened PubMed-Medline, Cochrane library and EMBASE databases until November 2016. Key words: ("Patient reported" OR "quality of life" OR fatigue OR FACIT) AND (spondyloarthritis OR "psoriatic arthritis" OR "ankylosing spondylitis") AND (anti-TNF OR certolizumab OR etanercept OR adalimumab OR infliximab OR golimumab). Articles selection: randomized controlled trials (RCTs), published in English, assessing efficacy of anti-TNF on PROs, in ankylosing spondylitis (AS), psoriatic arthritis (PsA) or SpA according to the ASAS criteria. Data collected: fatigue assessed by FACIT score, quality of life assessed by Short Form 36 (SF36) mental and physical component or by Health Assessment Questionnaire Disability Index (HAQ). Data analysis: Article quality was evaluated by the JADAD scale. For SF36 and HAQ outcomes, pooled variations at 12 and 24 weeks were computed by meta-analysis. Heterogeneity was measured by I² index.

Results: Of the 604 articles identified, 37 references were eligible for systematic review and 13 for meta-analysis. Our systematic review identified 10 RCTs concerning AS, 20 concerning PsA and 7 concerning axial SpA. However due to the heterogeneity in available statistical data, references eligible for meta-analysis were mainly related to PsA.

HAQ assessment was available for a meta-analysis in 8 studies. HAQ was significantly improved at 12 and 24 weeks with anti-TNF. The impact on HAQ variation at week 24 was -0.29 points [95% CI: -0.37, -0.22]. Heterogeneity was important (I² =57%; see figure).

Ten studies were eligible for a meta-analysis of anti-TNF effect on SF36 mental form. An improvement was observed at 12 and 24 weeks, although superior at 24 weeks. The effect at week 24 was 2.78 [95% CI: 1.87 - 3.68], without heterogeneity (I² =0%; see figure).