

conditions like ankylosing spondylitis (AS). Despite good treatment options such as tumor necrosis factor alpha (TNF $\alpha$ ) inhibitors in AS, it is seen that patients have applied for CAM use for many reasons including local regulatory funding requirements, potential risks and accessibility of biological treatments. Few studies have examined the frequency of CAM use, and associations between demographic and disease-related factors of it in AS.

**Objectives:** To investigate the CAM usage of patients with AS and to determine the associated factors.

**Methods:** Total of 123 patients with AS, who were being followed in a tertiary rheumatology outpatient clinic, were included to the study. The demographic and clinical features along with the behaviors about the CAM usage of the patients agreeing to participate were recorded to the "Patient Assessment Form". The activity of the disease were determined with doctor global assessment (numeric visual analog scale (nVAS; 0–10), and Routine Assessment of Patient Index Data (RAPID)-3 score. The treatment adherence of the patients was assessed with the Morisky Green Levine Scale.

**Results:** One hundred eleven patients (%90.2) were male, and mean age was 36.5 $\pm$ 8.8 years. The mean disease duration and mean delay in diagnosis were 10.9 $\pm$ 6.4, and 3.7 $\pm$ 3.9 years, respectively. The mean RAPID3 score, doctor and patient global assessment were; 9.9 $\pm$ 5.3, 2.8 $\pm$ 1.9, and 4.6 $\pm$ 2.7, respectively. While 79 patients (%64.2) were on anti-TNF treatment, 76 patients were receiving NSAIDs, and 35 patients (%28.5) reported an adverse event related with the treatment. Forty-five patients (%36.6) reported to use any CAM (previous or current) (Table1). The reasons reported by the patients for the usage of CAM; media in %13, recommendations from family members or relatives in %10.6. It has been found that in married patients, the ones with lower the Morisky Green Levine Scale score (high adherence), CAM usage was statistically high ( $p < 0.05$ ). Receiving NSAIDs or anti-TNF agents was not statistically associated with CAM usage. The underlying expectations for the usage of CAM were; considering it might be helpful in %27.6; considering it might heal in %17.9; to relieve the pain in %14.6; and preventing to deteriorate the disease status in %12.2.

Table 1. Types of CAM use

CAM Type	n*	%
Plants and herbs	31	25.2
Massage	13	10.6
Spa	10	8.1
Praying/spiritual approach	6	4.9
Cupping	3	2.4
Imagining	2	1.6
Naturapati	2	1.6
Acupuncture	1	0.8

CAM, complementary and alternative medicine. \*There are patients marked the method more than one.

**Conclusions:** In our study, we found that approximately one third of our AS patients were using CAM. When compared with the literature related with other diseases, CAM usage in AS patients was somewhat lower. Our results have demonstrated that treatment adherence was higher in those using concomitantly CAM in their therapy.

**Disclosure of Interest:** None declared

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#### AB0699 EFFECTS OF GLOBAL POSTURAL REEDUCATION EXERCISE AND ANTI-TNF TREATMENTS ON DISEASE ACTIVITY, FATIGUE, MOBILITY, SLEEP QUALITY AND DEPRESSION IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS (PROSPECTIVE-CONTROLLED TRIAL)

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**Background:** Ankylosing spondylitis (AS) is chronic inflammatory disease that affects primarily the spine and the sacroiliac joints. ASAS/EULAR guidelines describe regular exercise as the cornerstone of non-pharmacological treatment and pharmacological treatments including non-steroidal anti-inflammatory drugs as first-line therapy, and a tumour necrosis factor (TNF) alpha inhibitor (anti-TNF $\alpha$ ) as second-line medication in patients with persistently high disease activity despite conventional pharmacological treatment in patients with AS.

**Objectives:** The purpose of this study was to investigate the effects of combination therapy with global postural reeducation exercise (GPR) and Anti-TNF treatments on pain, disease activity, mobility, fatigue, sleep quality, and depression in patients with active AS.

**Methods:** 60 active AS patients who meet the criteria of Modified New York and/or ASAS axial spondyloarthritis were included in the study. Patients were divided into 3 groups. The first group was given anti-TNF therapy plus GPR exercise program. The 2nd group was given anti-TNF and conventional exercise therapy. The 3rd group was given routine exercise program along with their existing treatments (NSAIDs and/or SLZ). Following inventories are used for clinical evaluation: for disease activity – Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), for functionality – Bath Ankylosing Spondylitis Functional Index (BASFI), for mobility – lumbar Schober, chest expansion, hand-finger to floor distance, for fatigue – fatigue Multidimensional Assessment Questionnaire (MAF), for sleep quality – Pittsburgh sleep quality index (PSQI), for depression

– Beck depression Inventory (BDI). All patients were evaluated before treatment and at 3 months.

**Results:** The demographic characteristics of the patients were compared and there was no significant difference between the groups. The improvements in all parameters were better in both groups receiving exercise and anti-TNF therapy than in the control group after treatment compared with baseline. The Anti-TNF + GPR exercise therapy resulted in greater improvements than the anti TNF+ conventional exercise therapy in pain, and mobility parameters.

**Conclusions:** Anti-TNF therapy and exercise were efficient in both groups on improving pain, disease activity, fatigue, sleep quality, and depression. However, the improvements in pain and mobility were greater in the active AS patients with GPR exercise method. Therefore motivated patients should be encouraged to perform this exercise program.

**References:**

[1] Lubrano E, Spadaro A, Amato S, et al. Tumour necrosis factor alpha inhibitor therapy and rehabilitation for the treatment of ankylosing spondylitis: A systematic review. *Seminars in Arthritis and Rheumatism*. 44(2015)542–550.

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#### AB0700 EFFICACY AND DRUG SURVIVAL OF ANTI-TUMOUR NECROSIS FACTOR-ALPHA THERAPIES IN PATIENTS WITH SPONDYLO-ARTHRITIS: ANALYSIS FROM THE THAI RHEUMATIC DISEASE PRIOR AUTHORIZATION (RDPA) REGISTER

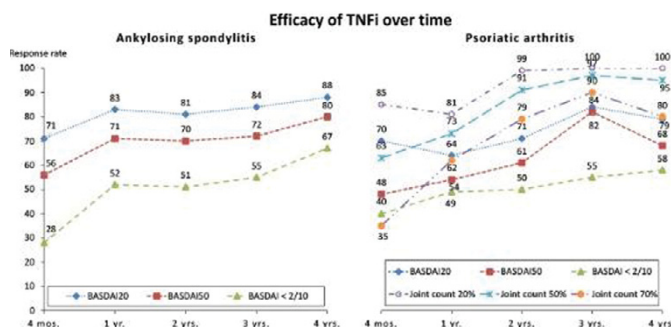
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**Background:** Treatment recommendations for patients with spondyloarthritis (SpA) who inadequately respond to non-steroidal anti-inflammatory drugs (NSAIDs) and/or traditional disease-modifying antirheumatic drugs (DMARDs) are anti-tumour necrosis factor-alpha therapy (TNFi). There has been no data on the long-term efficacy and safety of TNFi in Thai patients with SpA.

**Objectives:** To evaluate the long-term efficacy and safety of the first TNFi in real-life practice and to identify the risk factors related to drug discontinuation in Thai patients with SpA from the RDPA registry.

**Methods:** Patients who fulfilled the 1984 Modified New York criteria for ankylosing spondylitis (AS), CASPAR criteria or Moll and Wright criteria for psoriatic arthritis (PsA) and the European Spondyloarthritis Study Group Criteria or Modified Amor criteria for undifferentiated SpA (uSpA), and were prescribed the first TNFi between December 2009 and October 2014 in the RDPA registry were enrolled. Baseline demographic and clinical data were retrieved. A Cox proportional hazard model was used to identify the factors associated with discontinuation. The P-value of <0.05, two-sided was considered statistically significant.

**Results:** Of the 142 patients included, 97 had AS, 41 had PsA, and 4 had uSpA. Most AS patients were male (54.6%) with mean (SD) age of 44.6 (10.6) years, median (P<sub>25</sub>–P<sub>75</sub>) baseline BASDAI was 6.5 (5.6, 8.2) [from a 10-cm visual analog scale (VAS)], and median baseline patient global assessment (bPGA) was 7.2 (P<sub>25</sub>–P<sub>75</sub> 6.0, 8.0) (from a 10-cm VAS). For PsA patients, most were female (68.3%) with mean age of 52.6 (SD 12.2) years, median baseline BASDAI was 6.6 (P<sub>25</sub>–P<sub>75</sub> 4.9, 7.4) in patients with active axial involvement and median baseline number of joint involvement was 13.5 (P<sub>25</sub>–P<sub>75</sub> 6, 18.3) joints per patient with active peripheral joint involvement. The efficacy of the TNFi treatment was good and it was increased over time in AS and PsA patients (figure 1). During the 5-year follow-up, AS, PsA, and uSpA patients had comparable discontinuation rate of their first TNFi treatment [25 (26%) in AS, 14 (34%) in PsA, and 1 (25%) in uSpA;  $p = 0.82$ ]. In univariate analysis, leflunomide use, and bPGA <3 comparing to >6 (from a 10-cm VAS) were associated with the discontinuation of TNFi in AS patients with hazard ratio (HR) (95% CI) of 2.56 (1.13, 5.81) and 8.59 (1.82, 40.65), respectively. For the patients with PsA, only infliximab use was associated with TNFi discontinuation with HR of 4.79 (95% CI 1.33, 17.20) in univariate analysis. The reasons for TNFi discontinuation were good response (38%), serious adverse effects (SAE) (30%), non-adherence (20%), and lack of efficacy (13%). Among SAE, 58% was infectious causes (57% tuberculosis and 43% non-mycobacterium infections). The others were non-infectious causes.



**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 $\alpha$  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).

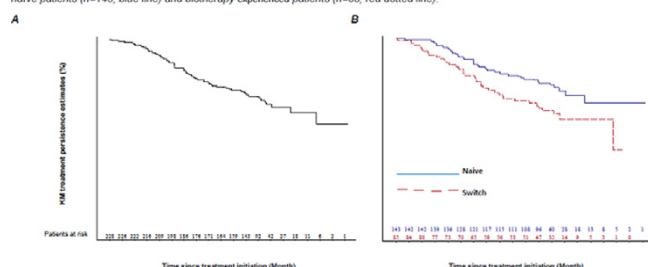
**Results:** A total of 754 patients (134 sites) were included between January 2015 and March 2016. Most of them had AS (64%), and 22% and 13% had RA and PsA, respectively. Mean age was 46 $\pm$ 13 years and 61% were female. Almost 37% had received prior biotherapy.

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:**

[1] Chaffier K, et al Clin Exp Rheumatol. 2013;31:864–70.

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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 I<sup>2</sup> 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 (I<sup>2</sup> =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 (I<sup>2</sup> =0%; see figure).