Figure. Predictors of Methotrexate Insufficient Response or Rapid Radiographic Progression in Patients with Early Rheumatoid Arthritis Receiving Methotrexate^a

BMI, body mass index; CRP, C-reactive protein; DAS28, Disease Activity Score 28; HAQ, Health Assessment Questionnaire; mTSS, modified Total Sharp Score; MTX, methotrexate; PGA, Physician Global Assessment of disease activity; Pt pain, patient's assessment of pain; RF, rheumatoid factor; TJC, tender joint count.
^aTime-averaged value through week 12 are shown.

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SAT0143 COMPARISON OF TREATMENT WITH GOLIMUMAB AND CERTOLIZUMAB-PEGOL IN ARTHRITIS- RESULTS FROM THE SOUTH SWEDISH ARTHRITIS TREATMENT GROUP (SSATG) REGISTER

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Background: "Head to head" studies comparing the efficacy and tolerability of different TNF inhibitors are scarce, in particular the comparison between certolizumab pegol and golimumab.

Objectives: To compare the efficaciousness, drug survival and tolerability of certolizumab-pegol and golimumab in adult patients with establish arthritis (RA, JIA, SpA or unspecified polyarthritis) starting these treatments between February 2010 and December 2013 at out-patient unit at the Skåne University Hospital, Department of Rheumatology Lund/Malmö and two associated private rheumatology units.

Methods: All patients starting treatment with biologics were consecutively included in the South Swedish Arthritis Treatment Group (SSATG) register and regularly followed up according the standard protocol including: SJC/TJC, CRP, ESR, physicians global assessment of disease activity, patients' assessment of disease activity and pain (VAS global and VAS pain) and HAQ. Last follow up date was October 17th 2016. Kaplan-Meier survival analysis was used to estimate the drug survival. Possible predictors of drug survival were analysed using Cox regression model.

Results: In total, 352 patients (71% women, mean age 51 years, mean disease duration 12 years, started these treatments during study period. Of these, 168 received golimumab and 184 certolizumab-pegol. Mean treatment time was 31 months (range 0-77). Percentage of patients with RA, SpA, JIA and unspecified arthritis were 58,4%, 16,4%, 5,7%, and 19,5% respectively. Certolizumab-pegol was more used in RA (67% vs 49%) and JIA (8% vs 2%) while golimumab was more frequent among patients with SpA (21% and 12%) or PsA (23% and 10, respectively). Only 7% of golimumab and 10% of certolizumab-pegol patients received these drugs as first biologic treatment and approximately 50% of patients received these drugs as ≥ 3 . biological treatment. In golimumab treated patients mean DAS28 decreased from 4,3 (baseline) to 3,3

(3 months); 2,8 (6 months) and 2,7 (12 months) but levelled off at 36 months follow up. Corresponding mean DAS28 levels in certolizumab-pegol treated patients were 4,6 (baseline); 3,2 (3 months); 2,8 (6 months) and 2,6 (12 months). The similar pattern was seen in changes in HAQ and CDAI over the study time. There were no statistically significant differences in DAS, HAQ or CDAI between treatments at any follow up visit. At the end of follow up 64 (38%) of golimumab and 60 (32%) of certolizumab-pegol patients remained on their treatment. No significant difference in drug survival was seen between the treatments (Figure). Patients with spondylarthropathy had significantly better survival on golimumab compared to RA patients ($p=0,005$) which remained after adjustment for age, gender, CRP, number of previous biologics and concomitant methotrexate at baseline.

Conclusions: Spondylarthropathy including psoriatic arthritis was associated with better drug survival on golimumab compared to certolizumab pegol. No other significant differences in efficacy, tolerability or drug survival were seen between golimumab and certolizumab pegol in patients with established arthritis in daily clinical practice. Approximately one third of patients starting these treatments remained on treatment after 3 years.

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SAT0144 TUMOR NECROSIS FACTOR-ALPHA INHIBITORS AND PSYCHIATRIC SIDE EFFECTS: RESULTS FROM THE FRENCH PHARMACOVIGILANCE DATABASE

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Background: Although Tumor Necrosis Factor alpha (TNF- α) is a major proinflammatory cytokine in the brain, potential psychiatric side effects of TNF- α inhibitors have been little investigated. Manic and psychotic disorders are not recognized as TNF- α inhibitors' side effects even though few reports of such complications have been reported.

Objectives: This study reports cases with psychiatric symptoms (in the spectrum of psychotic and manic disorders) that occur during treatment with tumor necrosis factor alpha (TNF- α) inhibitors and aims to evaluate the role of these agents as causative factors.

Methods: We searched the French Pharmacovigilance Database for consecutive cases of positive psychiatric side effects reported during treatment with TNF- α inhibitors. Major psychiatric symptoms were defined, according to DSM-V, as mania and psychosis, and minor psychiatric symptoms as psychomotor agitation, euphoria, hallucinations, personality distortion, and increased libido. Each case had one major symptom or at least one minor symptom.

Results: Among 7912 consecutive cases of side effects registered in the database for TNF- α inhibitors, 184 reported psychiatric symptoms, and of these, 71 met inclusion criteria, whereas 113 met an exclusion criterion. Depression was the most frequent cause for exclusion. TNF- α inhibitors were the only medication suspected in 56 cases (79%). The time between beginning TNF- α inhibitors and onset of symptoms varied from hours to months with a median time of 49 days (IQR=156); initial symptoms mostly worsened under treatment. TNF- α inhibitors were withdrawn in 42 (61%) cases. The improvement of symptoms was significantly associated with treatment withdrawal (78% versus 22%, $p=0.01$). Relapses occurred after rechallenge of TNF- α inhibitors in three of four patients.

Conclusions: We report the first cohort of 71 cases with psychiatric symptoms in the spectrum of manic and psychotic disorders during treatment with TNF- α inhibitors. Our experience suggests that anti-TNF α therapy may cause manic or psychotic side effects.

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