by spring (24.1%), fall (22.8%), and winter (20.3%). The clinical and laboratory characteristics at presentation are shown in Table 1. Muscle biopsy was performed in 93% of patients. Notably, patients with swallowing difficulties had more commonly had Raynaud phenomenon (RR 3.7 (95% CI 1.4–9.4), p=0.008).

Table 1. The clinical and laboratory characteristics at presentation

	# (%)
Myositis	72 (91)
Skin rash	42 (53)
Weight loss	35 (44)
Interstitial lung disease	29 (37)
Swallowing difficulties	31 (39)
Arthritis	20 (25)
Raynaud phenomenon	14 (18)
Fever	9 (11)
median ESR	27 (16-45)
MEDIAN CRP	7 (1-22)
Hep-2 test: ANA (≥1:160)	41 (52)
Hep-2 test: nonspecific cytoplasmic IF	20 (25)
Anti-ENAs	43 (54)
aJo-1	17 (22)
aPL-12	3 (4)
aMI-2	2 (2.5)
aPM/Scl	5 (6)
aKu	1 (1.3)
aU1-RNP	1 (1.3)
ACA	1 (1.3)
aRo	6 (8)
aSRP	1 (1.3)
aSAE	1 (1.3)
3HHMGCoaR	3 (4)
RTE/HSE	19 (24)
Histopathologically proven IM	86.5%

Legend: ACA – anti-centromere antibodies, ANA – anti-nuclear antibodies, anti-ENAs – autoantibodies against extractable nuclear antigens, CRP – C-reactive protein, EMG – electromyogram, ESR – erythrocyte sedimentation rate, RTE/HSE – rabbit thymus extract/human spleen extract used in the in-house anti-ENA counter-immuno-diffusion assay, IF – immunofluorescence, IM – inflammatory myopathy.

Conclusions: The averaged 12-year annual incidence of IM in the population under study was 9.4 (95% CI 7.5–11.8) per 10^6 adults.

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Spondyloarthritis - treatment

AB0683 TROUGH INFLIXIMAB LEVELS AND ANTI-INFLIXIMAB ANTIBODIES IN SPONDYLOARTHRITIS PATIENTS ON TREATMENT WITH LOW DOSE INFLIXIMAB: A SINGLE CENTRE CROSS-SECTIONAL STUDY

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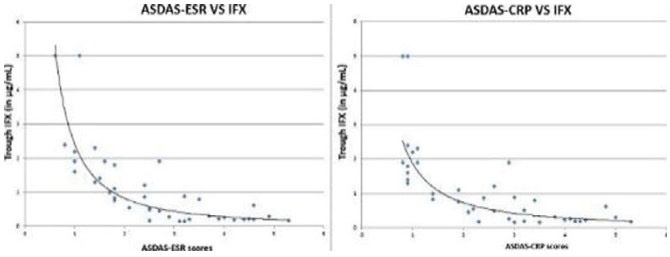
Background: Infliximab (IFX) is an anti-TNF, chimeric, monoclonal antibody approved for use in refractory spondyloarthritis (SpA). Studies done in patients with Rheumatoid arthritis[1] and Inflammatory bowel disease[2] have demonstrated the clinical utility of the measurement of serum trough IFX and antibodies to IFX (ATI). In India, many centres including ours use IFX at lower doses of 3–5 mg/kg and on demand IFX treatment without the use of the loading dose IFX in SpA patients[3]. Data on the utility of measuring trough IFX and ATI levels and their correlation with disease activity in such group of patients is lacking.
Objectives: To evaluate the co-relation between trough Infliximab levels and disease activity measures, viz ASDAS ESR and ASDAS CRP in SpA patients on low dose IFX therapy
To compare the mean ASDAS- ESR/CRP scores between ATI positive and ATI negative patients
Methods: Thirty-nine adult spondyloarthrtitis patients in the age group of 18–70 years, meeting the ASAAS classification criteria for peripheral and/or axial spondyloarthritis were recruited into the study. The inclusion criteria required the patients to have had received three or more infusions of IFX at 3–5 mg/kg/dose over the past 6 to 9 months. Blood samples were collected between two to three months after the previous IFX infusion for the measurement of the ATI and the trough IFX levels using the Matriks Biotek Shikari Q-ATI ELISA and Q-IFLIXI ELISA kits respectively. At the same time, disease activity of the patients was quantitated using ASDAS ESR and ASDAS CRP scores.
Correlation between the ASDAS scores and the trough IFX levels was analysed by Pearson's product moment correlation assay. The difference in mean trough IFX and ASDAS scores between the ATI positive and ATI negative patients were assessed using Welch two sample t-test.
Results: There was a moderately significant negative correlation between the trough IFX levels and the ASDAS-ESR ($r = -0.69$, $p<0.001$), ASDAS-CRP scores ($r = -0.67$, $p<0.001$) (Fig 1). ATI positive patients in comparison to ATI negative, had significantly higher ASDAS ESR and ASDAS CRP scores (Table 1).

Table 1. Table showing differences in ASDAS scores between ATI positive and negative patients

	ATI +ve patients	ATI –ve patients	P value
Mean ASDAS ESR	3.13	1.56	<0.001
Mean ASDAS CRP	3.06	1.45	<0.001



Conclusions: SpA patients from India on low dose, on demand IFX therapy, have both the trough IFX and ATI correlate significantly with the measures of disease activity. Therefore, these may be used in addition to clinical activity scores for a more cost effective on demand IFX therapy in SpA patients, especially in an expense constrained country like India.

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AB0684 CLINICAL RESPONSE AND RADIOGRAPHIC PROGRESSION IN ANKYLOSING SPONDYLITIS PATIENTS UNDER ANTI-TNF THERAPY: IMPACT OF HIP INVOLVEMENT

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Background: Hip involvement is considered an important prognostic factor associated with radiographic progression in ankylosing spondylitis (AS) patients. However, there are no studies regarding hip involvement impact on clinical response and radiographic progression in AS patients under anti-TNF therapy.
Objectives: Compare clinical and radiographic progression in AS patients receiving anti-TNF therapy with and without moderate-severe hip involvement.
Methods: Forty-seven AS patients referred to receive anti-TNF treatment were included and classified according to baseline hip involvement based on Bath Ankylosing Spondylitis Radiology Hip Index (BASRI-Hip): none-minimal hip disease (hip grade <3) or moderate-severe disease (hip grade ≥3). Demographic data, presence of HLA-B27, extra-articular involvement, DMARD and NSAID use, clinical and laboratorial disease parameters (BASDAI, BASMI, BASFI, ASQol, mSASSS and inflammatory markers) were assessed at baseline and two years after anti-TNF treatment.
Results: Thirty-four (72.3%) patients were classified as none-minimal hip disease and 13 (27.7%) as moderate-severe hip involvement. Both groups were similar at baseline considering age, HLA-B27, extra-articular involvement and comedication use. Laboratorial markers (ESR, CRP) and disease parameters (BASDAI, BASFI and mSASSS) showed no difference at baseline. Moderate-severe group had longer disease (10.0±7.6 vs. 14.9±8.6, P=0.002, years), higher BASMI (3.8±2.4 vs. 6.5±2.5, P=0.002) and lower ASQoL (13.7±4.4 vs. 9.9±4.9, P=0.007). After two-years of anti-TNF therapy, both groups presented similar BASDAI response (delta BASDAI, p=0.134; final BASDAI, p=0.324) and an increase in mSASSS [no-minimal involvement: 13.6±18.3 vs. 16.1±19.4, P<0.001); moderate-severe involvement: 21.7±19.9 vs. 28.6±18.5, P=0.003]. At final evaluation patients with moderate-severe hip involvement presented higher mSASSS (28.6±18.5 vs. 16.1±19.4, P=0.02), despite similar delta BASDAI and final BASDAI.
Conclusions: Our study provides evidence that hip involvement did not impact on clinical response in AS patients under anti-TNF therapy but may have an effect on radiographic progression of these patients.

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AB0685 SECUKINUMAB PROVIDES SUSTAINED IMPROVEMENTS IN WORK PRODUCTIVITY AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH ANKYLOSING SPONDYLITIS: LONG-TERM RESULTS FROM MEASURE 1 AND MEASURE 2

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Background: Patients (pts) with ankylosing spondylitis (AS) experience significant restrictions in work productivity and health-related quality of life (HRQoL). Secukinumab (SEC) demonstrated rapid improvements in signs, symptoms and physical functioning in pts with AS.[1]
Objectives: To assess whether the beneficial effects of SEC on AS signs and symptoms were reflected in improvements in work productivity and HRQoL in the overall population and in TNF inhibitor (TNF)-naïve pts and pts with an inadequate response or intolerance to TNF inhibitors (TNF-IR) for up to 52 weeks (wks) in MEASURE 2 and 104 wks in MEASURE 1.
Methods: 371 and 219 pts were randomized to SEC or placebo (PBO) in MEASURE 1 (10 mg/kg IV followed by 150 or 75 mg SC) and MEASURE 2 (150 or 75 mg SC), respectively. At Wk 16, PBO pts were re-randomized to SEC 150 or 75 mg SC (PBO pts with ASAS20 response at Wk 16 were switched to SEC at Wk 24 in MEASURE 1). Productivity was measured using the Work Productivity and Activity Impairment-General Health (WPAI-GH) questionnaire, which includes questions to assess absenteeism, presenteeism and overall work productivity impairment in employed pts, and general activity impairment in all pts during the preceding 7 days (0–100%). HRQoL was assessed with the ASQoL questionnaire (0–18 points). Across both studies, approximately 69% of pts were TNF-naïve and 31% were TNF-IR. Observed data are presented from the full analysis set and in subgroups stratified by prior TNF exposure. Only data with the approved dose (SEC 150 mg) are shown.

Table. WPAI-GH and ASQoL outcomes in MEASURE 1 and MEASURE 2 through Week 104

	MEASURE 1			MEASURE 2[a]		
	Overall	TNF-naive	TNF-IR	Overall	TNF-naive	TNF-IR
WPAI GH[b] (change from BL)						
Absenteeism (% work time missed due to health)[c]						
Wk 52	−2.1 (n=60)	−3.5 (n=47)	3.0 (n=13)	−4.9 (n=38)	−12.8 (n=23)	7.1 (n=15)
Wk 104	1.3 (n=49)	0.2 (n=41)	6.8 (n=8)	–	–	–
Presenteeism (% impairment while working due to health)[c]						
Wk 52	−20.2 (n=57)	−21.6 (n=45)	−14.9 (n=12)	−19.2 (n=37)	−25.5 (n=22)	−10.0 (n=15)
Wk 104	−25.1 (n=49)	−27.8 (n=41)	−11.3 (n=8)	–	–	–
Work Productivity (% overall work impairment due to health)[c]						
Wk 52	−21.2 (n=57)	−23.2 (n=45)	−13.8 (n=12)	−21.3 (n=37)	−29.5 (n=23)	−7.9 (n=14)
Wk 104	−23.0 (n=49)	−26.1 (n=41)	−6.9 (n=8)	–	–	–
Activity Impairment (% activity impairment due to health)[d]						
Wk 52	−25.4 (n=107)	−26.7 (n=83)	−20.8 (n=24)	−26.4 (n=61)	−30.5 (n=40)	−18.6 (n=21)
Wk 104	−27.3 (n=85)	−27.5 (n=67)	−26.7 (n=18)	–	–	–
ASQoL (change from BL)[c,e]						
Wk 52	−4.7 (n=109)	−5.0 (n=85)	−3.4 (n=24)	−5.2 (n=61)	−6.0 (n=40)	−3.7 (n=21)
Wk 104	−4.8 (n=86)	−5.0 (n=68)	−4.1 (n=18)	–	–	–

[a] WPAI-GH and ASQoL were not assessed at Week 104 of MEASURE 2; [b] In all categories, higher scores indicate higher impact on patients, employers, and society; a decrease from baseline represents improvement; [c] Assessed in 'employed' subjects only; [d] Assessed regardless of subject's employment status; [e] Higher scores represent greater impact on patients' QoL. A decrease from baseline represents improvement

BL, baseline; n, number of patients with sufficient data for evaluation; s, number of responders; SEC, secukinumab

Results: At baseline (BL), 77 of 125 and 45 of 72 randomized pts were employed and working in the SEC groups in MEASURE 1 and 2, respectively. Improvements in all WPAI domains were observed with SEC in the overall, TNF-naïve and TNF-IR populations at Wk 16 in both studies, and effects were generally sustained through Wks 52 and 104 (Table). In MEASURE 1, activity impairment in the total group improved by 49% and overall work productivity in those employed improved by 45% from BL at Wk 104. Improvements were 51%/49% in TNF-naïve and 42%/19% in TNF-IR pts, respectively. In MEASURE 2, activity impairment and work productivity improved by 43% and 40% vs BL, respectively at Wk 52; improvements in activity impairment/work productivity in TNF-naïve and TNF-IR pts were 49%/54% and 32%/16%, respectively. Similar responses were seen in the other WPAI scores across both studies. Early improvements in ASQoL were sustained through Wk 104 in MEASURE 1 and Wk 52 in MEASURE 2. At Wk 104 of MEASURE 1, ASQoL scores had improved by 48% vs. BL with SEC; improvements were 50% and 39% in TNF-naïve and TNF-IR pts, respectively.
Conclusions: SEC provides sustained improvements in work productivity and ASQoL for up to 104 wks among AS pts, regardless of prior TNF exposure.
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[1] Baeten. NEJM 2015;373:2534–48.
Disclosure of Interest: A. Deodhar Grant/research support from: Amgen, Abbvie, GSK, Eli Lilly, Janssen, Novartis, Pfizer, UCB, Speakers bureau: Eli Lilly, Janssen, Novartis, Pfizer, UCB, P. Conaghan Consultant for: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, Speakers bureau: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, V. Strand Consultant for: AbbVie, Amgen, BMS, Celgene, Celltrion, CORRONA, Genentech/Roche, GSK, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sanofi, and UCB, A. Boonen Grant/research support from: Merck, Pfizer, Abbvie and Amgen, Speakers bureau: Sandoz, Janssen, Lilly, G. Ferraccioli Grant/research support from: BMS, Roche, MSD, Speakers bureau: AbbVie, Pfizer, UCB.Roche, MSD, Eli Lilly, GSK, Novartis, F. Van den Bosch Consultant for: Abbvie, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Merck, Novartis, Pfizer, UCB, Speakers bureau: Abbvie, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Merck, Novartis, Pfizer, UCB, V. Bhosekar Employee of: Novartis, B. Porter Shareholder of: Novartis, Employee of: Novartis, K. Gandhi Shareholder of: Novartis, Employee of: Novartis, S. Jugl Shareholder of: Novartis, Employee of: Novartis
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AB0686 ASSOCIATION BETWEEN DRUG SERUM LEVELS AND DISEASE ACTIVITY IN ESPONDILOARTHRITIS PATIENTS TREATED WITH GOLIMUMAB

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Background: Efficacy and safety of Golimumab (Glm) has been demonstrated for spondiloarthritis (SpA). Nonetheless, there is little data determining an association between an optimal drug levels concentration and the maintenance of a good control of disease activity. In Spa-Paz cohort we defined previously an optimal Glm levels concentration associated with a good clinical response.
Objectives: To investigate the association between serum levels of Glm, based on the optimal concentration defined previously in Spa-Paz cohort, and disease activity in a larger cohort of SpA.
Methods: Observational prospective SpA-Paz cohort study treated with Glm. Disease activity was measured by ASDAS and clinical improvement using Delta-ASDAS at baseline, 6 and 12 months of biologic therapy. ASDAS$<$2.1 was considered as low activity and clinically important improvement as Delta-ASDAS$\geq$1.1. Drug levels were measured by ELISA at 6 and 12 months of therapy and classified in 3 groups based on the optimal concentration range previously defined in our cohort: Group 1:$<$0.7 mg/L, group 2: 0.7–1.4 mg/L, group 3: $>$1.4 mg/L. At 12 months we made a LOCF analysis to include patient data (11 patients) with less than 12 months of treatment. We used the software Graph-Pad Prism 6 for statistical analysis.
Results: 46 patients of 79 with SpA treated with Glm were included in this study. The average age was 49 years old (age range 22–72 years old), 31 men (67%) and 15 women (33%). 22 patients (48%) were non-smokers and 13 (28%) active smokers. 25 (54%) were HLA-B27 positive. In total, 17 patients (37%) were classified in group 1, 16 (35%) in group 2 and 13 (28%) in group 3. At 12 months of therapy, most patients in low disease activity were in groups 2 and 3 but nevertheless, the majority of high disease activity patients were in group 3 (76% in groups 2 and 3 vs. 41% in group 1 with ASDAS$<$2.1; 24% in group 2 and 3 vs. 53% in group 1 with ASDAS$\geq$2.1; $p<0.0001$). Likewise, clinical improvement was significantly higher in groups 2 and 3 patients (62% in groups 2 and 3 vs. 35% in group 1, $p>0.0002$). There were no differences in clinical improvement between group 2 and 3. 11 patients (24%) discontinued the treatment, 1 for adverse effect and 10 for inefficacy, 50% of which (5 patients) were in group 1 at the suspension moment.
Conclusions: In our Glm treated SpA cohort, the majority of low activity patients and higher clinical improvement were classified in optimal or supraoptimal concentration group. Overoptimal concentration drug levels do not seem to contribute to major benefit in clinical improvement.
Disclosure of Interest: None declared
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