after week 12 is the same. Infections, but not tumours, are the most frequent side-effects of biological treatment in RA patients.

Disclosure of Interest: None declared

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AB0434

THE INFLUENCE OF BODY MASS INDEX ON THE EFFICACY OF TUMOUR NECROSIS FACTOR BLOCKING THERAPY AND DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: The impact of Body Mass Index (BMI) on efficacy of TNF blocking therapy in Rheumatoid Arthritis (RA) patients and therefore on control of the disease is an important question.

Objectives: The aim of this study is to determine the influence of BMI on the efficacy of TNF blocking therapy in terms of disease activity in patients with RA.

Methods: A retrospective, observational study of 168 consecutive RA patients who received subcutaneously (SC) TNF blocking treatment (adalimumab, etanercept, golimumab and certolizumab pegol). Their follow-up data, for at least 26 weeks, and their baseline BMIs were available. The WHO definition for normal weight, overweight and obesity was applied, whereas clinical response was compared by BMI subgroups.

Results: The average BMI was 26.83±4.34 kg/m² and the baseline Disease Activity Score in 28 joints (DAS28 [ESR]) was high at 5.72±0.84. Mean age was 63.47±12.58 years and 135 (80.36%) were female. The median disease duration was 13.01±8.57 years. Overall, patients with normal weight responded better to treatment regimen, followed by overweight and obese subgroups. After a follow-up period of 26 weeks, the obese group had significantly higher DAS28 (ESR) and Health Assessment Questionnaire (HAQ) than either normal or overweight subgroups (3.26±0.84 vs 2.72±0.78 vs 2.81±0.82, p<0.001, 0.423±0.002 vs 0.076±0.01 vs 0.178±0.01, p<0.001 respectively). Furthermore, obesity was significantly associated with a decreased tendency of achieving week 26 remission, based on DAS28 (<2.6) p:0.002 and normal HAQ (≤0.5) p: 0.003.

Abstract AB0434 – Table 1. Summary of responses to TNF-blocking therapy (SC) by BMI category at week 26 in subjects with RA

Variable		% (n/N)			p value [95% CI]
		BMI <25 kg/m ²	BMI 25–30 kg/m ²	BMI >30 kg/m ²	
DAS28 HAQ	Remission (<2.6)	58.18 (22/55)	35.8 (29/81)	0 (0/32)	0.002 [15–16.5]
	LDA (>2.6 – <3.2)	9.09 (5/55)	40.74 (33/81)	37.5 (12/32)	0.001 [16.6–16.7]
	MDA (>3.2 – <5.1)	30.91 (17/55)	23.46 (19/81)	62.5 (20/32)	0.001 [15.2–16.9]
	HDA (>5.1)	1.82 (1/55)	0 (0/81)	0 (0/32)	ns
	<0.5	61.81 (34/55)	58.02 (47/81)	46.88 (15/32)	0.003 [8.9–16.6]

LDA: low disease activity, MDA: moderate disease activity, HDA: high disease activity

Conclusions: Patients with RA and higher BMIs demonstrated a diminished clinical response after 26 weeks of SC-administered TNF-blocking treatment compared with their counterparts with lower BMIs.

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AB0435

THE TREATMENT PATTERN OF TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS IN CHINA: A MULTICENTER OBSERVATIONAL STUDY

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Background: Tocilizumab (TCZ) is a humanised monoclonal antibody targeting interleukin-6 receptor. Since TCZ Label for RA has been issued in many countries, administration patterns and dose modifications for managing adverse events (AEs) seems differ depending on clinical opinion. Few data are available from real world practice in China.

Objectives: To observe in routine clinical practice the treatment patterns of TCZ in RA patients with regard to persistence on drug and adherence to the licensed label recommendations.

Methods: This a 6 month non-interventional, multi-centre study enrolled patients with moderate to severe RA diagnosed per revised 1987 ACR criteria (age ≥18 years) and being treated with TCZ. Data was recorded during routine visit. The primary variable was the proportion of patients on TCZ treatment after 6 months.

Results: Of 407 patients from 23 centres in China, 396 were eligible, including 330 (83.3%) women. The mean age was 49.1±13.44 years. The mean RA diagnosis course was 5.4±6.24 years. Among 396 patients, 250 (63.1%) were RF positive, 235 (59.3%) were anti-CCP positive and 123 (31.1%) had anaemia (Hb <90 g/L). Of eligible patients, 293 (74.0%) completed the study. The primary reason of premature termination was treatment costs (n=49, 12.4%). There were 37 (9.3%) patients received anti-TNF biologics previously and 330 (83.3%) received concomitant DMARDs, of which 84 (21.2%), 149 (37.7%) and 97 (24.5%) received single, 2 or ≥3 types of DMARDs, respectively. Methotrexate (n=255, 64.4%) and Leflunomide (n=184, 46.5%) were the most commonly used DMARDs. A total of 126 and 197 patients received corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs), respectively. During 6 months observation, 21.0% and 67.7% had TCZ dose modification or discontinuation, respectively. At month 3 and month 6, 161 (40.7%) and 102 (25.8%) kept TCZ treatment, respectively. The mean frequency of TCZ usage was 3.7±1.62. Effectiveness of TCZ was analysed in patients who were still using TCZ at month 6. The mean score of total TJC (28-joint count) at baseline and at month 6 was 11.2±8.0 (n=63) and 2.3±4.12 (n=77), respectively; mean change from baseline was -9.5±8.02 (n=53). The mean score of total SJC (28-joint count) at baseline and at month 6 was 8.0±6.81 (n=63) and 1.7±2.35 (n=77), respectively; mean change from baseline was -6.5±7.2 (n=53). The mean score of DAS28 at baseline and at month 6 was 6.13±1.33 (n=56) and 2.79±1.39 (n=66); mean change from baseline was -3.45±1.48 (n=46). Patients in low disease activity (DAS28 <3.2) or remission (DAS28 <2.6) in those who still using TCZ at month 6 was 63.6% and 51.5%. The mean change from baseline in SDAI and CDAI was -28.03±16.75 (n=41) and -24.25±16.94 (n=51), respectively. Of 396 patients, 90 (22.7%) and 8 (2.0%) experienced at least one treatment-emergent AE and SAE, respectively. One patient died of severe pneumonia.

Conclusions: This was the first real-world study in RA patients treated with TCZ in China. The results show that Chinese RA patients have long disease history. TCZ was frequently used in combination with DMARDs, especially with ≥2 types of DMARDs. Compared with the dose recommendations, shorter treatment duration and longer dose interval of TCZ were found in China. TCZ demonstrated effectiveness in treatment of Chinese RA patients in real-life clinical practice with manageable safety profile.

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AB0436

CONSOLIDATED LONG-TERM SAFETY OF INFLIXIMAB IN INFLAMMATORY ARTHRITIS FROM A PROSPECTIVE, OBSERVATIONAL REGISTRY

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Background: The Biologic Trial Registry Across Canada (BioTRAC) was a multi-centre, prospective, longitudinal, observational program that gathered and analysed data on inflammatory arthritis patients treated with infliximab (IFX), golimumab and ustekinumab. Patients specifically treated with IFX were recruited from July 2002 to June 2015 and followed up to June 2017.

Objectives: The objective of this abstract is to document the final consolidated safety data from the BioTRAC IFX cohort.

Methods: Treatment was prescribed by the physician per actual clinical practice or standard of care for rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA); there was no randomised assignments to treatment. There were no restrictions on the use of concomitant medications. At enrolment (baseline) and approximately every 6 months thereafter, information was collected to assess safety, clinical outcomes, quality of life, comorbidities, pharmacoeconomics and treatment regimens.

Results: A total of 1390 patients were enrolled and used for this analysis. The proportion of patients by indication was 59.2% for RA (n=890), 25.9% for AS (n=389) and 7.4% for PsA (n=111). The mean (SD) exposure was 3.10 (3.26) years for a sum of 4290.25 patient-years. Treatment with IFX was generally safe, with AEs and SAEs being reported for 64.3% and 19.5% of patients, respectively. The incidence rate of AEs and SAEs was 116.0 and 11.2 events per 100 pt-years, respectively. More specifically, 338 SAEs were reported by 189 (21.2%) RA patients [SAEs/100 pt-yrs: 11.7], 130 SAEs were reported by 60 (15.4%) AS patients [SAEs/100 pt-yrs: 10.5] and 28 SAEs were reported by 22 (19.8%) PsA patients [SAEs/100 pt-yrs: 8.82]. The most commonly reported AE identified was arthralgia, viral upper respiratory tract infection, upper respiratory tract infection and nausea. For SAEs, the most commonly reported SOC ($\geq 3\%$ of patients) was "Infections and infestations" [5.3% (n=73); 2.16 SAEs/100 pt-yrs] and "Neoplasms benign, malignant and unspecified" [3.5% (n=49); 1.24 SAEs/100 pt-yrs] which occurred at similar rates to the general RA patient population¹ and included two lymphomas [0.1%; 0.05/100 pt-yrs]. Across 3 closely monitored categories of AEs, a total of 302 closely monitored AEs were reported by 293 (21.1%) patients, including cancer (3.7%), lack of efficacy (17.1%) and tuberculosis (0.2%). A total of 21 deaths were reported during the study in 18 RA, 1 AS and 2 PsA patients. Cause of death included MACE (x5), lung cancer (x2), pulmonary fibrosis (x2), pneumonia (x2), respiratory failure, bronchitis, intestinal cancer, throat cancer, intestinal gangrene, disseminated TB, septic shock, procedural complication and drowning. The cause of death was not known for one patient.

Conclusions: The results of this longitudinal observational study showed that treatment with IFX was well tolerated in people living with AS, PsA and RA over a 15 year period in a real-world setting.

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AB0437 ADALIMUMAB THERAPY RESULTS IN SUSTAINED RESPONSE IN RHEUMATOID ARTHRITIS PATIENTS OVER 5 YEARS: THE GERMAN NONINTERVENTIONAL AGIL STUDY

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Background: Observational studies provide important insights into therapeutic response during daily clinical practice, including data on the effects of long-term treatment.

Objectives: To evaluate treatment responses in rheumatoid arthritis (RA) patients during 5 years of adalimumab (ADA) therapy.

Methods: We analysed data from a large German multicenter observational study of patients with active RA who initiated ADA therapy during routine clinical care (the AGIL study). Outcomes of interest included Disease Activity Score-28 joints (DAS28), DAS28 therapeutic response as assessed by the statistical critical difference (dcrit),¹ Health Assessment Questionnaire-Disability Index (HAQ-DI), and patient-reported global health and pain.

Results: A total of 4283 patients had data available for analysis at baseline. The mean age was 55.2 years, 74% of patients were female, the mean disease duration was 9.3 years, and 26% had received previous treatment with one or more biologic drugs. At month 60, 726 patients (17%) of patients remained in the study. During the 5 year study, 41.3% of patients were lost to follow-up, 22.3% discontinued due to lack of effectiveness (about half within the first 6 months), and 4.0% discontinued due to

adverse events. Mean values in patients treated with ADA showed a rapid response to treatment by both objective and patient-reported measures. Responses were maintained over 5 years in patients remaining on therapy (table 1). ADA was well tolerated and no unexpected safety signals were observed.

Abstract AB0437 – Table 1. Therapeutic response to ADA in the AGIL study. Values are presented as mean (standard deviation) unless otherwise indicated

	0	3	6	12	24	36	48	60
DAS28 outcomes								
n	4283	3595	3106	2532	1761	1222	906	644
DAS28	5.13 (1.15)	3.82 (1.38)	3.56 (1.36)	3.39 (1.35)	3.21 (1.32)	3.10 (1.28)	3.01 (1.21)	2.94 (1.22)
DAS28 therapeutic response (dcrit), %	—	36.7	42.7	45.9	49.7	53.7	55.3	59.5
DAS28 remission, %	0	20.3	25.9	30.1	36.8	39.2	42.7	45.2
HAQ-DI outcomes								
n	4269	3973	3409	2778	1957	1368	988	722
HAQ-DI	1.3 (0.70)	1.08 (0.73)	1.02 (0.74)	0.98 (0.74)	0.95 (0.74)	0.94 (0.73)	0.90 (0.72)	0.92 (0.71)
HAQ-DI remission, %	16.9	26.1	32.1	34.6	35.6	35.8	37.2	35.2
Patient-reported disease activity								
n	4283	3969	3442	2799	1975	1381	998	726
Patient global health*	6.05 (2.25)	4.49 (2.34)	4.24 (2.37)	4.03 (2.38)	3.76 (2.35)	3.60 (2.39)	3.46 (2.32)	3.45 (2.35)
Patient-reported pain								
n	4272	4006	3443	2796	1975	1380	998	724
Pain*	6.04 (2.27)	4.34 (2.47)	4.15 (2.46)	3.93 (2.46)	3.66 (2.41)	3.48 (2.38)	3.28 (2.39)	3.26 (2.44)

*Measured on a scale ranging from 0 (best) to 10 (worst)

Conclusions: The AGIL study is one of the largest observational cohorts to provide long-term data on ADA therapy. Both objective and subjective measures support the effectiveness and safety of ADA in patients with RA during 5 years of therapy. Approximately 43% of patients experienced a therapeutic response to treatment at 6 months as assessed by statistical methods (DAS28-dcrit),¹ and this level of response increased to 60% at 5 years in patients remaining on therapy. About one-third of patients recovered full functional ability (HAQ-DI remission) at the 6 month and subsequent visits. Our data indicate that ADA is an effective and safe long-term therapy in RA patients who continue on treatment.

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AB0438 SAFETY OF TNF BLOCKERS IN CASE OF NON-ALCOHOLIC FATTY LIVER DISEASE AND CIRRHOSIS: A SYSTEMATIC REVIEW

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Background: The management of inflammatory rheumatism and psoriasis has largely evolved over the last 15 years with the emergence of biotherapies whose main adverse effect is the increased infection risk. The prevalence of metabolic syndrome is increasing and has been estimated at 30% in patients with rheumatoid arthritis with an excess of 45% compared to healthy subjects. One of the major complications of the metabolic syndrome is the Non Alcoholic Fatty Liver Disease (NAFLD), which prevalence is 25% in the global population, and 30% in a cohort of patients with rheumatoid arthritis. The main complication of NAFLD is