College of Rheumatology; BID, twice daily; BMI, body mass index; CI, confidence interval; FAS, full analysis set; NRI, non-responder imputation

Methods: Data were analysed from six Phase 3 studies for pts who were methotrexate-naïve (NCT01039688) or had an inadequate response to DMARDs (NCT00960440, NCT00847613, NCT00814307, NCT00856544, NCT00853385) and received ≥ 1 dose of tofacitinib 5 or 10 mg twice daily (BID) or placebo (PBO). Pts were stratified by BL BMI (<25, 25 to <30, ≥ 30). Efficacy endpoints (American College of Rheumatology [ACR]20/50/70 response rates at Month [M]6; changes from baseline [Δ] in Health Assessment Questionnaire-Disability Index [HAQ-DI], Disease Activity Score in 28 joints based on Erythrocyte Sedimentation Rate [DAS28-4(ESR)], DAS28 based on C-reactive protein [DAS28-4(CRP)] and Clinical Disease Activity Index [CDAI] at M3 and M6) were assessed. Non-responder imputation was used for the binary endpoints. No imputation was used for continuous endpoints. No multiplicity adjustment was performed in this post hoc analysis.

Results: Overall, 1589, 1611 and 681 pts received tofacitinib 5 and 10 mg BID and PBO, respectively, with 1690, 1173 and 1017 pts in the BMI <25, 25 to <30 and ≥ 30 categories, respectively. BL demographics were generally similar between BMI categories with the exception of higher rates of diabetes (12.9-14.2% vs 3.5-9.8%), hypertension (53.2-58.9% vs 22.0-39.8%), and use of prior TNFi (23.7-46.8% vs 15.0-26.9%), and numerically higher tender (28.8-29.9 vs 23.5-26.9) and swollen joint counts (16.5-17.1 vs 14.5-16.3) and HAQ-DI scores (1.6 vs 1.4-1.5) in the BMI ≥ 30 group vs BMI <25 or 25 to <30. ACR response rates were significantly higher ($p < 0.05$) in the tofacitinib vs PBO groups, regardless of BMI category (figure 1). In general, there appeared to be a trend towards lower ACR20/50/70 response rates with increasing BMI at M6 in tofacitinib- and PBO-treated pts; however, confidence intervals (CI) overlapped. At M6, Δ HAQ-DI was numerically smaller for pts receiving tofacitinib 5 mg BID with BMI ≥ 30 vs lower BMI categories, with overlapping CI. The Δ DAS28-4(ESR), Δ DAS28-4(CRP) and Δ CDAI scores were similar within each treatment group regardless of BL BMI. Generally similar trends were observed when stratified by weight.

Conclusions: Results of this post hoc analysis suggest that tofacitinib is associated with improvements in RA outcomes compared with PBO regardless of BL BMI category. In both tofacitinib and PBO groups, similar trends in improvements were seen in most endpoints regardless of BMI category, implying that the effect of BL BMI is not specific to tofacitinib. Further investigation is needed to assess the degree of impact of BMI on tofacitinib efficacy.

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SAT0128

THE RISK FACTORS FOR SEVERE EXACERBATION OF INTERSTITIAL LUNG DISEASE IN RHEUMATOID ARTHRITIS DURING bDMARD THERAPY

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Background: Rheumatoid arthritis (RA) is a systemic inflammatory disease that affects joints and various organs. The lung is one of the most common site of extra-articular involvement. Interstitial lung disease (ILD) is one form of the lung involvement and influences prognosis of the patients. RA-ILD frequently developed acute exacerbation. Once acute exacerbation occurs, the prognosis of patients is poor. However, it is not fully elucidated what the risk factors for severe exacerbation of ILD are.

Objectives: The purpose of this study was to identify the risk factors for severe exacerbation of ILD in RA patients during bDMARDs therapy. The purpose of this study was to identify the risk factors for exacerbation of ILD in RA patients under the bDMARDs therapy.

Methods: A retrospective cohort study. Subjects were consecutive 208 RA patients who were treated with bDMARDs from 2004 to 2015 in our department and received HRCT scan before and during the therapy. Based on HR-CT imaging, pulmonary abnormalities were classified into 4 categories (ILD, nodular lesions, airway disease (AD) and others) and 20 lesions such as ground-glass opacity (GGO), reticular pattern, bronchiolitis and bronchiectasis. We recorded their existence and distribution before and during the therapy and examined their changes. Severe exacerbation of ILD was judged when patients revealed newly emerging/worsening of ILD lesions regardless of pre-existing pulmonary lesions and deceased or had to stop bDMARDs due to exacerbation of ILD. To identify risk factors, logistic regression analysis was conducted.

Results: Subjects were 208 RA patients, M/F; 64/144, mean age; 59.2 years old, disease duration; 7.9 years positive for RF in 84.1%. bDMARDs used for the longest period were TNFi in 79.8% of the subjects, abatacept in 15.4% and tocilizumab in 4.8%.

Pulmonary abnormalities were found in 146 (70.2%) of RA patients before bDMARDs (ILD 81, (38.9%); nodular lesions 45, (21.6%); and ADs, 115, (55.3%)). GGO, consolidation, reticular pattern and honeycombing was found in 14.8%, 19.8%, 51.9%, and 17.3% of ILD patients. Most of ILD lesions coexisted with ADs. During the observation period (3.26 $\pm$ 2.61 years), newly emerging/worsening pulmonary lesions were found in 42.3% of patients and the incidence of which was 13.7/100 person year. The incidence of newly development and worsening of ILD were 7.0/100 person years and 1.5/100 person years, respectively.

Severe exacerbation of ILD was developed in 13 patients (6.3%) and the incidence of which was 2.0/100 person year. Of 13 patients, 9 died of respiratory failure. All patients with severe exacerbation revealed GGO/consolidation. Interestingly, all these active ILD lesions were newly emerging lesions, however, most of the patients had pre-existing pulmonary lesions.

We identified risk factors for severe exacerbation of ILD (Table 1). The risk factors for severe exacerbation of ILD were older age and pre-existing pulmonary lesions of ILD and of ADs, particularly reticular pattern, honeycomb and bronchiectasis. Sero-positivity and choice of biologics were not identified as risk factors.

Risk factors for severe exacerbation of ILD

	Frequencies of an indicated factor in severe ILD exacerbation (%) vs (+)	Odds (95% CI) (ref: -)	P
Male	59/195 (30.3%) vs 5/13 (38.5%)	1.44 (0.45-4.59)	0.54
Age of the entry	58.70 $\pm$ 13.30** vs 67.32 $\pm$ 10.36		0.022
Age of RA onset	50.71 $\pm$ 15.19 vs 60.30 $\pm$ 13.96		0.028
Disease duration (year)	8.00 $\pm$ 9.37 vs 7.01 $\pm$ 8.64		0.71
Smoking	65/144 (45.1%) vs 8/12 (66.7%)	2.43 (0.70-8.44)	0.15
RF positive	162/195 (83.1%) vs 13/13 (100%)	5.57 (0.32-95.9)	0.03
Anti-CCP antibody Positive	144/166 (86.2%) vs 8/10 (80.0%)	0.63 (0.13-3.20)	0.60
DAS28-ESR of the entry	4.36 $\pm$ 1.43 vs 3.66 $\pm$ 0.93		0.28
DAS28-ESR at following CT scan	3.26 $\pm$ 1.27 vs 3.73 $\pm$ 0.69		0.40
TX			
TNF vs non-TNF	156/39 (80.0%) vs 10/3 (76.9%)	0.83 (0.22-3.17)	0.79
Methotrexate	127/195 (65.1%) vs 9/13 (69.2%)	1.20 (0.36-4.06)	0.76
Glucocorticoid	147/195 (75.4%) vs 10/13 (76.9%)	1.09 (0.29-4.12)	0.90
Pre-existing pulmonary abnormalities			
Pulmonary abnormality	134/195 (68.7%) vs 12/13 (92.3%)	5.46 (0.69-42.96)	0.044
Interstitial lung disease	71/195 (36.4%) vs 10/13 (76.9%)	5.81 (1.05-21.85)	0.004
Reticular pattern	34/195 (17.4%) vs 8/13 (61.5%)	7.58 (2.34-24.58)	0.0007
Honeycomb	9/195 (4.6%) vs 5/13 (38.5%)	13.92 (3.51-47.50)	0.0004
Nodular lesions	43/195 (22.1%) vs 2/13 (15.4%)	0.64 (0.14-3.01)	0.56
Airway disease	104/195 (53.3%) vs 11/13 (84.6%)	4.81 (1.04-22.28)	0.030
Bronchiectasis	75/195 (38.5%) vs 11/13 (84.6%)	8.80 (1.90-40.80)	0.0009

* Positive number/ number of live or dead cases, ** mean $\pm$ SD

Conclusions: The incidence of severe exacerbation of ILD was 2.0/100 person years. The risk factors for severe exacerbation of ILD were older age and pre-existing reticular pattern, honeycomb and bronchiectasis.

Disclosure of Interest: None declared

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SAT0129

TRENDS IN THE INCIDENCE OF CARDIOVASCULAR DISEASES IN PATIENTS WITH RHEUMATOID ARTHRITIS IN SPAIN: AN OBSERVATIONAL COHORT STUDY OF HOSPITAL DISCHARGES FROM 1999 TO 2015 (TRENDA-R STUDY)

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Background: Several changes have appeared in the last years in the management of Rheumatoid Arthritis (RA), and also a greater awareness about cardiovascular risk has emerged. However, the trend of CVDs in RA in Spain is unknown.

Objectives: To analyze the incidence and trend of hospital admissions for CVDs in patients with RA in Spain during the period between 1999 and 2015.

Methods: We performed an observational retrospective population study analyzing the Spanish administrative database that includes a Minimum Basic Data Set (MBDS) of hospital admissions of patients with RA 1999-2015. We selected the MBDSs for CVDs, myocardial infarction (MI), ischemic heart disease (IHD), congestive heart failure (CHF), cerebrovascular disease (CeVD) and aortic aneurysm (AA). Cases were identified by the presence in primary and secondary diagnosis of ICD9 codes. The population at risk was estimated through the population census with an estimated prevalence of RA of 0.5% (0.8% women, 0.2% men). Crude and adjusted rates were calculated, and the trend was analyzed using the Generalized Linear Model (GLM) with the year as the analysis variable. SPSS statistical package version 20 (SPSS Inc, Chicago, IL) was used.

Results: 338,343 RA hospital admissions were detected in the period, being 207,597 (61.3%) due to CVDs. Table 1 summarizes the data of the six subgroups of CVDs.

Conclusions: CVDs were the first cause of hospital admissions in Spain in RA patients during the period 1999-2015. Moreover, in that period there was an increasing incidence of hospital admissions due to CVDs in all the studied subgroups, being strikingly higher in men after age-adjusted rates. An annual rate increase is estimated in all the different studied subgroups oscillating between 5 and 9% annual increasing.

	Cardiovascular disease	Myocardial infarction	Ischemic heart disease	Congestive heart failure	Cerebrovascular disease	Aortic aneurysm
Total admissions	207597	12274	37691	31765	18445	2144
Men (%)	71724 (34.5)	6809 (55.4)	19845 (52.6)	9970 (31.4)	6509 (35.3)	1492 (69.6)
Women (%)	135873 (65.5)	5465 (44.6)	17846 (47.4)	21795 (68.6)	11936 (64.7)	652 (30.4)
Mean age (SD)	72.6 (12.1)	72.24 (10.38)	72.38 (10.37)	72.4 (10.37)	72.8 (10.37)	74.52 (9.06)
Deaths (%)	14649 (7.1)	1166 (9.5)	2918 (7.5)	4224 (13.3)	2282 (12.4)	204 (9.5)
Diabetes mellitus (%)	39639 (19.1)	2971 (24.2)	9404 (25)	6681 (21)	3746 (20.3)	258 (12)
Age-adjusted rate	7497.36	440.02	1348.95	1151.25	664.11	322.89
Men	13275.48	1266.00	3685.64	1873.95	1221.71	1425.31
Women	5830.59	273.46	772.92	950.36	516.58	116.13
Age-adjusted rate increase 1999-2015	3795.03 → 9070.71	212.71 → 553.56	600.76 → 1776.24	542.62 → 1739.70	356.13 → 934.61	30.13 → 130.06
Men	6489.91 → 18200.19	598.73 → 1527.08	1704.03 → 4769.61	868.77 → 2889.88	619.66 → 1710.68	115.07 → 437.35
Women	3038.71 → 7933.63	118.21 → 312.01	425.61 → 1037.64	446.93 → 1431.47	276.31 → 721.72	10.10 → 54.83
Annual increase % estimation (CI 95%)	5.48 (1.58-9.10)	5.02 (1.01-10.01)	5.48 (1.04-10.02)	6.81 (1.05-10.02)	6.31 (1.05-10.02)	9.31 (1.07-11.07)
Relative risk men : women	2.28	5.33	4.7	1.97	2.36	12.27

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SAT0130

IMPROVEMENT OF NUTRITIONAL CONDITIONS IN PATIENTS WITH RHEUMATOID ARTHRITIS STARTING FIRST DISEASE MODIFYING ANTI-RHEUMATIC DRUGS

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Background: Rheumatoid arthritis (RA) is a chronic inflammatory condition, and has been associated with decreased life expectancy. Although life expectancy has improved in many RA patients recently, the reason for this is not entirely clear.

Objectives: We hypothesized that better disease activity control of RA led to relief from chronic inflammation, which resulted in better nutritional conditions, and contributed to a longer life expectancy. The aim of this analysis was to examine the relationship between RA disease control and the improvement of nutritional conditions.

Methods: We analyzed data obtained from 111 patients with RA (male 44, female 67) who were referred to our hospital and received first disease modifying anti-rheumatic drugs (DMARD) in 2016 and 2017, retrospectively. The patient data were obtained retrospectively from medical records for a 6-month period starting at the date DMARDs were initiated. We chose serum albumin (Alb), total lymphocyte count (TLC), and hemoglobin (Hb) concentration, as the indicators of the nutritional condition. Furthermore, D-values and nutrition index 40 (N.I.40), indicators of anastomotic leakage after gastrointestinal surgery were also analyzed. Comparisons between the two groups were performed using Mann-Whitney U test. Comparisons between the parameters at different time points were performed using Wilcoxon signed-rank test. The association among the ordered European League Against Rheumatism (EULAR) response rate and the magnitude of improvement in the nutritional condition were analyzed by using the Jonckheere-Terpstra test. Data on each patient's age and duration of RA were calculated as median (IQR_{1/4-3/4}) values.

Results: The patient age was 64.0 (54.0-74.5) years, and the duration of RA was 3.0 (1.0-7.0) months. Oral prednisolone (PSL) was used in 51 patients. Other drugs administered to patients over the 6-month period included: methotrexate (63 patients), iguratimod (42 patients), bucillamine (29 patients), sulfasalazine (25 patients), tacrolimus (6 patients), and bDMARD (13 patients). The level of C-reactive protein (CRP) and the disease activity score for 28 joints based on erythrocyte sedimentation rate (DAS28-ESR) before and 6 months after the initiation of DMARD treatment improved from 0.50 (0.12-1.7) mg/dL to 0.10 (0.010-0.20), $p < 0.001$, and from 4.62 (3.51-5.52) to 2.52 (1.53-3.13), $p < 0.001$, respectively. The EULAR good response was achieved in 59 patients, and moderate response was

achieved in 31 patients. Serum Alb level, Hb concentration, D-value, and N.I.40 showed significant improvement 6 months after the starting of DMARD [3.9 (3.6-4.3) vs 4.2 (4.0-4.5) mg/dL, $p < 0.001$; 12.5 (11.7-13.4) vs 12.6 (11.8-13.6) g/dL, $p = 0.0164$; 0.155 (-0.47-0.91) vs -0.26 (-0.72-0.18), $p < 0.001$; 47.2 (41.8-51.1) vs 49.8 (46.1-52.2), $p < 0.001$, respectively]. Furthermore, we found a significant trend towards improvement of serum Alb level, Hb concentration, D-value, and N.I. 40 in patients with a better EULAR response (p value for trend = 0.0124, 0.033, 0.0057, and 0.0040, respectively).

Conclusions: There was a statistically significant trend towards better nutritional improvement in patients with a better EULAR response. Control of RA may contribute not only to joint deterioration prevention, but may also help to improve the nutritional condition of patients.

Disclosure of Interest: None declared

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SAT0131 THE ROLE OF ULTRASOUND FOR THE ASSESSMENT OF PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) a chronic systemic connective tissue disease, one of the main symptoms is inflammation that is mainly present in hands and feet. The evaluation and follow-up of disease activity relies on composite indexes with clinical outcomes. However, many studies have shown there are differences between disease activity measured by clinical examination and ultrasound findings (1).

Objectives: The aim of this study was to evaluate the utility of ultrasound in patients with RA stratified as moderate or severe disease activity based on DAS28.

Methods: We performed across-sectional study including patients with RA; patients were followed-up under T2T standards and a multidisciplinary approach. Clinical follow-up was designed by the authors according to DAS28 as follows: every 3-5 weeks (DAS28 >5.1), every 7-9 weeks (DAS28 ≥3.1 and ≤5.1), and every 11-13 weeks (DAS28 <3.1). Additionally the patient was evaluated by a rheumatologist expert in ultrasound; US studies were carried out with a Esaote MyLab Seven® US equipment (Biomedica, Genoa, Italy) equipped with a 10-18 MHz linear transducer; PD was adjusted according to the following parameters: frequency, 8.0, PRF, 0.500, wall filter 3, gain between 50 and 70. The rheumatologist reported erosions, synovitis, osteophytes and power Doppler; we defined as active disease when patients had synovitis or positive power Doppler. We calculated means, and standard deviations for continuous variables and categorical variables were presented as rates. We performed a bivariate analysis using Pearson's Chi².

Results: 272 patients meet the inclusion criteria; most of patients were woman 87%, mean age were 57 years ± 11, mean DAS was 4.45 ± 1.1, 70% of patients were in moderate disease activity (MDA), and 30% in severe disease activity (SDA), 81% of patients were receiving conventional DMARDs therapy and 19% biological therapy. Regarding the findings of the ultrasound, the most prevalent elementary lesions in hands and feet were erosions, 75% and 6% see table 1. Active disease was found in 66% (11% of patients had only synovitis and 55% had synovitis plus Doppler) see table 2. Thus, in patients where we assumed that had MDA or SDA, by ultrasound we found that 34% did not have disease activity. We did not find statistical association between ultrasound and age, sex or type of pharmacological therapy.

VARIABLE	PRESENT		ABSENT	
	n	%	n	%
HANDS				
SYNOVITIS	181	67	91	33
POWER	152	56	120	44
DOPPLER				
EROSIONS	204	75	68	25
OSTEO	108	40	164	60
PHYTES				

FEET				
SYNOVITIS	9	4	263	96
POWER DOPPLER	5	2	267	98
EROSIONS	16	6	256	94
OSTEOPHYTES	19	7	253	7

Conclusions: In RA patients with moderate or severe disease activity ultrasonography can complement the clinical evaluation, since there are a third of patients without disease activity according to ultrasound findings; where by there is a need