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was higher for the most stringent definitions. However, this also meant that, for the most stringent criteria, many patients in non-remission had HAQ≤0.5. The strongest degree of association between remission and HAQ<0.5 was observed for the SDAI. However, only minor differences were noted between definitions (table 1). Sensitivity analyses yield similar results (not shown).

Conclusions: The various remission definitions confirmed their validity in terms of physical function in a large international clinical practice setting. However, many patients in non-remission will still have good functional status and being in clinical remission does not equate to having HAQ < 0.5. A multidimensional approach should be taken to help patients achieve this functional goal. Achievement of remission according to any of the indices is more important than the use of a specific index

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FRI0127 OUTCOMES OF DISEASE ACTIVITY IN A 5-YEAR LARGE COHORT OF RHEUMATOID ARTHRITIS PATIENTS TREATED UNDER TREAT TO TARGET RECOMMENDATIONS AND A MULTIDISCIPLINARY CARE MODEL - A REAL-LIFE **EXPERIENCE** 

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Background: Treat to Target (T2T) strategy becomes from the need to develop therapeutic targets and tools to achieve defined outcomes in rheumatoid arthritis (RA), this strategy has become recognized as a standard of good practice embodying the principle that rapid attainment of remission, or low disease activity, can halt joint damage and maintain good quality of life.

Objectives: The aim of this study was to describe global change in Disease Activity Score 28 (DAS28) using T2T strategy for a 60 month period in a large cohort of patients from a Colombian specialized in RA center.

Methods: A descriptive cohort study was conducted. Medical records of patients from specialized in RA center were reviewed; those patients were followed-up under T2T standards and a multidisciplinary approach. Each patient had a minimum of 6 follow-up visits. 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  $\geq$ 3.1 and  $\leq$ 5.1), and every 11-13 weeks (DAS28 <3.1). Tender joint count (TJC), swollen joint count (SJC) and DAS28 were measured on each visit. Therapy had to be adjusted with DAS28 >3.2 unless patient's conditions don't permit it; we considered this follow-up type as implementation of a T2T strategy in patients with RA. We divided patients in four groups: remission (REM), low disease activity (LDA), moderate disease activity (MDA) and severe disease activity (SDA) patients and the aim of the study was to look at what percentage of patients who were in moderate or severe disease activity reached a low disease activity or remission. Descriptive epidemiology was done, percentages and averages were calculated; the median of each variable was analyzed using t-Student assuming normality for DAS28 distribution and the level activity disease was analyzed using Pearson's statistics.

Results: 3618 patients meet the inclusion criteria. 72% were receiving conventional DMARDs therapy and 28% were receiving biological therapy. 83% were woman and 17% were men. Mean age was 61 years ±11. Mean DAS28 at beginning was 3.3±1.3 and at the end of five year period was 2.8±0.7. The difference of medians for DAS28 at begging and at the end showed improvement with statistical significance (p<0.00). It was found a global increase in the percentage of patients in remission and LDA and decrease in moderate and severe disease activity groups (from 31% to 19% and from 12% to 2% respectively) with statistical significance.

ACTIVITY LEVEL	TIME 0 n(%)	2011-2012 n(%)	2013-2014 (%)	2015-2016(%)
REM	1512 (42)	1548 (43)	1751 (48)	1826 (50)
LDA	536 (15)	955 (26)	969 (27)	1033 (29)
MDA	1128 (31)	875 (24)	809 (22)	694 (19)
SDA	442(12)	240 (7)	89(2)	65 (2)

Conclusions: This study show evidence of an improvement in DAS28 and level of disease activity in a cohort of RA patients from a specialized center in Colombia treated under recommendations of T2T strategy; it was found a global increase in the percentage of patients in remission (REM) and decrease in moderate and severe disease activity groups. This revision shows the importance of T2T follow-up and a multidisciplinary treatment for the management or RA.

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FRI0128 PRISM – PICTORIAL REPRESENTATION OF ILLNESS AND SELF MEASURE: THE USE OF A SIMPLE NON-VERBAL TOOL AS A PATIENT-CENTRED OUTCOME MEASURE IN EARLY RHEUMATOID ARTHRITIS COHORTS

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Background: Treatment recommendations in early RA advocate a treat to target approach with the ideal goal of remission. But not all patients attain this goal. There is a need for outcome measures that are meaningful to patients and inform management of which alleviation of suffering is a key aim. PRISM1 is a novel, validated, brief method of measuring suffering consistent with Cassell's seminal conceptualisation2.

Objectives: To understand the relationships between a patient's perception of the totality of the impact of RA and commonly used clinical assessments of disease activity, depression and illness intrusiveness

Methods: Basic sociodemographic and clinical data were collected from 182 RA patients from 3 international centres, assigned to one of four cohorts (two early RA and two established RA), at baseline, weeks 12 and 24. The two early RA cohorts (diagnosis <2 yr) comprised Group 1 on stable treatment (n=37) and Group 2 requiring csDMARD adjustment (n=34). Using the iPRISM App on a tablet, all patients were asked to complete the basic PRISM task to measure self-illness separation (SIS). The smaller the SIS, the greater the person's perceived suffering. In the PRISM+ task, patients were asked to identify two valued aspects of their life at the moment (X and Y) which bring pleasure, satisfaction, a sense of achievement, or a sense of purpose. The iPRISM App automatically records the distance between the centres of each of these disks and the Self disk to measure patients' perceptions of the intrusiveness of their illness on two personally valued aspects of their lives.

For both groups, direction of change in SIS and the PRISM+ measures were compared with direction of change in disease activity measures and patient global disease activity (ptGbl), assessed at wks 12 and 24, using the sign test.

Results: PRISM was easy to use and most patients understood the simple instructions. Of 182 patients at baseline, SIS showed significant correlations with ptGbl ( $r_s$ =-0.48, p<0.0001), pain VAS ( $r_s$ =-0.45, p<0.0001), PHQ9 ( $r_s$ =-0.45, p<0.0001) and illness intrusiveness scale ( $r_s$ =-0.51, p<0.0001). Suffering was inversely correlated with the perceived controllability of the symptoms of RA; for Group 1,  $r_s=0.41$ , p<0.0001, for Group 2,  $r_s=0.32$ , p<0.0001.

In Group 2, SIS and DAS28-ESR showed small trends to improvement by wk 12 (DAS28-ESR  $\Delta$ =-0.11, p=0.557; SIS  $\Delta$ =1.7, p=0.296) with significant improvement by wk 24 (DAS28-ESR  $\Delta$ =-0.82, p=0.002; SIS  $\Delta$ =3.85, p=0.029). However, there was no significant improvement in the intrusiveness of the illness on the valued aspects of life over this time period (Actual X,  $\Delta$ =-0.25, p=0.557; Actual Y,  $\Delta = 1.89$ , p=0.169).

Conclusions: PRISM is a novel PRO that quantifies factors salient to each individual with respect to the impact of RA and its treatment while allowing for incorporation of a wide range of such influences. It may have utility as an adjunct to disease activity measures in setting agreed personalised therapeutic targets. References:

[1] T Sensky & S Buchi. PLoS ONE 11(5):e0156284, 2016.

[2] EJ Cassell. NEJM 306:639-645,1982.

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### **FRIDAY, 16 JUNE 2017**

# Rheumatoid arthritis - comorbidity and clinical aspects

FRI0129

COMPARATIVE SAFETY OF BIOLOGIC DMARD INITIATION IN RA: A POPULATION-BASED OBSERVATIONAL STUDY OF **MALIGNANCY RISK** 

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Background: Patients (pts) with RA are at increased risk for some malignancies and the use of biologic (b)DMARDs has been reported to further increase this risk.1 Abatacept (ABA), the first selective T-cell co-stimulation modulator for RA treatment, is now often prescribed as a first-line bDMARD, but long-term effects 530 Friday, 16 June 2017 Scientific Abstracts

Objectives: To assess in a real-world, observational study whether treatment with ABA had a similar malignancy risk as other biologics, with or without MTX, when used as the initial bDMARD for RA.

Methods: The Truven MarketScan® Commercial and Supplemental Medicare databases were used to identify adult pts diagnosed with RA who initiated bDMARD treatment with ABA or another bDMARD between Jan 2007 and Dec 2014. Other bDMARDs included adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab and tocilizumab. Pts were required to have ≥6 months (M) of continuous health plan enrolment before bDMARD initiation (index date) and deemed to have initiated a treatment if there was no claim for any bDMARD in the limited 6M period before bDMARD initiation. Pts who had a malignancy in the baseline 6M period were excluded. Pts were followed up from the date of the first bDMARD prescription initiation, either ABA or another bDMARD, until occurrence of a malignancy (identified by ICD-9 diagnosis code), end of enrolment in the database or end of data collection, whichever occurred first. A 6M latency period was included. Propensity scores of ABA initiation were estimated from the baseline covariates using a logistic regression model, and trimmed to include only pts with ranges common to both ABA-exposed and comparator bDMARD cohorts. The Cox proportional hazard regression model was used to provide an estimate of the hazard ratio (HR) of malignancy associated with ABA initiation compared with initiation of another bDMARD, adjusted for age and deciles of the propensity score after trimming.

Results: A total of 5391 pts were identified as above as having initiated bDMARD therapy with ABA and 74,315 initiated with another bDMARD, with follow-up of <8 yrs (mean 2.1 yrs). Pts who initiated ABA vs other bDMARDs were older (mean 55 vs 52 yrs), had more co-morbidity, used less MTX (49 vs 57%) and more other non-bDMARD (41 vs 36%) at baseline. After trimming on propensity scores, 565 pts developed a malignancy after ABA (incidence rate 5.0 per 100/yr) compared with 5750 after another bDMARD (incidence rate 3.6 per 100/yr). The adjusted HR (95% CI) of any malignancy with ABA initiation relative to other bDMARDs was 1.18 (1.06, 1.30), while for any malignancy excluding non-melanoma skin cancer it was 1.17 (1.02, 1.34). The risk (HR; 95% CI) was not significantly elevated for lung cancer (1.11; 0.70, 1.76), female breast cancer (1.21; 0.91, 1.62) and lymphoma (1.21; 0.77, 1.90).

Conclusions: In this large, real-world study of pts treated for RA, the incidence of the most common malignancies of breast, lung and lymphoma were not significantly increased in pts using abatacept as first-line bDMARD treatment compared with other bDMARDs, though the confidence intervals were wide. The slight increase in the risk of overall malignancy with abatacept needs further investigation, particularly to assess the potential for residual confounding and the impact of the short baseline period.

## References:

[1] Mercer LK, et al. Ann Rheum Dis 2015;74:1087-93.

Disclosure of Interest: S. Suissa Consultant for: Bristol-Myers Squibb, S. Dell'Aniello: None declared, T. Simon Shareholder of: Bristol-Myers Squibb, Employee of: Bristol-Myers Squibb

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### FRI0130 RATES AND RISK FACTORS OF NEW-ONSET PSORIASIS UNDER DIFFERENT BIOLOGIC AGENTS AND CONVENTIONAL SYNTHETIC DMARD TREATMENT

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Background: Psoriatic skin disease is a burdensome, sometimes painful, dermatologic condition which was reported to occur as an adverse event (AE) during TNF-inhibitor (TNFi) treatment of rheumatoid arthritis (RA). Single case reports revealed the occurrence of psoriasis also during treatment with non-TNFi, but the magnitude under those agents remains unclear.

Objectives: To compare incidence rates of psoriasis in RA under treatment with different biologic and conventional synthetic (b/cs)DMARDs and to investigate

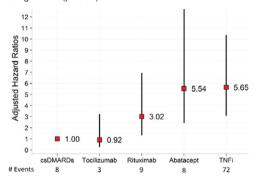
Methods: We used data of 12,722 patients (53,585 patient years (py)) enrolled with the start of a b/csDMARD in the German biologics register RABBIT. Patients were required to have no psoriasis at baseline and at least one follow-up. All psoriatic events (PsE) reported until 30 April 2016 were selected and assigned to treatments administered within 3 months prior to the event. Crude incidence rates (IR) of PsE were calculated per 1,000py. Cox regression was applied to investigate risk factors for the occurrence of PsE with and without inverse probability weights (IPW) to adjust for confounding by indication.

Results: 96 PsE were reported, with only 6 of them categorized as being serious. The median time between enrollment in the cohort and onset of psoriasis was 19 months (IQR:11-45 months). 21 of all PsE (22%) were palmoplantar manifestations of which 9 were reported as pustular type.

Compared to csDMARD treatment with a crude IR of 0.44/1.000pv (95% CI 0.2;0.9), the IRs found under TNFi (IR 2.99 (95% CI 2.3;3.8)) and abatacept (IR 3.99 (95% CI 1.7;7.9)) were significantly higher. In patients treated with rituximab (IR 1.8 (95% CI 0.8;3.4)) or tocilizumab (IR 0.7 (95% CI 0.1; 2.0)) IRs for PsE

were not significantly different from csDMARD patients. Across TNFi, the IR varied insignificantly.

Adjusted regression analysis showed higher risk for PsE with TNFi, abatacept and rituximab (graph). Female sex (adjusted hazard ratio (HR) 1.8 (1.0;3.3)) and being rheumatoid factor negative (HR 1.6 (1.0:2.6)) were additional significant risk factors. Smoking (HR 1.6 (1.0; 2.5)), age (HR 1.0 (0.98;1.01)), glucocorticoids per 5 mg/d increase (HR 1.1 (1.0;1.2)), and prior (≤6months) skin infections (HR 2.2 (0.5;9.7)) were not significantly associated. Replacing glucocorticoids with DAS28 did not show differing results. Adjustment with IPW attenuated the effect of rheumatoid factor (p=0.4) but smoking was significantly associated with a higher risk (p<0.01).



Conclusions: This is the first analysis comparing the incidence of psoriasis under biologics with different modes of action within one cohort. Our results confirmed a higher risk for TNFi 1 and showed a similar result for abatacept. A lower but still significant increased risk was found for rituximab, whereas there was no difference for tocilizumab compared to csDMARDs. New onset psoriasis is a rare and most often non-serious event. The number needed to harm is 334 patients treated with TNFi for one year to observe one PsE.

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[1] Hernandez et al., Arthritis Care Res 2013; 65:2024-31.

Disclosure of Interest: A. Strangfeld Speakers bureau: BMS, MSD, Pfizer, Roche, Sanofi-Aventis, L. Baganz: None declared, A. Richter Consultant for: Pfizer, B. Manger Consultant for: Abbvie, BMS, MSD, Pfizer, Roche, UCB, G.-R. Burmester Consultant for: AbbVie. BMS. MSD. Pfizer. Roche. UCB. C. Eisterhues: None declared, S. Wassenberg Consultant for: AbbVie, Pfizer, Novartis, Janssen. Roche-Chugai, Celltrion, BMS, Fuji, Speakers bureau: AbbVie, Celgene, Novartis, Pfizer, MSD, Lilly, Janssen, UCB, A. Zink Speakers bureau: AbbVie, BMS, MSD, Pfizer, Roche, UCB, J. Listing Consultant for: Sandoz, Pfizer

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### FRI0131 THE 2010 ACR/EULAR CRITERIA ARE INSUFFICIENTLY ACCURATE IN THE EARLY IDENTIFICATION OF **AUTOANTIBODY-NEGATIVE RHEUMATOID ARTHRITIS:** RESULTS FROM THE LEIDEN-EAC AND ESPOIR COHORTS

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Background: The 2010-ACR/EULAR criteria were derived to classify RA earlier in time. Previous studies indeed observed that the 2010-criteria were fulfilled earlier than the 1987-criteria. This study determined whether the 2010-criteria perform equally in the early detection of autoantibody-positive and autoantibody-negative

Objectives: To compare the performance of the 2010-criteria between autoantibody-positive and autoantibody-negative RA within two different early arthritis cohorts

Methods: From the total Leiden-EAC (n=3448) and ESPOIR (n=813) RA-patients who fulfilled the 1987-RA criteria at 1-year but not at presentation were selected (n=515 and n=53, respectively). These RA-patients were studied on the presence of ACPA and RF, and on fulfilling the 2010-criteria at baseline, as 2010-positivity indicated that these RA-patients were earlier identified.

Results: In the EAC, 67% of the selected RA-patients did already fulfil the 2010-criteria at baseline. In ESPOIR this was 57%, indeed demonstrating early classification with the 2010-criteria. Among the selected autoantibody-positive RA-patients of the EAC, 85% was identified at baseline already with the 2010criteria. Within autoantibody-negative RA this was 45% (p<0.001). Similarly within autoantibody-positive RA-patients in ESPOIR 92% was 2010-positive at baseline, whereas this was only 25% within autoantibody-negative RA (p<0.001).

Conclusions: The 2010-criteria perform well in the early identification of autoantibody-positive RA, but autoantibody-negative RA-patients are still frequently missed with these criteria. As it has been demonstrated that early