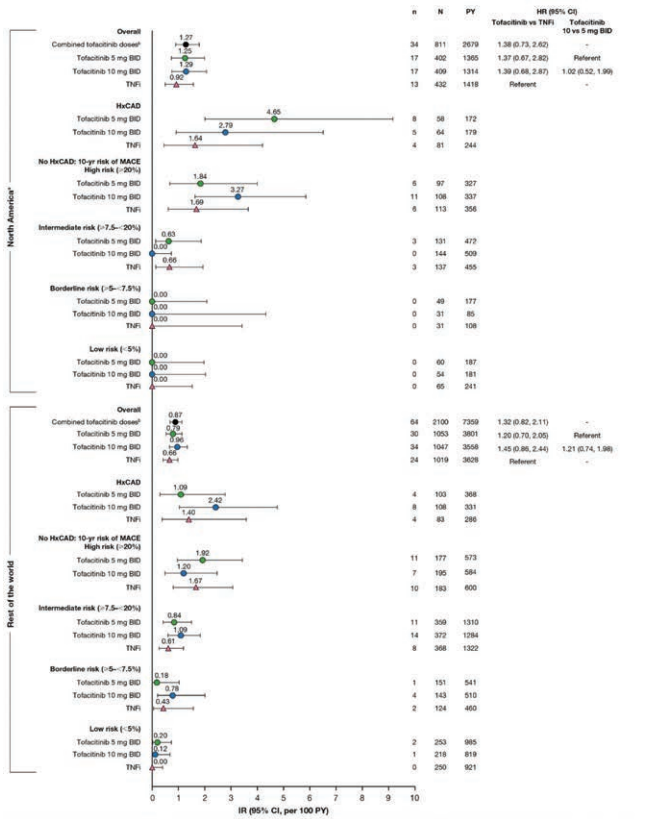
in pts in NA vs RoW (Figure 1). Incidence and risk of MACE were higher with tofacitinib vs TNFi in both NA and RoW (Figure 1). In NA, MACE IRs were higher for tofacitinib 5 mg BID vs TNFi in pts with a HxCAD, and tofacitinib 10 mg BID vs TNFi for pts with a high 10-yr risk of MACE; pts with low or borderline 10-yr MACE risk had no MACE across tofacitinib groups (Figure 1). Compared with NA, similar trends for MACE were generally observed across treatments in RoW, particularly for intermediate, borderline and low CV risk categories (Figure 1).

Table 1. Percentages of pts in NA and RoW with a HxCAD and pts without a HxCAD categorised by 10-yr risk of MACE, per ASCVD-pooled cohorts equation risk calculator[1] with a 1.5 multiplier applied[2]

	NA[a]			RoW		
	Tofacitinib 5 mg BID (N=402)	Tofacitinib 10 mg BID (N=409)	TNFi[b] (N=432)	Tofacitinib 5 mg BID (N=1053)	Tofacitinib 10 mg BID (N=1047)	TNFi[b] (N=1019)
HxCAD, n (%)	58 (14.4)	64 (15.6)	81 (18.8)	103 (9.8)	108 (10.3)	83 (8.1)
No HxCAD: 10-yr risk of MACE, n (%)						
High (≥20%)	97 (24.1)	108 (26.4)	113 (26.2)	177 (16.8)	195 (18.6)	183 (18.0)
Intermediate (≥7.5–<20%)	131 (32.6)	144 (35.2)	137 (31.7)	359 (34.1)	372 (35.5)	368 (36.1)
Borderline (≥5–<7.5%)	49 (12.2)	31 (7.6)	31 (7.2)	151 (14.3)	143 (13.7)	124 (12.2)
Low (<5%)	60 (14.9)	54 (13.2)	65 (15.0)	253 (24.0)	218 (20.8)	250 (24.5)
Missing data	7 (1.7)	8 (2.0)	5 (1.2)	10 (0.9)	11 (1.1)	11 (1.1)

HxCAD was defined as any history of MI, coronary heart disease, stable angina pectoris or coronary artery procedures. [a]United States, Puerto Rico and Canada. [b]For pts randomised to the TNFi group, adalimumab and etanercept were administered in NA and RoW, respectivelyn, number of pts with specified characteristics; N, number of evaluable pts

Fig. IRs (pts with first events/100 pt-yrs; 95% CI) for MACE, stratified by HxCAD, BL CV risk and geographic region in ORAL Surveillance



Because of missing data to derive ASCVD-pooled cohort equations scores, 2 pts with MACE within the 60-Day risk period were not included in the risk score category analysis (n=1, tofacitinib 5 mg BID [NA]; n=1, tofacitinib 10 mg BID [RoW])
Data collected after pts who were randomised to tofacitinib 10 mg BID had their dose reduced to 5 mg BID were included in the tofacitinib 10 mg BID group
Risk period was defined as the time from first study dose to last study dose +60 days, or to the last contact date, whichever was earliest
HxCAD was defined as any history of MI, coronary heart disease, stable angina pectoris or coronary artery procedures
95% CIs for IRs were constructed using Exact Poisson Distribution
ORAL Surveillance (NCT02096467)
[a]United States, Puerto Rico and Canada
[b]Includes pts who received tofacitinib 5 or 10 mg BID in ORAL Surveillance
CI, confidence interval; HR, hazard ratio; PY, pt-yrs

Conclusion: This post hoc analysis of data from ORAL Surveillance suggests that differences in MACE IRs across geographic regions are largely driven by HxCAD and high BL CV risk scores in NA vs RoW. Results should be interpreted with caution due to low pt and event numbers, particularly restricting the evaluation of tofacitinib vs TNFi in NA and RoW. Noting this limitation, these findings emphasise the importance of assessing and addressing BL CV risk when treating pts with RA.

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POS0111

MORE METICULOUSLY FOLLOWING TREAT-TO-TARGET IN RA DOES NOT LEAD TO LESS RADIOGRAPHIC PROGRESSION: A LONGITUDINAL ANALYSIS IN BIODAM

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Background: A Treat-to-Target approach (T2T) is broadly considered to lead to better clinical outcomes and recommended in patients with RA. However, very few studies have analyzed the effect of T2T on radiographic progression, and any such studies have provided inconsistent results.

Objectives: To investigate whether meticulously following a treat-to-target (T2T)-strategy in daily clinical practice leads to lower radiographic progression in RA.

Methods: Patients from the multicenter RA-BIODAM cohort with ≥2 consecutive visits with radiographs available were included. In RA-BIODAM patients were enrolled as they were initiating a new csDMARD/bDMARD treatment were followed-up with the intention to benchmark and intensify treatment. The primary outcome of this analysis was the change in Sharp-van der Heijde score (SvdH, 0-448), assessed every 6 months, using average scores from 2 readers (scores with known chronological order). Following a DAS44-T2T remission strategy, which was defined at each 3-month visit, was the main variable of interest. Patients were categorized based on the proportion of visits in which T2T was followed according to our definition: very low (≤40% of the visits, low (>40%, <62.5%), high (≥62.5%, ≤75%) and very high (>75%). Radiographic progression at 2 years was visualized across groups by cumulative probability plots. Per 3-month interval T2T could be followed zero, one or two times (in a total of 2 visits). Associations between the number of visits with T2T in an interval and radiographic progression, both in the same and in the subsequent 6-month interval, were analysed by generalised estimating equations, adjusted for age, gender, disease duration and country.

Results: In total, 511 patients were included (mean (SD) age: 56 (13) years; 76% female). After 2 years, patients showed on average 2.2 (4.1) units progression (median:1 unit). Mean (SD) 2-year progression was not significantly different across categories of T2T: very low: 2.1 (2.7)-units; low: 2.8 (6.0); high: 2.4 (4.5), very high: 1.6 (2.2) (Figure 1). Meticulously following-up T2T in a 3-month interval neither reduced progression in the same 6-month interval (parameter estimates (for yes vs no): +0.15 units (95%CI: -0.04 to 0.33) for 2 vs 0 visits; and +0.08 units (-0.06;0.22) for 1 vs 0 visits) nor did it reduce progression in the subsequent 6-month interval (Table 1).

Table 1. Effect of following DAS44-remission-T2T strategy on 6-month radiographic progression over 2 years

	Change in radiographic damage (regression coefficient (95% CI)) N=506
T2T during 3 months on radiographic progression in the same 6-month period	
2 visits vs 0 followed	0.15 (-0.04; 0.33)
1 visit vs 0 followed	0.08 (-0.06; 0.22)
T2T during 3 months on radiographic progression in the subsequent 6-month period	
2 visits vs 0 followed	-0.09 (-0.28; 0.10)
1 visit vs 0 followed	-0.10 (-0.24; 0.05)

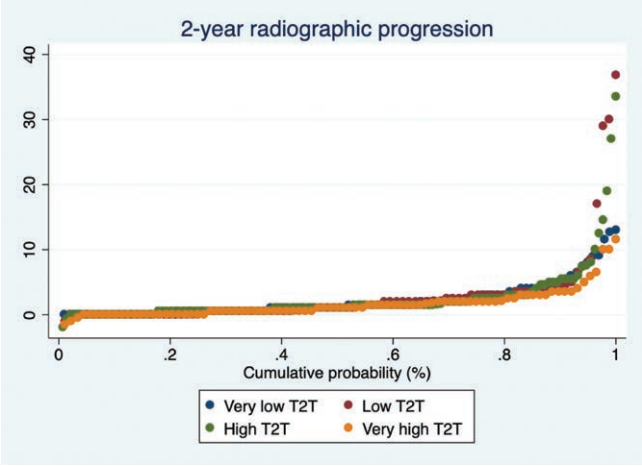

Figure 1. Cumulative probability plot with 2-year radiographic progression according to the proportion of 3-monthly visits with T2T followed

Conclusion: In this daily practice cohort, more meticulously following T2T principles did not result in more reduction of radiographic progression than a somewhat more liberal attitude toward T2T. One possible interpretation of these results is that the *intention* to apply T2T already suffices and that a more stringent approach does not further improve outcome.

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POS0112 CLASSIFYING SELF-REPORTED RHEUMATOID ARTHRITIS FLARES USING DAILY PATIENT-GENERATED DATA

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Background: Flares are an inherent part of the rheumatoid arthritis (RA) disease course and may impact clinical and patient outcomes. The ability to predict flares between clinic visits based on real-time longitudinal patient-generated data could potentially allow for timely interventions to avoid disease worsening. For intensively-collected patient-generated data, machine learning methods offer benefits over traditional statistical tools for accurate prediction, but examples in rheumatology are sparse.

Objectives: Investigate the feasibility of using machine learning methods to classify self-reported RA flares based on a small dataset of daily symptom data collected on a smartphone app.

Methods: We used data from the Remote Monitoring of Rheumatoid Arthritis (REMORA) study, which aimed to improve monitoring of disease severity in RA. Patients tracked daily symptoms (pain, fatigue, function, sleep, coping, physical and emotional wellbeing) on a 0-10 numerical rating scale, duration of morning stiffness, and weekly flares on the REMORA smartphone app for three months. The outcome was the binary yes/no answer to the weekly flare question "*Have you experienced a flare in the last week?*" Several summaries of the eight daily symptom scores collected in the week leading up to the flare question (the exposure period) were used as predictors. These included the mean, min, max, standard deviation and slope. Where exposure periods overlapped, the intersecting symptom reports were allowed to correspond to multiple outcomes.

We fitted three binary classifiers: logistic regression +/- elastic net regularization, a random forest and naïve Bayes. The models were benchmarked using the R package mlr3 and 10-fold cross-validation, with two participants comprising the test set and the remaining 18 the training set.

Finally, the performance of the classifiers was evaluated according to the area under the curve (AUC) of the receiver operating characteristic curve. The model with the highest AUC in the test dataset was considered as the best final model.

Results: Twenty patients tracked daily symptoms over three months. 60% were female, all but one were white British, and mean age was 56.9±11.1 years. The median number of days in the study was 81 (interquartile range (IQR) 80, 82). The collected data comprised an average of 60.6 daily reports and 10.5 weekly reports per participant over the study period. Participants reported a median of 2 flares (IQR 0.75-4.25) resulting in 57 flares in total.

Classifier performances are visualized in Figure 1. The best performing model was logistic regression with elastic net with an AUC of 0.82. At a cut-off point requiring specificity to be 0.80, the corresponding sensitivity to detect flares was 0.60 for this model, meaning that the prediction model correctly identified three in every five self-reported flares, and four in every five non-flares. At this cut-off, the positive predictive value, i.e. the probability that those with a predicted flare indeed go on to have a flare was 53%. The negative predictive value, i.e. the probability that those with a predicted non-flare indeed do not experience a flare, was 85%.

Conclusion: Predicting self-reported flares based on daily symptom scorings in the preceding week using machine learning methods was feasible, although regularized logistic regression outperformed the other machine learning methods in this small dataset. The perceived advantage of machine learning may therefore be attributed to overfitting. It is possible that the observed predictive accuracy will improve as we obtain more data.

Our results point to a future where regular analysis of frequently collected patient-generated data may allow us to predict imminent flares before they unfold with decent accuracy, opening up opportunities for just-in-time adaptive interventions (JITAIs). Depending on the nature and implications of a JITAI, different cut-off values should be explored: different interventions will require different levels of predictive certainty before an action is triggered (eg self-management advice vs. a patient contact).

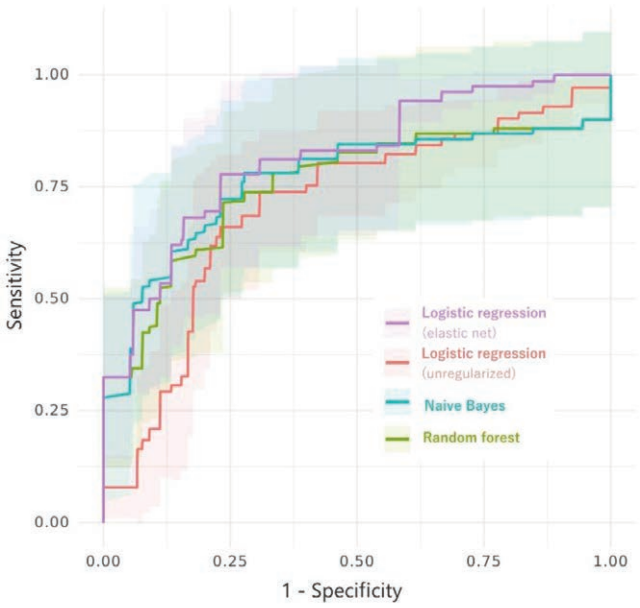

Figure 1. Performance of binary flare classifiers fitted to data from the REMORA study: Logistic regression with and without regularization, naïve Bayes and random forest.

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POS0113 THE PREDICTIVE VALUE OF HEALTH LITERACY ON DISEASE ACTIVITY AND MEDICATION USE OVER TIME IN RHEUMATOID ARTHRITIS PATIENTS.

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Background: Health literacy is a multidimensional concept comprising various individual skills and situational resources and is increasingly recognized as a critical determinant of health. Limited health literacy has been demonstrated to associate negatively with health outcomes in multiple chronic diseases, but data on the relevance of health literacy for treatment and outcomes in rheumatoid arthritis (RA) is still limited.

Objectives: The aim of this study was to explore the longitudinal association between health literacy profiles, disease activity and medication prescription in patients with RA.

Methods: We conducted a single center, retrospective, cohort study including patients from the Medisch Spectrum Twente hospital (Enschede, the Netherlands) who completed the Health Literacy Questionnaire (HLQ) and were previously clustered into 10 "health literacy profiles".[1] The 10 profiles were further aggregated, based on similarities in profile characteristics, into three groups: "several health literacy limitations", "some health literacy limitations" and "good health literacy". Up to 1 year of follow-up data on disease activity (DAS28-ESR) and medication use were obtained from patients' electronic health records. Linear mixed modelling (LMM) was used to analyze DAS28-ESR scores over time using health literacy group, time and their interaction term as fixed effects and gender and age as random effects. Drug prescriptions were constant over time, therefore chi-square tests were used to compare prescribed medication between the health literacy groups.

Results: 108 patients with RA were included and assigned to "several health literacy limitations" (n=21), "some health literacy limitations" (n=33) or "good health literacy" (n=54). LMM showed a significant main effect of health literacy group on DAS28-ESR scores over time (F (2,105) = 4.941, p=0.009). Post hoc contrast analysis showed that patients with "good health literacy" had significantly lower disease activity scores than patients with "several health literacy limitations". In addition, there was a significant effect of time on DAS28-ESR scores (F (2,141) = 4.601, p=0.012) in the total sample, indicating significantly lower scores at the 6-month follow-up. There was no significant interaction between group and