lasted until November 2005. Gradual dose escalation up to 20 mg/week was required during 2006 in view of RA exacerbations, nevertheless, clinical and lab RA activity persisted. Therefore tofacitinib (Jakvinius) was administered in November 2015 at 10 mg/day, with rapid achievement of minimum RA activity (DAS28=3.0). By the end of May 2016 clinical manifestations of vasculitis emerged, and in June 2016 tofacitinib was discontinued due to increasing lab activity of the disease. Clinical examination: patient's condition is moderately grave. The thinned skin looks dry, showing multiple regenerating ulcers on the anterior leg surface and sharply painful ulcerated indurations on the right inner thigh producing serosanguinous fluid. The RA activity is equal to DAS28=5.72, Hb 125 g/L, WBC $6.0 \times 10^9/L$, platelets $40 \times 10^9/L$, ESR 22 mm/h, CRP 42 mg/L, RF 413 IU/ml, antibody to cyclic citrullinated peptide (ACPA) is 195 U/ml, TNF – 13.9 pg/ml. Wrist and distal foot radiographs show moderate extended osteoporosis, narrowing of some joint spaces, rare bone and articular surface erosions, subluxation of some joints. Histopathology of skin and subcutaneous fat biopsy samples is presented on figure 1a,1b. Histopathology data suggests the presence of cutaneous and subcutaneous fat productive and destructive vasculitis and acute, predominantly lobular, panniculitis; such structural changes are usually present in cutaneous polyarteritis nodosa and other systemic vasculitis. The casual relationship between this ADR and tofacitinib therapy was assessed as probable using Naranjo scale.

Abstract AB0413 – Figure 1

Conclusions: development of vasculitis (polyarteritis nodosa) in RA patient can be caused by tofacitinib.

Disclosure of Interest: None declared

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AB0414 RELATIONSHIP BETWEEN SERUM OXYTOCIN LEVELS AND DEPRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Oxytocin (OXT), also referred to as a happy hormone, has been associated with various psychiatric disorders, including depression. However, the relationship between depression and rheumatoid arthritis (RA) has not yet been clarified.

Objectives: The objective of this study was to investigate the relationship between serum oxytocin levels and disease activity, depressive state, activity of daily life (ADL), and quality of life (QOL) in RA.

Methods: This study included 119 RA patients. We measured the following variables: baseline characteristics including age, sex, disease duration, smoking history, body mass index, prednisolone dose, and methotrexate (MTX) dose, serum levels of rheumatoid factor, matrix metalloproteinase-3, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) level. The disease activity of RA was assessed using the Simplified Disease Activity Index (SDAI); depression was assessed using the Hamilton Depression Rating Scale (HAM-D); ADL were assessed using the Health Assessment Questionnaire; and QOL was assessed using the 36-Item Short Form Health Survey (SF-36). Serum OXT levels were determined by enzyme-linked immunosorbent assay. The subjects were divided into two groups according to the higher or lower of the serum OXT levels, and a retrospective study was performed.

Results: The serum OXT levels were correlated with the disease duration ($r=0.443$, $p=0.000$). Weak correlations of MTX dose ($r=0.208$, $p=0.030$), swollen

joint count (SJC) ($r=-0.306$, $p=0.001$), ESR ($r=-0.245$, $p=0.010$), CRP ($r=-0.283$, $p=0.003$) and the mental component summary (MCS) score ($r=-0.196$, $p=0.041$) of SF-36. The binominal logistic analyses findings were as follows: younger age ($p=0.0209$, odd ratio: 0.96, 95% CI: 0.94–0.99) and longer disease duration ($p=0.0053$, odd ratio: 1.08, 95% CI: 1.02–1.13). Other items did not correlate to the serum OXT levels included with the HAM-D score.

Conclusions: The serum oxytocin levels were correlated with longer disease duration and younger age.

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Rheumatoid arthritis – biological DMARDs

AB0415

DISEASE FLARES AMONG EARLY RHEUMATOID ARTHRITIS PATIENTS TREATED WITH CONTINUED METHOTREXATE EITHER ALONE OR IN COMBINATION WITH ADALIMUMAB

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Background: Some rheumatoid arthritis (RA) patients (pts) may experience flares in their disease even after reaching stable low disease activity (sLDA), but the consequences of even temporary elevations in disease activity are poorly understood.

Objectives: The purpose of this analysis was to explore the rates of flares after reaching sLDA in pts treated to target with either methotrexate (MTX) monotherapy or adalimumab combination therapy (ADA+MTX).

Methods: This post hoc analysis included pts from the randomised, double-blind, double-period OPTIMA¹ trial achieving sLDA [DAS28(CRP) <3.2 at weeks (wks) 22 and 26] at the end of period 1 (P1). In P1, pts were randomised to receive ADA +MTX or placebo (PBO) +MTX for 26 wks. Pts on ADA +MTX achieving sLDA were randomised to receive PBO +MTX (ADA Withdrawal) or continue on ADA +MTX (ADA Continuation) for an additional 52 wks in period 2 (P2). Pts who achieved sLDA on PBO +MTX in P1 continued their treatment in P2 (MTX Continuation). Pts achieving sLDA in each treatment group were categorised based on whether they experienced a flare [change in DAS28(CRP) ≥ 0.6 at consecutive visits and DAS28(CRP) ≥ 3.2]; the proportion of pts experiencing flares and time to flare were assessed. For each group, mean change from wk 26 to wk 78 in disease activity [DAS28(CRP)], functional (HAQ-DI) and structural (mTSS) measures were analysed.

Results: In pts achieving sLDA at the end of P1, flare rates in P2 differed based on initial treatment assignment (ADA Continuation: 11.7% [11/94]; MTX Continuation: 22.4% [22/98]). Interestingly, flare rates in pts randomised to withdraw ADA in P2 (ADA Withdrawal: 25% [22/88]) were numerically similar to the MTX Continuation group. The mean time to flare was 193, 191, and 177 days in the ADA Withdrawal, ADA Continuation, and MTX Continuation groups, respectively. During P2, the mean DAS28(CRP) scores were predictably higher in pts who flared compared with those who did not across treatment groups. In pts experiencing flares in P2, disease activity and functional measures worsened from wk 26 to wk 78 as compared with pts without flares (table 1). Of the individual DAS28(CRP) components, pt global assessment of disease activity (PtGA) showed the greatest worsening. There were small differences in radiographic progression between pts experiencing flares compared with pts without flares.

Abstract AB0415 – Table 1. Change from Week 26 in Disease Activity, Functional and Structural Measures Based on Flare Status in Patients Achieving Stable LDA*

Outcome measure Mean (SD)		Visit Mean at Week 26		Mean Change (Δ) from Week 26 to Week 78	
		Flare	No Flare	Flare	No Flare
DAS28(CRP)	ADA Withdrawal	2.2	2.0	1.0 (1.2)	-0.1 (0.6)
	ADA Continuation	2.1	2.0	0.6 (1.1)	-0.2 (0.7)
	MTX Continuation	2.2	2.1	1.0 (1.2)	-0.1 (0.8)
HAQ-DI	ADA Withdrawal	0.4	0.2	0.3 (0.6)	0.0 (0.3)
	ADA Continuation	0.5	0.3	0.2 (0.5)	-0.1 (0.3)
	MTX Continuation	0.4	0.3	0.2 (0.5)	0.0 (0.4)
mTSS	ADA Withdrawal	8.4	11.5	0.3 (0.7)	0.2 (1.1)
	ADA Continuation	6.9	12.7	0.1 (0.5)	-0.1 (0.7)
	MTX Continuation	10.5	9.2	0.1 (0.6)	0.1 (1.0)

*Flare was defined as change in DAS28(CRP) ≥ 0.6 at consecutive visits and DAS28(CRP) ≥ 3.2 .

LDA=low disease activity; DAS28(CRP)=28 joint disease activity score based on C-reactive protein; ADA=adalimumab; MTX=methotrexate; HAQ-DI=health assessment questionnaire disability index; mTSS=modified total Sharp score.

Conclusions: In early RA pts achieving sLDA, flares were generally infrequent; however, they were more prevalent in pts receiving PBO+MTX compared with ADA+MTX. Flares were numerically associated with higher disease activity, functional deterioration, and higher PtGA, underscoring its impact on health-related quality of life and the importance of preventing flares as a therapeutic outcome.

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AB0416 ESTIMATING THE SHORT-TERM COSTS ASSOCIATED WITH NON-MEDICAL SWITCHING IN RHEUMATIC DISEASES

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Background: As biosimilars are approved and commercialised for rheumatic diseases, patients may be switched from originator biologic treatment to biosimilars due to perceived cost savings between the two biologic products. However, in the short term, non-medical switching (NMS) may require additional patient education, office visits, lab/imaging tests, and administrative support which could lead to substantial costs.

Objectives: To estimate the short-term costs associated with NMS from originator biologics to biosimilars among stable patients with rheumatic conditions (e.g., rheumatoid arthritis, RA; ankylosing spondylitis, AS; psoriatic arthritis – PsA) from the perspective of a rheumatology medical centre in the United Kingdom.

Methods: An economic model was constructed including two components: the administrative burden for NMS program set-up and support, and the provider burden for initiating and managing NMS. Administrative burden was modelled at the center-level and considered staff time for program set-up, patient education, scheduling, documentation, and departmental meetings from pre-NMS planning

to post NMS implementation (<1 year). The provider burden was modelled at the patient-level and considered the expected additional provider time needed and extra laboratory/imaging tests when managing NMS from the time of switching until 3 month post NMS implementation. Model inputs for the administrative burden came from the literature¹ and for provider burden from survey of physicians. Literature was used to inform both the total number of rheumatology patients that underwent NMS, and the unit cost associated with provider/staff time and laboratory/imaging tests.

Results: From a rheumatology centre perspective, setting up an NMS program and the subsequent administrative support was estimated to cost £19 617 per centre, attributed to general overhead (40%), pharmacist time (26%), consultant time (21%), and nurse time (13%). After the set-up, provider burden for initiating and managing NMS was estimated to be £113 per switched patient. Assuming 5000 patients with relevant rheumatoid conditions in a centre, 572 stable patients with RA, PsA or AS were estimated to switch to biosimilars. The overall short-term cost associated with NMS was estimated to be £84 174 for the entire centre, with 23% attributed to the NMS program set-up and support, and 77% attributed to extra provider time and monitoring (on average £147 cost per switched patient).

Conclusions: Switching stable patients with a rheumatic condition from originator biologics to biosimilars could have considerable short-term costs for a centre. Additional real world studies are needed to better weigh the potential saving vs. cost associated with NMS.

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AB0417 BIOLOGICAL DRUGS IN THE TREATMENT OF RHEUMATOID ARTHRITIS: REAL LIFE DATA IN A BRAZILIAN MULTICENTRIC STUDY

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Background: Rheumatoid arthritis (RA) is a chronic disease, characterised by inflammatory involvement of the synovial joints. The "treat to target" concept is well established in the rheumatologic community, however, in many patients, especially in developing countries, its implementation is not feasible. Considering the high costs of treatment com of RA and the limited national epidemiological data available on this disease, we sought to describe the profile of use of biological drugs in Brazilian patients with RA to help the decision-making process by public health managers.

Objectives: To describe the frequency and time of use of biological drugs in Brazilian patients with rheumatoid arthritis.

Methods: The REAL – RA in real life in Brazil – is a multicenter prospective cohort study, with twelve-month follow-up period. To be included in this study, consecutive patients from 11 tertiary rheumatology centres had to meet the 1987 ACR or the 2010 ACR/European League Against Rheumatism (EULAR) criteria. Data were collected during routine clinical care and previous medical records were used as secondary sources. The present study present data taken from the participants' initial assessment. This research was approved by the Ethics Committees of each centre.

Results: A total of 1125 patients were analysed. 89% were women with a mean age of 56.6 years. The main clinic data were: DAS 28 (median)=3.52, HAQ (median)=0.87 and CDAI (median)=9. 1022 (90.84%) used synthetic DMARDs