

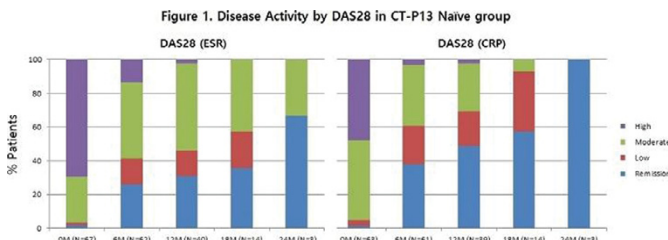
For Naïve group, 50% (52/104) of patients had at least one positive anti-drug antibody result and it is consistent to other published study [2]. Overall safety summarized as the percentage of patients with at least one treatment emergent AE (TEAE) was similar or lower after switching to CT-P13 (Table 2). No cases of active tuberculosis were reported.

Table 1. DAS28 in CT-P13 Naïve group over 24 months

		Baseline	6 months	12 months	18 months	24 months
DAS28 (ESR)	n	67	62	40	14	3
	Mean	5.78	3.61	3.30	3.01	2.42
	SD	1.14	1.40	1.22	1.03	0.74
DAS28 (CRP)	n	63	61	39	14	3
	Mean	5.06	2.97	2.59	2.35	1.81
	SD	1.19	1.21	1.06	0.69	0.63

Table 2. Safety results in CT-P13 Naïve and Switching group

	Naïve group	Switching group
TEAEs	80.8% (84/104)	66.7% (14/21)
Related TEAEs	31.7% (33/104)	28.6% (6/21)
Infection and Infestation	42.3% (44/104)	33.3% (7/21)



Conclusions: The overall safety profile revealed that CT-P13 is well-tolerated in patients with RA and remission rate for 24 months also showed that CT-P13 is efficacious under real world practice.

References:

- [1] Grintborg et al. ACR 2016.
[2] Krintel et al. Rheumatology 2013.

Disclosure of Interest: None declared

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AB0393 ADVERSE SKIN REACTIONS IN RHEUMATOID ARTHRITIS PATIENTS RECEIVING TUMOR NECROSIS FACTOR ALPHA INHIBITOR – AN ANALYSIS OF DATA FROM THE SLOVENIAN BIOLOGICAL REGISTRY

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Background: Paradoxical skin reactions (PSR) are defined as a new onset or worsening of skin conditions during treatment with tumour necrosis factor alpha (TNF- α) inhibitors that generally improve or respond to this therapy. The list of PSR is growing. The most commonly reported are psoriasisiform skin eruptions.

Objectives: To evaluate the frequency of PSR in the group of rheumatoid arthritis (RA) patients treated with TNF- α inhibitor at the time of development of skin eruption.

Methods: We conducted the analysis of the data from the mandatory Slovenian national registry of patients treated with bDMARDs (BioRx.si) which includes spontaneous adverse reaction reports between 01.01.2008–31.05.2016. The analyses were limited to patients with RA.

Results: During the observation period, 1,046 RA (82% female; median (IQR) age at initiation of TNF- α inhibitors 56 (49–63) years) patients treated with TNF- α inhibitors for 3,140 person-years. We identified 14 cases with PSR (71% female, median age (IQR) 45 (53–62)). There were 6 PSR cases on adalimumab, 4 on etanercept, 3 on certolizumab – pegol, and 1 on infliximab. 10 patients developed psoriatic/psoriasisiform eruptions, 2 patient leucocytoclastic vasculitis, one had lichen planus, and one undifferentiated skin changes. The incidence rate of new onset of psoriasis in RA patients treated with TNF- α inhibitors was estimated at 3.2 cases/1000 patient-years (95% CI 2.58 to 3.82). The incidence rate of leucocytoclastic vasculitis was 0.64/1000 person-years (95% CI 0.36 to 0.92), and of lichen planus 0.32/1000 person-years (95% CI 0.12 to 0.52).

Conclusions: The most commonly reported PSR in RA patients treated with TNF- α inhibitor was psoriasisiform PSR, which is in line with published data.

Disclosure of Interest: None declared

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AB0394 TAPERING TNF INHIBITORS IN RHEUMATOID ARTHRITIS: A RETROSPECTIVE STUDY

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Background: Increasing evidence suggests the feasibility of biologic DMARD tapering in RA patients after achieving and maintaining good control of disease activity. Current guidelines on RA treatment also recommend tapering of biologic and non-biologic DMARDs for patients in remission. Data on biologic DMARD tapering reflecting real life settings are limited.

Objectives: To collect information on biologic DMARD tapering and its outcome in RA patients who are followed-up in a rheumatology outpatient clinic.

Methods: In this retrospective study we used the hospital administrative database to identify patients with a diagnosis of RA and a first time prescription of a biologic DMARD that was specifically limited to one of the 3 TNF inhibitors (etanercept, adalimumab, infliximab) between January 2012 and the end of December 2013. Demographics and information regarding treatment and outcome were taken from the medical charts.

Results: Of the 125 patients identified at the database search, 104 were belonging to our clinic and had available follow-up data until June 2016. Seventy-nine of them were women and 25 were men. Their mean age was 47.7 \pm 13 SD years and their mean disease duration was 7.4 \pm 6.9 SD years. 60% were prescribed etanercept, 23% adalimumab and 17% infliximab. After a mean duration of 14.0 \pm 7.6 SD months a dose reduction of TNF inhibitors was made in 44 patients (42%). This was in the form of spacing in 39 patients (Etanercept =16, Infliximab =14, Adalimumab =9) and dose tapering in 5 (all Etanercept). All of these were due to good clinical response except for 1 patient's own request for fear from adverse effects. Following dose reduction increased disease activity was seen in 16 patients (36%) mandating restoration to original dose within a mean of 8.8 \pm 9.7 SD months with good response. Twenty-eight patients (64%) preserved their good clinical response during a mean follow-up of 46.1 \pm 6.3 SD months which enabled further dose reductions in 20 patients. There was also reductions in the mean number of synthetic DMARD's (1.4 \pm 0.8 SD at the initiation of TNF inhibitors and 0.7 \pm 0.8 SD at the end of follow-up) and in the percentage of patients using steroids (78% to 33%). At the end of the follow-up, among the whole group of 104 patients, only 73 (70%) were using biologics (TNF inhibitors =49, non-TNF biologics =24). The reasons for stopping biologics in the remaining 31 patients were ongoing remission (16 patients), pregnancy (1 patient), non-compliance (4 patients), injection site reactions (3 patients), fear from adverse events (1 patient), deciding to try complementary medicine (1 patient) and other issues such as losing insurance and family issues (5 patients).

Conclusions: Tapering of TNF inhibitors was possible in 40% of RA patients during their routine follow-up. Half of the patients maintained good clinical response after tapering allowing further dose reductions in one third.

Disclosure of Interest: None declared

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Rheumatoid arthritis - other biologic treatment

AB0395 SUBCUTANEOUS TOCILIZUMAB AS MONOTHERAPY OR IN COMBINATION WITH A CSDMARD IN PATIENTS WITH RHEUMATOID ARTHRITIS: 24 WEEKS RESULTS OF THE FRENCH PHASE IIIIB STUDY, "TOSCA"

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Background: After the two global pivotal studies, which evaluated the safety and efficacy of subcutaneous tocilizumab (TCZ-SC) in combination (combo) with conventional synthetic disease-modifying antirheumatic drugs (csDMARDs), it was important to understand the efficacy and safety profile of TCZ-SC both as monotherapy (mono) and in combo with csDMARDs in patients (pts) managed in conditions less strict than those of pivotal clinical trials.

Objectives: To evaluate the efficacy and safety of TCZ-SC 162 mg once weekly (qw) as mono and in combo with csDMARDs over 24 weeks in adult pts with moderate to severe RA. The primary efficacy criterion was the change in DAS28-ESR from baseline to week 24 (W24).

Methods: TOSCA is a national, multicenter, open-label phase IIIb study, part of the international umbrella study (TOZURA). It aimed to enroll TCZ-naïve pts who were csDMARDs inadequate responders (IR) and/or biological DMARD-IR. Pts received TCZ-SC 162 mg qw for 24 weeks, administered at the investigator's discretion as mono or in combo with a csDMARD. Stable oral corticosteroids (CCS), \leq 10 mg/day prednisone or equivalent (eq.pred), were allowed.