While the total number of AE was comparable between the TOC cohort (58/100PY) and in the control cohort (54/100PY; RR 1.1; 95%CI 0.9-1.4), more serious AE (SAE) were reported with TOC (4.8/100PY compared to 1.4/100PY; RR 3.5; 95% CI 1.0-9.9). Medically important infections and uveitis events were documented at significantly lower frequency in the TOC (0.8/100PY) than in the control cohort (4.1/100PY; RR 0.2; 95% CI 0.04-0.9). SAE with TOC were suicidal intent (n=3), depression (n=2), exacerbation of JIA, abscess, gastrointestinal infection, abdominal pain, colitis, bone surgery and fracture (n=1). SAE in the control cohort were depression, osteomyelitis, gastrointestinal infection and superinfected eczema (n=1). No significant differences regarding cytopenia and elevated transaminases were observed. No gastrointestinal perforation, no vascular event, no malignancy and no death occurred.

Conclusion: The efficacy of tocilizumab is comparable to that of alternative biologics. Tolerability was acceptable. As Tocilizumab was given as a second-line biologic in the vast majority of patients, comparisons between the cohorts have to be interpreted carefully. Observation in the registry is ongoing.

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SAT0491

PSORIASIS ASSOCIATED WITH MONOCLONAL-ANTIBODY-TNF-A INHIBITORS VS. FUSION PROTEIN ETANERCEPT IN JUVENILE IDIOPATHIC ARTHRITIS PATIENTS - ANALYSIS OF THE BIKER REGISTRY

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Background: Although efficacy of Tumor necrosis factor inhibitors (TNFi) for treatment of psoriasis is well established, patients may develop psoriasis for the first time while on TNFi as a paradoxical effect. Few data are available in patients with juvenile idiopathic arthritis (JIA).

Objectives: To analyze the incidence of psoriasis in TNFi – treated JIA patients and to identify associated factors.

Methods: Safety data from patients registered in the German Biologics registry (BiKeR) were analyzed. Cohorts of patients were grouped by treatment: any or multiple TNFi, single TNFi, biologics other than TNFi and no biologics (control group on methotrexate (MTX) only). TNFi-associated psoriasis was defined as incident diagnosis of psoriasis after starting a TNFi. Patients with personal history of psoriasis prior to TNFi therapy were excluded. Rates and events per

100 patient-years (PY) of exposure were calculated using AEs reported after first dose under therapy and under the age of 18 years. Rates were compared by X2-test, event rates by Wald test.

Results: A total of 4149 treatment episodes with TNFi (Etanercept, Adalimumab, Golimumab, Infliximab), with a total exposure time of 8437 PY, were identified. There were 676 treatments with a non-TNFi- biologic (Tocilizumab, Abatacept, Anakinra, Canakinumab) with a total exposure time of 1112 PY. MTX monotherapy was conducted in 1692 patients with a total exposure time of 3971 PY. In total, 31 patients were diagnosed with incident psoriasis on JIA-treatment (Table 1). The mean duration of therapy until incident psoriasis was 2.2 (± 1.8) years. Multiple psoriatic skin manifestations were observed.

Psoriasis events were significantly more frequent in any or multiple TNFi compared to MTX-monotherapy, and specifically in the subgroup of TNF-antibody treatment (all) or Adalimumab compared to MTX or Etanercept (Table 2). Interestingly, psoriasis events were also observed with non-TNFi at high frequency. At occurrence of the event, patients exposed to biologics received MTX or steroids less frequently compared to the total patient cohort and had a higher JADAS10.

Table 2.

Reference	Psoriasis event n/100 PY	Comparator	Psoriasis event n/100 PY	Risk ratio	P-value
Non-TNFi	0.63	TNFi	0.27	0.4 (0.2 -1.0)	0.052
MTX	0.03	TNFi	0.27	10.8 (1.5-80.1)	0.019
MTX	0.03	ETA	0.11	4.4 (0.5-35.8)	0.165
MTX	0.03	TNF-antibodies	0.75	42.9 (5.8-317)	0.0002
ETA	0.11	TNF-antibodies	0.75	6.8 (2.8-16.5)	0.00002
MTX	0.03	ADA	0.69	27.4 (3.6-2209)	0.001
Non-TNFi	0.63	ADA	0.69	1.1 (0.4-2.7)	0.847
Non-TNFi	0.63	ETA	0.11	0.2(0.1-0.5)	0.0012
ETA	0.11	ADA	0.69	6.2 (0.5-15.6)	0.0001

Conclusion: Our findings demonstrate a higher incidence of psoriasis in monoclonal-antibody-TNFi-treated JIA-patients, whereas in Etanercept-treated JIA patients no significant increase was detected. On average, psoriasis-manifestation occurred more than two years after treatment-initiation. Teenage females with ANA-positivity were most often affected.

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SAT0492

RAPID IMPROVEMENT AND ACHIEVEMENT OF INACTIVE DISEASE IN CHILDREN WITH SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS UNDER 4 YEARS OF AGE DEPENDING ON DISEASE DURATION ON TOCILIZUMAB TREATMENT

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Table 1

N/PY	TotalCohort* 4792/13519	All TNFi 4149/8437	ADA 1105/1859	ETA 2824/6307	GOL 144/145	INF 76/126	Non-TNFi 676/1112	MTX only 1692/3971
Psoriasis events/rate(%)	31/0.6	23/0.6	13/1.2	7/0.2	2/1.4	1/1.3	7/0.6	1/0.1
Pso**/100 PY (95%CI)	0.2 (0.2-0.3)	0.3 (0.2-0.4)	0.7 (0.4-1.2)	0.1 (0.1-0.2)	1.4 (0.3-5.5)	0.8 (0.1-5.6)	1.0 (0.5-2.1)	0.03 (0.004-0.2)
Age at event	13.9	13.9	14.0	13.0	15.1	16.4	13.4	17.3
Mean ± SD	(±3.1)	(± 3.2)	(±3.0)	(±4.0)	(±3.4)		(±3.1)	
Female	24	18	10	5	2	1	5	1
ANA positive	(77%)	(78%)	(77%)	(71%)	(100%)	(100%)	(71%)	(100%)
Treatment duration until event (years) Mean ±SD	2.2 ±1.8	2.4 ±2.3	2.2 ±1.4	2.8 ±2.2	0.6 ±0.5	3.8 ±2.0	1.4 ±2.0	5.6 ±2.0
Concomitant	11	6	3	2	1	0	4	1
MTX	(36%)	(26%)	(23%)	(29%)	(50%)		(57%)	(100%)
Concomitant	4	2	0	1	0	1	2	0
Steroids	(13%)	(9%)		(14%)		(100%)	(29%)	
JADAS10 Median [IQR]***	2.5 (0.6-8.8)	4.2 (1.0-11.0)	2.0 (0.6-10.1)	5.8 (1.5-11.4)	18.0	6.6	1.3 (0.8-3.4)	1.7

*individual therapy numbers add to a sum > the total cohort number, because some patients switched between multiple drugs; ** Pso= Psoriasis event; *** at time of event