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.

Disclosure of Interests: Ariane Klein Consultant of: Celgene, Toni Hospach: None declared, Frank Weller-Heinemann: None declared, Sandra Hansmann Consultant of: Advisory board Novartis Pharma, Jasmin Kuemmerle-Deschner Grant/research support from: Novartis, Sobi, Consultant of: Novartis, Sobi, Speakers bureau: Novartis, Sobi, Maria Fasshauer Consultant of: Shire, CSL Behring, Kirsten Minden Consultant of: GlaxoSmithKline, Sanofi, Speakers bureau: Roche, Ivan Foeldvari Consultant of: Novartis, Christoph Rietschel Consultant of: Pfizer, Abbvie, Novartis, Chugai, and Sobi, Tobias Schwarz: None declared, Ralf Trauzeddel: None declared, Markus Hufnagel: None declared, Dirk Foell Grant/research support from: Novartis, Sobi, Pfizer, Speakers bureau: Novartis, Sobi, Rainer Berendes: None declared, Gundula Boeschow: None declared, Prasad Oommen Consultant of: Novartis, Frank Dressler: None declared, Astrid Helling-Bakki: None declared, Gerd Horneff Grant/research support from: AbbVie, Chugai, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Speakers bureau: AbbVie, Bayer, Chugai, Merck Sharp & Dohme, Novartis, Pfizer, Roche

DOI: 10.1136/annrheumdis-2020-eular.4363

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.

Disclosure of Interests: Angela Zimmer: None declared, Ariane Klein Consultant of: Celgene, Gerd Horneff Grant/research support from: AbbVie, Chugai, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Speakers bureau: AbbVie, Bayer, Chugai, Merck Sharp & Dohme, Novartis, Pfizer, Roche

DOI: 10.1136/annrheumdis-2020-eular.4883

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

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Background: Early-onset form of systemic juvenile idiopathic arthritis (sJIA) often presents severe disease course. Choosing the optimal therapy option as first-line treatment is necessary for rapid improvement of patients' quality of life and prevention of further radiologic progression.

Objectives: To evaluate the long-term effectiveness and safety of tocilizumab (TOC) in sJIA patients depending on the duration of the disease treated in the National Medical Research Center of Children's health, Moscow, Russia.

Methods: The study was conducted as a subanalysis of the prospective cohort study to evaluate the efficacy of biologics in children with sJIA. Analysis included sJIA patients younger than 4 years of age at the moment of TOC initiation. Patients were divided into 2 groups: with disease duration shorter than 6 month (ShorterDD group, n=35) and more than 6 month (LongerDD group, n= 19). Treatment efficacy was evaluated according to the dynamics of clinical and laboratory signs using the ACRPedi criteria. The Wallace criteria were used to evaluate whether or not remission had been achieved. Treatment safety was evaluated according to the data presented in the Adverse Event Reports.

Results: TOC was first biologics in 34/35 (97.1%) patients in ShorterDD group and 18/19 (94.7%) patients in LongerDD group. Groups were comparable in terms of disease activity at TOC initiation with 100% of patients presented active systemic features. 31/35 (88.6%) patients in ShorterDD group and 17/19 (89.5%) patients in LongerDD group have median 3 (IQR 1: 6) and 5 (IQR 3: 7.5) active joints, respectively (p=0.119). JADAS-71 level was 17.14 ± 6.25 ShorterDD group and 17.36 ± 5.45 in LongerDD group (p=0.895).

TOC showed high efficacy after first months of treatment with only 6/35 (17.1%) patients in ShorterDD group and 7/19 (36.8%) in LongerDD group remained with active systemic features (p=0.181). JADAS-71 level decreased to 0 points 26/35 patients (74.3%) in ShorterDD group and in 11/19 patients (57.9%) LongerDD group (p=0.237). After 3 month of treatment, WID was achieved by 27/35 patients (77.1%) in ShorterDD group and by 9/19 patients (47.4%) LongerDD group (p=0.038). ACR Pedi 50/70/90 was achieved by 88.6%/85.7%/80% of patients in ShorterDD group and by 84.2%/73.7%/68.4% of patients in LongerDD group after 1 months of treatment and in 77.1%/74.3%/74.3% and 84.2%/78.9%/68.4%, respectively, after 3 months of treatment.

Conclusion: Initiation of tocilizumab treatment in sJIA patients under 4 years of age is highly effective. However, early treatment within first 6 month after disease onset had advantages in speed of reaching an inactive disease as soon as after 3 months of therapy.

Disclosure of Interests: Elizaveta Krekhova: None declared, Ekaterina Alexeeva Grant/research support from: Roche, Pfizer, Centocor, Novartis, Speakers bureau: Roche, Novartis, Pfizer., Tatiana Dvoryakovskaya: None declared, Ksenia Isaeva: None declared, Aleksandra Chomakhidze: None declared, Evgeniya Chistyakova: None declared, Olga Lomakina: None declared, Rina Denisova: None declared, Anna Mamutova: None declared, Anna Fetisova: None declared, Marina Gautier: None declared, Dariya Vankova: None declared, Meyri Shingarova: None declared, Alina Alshevskaya: None declared, Andrey Moskalev: None declared, Ivan Kriulin: None declared

DOI: 10.1136/annrheumdis-2020-eular.5770

SAT0493

CLINICAL PROFILE OF JIA PATIENTS WITH THE CERVICAL SPINE INVOLVEMENT: A SINGLE CENTER RETROSPECTIVE CONTINUOUS STUDY.

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Background: JIA is the most common chronic condition in pediatric rheumatology. The cervical spine (CS) involvement is associated with severe disease activity and disability and has been recognized as a factor of a poor prognosis. Data about the CS involvement is contradictory due to silent CS involvement in some patients.

Objectives: the aim of our study was to provide a clinical profile of the patients with the CS involvement.

Methods: 753 patients for last 10 years with JIA were analyzed. Patients were divided depending on the CS involvement, which was confirmed by clinical (pain, LOM) and radiological features (effusion in the CS joints). We evaluated active joints and routine tests, such as CRP, ESR, ANA-positivity and HLA B27

Results: The CS involvement was in 101 patients (13.4%). The data are in the table. The CS involvement was more frequently associated with joints of upper body, such as TMJ (23.7% vs 2.9%, p=0.000001), shoulder (29.7% vs 2.9%, p=0.000001), elbow (34.2% vs 12.2%, p=0.000001), wrist (61.4% vs 21.8%, p=0.000001), MCP (43.6% vs 18.4%, p=0.000001), PIP (52.5% vs 21.3%, p=0.000001), DIP (23.8% vs 7.1%, p=0.000001) and hip (44.6% vs 16.6%, p=0.000001), and ankle (60.4% vs 40.2%, p=0.0001) from lower body.

Parameters	CS, yes (n=101)	CS, no (n=652)	p
Female, n (%)	69 (68.3)	388 (59.5)	0.092
ANA-positivity, n (%)	22/57 (38.6)	190/403 (47.2)	0.226
HLA B27-positivity, n (%)	12/33 (36.4)	88/275 (32.0)	0.613
Onset age, years	5.3 (2.7-10.1)	6.1 (3.0- 10.4)	0.241
ESR, mm/h	12.0 (5.0-31.0)	7.0 (3.0- 18.0)	0.0006
CRP, mg/l	3.9 (0.0- 20.0)	1.1 (0.0-9.2)	0.002
Active joints, n (%)	16.0 (9.0-28.0)	5.0 (3.0-10.0)	0.000000
Time before remission, years	2.9 (1.5-5.1)	2.2 (1.4-4.6)	0.046
Oligoarthritis	5 (5.0)	199 (30.5)	0.0000001
Polyarthritis	48 (48.0)	217 (33.3)	
Psoriatic arthritis	7 (7.0)	33 (5.1)	
Enthesitis-related arthritis	22 (21.8)	164 (25.2)	
Systemic arthritis	19 (18.9)	39 (6.0)	
Uveitis, n (%)	9/76 (11.9)	107/444 (24.1)	0.018
Oral glucocorticosteroids, n (%)	37 (36.7)	115/651 (17.7)	0.00001
Biologic, n (%)	68 (67.3)	283 (43.4)	0.000007
Remission, n (%)	57 (56.4)	428 (65.6)	0.072
Flare, n (%)	10 (9.9)	128/651 (19.7)	0.018

Conclusion: The main risk factors of CS involvement in JIA were polyarthritic and systemic arthritis, high inflammatory activity and involvement of joints of upper body. Patients with CS involvement required more often biologics.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.3841

SAT0494

RITUXIMAB IN REFRACTORY PEDIATRIC RHEUMATIC DISEASES: FOCUS FOR THE SAFETY IN REAL CLINICAL PRACTICE

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Background: Rituximab (RTX) is now approved only for pediatric patients (pts) 2 years of age and older with granulomatosis with polyangiitis or microscopic polyangiitis, but it has been used with success to treat another rheumatic diseases (RD) in children despite the status "of label".

Objectives: to analyze the safety of RTX in children with various RD who did not respond to conventional therapy.

Methods: In our retrospective study safety data was analyzed for all pts, who received at least one infusion of RTX. The dose of RTX was established as 375 mg/m² of body surface area, administered by intravenous infusion once weekly for 1 to 4 weeks, depending on the CD19 lymphocyte count.

Results: 81 patients with RD, who received RTX, were included: 38 (46.9%) with systemic lupus erythematosus (SLE), 16 (19.75%) – JIA, polyarthritis (2 pts - RF negative, 14 - RF positive), 9 (11.1%) - systemic JIA (sJIA), 6 (7.4%) – systemic sclerosis (SSc), 5 (6.2%) – primary Sjogren's syndrome (pSS), 2 (2.5%) – juvenile dermatomyositis (JDM), 4 (4.9%) – mixed connective tissue disease (MCTD) and 1 with livedoid vasculitis (LV). Most were female – 69 (85.2%). The median age at onset – 11.6 years [interquartile range (IQR) 7.9; 14.3], median age of the starting therapy – 15.2 [IQR 12.5; 16.85] and median disease duration – 2.8 [IQR 1.0; 4.6]. 53 pts (65.4%) reported more than one course of RTX, maximum – 10. The median time between each course was 182 days [IQR 156–315]. The RTX was effective in 95% pts, ineffective in 5% (2 pts with sJIA, 2 pts with SLE and macrophage activation syndrome (MAS)). Adverse events (AE) were recorded in 23 (28.4%) pts, included upper respiratory tract infections – 7 (8.6%), urinary tract infections – 2 (2.5%), short-term infusion reactions that did not require discontinuation of therapy – 2 (2.5%), clinically insignificant neutropenia (grade I-II) – 4 (4.9%), decrease of IgG level was detected in 14 (17.5%) pts (median 5.5 g/l [IQR 4.0; 6.9]). The infection rate in pts with a low IgG level was 35.7%, in pts with neutropenia wasn't recorded. Serious AE were recorded in 16 (19.7%) pts: sepsis – 4, pneumonia – 3, herpes zoster – 1, serious infusion reactions – 2, serious postinfusion reactions within 3 to 10 days – 4 (3 – MAS, 1 – hemorrhagic vasculitis), death – 2 pts with SLE and MAS (therapy of RTX was inefficiency). In general, various AE were registered in 55.6% of pts with sJIA, in 52.6% of pts with SLE, 50% of pts with SSc and JDM, and 80% of pts with pSS. Discontinuation of therapy due to SAE was observed in 15 pts (18.5%).