Figure 1

Conclusion: There was an association between etanercept dose used and serum trough concentration and it was more evident when medication was started early after diagnosis, when the patients were younger and BSA lower.

References:

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SAT0489

CLINICAL COURSE AND THERAPY RESPONSE IN TAKAYASU ARTERITIS: COMPARISON BETWEEN CHILDHOOD AND ADULT ONSET

E. Cocchiara¹, E. Galli¹, A. De Fanti², C. Malattia³, A. Ravelli³, C. Salvarani¹.
¹Policlinico di Modena University Hospital of Modena, Rheumatology, Modena, Italy; ²Arcispedale Santa Maria Nuova, Reggio Emilia, Italy; ³Istituto Giannina Gaslini, Genova, Italy

Background: Takayasu arteritis (TA) is a granulomatous vasculitis of the large vessels of unknown origin, which mainly affects the aorta and its main branches. TA is a disease of the young age with onset usually before 40 years and in more than 20% of patients the diagnosis is made before 19 years. Very few clinical series have compared the clinical manifestations, treatment and outcomes between pediatric and adult patients.

Objectives: Objective of our study was to compare childhood and adult onset TA evaluating clinical manifestations, treatment (including biotechnological agents) and outcomes.

Methods: All consecutive patients with childhood-onset TA (onset <18 years) and adult-onset (onset ≥ 18 years) TA followed from 2002 to 2019 in two Italian centers (Genoa Gaslini Hospital and Santa Maria Nuova Hospital of Reggio Emilia) were retrospectively evaluated and compared.

All patients met TA classification criteria (ACR 1990 and EULAR/Printo/PrES 2010 for children).

Clinical, demographic, laboratory, radiological, therapeutic data were collected retrospectively at baseline, at 6-month follow-up and at the last follow-up.

Disease activity at each follow-up visit was evaluated according to NIH criteria.

Results: 58 patients were consecutively enrolled: 18 children (C) and 40 adults (A). In both groups there was a higher prevalence of females (83.3% C vs 77.5% A; p NS).

The diagnostic delay was lower in the pediatric group (median of 5 months VS 10 months in A; p NS).

Fever and headache as presenting manifestations affected more frequently children with statistically significant differences (55,6% C vs 17,5% A, p 0,003; 27,8% C vs 5% A, p 0,025)

Adults had a higher frequency of claudication of the upper limbs and carotid/subclavian bruits (30% and 55% A vs 5,6% and 38,9% C respectively; p NS), while the discrepancy in blood pressure of the four limbs was higher in children (22,2% C vs 12,5% A; p NS).

Hypertension was not significantly different between the two groups at baseline and during the follow-up.

We found a significantly more frequent inflammatory involvement of the aorta (arch, thoracic, or abdominal) in children (72,2% C vs 30% A, p 0.003).

The subclavian arteries were most affected in the adults (65% A vs 38,9% C; p NS), although the difference was not statistically significant.

Treatment regimen were different between the groups: glucocorticoid monotherapy was more frequently used in adults (45% A vs 27,8% C; p NS), glucocorticoids in combination with Cyclophosphamide or anti-TNF were more significantly used to induce remission at the beginning in the pediatric group (22% C vs 0 A, p 0,007 and 22% C vs 2,5% A, p 0,029).

At the last follow-up the disease was significantly more active in children according to NIH criteria (55.6% C vs 27.5% A, p 0,04).

Conclusion: We reported some differences between children and adults. TA in children was characterized by a shorter diagnostic delay, a more frequent inflammatory involvement of the aorta and a more refractory disease. Patients with pediatric TA were treated more aggressively at the beginning.

Disclosure of Interests: None declared

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SAT0490

MATCHED CONTROLLED SURVEILLANCE OF TOCILIZUMAB TREATMENT FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS—AN INTERIM ANALYSIS

A. Klein¹, T. Hospach¹, F. Weller-Heinemann¹, S. Hansmann¹, J. Kuemmerle-Deschner¹, M. Fasshauer¹, K. Minden¹, I. Foeldvari¹, C. Rietschel¹, T. Schwarz¹, R. Trauzeddel¹, M. Hufnagel¹, D. Foell¹, R. Berendes¹, G. Boeschow¹, P. Oommen¹, F. Dressler¹, A. Helling-Bakki¹, G. Horneff¹. ¹BIKER Registry, Sankt Augustin, Germany

Background: Tocilizumab (TOC) is approved for treatment of polyarticular juvenile idiopathic arthritis (pJIA). Data out of clinical practice are limited.

Objectives: Long-term surveillance of patients initiating TOC treatment compared to a cohort of patients initiating a comparator biologic using the BIKER-registry.

Methods: Baseline parameters, efficacy and safety parameters were compared. Efficacy outcomes were JADAS10 and joint counts. Functional status was determined with the Childhood Health Assessment Questionnaire disability-index (CHAQ-DI). Safety was assessed by adverse events (AE) reports.

Results: Until January 2020, 152 patients have been recruited to each cohort. Patients starting on TOC were older at treatment start (12.1 vs. 10.1 years (y); p<0.0001) and had a longer disease duration (5.4y vs. 3.0y; p<0.0001). TOC was significantly more often a second-line biologic (84% vs 13%, p< 0.0001). Otherwise patients were comparable (Table 1).

Table 1. Comparison of TOC patients and matched controls.

	Tocilizumab N=152	Matched controls N=152	p
Gender female, n (%)	128 (84)	124 (81)	0.65
Disease duration, mean (SD), years	5.4 (4.1)	3.0 (2.9)	<0.0001
RF neg. polyarthritis, n (%)	104 (68.4)	92 (60.5)	0.19
RF pos. polyarthritis, n (%)	14 (9.2)	19 (12.5)	0.46
Extended oligoarthritis, n (%)	34 (22.4)	41 (27)	0.42
Pretreatment with biologics, n(%)	127 (83.5)	20 (13.2)	<0.0001
Active joint count, mean (SD)	6.7 (7.1)	6.1 (5.1)	0.4
CHAQ DI, mean (SD)	0.63 (0.63)	0.65 (0.64)	0.8
ESR, mm/h, mean (SD)	17.5 (14.9)	20.9 (20.6)	0.1
JADAS10, mean (SD)	16.8 (9.8)	15.1 (5.8)	0.067
Efficacy Month 12	N=87	N=105	
JADAS MDA, n (%)	50 (57.5)	63 (60.0)	0.77
JADAS REM, n (%)	32 (36.8)	39 (37.1)	1.0
JIA ACR 30/50/70/90, %	80/75/61/53	86/84/70/56	0.34/0.15/0.17/0.66
Adverse events	248,65 PY	290.4 PY	RR (95%CI); p
N (rate/100PY; 95%CI)			
AE	145 (58.3; 50-69)	157 (54.1; 46-63)	1.1 (0.9-1.4); 0.5
SAE	12 (4.8; 2.7-8.5)	4 (1.4; 0.5-3.7)	3.5 (1.1-10.9); 0.03
Medically important infection	2 (0.8; 0.2-3.2)	12 (4.1; 2.3-7.3)	0.2 (0.04-0.9); 0.03
Uveitis event	2 (0.8; 0.2-3.2)	12 (4.1; 2.3-7.3)	0.2 (0.04-0.9); 0.03

Upon TOC a substantial response to treatment with a significant reduction in JADAS 10 from 16.8 to 3.4 (p<0.0001) after 12 months was observed. There were no significant differences between patients from the TOC cohort and their matched controls regarding JIA ACR 30/50/70/90 criteria and active joint counts. JADAS 10, JADAS remission (REM) and minimal disease activity (MDA) was reached by comparable numbers in the TOC (37% and 58%) and the control cohort (37% and 60%).

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

A. Zimmer¹, A. Klein¹, G. Horneff¹. ¹Asklepios Kinderklinik Sankt Augustin, Sankt Augustin, Germany

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

E. Krekhova¹, E. Alexeeva^{1,2}, T. Dvoryakovskaya^{1,2}, K. Isaeva², A. Chomakhidze², E. Chistyakova^{1,2}, O. Lomakina², R. Denisova², A. Mamutova², A. Fetisova², M. Gautier², D. Vankova², M. Shingarova¹,

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