Methods: This was an open-label, randomized, parallel group study comparing PTX gel in addition to colchicine (PTX-COL) with colchicine alone (COL). Patients with BS who were treated with colchicine and not using any other systemic medications for BS, having at least one oral ulcer that appeared during the last 48 hours were included. PTX 5% gel with a dose of 1000mg/day was applied in 4 divided doses per day for 14 days. Patients were contacted daily for 14 consecutive days. Photographs were taken every 24 - 48 hours and graphical processing software was used to calculate the area of the index ulcer. Duration of the index ulcer, time to start of index ulcer shrinkage, time to 50% reduction in oral ulcer pain, and number of patients with no detectable ulcers on day 4 in each group were lower in the PTX-COL group as presented in the Table. Change from baseline in the area of index ulcer and pain score over time is shown in the Figure. There were no serious adverse events. Fifteen (75%) patients reported nausea, 11 (55%) reported dysgeusia and 2 reported vomiting in the PTX-COL group, while 2 patients (10%) reported nausea in the COL group.

Results: A total of 41 patients were randomized, 39 patients (18 in the PTX-COL group and 21 in the COL group) completed the study and 2 patients in PTX-COL group withdrew from the study due to unacceptable dysgeusia and nausea. Mean duration of index ulcer, time to start of index ulcer shrinkage, time to 50% reduction in oral ulcer pain, and number of patients with no detectable ulcers on day 4 in each group were lower in the PTX-COL group as presented in the Table. Change from baseline in the area of index ulcer and pain score over time is shown in the Figure. There were no serious adverse events. Fifteen (75%) patients reported nausea, 11 (55%) reported dysgeusia and 2 reported vomiting in the PTX-COL group, while 2 patients (10%) reported nausea in the COL group.

Conclusion: This pilot phase 2 open label, randomized controlled study supports the hypothesis that topical PTX in addition to colchicine accelerates the healing of BS oral ulcers compared to colchicine alone. A phase 3 controlled study with a higher number of patients is planned with improving the taste for tolerability of the product.

Disclosure of Interests: Gulen Hatemi Grant/research support from: BMS, Celgene Corporation, Silk Road Therapeutics – grant/research support, Consultant of: Bayer, Eli Lilly – consultant, Speakers bureau: AbbVie, Mustafa Nevzat, Novartis, UCB – speaker, Berna Yurtas: None declared, Zekayi Kutlubay: None declared, Tim Cote Employee of: Silk Road Therapeutics is in Washington, DC, USA, Şemsi Burak Derkunt Employee of: Silk Road Therapeutics is in Washington, DC, USA, Yusuf Yazici: None declared, Hasan Yazici: None declared

DOI: 10.1136/annrheumdis-2020-eular.5610

SAT0261

FEATURES AND RISK FACTORS OF SERIOUS INFECTIONS IN ANCA ASSOCIATED VASCULITIS: LONG TERM FOLLOW UP OF 186 PATIENTS

B. Ince¹, M. Bektas¹, F. Kemik², A. E. Aytun³, Y. Yalçinkaya¹, B. Artım-Esen¹, A. Gül¹, M. L. Ocal¹, M. Inanc¹. ¹Istanbul University, Istanbul Faculty of Medicine, Dept. of Internal Medicine, Division of Rheumatology, Istanbul, Turkey; ²Istanbul University, Istanbul Faculty of Medicine, Dept. of Internal Medicine, Istanbul, Turkey; ³Istanbul Faculty of Medicine, Istanbul, Turkey

Background: Serious infections (SI) are one of the main complications in patients with ANCA associated vasculitis (AAV).

Objectives: We planned to investigate the prevalence, features and risk factors of SI in our AAV cohort during follow-up.

Methods: Outpatient and hospital data of patients diagnosed with granulomatous polyangiitis (GPA), microscopic polyangiitis (MPA) and eosinophilic granulomatous polyangiitis (eGPA) between 1999 and 2019 according to Chapel Hill Consensus Criteria and followed up at least 6 months in our vasculitis clinic were evaluated. Development of sepsis, requirement for intravenous (IV) antibiotherapy and / or hospitalization during infection episodes were considered as SI. Chi-square, student's t-test and logistic regression analysis were used for statistical analysis.

Results: Study was conducted with 186 (53.6% female) patients with adequate follow-up data. Mean age of diagnosis was 54.3±14.5 (23-79), mean follow-up duration was 86.4 ± 54.3 (6-251) months. Number of GPA, MPA and eGPA patients were 132 (71%), 42 (22.5%) and 12 (6.5%), respectively. IV cyclophosphamide (CYC) was used in 148 (79.6%), azathioprin in 105 (56.5%), rituximab (RTX) in 69 (%37.1), methotrexate in 29 (15.6%) and mycophenolate mofetil in 14 (7.5%) patients. Number of patients developed SI was 66 (34.7%), total SI episode was 86, patients who had multiple episodes was 15. All SI is shown in Table-1. Bacterial pneumonia was the most common diagnosis and 26 of SI (30.2%) were considered as opportunistic (systemic viral, parasite, fungus) infections. Thirty-one of patients developed SI (40.7%) in the first year after diagnosis. SI were observed more frequently in the presence of major organ involvement (kidney, lung, neurological) (65/173 vs. 1/13 p = 0.02 OR = 8.7 95% CI 1.06-64.4). Diffuse alveolar hemorrhage (DAH) was associated with SI in multivariate analysis (12/52 vs. 0/34 p=0.007 OR=1.6 95% CI 1.3-1.96). Cumulative CYC dose was significantly higher in patients with SI (14,2±21 vs. 8.2±13.9 p=0.045). During maintenance, patients treated with RTX had significantly more SI (18/53 vs. 17/99 p=0.19 OR=3.3 95% CI 1.55- 7.07). Hypogammaglobulinemia (HlgG) (IgG<700mg/dL) was present in 12 (14%) SI episodes. HlgG was associated with SI in RTX-treated patients (5/13 vs. 7/47 p=0.03 OR=4.2, CI=1-16.5). Hospitalization need for SI was 65%. Disease flares (34/128 vs. 32/62 p = 0.001 %95 CI = 2.9 95% CI 1.6-5.6) and organ damage presence were more common (64/65 vs. 109/125 p = 0.01 95% OR= 8.9 95% CI 1.1-68.9) in patients with a history of SI in multivariate analysis. SI was confirmed as cause of death in three cases.

Conclusion: Long-term follow-up results of a single center cohort of AAV patients revealed that approximately one third of patients developed SI, most frequently in the first year of treatment. During the maintenance period, the risk of SI continues. Cumulative CYC dosage and maintenance with RTX is associated with SI, especially in patients who developed hlgG. Major organ involvement, disease flares and organ damage are significant risk factors for SI. In this regard, protection measures (vaccination, prophylaxis) should be reviewed and the quality of follow-up should be improved.

Table 1. Serious infections in AAV patients.

BACTERIAL	N	FUNGAL	N	VIRAL	N	PROTOZOAN	N
Pneumonia	37	PJP	7	Zoster Zona	3	Intramuscular abscess (Nocardiosis)	1
Urinary Tract Infection (UTI)	8	Aspergilloma	1	CMV Pneumonia	1		
Gr (-) sepsis	2	Invasive Fungal Infection	3	CMV Colitis	1		
Perianal abscess	2	Candida	4	CMV Gastritis	1		
Intraabdominal abscess	2	Candidemia	2	HSV	1		
Catheter infection	2	UTI	1	Eosinophilic			
Sellulitis	1	Fungal otitis	1				
Orbital cellulitis	1						
Maxillary sinus abscess	1						
Mastoiditis	1						
Prosthesis infection	1						
Septic arthritis	1						
Lung tuberculosis	1						

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.4397

SAT0262

PROPOSAL FOR OPTIMIZATION OF DIAGNOSTIC IMAGING FOR GIANT CELL ARTERITIS USING THREE-DIMENSIONAL COMPUTED TOMOGRAPHY ANGIOGRAPHY IMAGE AND CONSTRUCTING VASCULAR MAPPING FROM VASCULAR ULTRASONOGRAPHY AS REFERENCES

T. Kawamoto¹, M. Ogasawara¹, Y. Mastuki-Muramoto¹, T. Kawaguchi¹, S. Ando¹, M. Matsushita¹, K. Yamanaka², K. Yamaji¹, N. Tamura¹. ¹Juntendo University

School of Medicine, Tokyo, Japan;²Juntendo University Koshigaya Hospital, Koshigaya, Japan

Background: The development of rapid and accurate methods of diagnosing giant cell arteritis (GCA) is critical to prevent blindness and stroke, which may develop rapidly in patients with GCA. In 2018, EULAR published recommendations that the first imaging modality for GCA should be vascular ultrasonography without biopsy. However, many institutions still consider biopsy to make an important contribution to the diagnosis of GCA.

Objectives: Our purpose is to eliminate blindness and stroke among GCA patients by optimizing diagnostic imaging and method to diagnose GCA employed by vascular ultrasonography (V-US), CT Angiography (CTA), MRI/A, and PET/CT without biopsy.

Methods: We evaluated the clinical and serological characteristics of 20 patients who were diagnosed with GCA at our hospital from 2012 to 2018, and compared the image and biopsy findings of these patients. We then evaluated the effect of optimizing diagnostic imaging and methods for patients with suspected GCA who visited our hospital during 2019. Vascular mapping was carried out using V-US for 3DCTA and other imaging methods as references.

Results: Table 1 shows the clinical characteristics of the study population. The sensitivity of CTA for GCA was 85.7% (12 of 14 patients), which was the highest of the studied imaging methods. All biopsy-positive cases were diagnosed as GCA, and we compared these cases with cases with positive imaging findings. This revealed that CTA findings were correct (i.e., positive) in 66.7% (four of six patients), MRI/A findings were correct in 33.3% (three of nine), V-US findings were correct in 50.0% (three of six). Therefore, CTA exhibited the highest sensitivity for positive findings. Comparison of biopsy-positive cases with cases in which imaging findings were negative revealed that CTA findings were correct (negative) in 33.3% (two of six patients), MRI/A findings were correct in 55.6% (five of nine), V-US was correct in 50.0% (three of six). Thus, CTA had the lowest sensitivity for negative findings. Comparison of CTA findings of positive cases with other imaging modalities which reported positive findings revealed MRI/A findings to be correct in 44.4% (four of nine patients), PET/CT findings to be correct in 50.0% (one of two), V-US to be correct in 63.3% (five of eight). Thus, V-US had the highest agreement with CTA. We carried out vascular mapping by V-US using 3DCTA and other imaging methods and produced references to improve the accuracy of diagnosis. Using these references, we diagnosed five cases of GCA among the 20 patients; the positive predictive value of V-US was 80% (four of five patients) and negative predictive value was 86.7% (13 of 15 patients).

The number of biopsies performed decreased from 50% (10 of 20 patients) from 2012 to 2018 to 15% (3 of 20 patients) in 2019. Two cases in the present study had positive findings in both biopsy and V-US; in one case, biopsy, CTA, and MRI/A were negative while V-US revealed positive findings. No patients with GCA developed blindness or stroke during 2019.

Age (years)	average 74.7 (median 74.5)
Female (%)	80.0
Cranial type (%)	60.0
LV type (%)	10.0
Cranial + LV type (%)	30.0
First symptom	Temporal 25%, Occipital 20%, Arthritis and myalgia 10%
Duration to diagnosis (days)	average 82.1
Ocular findings (%) (blindness)	30.0 (15)
PMR (%)	50.0
Jaw claudication (%)	50.0
Headache (%)	85.0
Cerebral infarction (%)	10.0
CRP (mg/dl)	average 8.18 (median 7.14)
ESR (mm/hr)	104.5 (median 104.6)
RF positive (%)	10.0
CCP Ab positive (%)	0.0
ANA positive (%)	80.0 (average 25x)
SS-A Ab (%)	0.0
Cl β 2GPI Ab positive (%)	30.0
TAB (%)	50 (giant cell positive 56)

Table 1. Baseline characteristics of the study sample

Conclusion: We propose that V-US should be performed as the first examination for the diagnosis of GCA by the creation of vascular mappings when GCA is suspected in order to prevent blindness and stroke.

References:

- [1] Christian Dejaco et al. EULAR recommendations for the use of imaging in large vasculitis in clinical practice. *Annals of the Rheumatic Diseases*, 2018 May;77(5):636-643
- [2] Kawamoto T et al. Diagnosis of giant cell arthritis by head-contrast three-dimensional computed tomography angiography. *Journal of Medical Case Reports* 2019 Sep 11;13(1):285.

Figure 1. Left side is before, right side is after therapy. (A) 3DCTA finding, (B) determination of V-US arrangement with vascular location to evaluate wall thickening of V-US, compression sign, stenosis and stoppage of vessels.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.512

SAT0263 LOW-DOSE IL-2 THERAPY EFFECTIVELY PROMOTES THE BALANCE BETWEEN TREG CELLS AND PRO-INFLAMMATORY LYMPHOCYTES IN PATIENTS WITH BEHCET'S DISEASE

X. Liu¹, X. Liu², G. Chai¹, X. Li¹ on behalf of Li Xiaofeng Team. ¹The Second Hospital of Shanxi Medical University, Taiyuan, China; ²Taiyuan University of Technology, Taiyuan, China

Background: Behcet's disease (BD) is a chronic multisystemic disease. Several studies have shown that immune mechanisms play an important role in the development of the disease and limited options of therapeutic medicines for BD. Low dose IL-2 has been reported to selectively promote the expansion of Treg.

Objectives: To evaluate the significance of Treg cells and cytokines in the pathogenesis and the changes of peripheral lymphocyte subsets and clinical indexes in patients with BD after low dose IL-2 therapy.

Methods: Absolute number of CD4+CD25+FOXP3+Treg, CD4+IL17+T (Th17) and other subsets in peripheral blood (PB) from 177 patients with BD and 160 healthy donors were characterized by flow cytometry combined with an internal microsphere counting standard. And cytokines were analyzed by cytometric beads array. Thirty-nine patients were treated with daily subcutaneous injections of 0.5 million IU of human IL-2 for five consecutive days, and then its effects were analyzed.

Results: As compared to healthy controls, the number of Treg cells were significantly decreased in BD patients (median:22.32 cells/ul VS median:33.12 cells/ul, $P<0.001$), while there was no difference about Th1, Th2 and Th17 cells. Accordingly, the median ratios of Th17/Tregs cells in patients were greatly higher than those of healthy volunteers. Besides, the circulating NK cells in the patients appeared to be lower than the proportion in the healthy donors. While no difference was observed for that of T, B, CD4+T, CD8+T cells between groups. Further, the correlation analysis showed that circulating Treg levels were negatively correlated with ESR, CRP and BDCAF respectively, suggesting an important role of Tregs in sustained high disease