rank-sum test) and third (p<0,0001, rank-sum test) month, while no differences were recorded at the other time points. Clinical outcomes were similar between the two groups.

Conclusion: Very early introduction of IT in GCA provided a greater steroid sparing in the first 3 months of treatment, leading to a lower incidence of diabetes. Relapse rate was even lower. IT was usually well tolerated without an increase incidence of infections. A randomized prospective trial is required to support this strategy in the management of GCA.

References:

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FRI0217 SENSITIVITY AND SPECIFICITY OF 2019 DCVAS DRAFT CLASSIFICATION CRITERIA FOR GIANT CELLS ARTERITIS AND TAKAYASU ARTERITIS IN A MONOCENTRIC COHORT OF PATIENTS WITH CLINICAL DIAGNOSIS OF LARGE VESSEL VASCULITIS

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Background: Recently, a new set of classification criteria for Giant Cells Arteritis (GCA) and Takayasu Arteritis (TA) has been developed by the DCVAS project and presented as draft criteria at the 19th International Vasculitis and ANCA Workshop held in Philadelphia in 2019.

Objectives: The purpose of the present study is to analyze the performance of the 2019 DCVAS Draft Classification Criteria in differentiating GCA and TA in a cohort of patients with Large Vessel Vasculitis (LVV), comparing their sensitivity and specificity to 1990 ACR Classification Criteria.

Methods: 2019 DCVAS Draft Criteria and 1990 ACR Criteria were retrospectively applied to a cohort of 130 consecutive patients with Large Vessel Vasculitis. In all patients the diagnosis of vasculitis was histologically and/or radiologically confirmed.

Results: One-hundred patients had a clinical diagnosis of GCA, 25 patients of TA and 5 patients of other form of LVV, different from GCA and TA (idiopathic isolated aortitis n:2, aortitis with retroperitoneal fibrosis n:2, isolated pulmonary arteritis n:1).

Among the 100 patients clinically diagnosed as GCA (F/M: 68/32, age: 74 (60-83)) only 82 fulfilled the 1990 ACR Criteria for GCA, while all of them fulfilled the 2019 DCVAS Draft Criteria for GCA.

Instead, among the 25 patients with a clinical diagnosis of TA (F/M: 21/4, age: 34 (16-48)), 22 (88%) could be classified as TA according to the 1990 ACR Criteria, 25 (100%) according to 2019 DCVAS Draft Criteria.

In the group of patients diagnosed with other form of LVV (F/M: 2/3, age: 56 (38-71)) 4 patients (80%) fulfilled the 2019 DCVAS Draft Criteria for GCA, while none of them fulfilled the 2019 DCVAS Draft Criteria for TA or the 1990 ACR Criteria for GCA or TA. One of these patients did not fulfilled any classification criteria.

On the contrary, one GCA patient could be classified both as GCA or TA according to the 2019 DCVAS Draft Criteria but didn't fulfilled the 1990 ACR Criteria for GCA or TA.

For GCA, 2019 DCVAS Draft Criteria shown a sensitivity of 100% and a specificity of 80%, compared to 82% and 100% of 1990 ACR Criteria. For TA, 2019 DCVAS Draft Criteria shown a sensitivity of 100% and a specificity of 99%, compared to 88% and 100% of 1990 ACR Criteria.

For GCA the agreement between the two different sets of criteria was 85.5% (Cohen's k coefficient: 0.64), for TA the agreement was 85.1% (k: 0.58).

Conclusion: The new draft classification criteria shown a lower specificity if compared to the older ones, but also a higher sensitivity: in particular 2019 DCVAS Draft Criteria can better identify GCA patients with extracranial involvement, historically excluded from the 1990 ACR criteria.

both GCA and TA 2019 DCVAS Draft Criteria, demonstrating that this classification well performs in differentiating GCA and TA.

Table:

	GCA (n:100)	TA (n:25)	Other LVV (n:5)
Morning stiffness in shoulders or neck	43 (43%)	3 (12%)	0 (0%)
Sudden visual loss	33 (33%)	2 (8%)	0 (0%)
Jaw or tongue claudication	35 (35%)	0 (0%)	0 (0%)
New headache/	77 (77%)/	5 (20%)/	1 (20%)/
Scalp tenderness	30 (30%)	0 (0%)	0 (0%)
Temporal Artery Exam: pathological findings	34 (34%)	0 (0%)	0 (0%)
Elevated ESR or CRP	100 (100%)	16 (64%)	5 (100%)
Temporal Artery Biopsy: vasculitis	53 (53%)	0 (0%)	0 (0%)
Temporal Artery halo sign (US)/	11 (11%)/	0 (0%)/	0 (0%)/
Bilateral axillary involvement	11 (11%)	4 (16%)	0 (0%)
FDG-PET activity throughout aorta	32 (32%)	13 (52%)	4 (80%)
Angina or ischemic cardiac pain	5 (5%)	4 (16%)	1 (20%)
Arm or leg claudication	5 (5%)	12 (48%)	0 (0%)
Arterial bruit	2 (2%)	19 (76%)	1 (20%)
Reduced pulse in upper extremity	1 (1%)	15 (60%)	0 (0%)
Carotid: reduced pulse or tenderness	0 (0%)	8 (32%)	0 (0%)
SBP difference in arms: >10/ >20 mmHg	0 (0%)/ 1 (1%)	14 (56%)/ 6 (24%)	0 (0%)/ 0 (0%)
Pathological Angiography or AngioCT:	19 (19%):	22 (88%):	5 (100%):
number of affected arteries: 1/2/>3	7/3/9	0/1/19	3/0/2
Paired branch arteries involvement	7 (7%)	20 (80%)	2 (40%)
Abdominal aorta with renal or mesenteric involvement	0 (0%)	17 (68%)	0 (0%)

Disclosure of Interests: None declared

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FRI0218 PREVALENCE, BURDEN OF DISEASE AND HEALTHCARE UTILIZATION AMONG PATIENTS WITH EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA) IN JAPAN 2005-2017

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Background: EGPA is a rare vasculitis condition with very limited data available from real-world settings on burden and health care utilization (HCU), particularly in Japan.

Objectives: To estimate the prevalence (overall and age, gender stratified) and describe HCU and treatment patterns among Japanese EGPA patients.

Methods: This was a retrospective descriptive cohort study using a large administrative claims database covering up to more than 5 million corporate employees and their dependents (JMDC claim database) in Japan. Annual prevalence from 2005-2017 was estimated using two EGPA case definitions: a) patients with ≥1 ICD-10 code (2003 version) for EGPA (M30.1), b) patients with ≥2 ICD-10 codes for EGPA (M30.1) during the year in which prevalence was calculated. Among newly identified EGPA patients with no EGPA code in at least 12 months before, clinical burden, comorbidities, after hour visiting (AHV), all cause hospitalization, and treatment with drugs, including oral corticosteroid (OCS) use was described. OCS dose was expressed as prednisone equivalent.

Results: The total number of newly identified patients in 2006-2016 was 45 persons and the mean (SD) age was 42.3 years (SD 14.7 years). The prevalence (per 1,000,000 patients) of EGPA with case definition a) in Japan in 2017 was estimated to be 38.0. The stratified prevalence (per 1,000,000) by age was: 2.3 in the group aged <18 years, 34.0 in those aged 18-50 years, and 91.1 in those aged ≥50 years, respectively. The prevalence in females (50.0) was approximately 1.7-fold higher than that in male (28.7). The prevalence, including stratified results, with definition b) was similar to that with definition a). In the newly identified patients, 60% of patients had at least one hospitalization and 55.6% had AHV, in the year after the first observed EGPA code during the study period. Following index date, new patients were treated: 77.8% with OCS, 11.1% with Azathioprine, 8.9% with intravenous immunoglobulin, 6.7% with Cyclophosphamide, 4.4% with Methotrexate, and 2.2% with Rituximab (non mutually exclusive). The mean (SD) maximum recorded daily dose of OCS in the 12 months follow up period was 53.5 (39.9) mg in new patients. The average dose (SD) of OCS in first month and last month in new patients was 39.1 (29.0) and 9.8 mg (4.8), respectively. Among those with at least a 14-day supply of OCS, 73.1% could be classified as adherent (≥80%) based on their 1-year proportion of days covered. 6.7% of EGPA patients experienced a potentially worsening with an increase of ≥10 mg daily OCS dose prescription following a previous prescription of <10mg.

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Conclusion: Analysis of the burden of disease and the use of medical resources in newly identified EGPA patients revealed that EGPA patients require hospitalizations and AHV, in addition to exposure to high doses of OCS. The appropriate medication for the treatment of EGPA to reduce burden on patients may need consider the pathophysiological state of EGPA patients.

Disclosure of Interests: KEN-EI SADA Speakers bureau: I received speaker's fee from GSK and Astra Zeneca K.K., Yoshiki Kojo Shareholder of: GSK, Employee of: GSK, Jolyon Fairburn-Beech Shareholder of: GSK, Employee of: GSK, Keiko Sato Shareholder of: GSK, Employee of: GSK, Etsuko Hayashi Shareholder of: GSK, Employee of: GSK, Shoko Akiyama Shareholder of: GSK, Employee of: GSK, melissa van-dyke Shareholder of: GSK, Employee of: GSK

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FRI0219 MEPOLIZUMAB FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS IN REAL WORLD DATA

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Objectives: To investigate the treatments of eosinophilic granulomatosis with polyangiitis (EGPA) and evaluate the usage of mepolizumab in clinical settings.

Methods: The subjects were consecutive EGPA patients who were hospitalized and treated at our department and the Rheumatology, Department of Internal Medicine IV, Osaka Medical College between 2002 and 2018. Their clinical data, treatments, and courses were examined, and the usage of mepolizumab was evaluated.

Results: Of 49 EGPA patients, 41 could be analyzed (14 males and 27 females, mean age of onset: 56.4 years). The percentage of positive ANCA was 31.7%, and affected sites were peripheral nerve (92%), central nervous system (17%), skin (51%), ENT (39%), lungs (29%), heart (22%), digestive organs (12%), and kidneys (15%). Remission induction therapy was performed with PSL (41 cases, 100%), PSL pulse (16 cases, 39%), IVCY (17 cases, 41%), RTX (4 cases, 10%), IVIG (22 cases, 54%), AZA (22 cases, 54%), MTX (4 cases, 10%), MMF (2 cases, 5%), MIZ (1 case, 2%), and MEPO (1 case, 2%). Maintenance therapy was performed with PSL (41 cases, 100%), AZA (21 cases, 51%), MTX (6 cases, 15%), MMF (2 cases, 5%), MIZ (3 cases, 7%), and MEPO (10 cases, 24%). In 10 patients who received mepolizumab, the percentage of positive ANCA was 40%, and the median dose of PSL was reduced from 9.5 mg to 5.5 mg after administration. Neither relapses nor adverse events occurred in patients who had received mepolizumab.

Conclusion: Mepolizumab reduced the dose of steroids and improved tolerability in EGPA patients with or without ANCA.

Disclosure of Interests: None declared

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FRI0220 EFFICACY OF ADJUNCTIVE METHOTREXATE IN PATIENTS WITH GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB PLUS PREDNISONE TAPERING: SUBANALYSIS OF THE GIACTA TRIAL

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Background: There is conflicting evidence regarding the efficacy of methotrexate (MTX) in giant cell arteritis (GCA).[1,2] The benefit of adjunctive treatment with MTX remains to be determined in these patients. Data are presented from a subanalysis of the 52-week, double-blind, randomized controlled GiACTA trial in a subgroup of patients with GCA who received MTX in addition to tocilizumab (TCZ) or placebo (PBO) in combination with prednisone tapering.

Objectives: Assess the efficacy of adjunctive MTX in patients with GCA.

Methods: In part 1 of GiACTA, patients were randomly assigned to TCZ administered subcutaneously every week (QW) or every other week (Q2W) plus 26-week prednisone tapering or PBO plus 26-week (PBO+26) or 52-week (PBO+52) prednisone tapering.[3] MTX could be initiated at a stable dose during screening, continued during the double-blind period, and reduced or discontinued at the investigator's discretion according to disease status. Efficacy was determined as the achievement of sustained remission (absence of GCA flare and C-reactive protein <1 mg/dL from weeks 12 to 52 and adherence to the prednisone taper).[3]

Results: During part 1 of GiACTA, 28 of 250 (11%) treated patients received adjunctive MTX for a median duration of 52.1 weeks: 14 of 149 (9%) TCZ-treated patients received MTX for a median of 52.1 weeks, and 14 of 101 (14%) PBO-treated patients received MTX for a median of 51.9 weeks. Baseline characteristics (Table 1) were balanced between patients who received and did not receive MTX, except for longer disease duration and a higher proportion of patients with relapsing GCA among those who received MTX. The MTX-treated patients tended to have lower prednisone doses at baseline. The median cumulative glucocorticoid dose received over 52 weeks was similar between PBO-treated patients who received MTX and those who did not (3033 mg and 3672 mg, respectively) and between TCZ-treated patients who received MTX and those who did not (1339 mg and 1862 mg, respectively). Sustained remission was achieved by 6 of 14 (43%) patients treated with TCZ + MTX and by 76 of 135 (56%) patients treated with TCZ without MTX (Figure 1). None of the 14 PBO + MTX-treated patients achieved sustained remission, whereas 16 of 87 (18%) patients who received PBO without MTX achieved sustained remission (among all patients in the primary analysis,[3] 82 of 149 [55%] in the TCZ groups and 16 of 101 [16%] in the PBO groups achieved sustained remission). The mean annualized relapse rate at 52 weeks was not different between the MTX-treated and MTX-untreated groups for the TCZ (0.76 with MTX vs 0.47 without MTX; $p = 0.2549$) or PBO (1.89 vs 1.46; $p = 0.4611$) groups (p values based on t tests). Rates of adverse events per 100 patient-years were numerically higher in MTX-treated than MTX-untreated patients: 1267 and 858, respectively, in the TCZ groups and 1331 and 952, respectively, in the PBO groups.

Conclusion: Preliminary data from a small subgroup of patients suggest that adjunctive MTX does not increase the likelihood of sustained remission, reduce disease relapse rate, or improve steroid sparing in patients with GCA. Response rates in TCZ-treated patients appear to be independent of treatment with MTX. The results from this post hoc analysis in a small sample of GCA patients treated with MTX should be confirmed in larger studies.

References:

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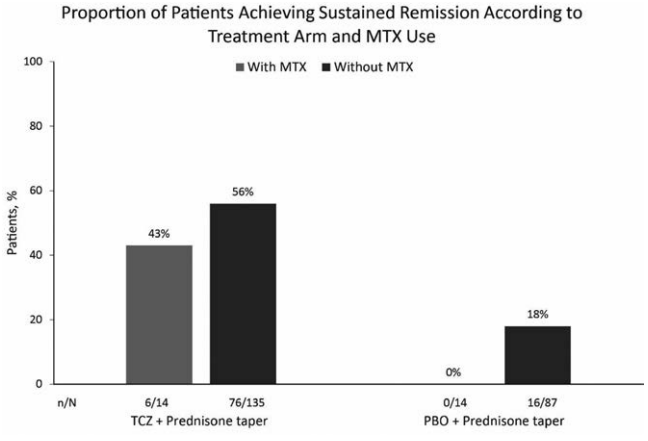
Baseline Demographics and Disease Characteristics

	PBO+Pred		TCZ+Pred	
	MTX n=14	No MTX n=87	MTX n=14	No MTX n=135
Age, y, median	71.5	68.0	63.0	71.0
Female, %	93	71	71	76
White, %	100	98	100	96
Body mass index, kg/m^2, median	27.5	24.8	25.6	25.5
GCA duration, days, median	303.0	42.0	306.5	42.0
Relapsing GCA, %	93	48	79	48
Pred dose ≤30 mg/day, %	71	49	86	47
CRP, mg/L, median	5.8	3.4	3.7	4.1
ESR, mm/h, median	16.0	20.0	15.5	17.5

Pred, prednisone.



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