Methods: Prospective, multicenter, observational, open-label, study of TA patients treated with infliximab originator.

Results: As of 2016 (2 years of follow-up), the study included 14 patients (13/14 were female; median age 32 [range 12–56] years) with TA (diagnosis according to Ishikawa criteria). At study entry, the median TA duration was 4.7 (0.4–16) years, 12 patients were already treated with infliximab originator (for a median duration of 34 [1–78] months) and 11 patients were receiving corticosteroids (CS). Infliximab originator was administered at a median dose of 5 (3–6) mg/kg with a median interval of 8 (2–67) weeks between each infusion. Seven patients had an improvement in at least 1 of the NIH disease activity criteria for TA [3] after a median follow-up time of 2 (0.4–11) months, 4 had smoldering disease and 1 patient worsened.

The median daily dose of CS decreased from 13 (5–35) mg/day of prednisone or equivalent at baseline to 7 (5–10) mg/day at 6 months, to 5 (5–6) mg/day at 12 months, and remained stable up to 22 months of follow-up.

Infliximab was discontinued in 6 patients due to inefficacy (n=3), prior to pregnancy (n=2), or remission of TA (n=1). Two adverse events (1 disease flare and 1 spontaneous miscarriage) were reported, without infliximab interruption.

Conclusions: Infliximab originator appears to provide an effective and favourable benefit:risk treatment option to refractory TA patients.

References:

[1] Mekinian et al, Efficacy of Biological-Targeted Treatments in Takayasu Arteritis: Multicenter, Retrospective Study of 49 Patients, *Circulation* 132(18) (2015) 1693–700.

[2] Mekinian et al, Efficacy and tolerance of infliximab in refractory Takayasu arteritis: French multicentre study, *Rheumatology* (Oxford) 51(5) (2012) 882–6.

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FRI0330 FATIGUE AND DEPRESSION IN PATIENTS WITH BEHCET'S DISEASE

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Background: Behcet's disease (BD) is a systemic vasculitis of unknown etiology defined by a classic triad consisting of aphthous ulcers of the mouth and genital and uveitis. In addition to these, BD may involve cardiovascular, pulmonary, neurological, articular and gastrointestinal manifestations. Fatigue, anxiety and depression are important problems in chronic inflammatory diseases. There are few studies on fatigue in BD patients. *Ilhan et al.*¹ reported more fatigue in BD patients than in healthy controls.

Objectives: The objective of this study was to investigate fatigue and depression in patients with BD and to examine the relationship between these symptoms and disease activity and gender.

Methods: Forty four patients with BD and thirty nine healthy controls (HC) were included in this study. Age, gender, disease duration and clinical involvements were recorded. All subjects completed the FACIT Fatigue Scale (FACIT-F), Short Form-36 (SF-36), Hospital Anxiety and Depression Scale (HADS) and Health Assessment Questionnaire (HAQ). Disease activity among BD patients was assessed using the Birmingham Vasculitis Activity Score (BVAS).

Results: The mean age was 40.0 years for BD patients and 38.7 for HC. 77% of BD patients were women. The mean disease duration for BD patients was 6.1 years. All patients had oral ulcers and genital ulceration; 20 had pseudofolliculitis; 9 had uveitis, 9 had erythema nodosum, 12 had articular involvement, 5 patients had vascular involvement, 4 had pathergia, 1 had orchitis and one had gastrointestinal involvement. Thirty two BD patients were taking medication, including colchicine or DMARDs or their combinations. Seventeen patients had inactive disease and

twenty seven had BVAS ≥ 1 . As shown in Table 1, both the HADS-depression (HADS-D) (4.7 vs 2.5) and HADS-anxiety (HADS-A) (8.3 vs 5.7) scores were elevated in BD patients compared to healthy controls. FACIT-F was higher in healthy controls in comparison with BD group (44.1 vs 36.6), revealing lower levels of fatigue. There were no differences between gender on these scores.

Table 1. Comparison of BD patients and HC

Scales	BD (n=44)	HC (n=39)	P-value
FACIT-F	36.6 $\pm$ 7.3	44.1 $\pm$ 6.4	<0.001
HADS-D	4.7 $\pm$ 2.4	2.5 $\pm$ 2.4	0.004
HADS-A	8.3 $\pm$ 4.2	5.7 $\pm$ 2.8	0.03

There were no significant differences in FACIT-F, HADS-A and HADS-D scores with the disease activity (P=0.952, P=0.391 and P=0.286, respectively). FACIT-F had a negative correlation with HAQ and HADS and a positive correlation with the different components of SF-36 and age. FACIT-F score was not correlated with disease duration (Table 2).

Table 2. Correlations between FACIT-F and HAQ, HADS-A, HADS-D, SF-36, age, disease duration in BD

	HAQ	HADS-A	HADS-D	SF-36	Age	Disease duration
r-value	-0.670	-0.569	-0.562	0.857	-0.370	0.053
P-value	<0.001	<0.001	<0.001	<0.001	0.013	0.103

Conclusions: In our study, fatigue and increased levels of anxiety and depression were more common in BD patients. Contrary to the study of *Ilhan et al*¹, we found that fatigue was not higher in patients with active disease. Similarly, there were no correlation between the assessed scores and gender. In spite of these results, the authors believe that controlling the symptoms may improve the quality of life in BD patients.

References:

[1] Ilhan et al. Fatigue in patients with Behcet's syndrome: relationship with quality of life, depression, anxiety, disability and disease activity. *International Journal of Rheumatic Diseases*. 2016.

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FRI0331 IDENTIFICATION AND VALIDATION OF POTENTIAL METABOLOMIC BIOMARKERS FOR RELIABLE DIAGNOSIS OF BEHCET'S DISEASE USING GAS CHROMATOGRAPHY WITH TIME-OF-FLIGHT MASS SPECTROMETRY

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Background: Although many diagnostic criteria have been developed and revised by experts in the field, diagnosing Behcet's disease (BD) is still complicated and challenging. Metabolomic studies can lead to a better understanding of pathophysiological processes and may uncover new diagnostic markers for classification of disease subgroups and assessment of disease activity in rheumatic diseases. No metabolomic studies on serum have been attempted to improve the diagnosis and to identify potential biomarkers of BD.

Objectives: The purposes of this study were to investigate distinctive metabolic changes in serum samples of BD patients and to identify metabolic candidate biomarkers for reliable profilosis of BD using the metabolomics platform.

Methods: Metabolomic profiling of 90 serum samples from 45 BD patients and 45 healthy controls (HC) was performed via gas chromatography with time-of-flight mass spectrometry (GC/TOF-MS) with multivariate statistical analyses. Thirty-five patients with BD and age- and sex-matched 35 HCs were randomly selected to form the discovery set, and the validation set is composed of 10 patients with BD and 10 HCs.

Results: We identified a total of 104 metabolites in the serum samples of the discovery set. To maximise the discrimination between groups BD and HCs, we applied supervised partial least squared-discrimination analysis (PLS-DA). A PLS-DA score plot of the discovery set indicated that the cluster of BD patients is well separated from HC clusters in component 1. The variation values of the PLS-DA model are R^2X of 0.246, R^2Y of 0.913, and Q^2 of 0.852, respectively, indicating strong explanation and prediction capabilities of the PLS-DA model. The PLS-DA models did not show clear and consistent discrimination between groups according to drug administration, indicating that drugs used in patients with BD had a negligible effect on the distinct metabolic profiles discriminating BD patients from HCs. A panel of five metabolic biomarkers, namely, decanoic acid, fructose, tagatose, linoleic acid, and oleic acid were selected based on their variable importance on projection values and adequately validated as putative biomarkers of BD (sensitivity 100%, specificity 97.1%, area under the curve 0.993) in the discovery set and validation set. Principal component analysis showed clear discrimination of BD and HC groups by the five metabolic biomarkers in the validation set.

Conclusions: This is the first report on detection of a characteristic metabolic profile of BD and identifying and validating potential metabolite biomarkers in

serum from BD patients using GC/TOF-MS. Further studies including a larger number of patients with BD would be warranted to validate the metabolite profiles for clinical use and to ascertain the feasibility of metabolomic analysis in BD.

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FRI0332 DIFFERENCES BETWEEN TEMPORAL ARTERY BIOPSY-POSITIVE AND BIOPSY-NEGATIVE GIANT CELL ARTERITIS: A COMPARATIVE COHORT STUDY

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Background: Giant cell arteritis (GCA) is the most common systemic vasculitis in patients aged 50 years or older. The presence of cranial features and an abnormal temporal artery biopsy have historically been the primary focus for diagnosis of this condition. A notable percentage of patients with symptoms of GCA have negative temporal artery biopsies, however, few cohort studies exist comparing the presentation and outcome of patients based on temporal artery positivity.

Objectives: To establish a large, single institution cohort of patients with temporal artery biopsy-negative GCA. To identify differences in presentation and outcome among patients with temporal artery biopsy-negative and temporal artery biopsy-positive GCA.

Methods: Patients with temporal artery biopsy-negative GCA diagnosed between 1/1/1998 and 12/31/2013 were identified retrospectively. Final diagnosis was confirmed by consensus among two rheumatologists and a physician abstractor. Baseline characteristics and outcomes were compared to a previously established biopsy-positive GCA cohort (n=286) from the same institution.

Results: 110 patients with temporal artery biopsy-negative GCA were identified. Unilateral biopsies were performed in 73, bilateral-sequential in 10, and bilateral same day in 27 cases. Median duration between steroid initiation and biopsy was 3 days. Median length of first biopsy was 14mm and second biopsy (if performed) was 22mm. Among biopsy-negative patients with advanced imaging within 6-months of diagnosis, 67% (41/61) had evidence of large vessel vasculitis. Patients with biopsy-negative GCA were younger (72.0±9.0 vs 75.0±7.6; p=0.001), met fewer ACR criteria (≥3 criteria 64% vs 95%; p<0.001) and had a shorter time from symptom onset to diagnosis (median 1.1 vs 2.1 months; p<0.001). Vascular risk factors evaluated at diagnosis showed a higher rate of pre-existing hypertension and obesity among patient with biopsy-negative GCA but similar rates of smoking and diabetes mellitus. Frequency of headache and vision loss at time of presentation were similar between groups. However, biopsy-negative GCA patients had more temporal artery tenderness (35% vs 16%; p<0.001) and arm claudication (13% vs 2%; p<0.001) but less frequent jaw claudication (19% vs 52%; p<0.001). Anorexia, fatigue, and arthralgia were also more commonly noted in biopsy-negative patients. Baseline CRP was lower among patients with negative biopsies (44.3±53.6 vs 70.4±63.9 mg/L; p<0.001).

Initial prednisone dose was similar among both cohorts. Although cumulative glucocorticoid (GC) was lower in biopsy-negative patients at 1 year (6.3±2.6 vs 7.2±2.7 g; p=0.004), cumulative GC doses at 2-years and 5-years were equivalent. Biopsy-positive patients (5-years, 56±3%) were able to discontinue GC sooner than biopsy-negative patients (5-years, 30±5%; p<0.001). The number of relapses, time-to-first relapse, annual relapse rate and mortality did not differ based on biopsy positivity.

Conclusions: While similarities are present, notable differences are observed at diagnosis in patients with biopsy-negative GCA. Further research is needed to confirm and understand the variability in GC duration.

Disclosure of Interest: None declared

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FRI0333 OCULAR INVOLVEMENT IN BEHÇET'S DISEASE ABOUT 221 CASES

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Background: Behçet's disease (BD) is a chronic systemic inflammatory disorder of unknown etiology. It's characterised by recurrent oral aphthosis and genital ulcer. Ocular involvement has been recognized since the time of Hippocrates. Estimates of the prevalence vary in different countries and may represent differences in the disease, in access to health care and in available treatments.

Objectives: The aim of this study is to describe the epidemiological and clinical characteristics in Moroccan patients with ocular BD.

Methods: retrospective study in internal medicine department over 13 years and including 221 patients with ocular BD. The diagnosis was performed by the International Study Group for Behçet's Disease and/or the International Criteria for Behçet's Disease.

Results: 221 (prevalence: 43%) had ocular involvement. 154 men and 63 women (sex ratio: 2.5). The mean age at the onset of ocular involvement was 30.5 years. This achievement was inaugural in 18.55% of cases. The average time of diagnosis in other cases was 3.41 years. There was a high prevalence of Uveitis (total: 34%, anterior: 32%, posterior: 31.2). Retinal Vasculitis was noted in 37 eyes and retinal detachment in 17 eyes. Neurological events were associated in 13.57% of cases, joint and vascular events in respectively 18 and 17 cases.

The topical corticosteroid therapy was prescribed in 27, 14% of cases, oral in 47, 51% and bolus in 29, 41%. 47, 51% of cases received Cyclophosphamide and 19% received Azathioprine. Cyclosporine was administered in 3 cases, interferon and Infliximab in 2 cases each. The evolution was good in 111 cases (50.22%), treatment failure was noted in 24% of cases and relapse in 16.74% of cases. 63 patients have evolved into blindness which was bilateral in 51.1% of cases.

Conclusions: Only early diagnosis and appropriate management can improve the prognosis of ocular involvement in BD.

Disclosure of Interest: None declared

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FRI0334 WHAT IS THE ABSOLUTE RISK OF DEVELOPING DIABETES MELLITUS IN PATIENTS WITH GLUCOCORTICOID-TREATED POLYMYALGIA RHEUMATICA AND GIANT CELL ARTERITIS? A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Polymyalgia rheumatica (PMR) and giant cell arteritis (GCA) are treated with glucocorticoids (GCs) but long-term GC use is associated with diabetes mellitus (DM). The absolute incidence of this serious complication in this patient group remains unclear.

Objectives: To quantify the absolute risk of GC-induced DM in PMR and GCA in published literature.

Methods: We identified literature from inception to February 2016 reporting diabetes following exposure to oral GC in patients with PMR and/or GCA without pre-existing diabetes. A random-effects meta-analysis was performed to summarise the literature. Risk of bias was assessed using the Cochrane Collaboration tool.

Results: 21 eligible publications were identified. In studies of patients with GCA, mean cumulative GC dose was almost two times higher than in studies of PMR (8.9g vs 5.0g), with slightly longer treatment duration but much longer duration of follow-up (8.8years vs 4.4years). The incidence proportion (cumulative incidence) of patients who developed new-onset DM was 6% (95% CI: 3–9%) for PMR and 12% (95% CI: 8–17%) for GCA. Heterogeneity between studies was high ($I^2=78.2\%$), as there were differences in study designs, patient population, geographical locations and treatment strategies. Based on UK data on incidence rate of DM in the general population¹, the expected background incidence rate of DM over 4.4 years in PMR patients and 8.8 years in GCA patients (the duration of follow-up) would be 4.8% and 9.7%, respectively. Very little information on predictors of DM in PMR or GCA patients was found. The overall risk of bias was high for many of the observational studies, especially relating to definition and recording of outcome and prognostic variables.

Conclusions: Physicians should screen patients treated for PMR/GCA for DM but it remains unclear what is the time-period of greatest risk and the influence of risk factors. Our meta-analysis produced plausible estimates of DM incidence in patients with PMR and GCA but there is insufficient published data to allow precise quantification of the DM risk or, crucially, which patients are at greatest risk.

References:

[1] Sharma M et al. BMJ Open, 2016. 6(1): p.e010210.

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