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SAT0521

A PROSPECTIVE OBSERVATIONAL STUDY ON THE SAFETY AND EFFICACY OF INFliximab-BIOSIMILAR IN PATIENTS WITH TAKAYASU'S ARTERITIS (TAKASIM): PRELIMINARY DATA

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Background: Takayasu arteritis (TA) is a large-vessel vasculitis¹. Treatment is mainly based on steroids, but in approximately 50% of patients a disease-modifying antirheumatic drug (DMARD) is required². Anti-TNF α agents are recommended for steroid tapering despite DMARDs³. Infliximab-originate (IFX-O) is a chimeric monoclonal antibody against TNF α effective in TA patients. Infliximab-biosimilar (IFX-B) is an immunoglobulin-G1 chimeric human-murine monoclonal antibody biosimilar to IFX-O.

Objectives: To assess safety and efficacy of IFN-B in TA patients requiring anti-TNF α therapy.

Methods: 30 TA patients, diagnosed according to ACR criteria at our tertiary centre, will be recruited from our cohort. Both biological therapy-naïve and IFX-O treated patients will be eligible. Disease activity will be assessed 6-monthly by means of magnetic resonance angiography (MRA) and 18 F-fluorodeoxyglucose (FDG) PET/CT. ITAS2010 and ITAS-ESR/CRP will be obtained 6-monthly. Baseline was defined as the time of IFX-B start. Non parametric statistic tests were used.

Results: At January 2018, 19 patients (18 female, 1 male) were included. 12 patients have been on IFX-B for at least 6 months. Median age at baseline was 45 years (range 25–70). At recruitment median disease duration was 52 months (range 24–180), all patients were on IFX-O. Median time on IFX-O at baseline was 35 months (range 14–150). 3 patients had been previously treated with other biologics: tocilizumab, 2 adalimumab. 18/19 patients (94.7%) were on concomitant steroid therapy (mean dose 5 $\pm$ 1.8 mg). It was significantly reduced to a mean dose of 4 $\pm$ 1.7 mg (p=0.043) at month 6. 15/19 patients (78.9%) were also on DMARDs, kept unchanged throughout treatment. 1 patient on IFX-B was switched to a different therapy because of poor disease control with both IFX-O and IFX-B. Mean IFX-B dose at baseline was 6.92 $\pm$ 1.76 mg/kg. Mean IFX-B dose at month 6 was 7.42 $\pm$ 2.19 mg/kg. IFX-B dose was increased in 5 patients. Mean time interval between IFX-B infusions was kept unchanged (5.79 $\pm$ 0.63 weeks). Mean CRP and ESR were 3.28 $\pm$ 2.64 mg/L and 19.68 $\pm$ 9.94 mm/1 hour at baseline and 3.4 $\pm$ 3.12 mg/L and 20.53 $\pm$ 14.06 mm/1 hour at month 6, the difference not being statistically significant. Mean ITAS2010 and ITAS-ESR/CRP were 7.6, 8.2 and 8 at baseline and 6.1, 6.8 and 6.3 at month 6, the difference not being statistically significant. At month 6 PET/CT showed no disease progression in all patients and MRA disclosed disease stability in 8/12 (66.7%), progression in 3/12 (25%) and improvement in 1 (8.3%) patient. No patient experienced side effects during infusion. 11/19 patients (57.9%) experienced low-grade side effects related to TNF α blockade. 6 patients experienced upper airway infection, 3 herpes simplex reactivation, 1 viral gastroenteritis, 1 vaginal candidiasis. No modification of IFX-B therapy was required.

Conclusions: Our preliminary data suggest that IFX-B is as effective and safe as IFX-O in TA patients.

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SAT0522

VASCULAR AND JOINT INFLAMMATION ARE NEGATIVELY CORRELATED IN PATIENTS WITH POLYMYALGIA RHEUMATICA, GIANT CELL ARTERITIS AND FEVER OF UNKNOWN ORIGIN

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Background: 18 F-Fluorodeoxyglucose positron emission tomography (PET) reveals the presence of large vessel vasculitis (LVV) in 30%–40% of patients with apparently isolated polymyalgia rheumatica (PMR), in 70%–80% of patient with giant cell arteritis^[1] and in about 20% of patient with fever of unknown origin (FUO)^[2], suggesting that these conditions may be different clinical manifestations of the same entity.

Objectives: To evaluate and compare the patterns of vascular and joint uptake in patients with PMR, GCA, and FUO.

Methods: Consecutive patients with a diagnosis of PMR, GCA or FUO underwent a thorough clinical examination and a PET/CT scan. Arterial and joint uptake of FDG were scored relative to liver uptake with a 4-point scale. The values of each district examined were summed to obtain a total vascular score (TVS) and a total joint score (TJS). A semi-quantitative analysis of FDG uptake was carried out. Arterial FDG uptake was quantified by calculating the mean standardised uptake value (SUV) within each region of interest (ROI) and the results expressed as the ratio between mean SUV value of each ROI and the blood-pool (SUV/BP). To assess joint metabolism, CT-based ROIs were bilaterally drawn on joint and bursal spaces.

Results: One hundred and thirty-one patients were included, 89 females and 42 males, with a median age of 74 years (range 47–92). Ninety-seven patients were diagnosed as PMR, 13 as GCA, 16 with both PMR and GCA and 5 patients presented with FUO. FUO patients showed a higher mean arterial SUV in comparison to PMR (0.77 vs. 1.15, p=0.004) and GCA patients (0.81 vs 1.15, p=0.052). Similar and more striking results were obtained using visual scoring. FUO patients showed always increased uptake in the large vessels. PMR patients showed statistically lower TVS than GCA +PMR, GCA and FUO patients. Patients with PMR showed a statistically significant higher mean joint SUV than GCA patients (p=0.01). The highest mean articular uptake was shown by PMR patients and the lowest by FUO patients. Mean TJS of PMR patients was significantly higher than that of GCA and FUO patients (p<0.001). TVS and TJS correlated negatively (p=0.01), as did mean vascular SUV and mean joint SUV (p=0.001).

Conclusions: Although patients with diseases different from PMR were few, our PET/CT study support the view that there is a continuum in the intensity of inflammation, with FUO >GCA>PMR+GCA> PMR for vessels, and the opposite for joints. Vascular and joint inflammation were negatively correlated. Our data support the view that similarities exceed differences in these conditions, with clinical features depending from the relative contribution of vessel and joint involvement.

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SAT0523

EVOLUTION OF VISUAL AFFECTATION IN PATIENTS WITH GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB

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Background: Giant cell arteritis (GCA) is a large vessel vasculitis that has a special predilection for extracranial branches of the external carotid artery. Among its most fearsome complications is visual affection. Tocilizumab (TCZ) is a monoclonal antibody directed against the interleukin 6 receptor that has shown utility in the treatment of GCA.

Objectives: Our aim was to assess the evolution of visual clinic in patients with GCA treated TCZ.

Methods: Retrospective multicentre study of 20 GCA patients with visual involvement treated with TCZ. The efficacy of this drug on visual symptoms was evaluated.

Results: We evaluated 20 patients (14 women and 6 men) with a mean age $\pm$ SD of 73.7 $\pm$ 10.1 years with GCA and visual symptoms. In total there were 23 affected eyes. The symptoms reported were: unilateral blindness (n=6), unilateral blurred vision (n=6), unilateral amaurosis fugax (n=3), unilateral hemianopsia (n=2), bilateral blindness (n=1), bilateral blurred vision (n=1), bilateral hemianopsia (n=1). Before starting treatment with TCZ all patients had received high doses of prednisone, with a mean $\pm$ SD of 54.2 $\pm$ 13.8 mg/day (range of doses: 40–80 mg/day). In addition, 9 of them also received intravenous corticosteroid boluses. In addition, 13 patients received traditional immunosuppressants: methotrexate (MTX) (n=12), cyclophosphamide (n=2), leflunomide (n=1) and azathioprine (n=1). Regardless of corticosteroids, TCZ was administered as monotherapy in 14 patients, while in 6 it was administered in combination with MTX. The TABLE shows the evolution of the visual affection of these patients. Throughout a median follow-up [RIC] of 9^d–18 months, none of the 7 patients who had a blindness regained vision. The 2 patients who presented unilateral hemianopsia recovered vision. The patient with bilateral hemianopsia and the patient with bilateral blurred vision experienced a partial improvement. The rest of the patients achieved a complete recovery.

	Month 1 n=20	Month 3 n=14	Month 6 n=10	Month 12 n=5
Visual improvement after starting TCZ, n (%)				
Complete improvement:	Complete improvement: 6 (30)	Complete improvement: 5 (35.7)	Complete improvement: 5 (50)	Complete improvement: 1 (25)
Partial improvement:	Partial improvement: 2 (10)	Partial improvement: 3 (21.4)	Partial improvement: 0 (0)	Partial improvement: 0 (0)
No improvement:	No improvement: 12 (60)	No improvement: 6 (42.8)	No improvement: 5 (50)	No improvement: 4 (75)

Conclusions: Although TCZ seems to be also useful in the treatment of visual manifestations of ACG, once blindness is established, it does not seem to be effective.

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SAT0524

THE ROLE OF POLYMORPHISMS OF HEMOSTASIS GENES IN VENOUS THROMBOEMBOLIC EVENTS IN ANCA-ASSOCIATED VASCULITIDES

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Background: The role of polymorphisms of hemostasis genes in venous thromboembolic events in ANCA-associated vasculitides.

Objectives: To evaluate the role of polymorphisms of hemostasis genes in the risk of VTEs in AAV patients and to the clinical features of AAV.

Methods: We studied 85 patients with AAV [69 with granulomatosis with polyangiitis (GPA), 11 with microscopic polyangiitis (MPA), 5 with eosinophilic granulomatosis with polyangiitis (EGPA)] diagnosed according to CHCC 2012 classification. There were 34 males and 51 females, aged of 55^{45;63} years. Duration of follow-up was 74.0 (36.5;120.3) months. Coagulation genes polymorphisms MTHFR 677 C/T (rs1801133), FV 1691 G/A (rs6025), FII 20120 G/A (rs1799963), FGB 455 G/A (rs1800790), PAI-1 675 5G/4G (rs1799889), ITGA2 807 C/T (rs1126643), ITGB3 1565 T/C (rs5918), FVII 10976 G/A (rs6046), FXIII 103 G/T (rs5985) were evaluated by real time polymerase chain reaction. VTEs (deep vein thrombosis, pulmonary embolism) were identified by ultrasonography and chest computed tomography, respectively. We used score system, according to which the presence of each minor allele was assigned one point.

Results: We retrospectively detected 12 (14.1%) VTEs in 85 patients with AAV, including 5 (7.2%) in GPA, 4 (36.4%) in MPA and 3 (60.0%) in EGPA. There were no significant differences in the prevalence of alleles of the each gene in patients with and without VTE (figure 1). However, the combination of integrin A2 (ITGA2 807 C/T), plasminogen activator inhibitor-1 (PAI-1 675 5 G/4G), fibrinogen (FGB 455 G/A) and FV^{FV 1691} G/A) polymorphisms was associated with a significantly higher occurrence of VTE in patients with AAV (p=0.007) (table 1).

Abstract SAT0524 – Table 1. The prevalence of minor alleles of ITGA2 807 C/T, PAI-1 675 5G/4G, F5 1691 G/A, FGB 455 G/A in patients with and without VTE

Minor allele sum score	VTE (n=12)	No VTE (n=73)
0	0 (0%)	4 (5.5%)
1	1 (8.3%)	17 (23.3%)
2	3 (25.0%)	34 (46.6%)
3	8 (66.7%)	18 (24.7%)
4	0 (0%)	0 (0%)
Median sum score*	3.0 (2.0;3.0)*	2.0 (1.0;2.5)*

*p=0.007

We observed a higher risk of lung involvement in carriers of methylenetetrahydrofolate reductase gene (MTHFR 677 C/T) polymorphism (p=0.007, OR 4.305 (95% CI 1.55 to 11.98), and an earlier AAV onset in patients with FXIII 103 G/T polymorphism (47.0 vs 50.0 years, p=0.049).

Abstract SAT0524 – Figure 1. Rates of minor alleles in patients with and without VTE

Conclusions: The combination of several genetic polymorphisms of hemostasis system is associated with an increased prevalence of VTE in AAV patients. The association between MTHFR 677 C/T and FXIII 103 G/T alleles and clinical features of AAV warrants further studies in the larger cohorts of patients.

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