SAT0529

SHORT-TERM EFFICACY AND SAFETY OF BIOSIMILAR RITUXIMAB IN PATIENTS WITH SYSTEMIC VASCULITIDES

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Objectives: To study efficacy and safety of biosimilar (intended copy) rituximab (Acellbia, BIOCAD) in patients with systemic vasculitides.

Methods: We enrolled in our case series all consecutive patients with systemic vasculitides diagnosed according to CHCC2012 and ACR criteria (if applicable) who were treated with biosimilar rituximab since 2015. Activity of vasculitis was evaluated using BVAS3. CD19+ B-cells count was measured by standard method. Patients received intravenous rituximab at a 500 mg dose (four weekly infusions for remission induction or two weekly every 6 months infusions for maintenance treatment).

Results: In total, 45 patients were treated with biosimilar rituximab (29 GPA, 12 MPA, 1 EGPA, 2 cryoglobulemic vasculitis, 1 rheumatoid vasculitis). In 12 patients (7 GPA, 3 MPA, 1 CryoVas, 1 RheumVas), rituximab was administered for induction of remission due to high activity and relapsing course of vasculitis and low efficacy of previous treatment. 33 patients (22 GPA, 9 MPA, 1 EGPA, 1 CryoVas) received rituximab for maintenance of remission. Median duration of follow-up was 12 months.⁶⁻²⁶

At 1 and 3 months, all patients achieved B-cell depletion. At 6 months, B-cell repopulation was shown in 9 patients (20%). Remission induction therapy with rituximab resulted in decrease of median BVAS from 16.10–24 to 1 (0–4) at 3 months and to 0 (0–2) at 6 months. At 3 and 6 months, median prednisone dose was tapered from 50 mg 35–80 to 25 mg 15–40 and 10 mg, 5–20 respectively.

In patients who received rituximab for maintenance treatment, median BVAS showed no disease activity (0–1) both at baseline and at 3 or 6 months. At baseline and at 3 months median doses of prednisolone were 5 mg (0–7.5) and 5 mg (0–5). At 6 months, it was reduced to 2.5 mg (0–5). Biosimilar rituximab had acceptable safety profile. Adverse events included mild infusion reaction,² urinary³ and bronchopulmonary⁵ infections which required intravenous antibiotics (median 4 months after infusions), hypogammaglobulinemia² that persisted for at least 12 months and 1 case of late-onset neutropenia in 8 months.

Conclusions: Biosimilar rituximab showed high efficacy and acceptable safety in patients with systemic vasculitides.

Disclosure of Interest: None declared

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SAT0530

CLINICAL FEATURES ASSOCIATION WITH HLA-B ALLELIC TYPES (B27, B51) IN KOREAN PATIENTS OF BEHCET'S DISEASE

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Background: The recurrent oral ulcer frequently occur as a first clinical manifestation of Behcet's disease (BD), but BD is characterised by considerable phenotypic variation, comprising a myriad of manifestations, e.g. recurrent genital ulcers and skin, joint, eye, vascular and/or CNS involvement. BD is well known to be associated with HLA-B51 antigen. HLA B27 antigen is famous for association with spondyloarthritis. But BD is also observed in HLA B27 positive patients.

Objectives: The aim of this study was to clarify the clinical features association with HLA-B antigens (B27, B51) in Korean patients of Behcet's disease.

Methods: We genotyped HLA-B alleles in 433 patients who showed recurrent oral ulcer. The diagnosis of BD was determined according to revised international study group criteria. Among them, 126 patients of BD were included. The genotyping was performed using 66 sets of sequence specific DNA probe (PCR-SSP). The clinical feature was assessed according to HLA B allele in the patients diagnosed with BD.

Results: HLA-B51 allele frequency was more frequent in both 126 BD patients and 433 total patients and the frequency was 40 (31.7%) and 110 (25.4%) respectively. Among the HLA B51 +BD patients (n=40), similar gender ratio was observed (Male 52.5%, Female 47.5%) and clinical features of diagnostic criteria were dominant. Among the HLA B27 +BD patients (n=17), genital ulcer and skin lesions were dominant. HLA B27 +B51+BD patient was one and clinical features were genital ulcer, skin lesion and arthritis.

Conclusions: The specific clinical features of BD were observed in HLA-B51 +BD patients. In HLA B27 +BD patients, genital ulcer and skin lesions were

more observed. The study about clinical features associated with HLA-B allele (B27, B51) in spondyloarthritis patients is also needed.

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SAT0531

ACUTE PHASE REACTANT LEVELS AND PREDNISONE DOSES AT DISEASE FLARE IN PATIENTS WITH GIANT CELL ARTERITIS: PROSPECTIVE DATA FROM THE GIACIA TRIAL

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Background: The relationship between acute phase reactant levels and giant cell arteritis (GCA) disease flares is not known, particularly in the era of interleukin-6 receptor blockade with tocilizumab (TCZ). Prednisone doses at which GCA flares can occur have not been studied thoroughly in prospective clinical trials.

Objectives: Investigate prednisone doses and acute phase reactant levels at the time of disease flare in patients with GCA.

Methods: Secondary analyses of prednisone doses, C-reactive protein (CRP) levels, and erythrocyte sedimentation rate (ESR) were performed for patients who experienced GCA flare after achieving remission during 52 weeks of treatment with TCZ-weekly or -every-other-week+26 week prednisone taper (TCZ-QW or TCZ-Q2W) or placebo +26 week or 52 week prednisone taper (PBO+26 or PBO +52). The last CRP and ESR values before first disease flare were used if values on the day of first flare were missing. Analyses are descriptive and were performed post hoc.

Results: GCA flare after remission was reported in 23% (23/100) of TCZ-QW patients, 26% (13/50) of TCZ-Q2W patients, 68% (34/50) of PBO +26 patients, and 49% (25/51) of PBO +52 patients.¹ Median CRP levels and ESR at the time of flare were lower in the TCZ groups than in the PBO groups (Table). In the TCZ groups, 92% (33/36) of flares were associated with normal CRP levels (≤ 1 mg/dL) and 89% (32/36) were associated with normal ESR values (< 30 mm/h). In the PBO groups, 34% (20/59) of flares were associated with normal CRP values and 31% (18/59) with normal ESR. Median (min–max) prednisone doses at the time of disease flare in the combined TCZ and combined PBO groups were 5.5 (0.0–310.0) and 9.0 (0.0–55.0) mg/day, respectively. Among 149 patients in the TCZ groups, 10 (7%) had disease flares while receiving prednisone doses greater than 10 mg/day, accounting for 28% of all disease flares in the TCZ groups. Among 101 patients in the PBO groups, 23 (23%) had disease flares while receiving prednisone doses > 10 mg/day, accounting for 39% of all disease flares in the PBO groups. Thus, 33 of the 95 disease flares in GiACTA (35%) occurred while the patient was receiving ≥ 10 mg/day prednisone.