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

J. Smirnova, P. Novikov, S. Molesev, A. Zykov, T. Shvetsova, E. Lebedeva, A. Reznichenko, V. Lebedev, A. Yatskova, Moscow State Medical University, Moscow, Russian Federation

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

Methods: We enrolled in the retrospective 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 BVAS. 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, 1 cryoglobulinemic vasculitis), 11 patients (7 GPA, 3 MPA, 1 CrysVas, 1 RhuemVas) received rituximab for maintenance treatment. Remission induction in patients who received rituximab for maintenance treatment, median BVAS showed no disease activity (0–1) both at baseline and 3 or 6 months. At baseline and at 3 months median doses of prednisone 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, urinary and bronchopulmonary infections which required intravenous antibiotics (median 4 months after infusions), hypogammaglobulinemia 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


SAT0531

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

H. Stone1, K. Tuckwell2, S. Dimonaco3, M. Kleereman, M. Aringer4, D. Blockmans3, E. Brouwer, M.C. Cid, B. Disquida, J. Rech9, C. Salvarani10, H. Schulze-Koops11, G. Schett12, R. Spiera13, S.H. Unizony1, N. Collinson2 on behalf of GIACTA investigators. 1Massachusetts Gen Hosp Rheumatol Unit, Harvard Med School, Boston; 2Genentech, South San Francisco, USA; 3Roche Products Ltd, Welwyn Garden City, UK; 4Katholieke Universiteit Leuven, Belgium; 5University of Gröningen, University Medical Center, Gröningen, Netherlands; 6University of Barcelona, Institut d’Investigacions Biomèdiques August Pi i Sunyer, Barcelona, Spain; 7Southend University Hospital, NHS Foundation Trust, Westcliff-on-Sea, UK; 8Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany; 9Arzneimittelsuche Sankt Marien-IVCCS, Reggio Emilia, Italy; 10University of Munich, Munich; 11University of Munich, Munich; 12Hospitalet Clinical Center Arteritis.

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 >25 week or 52 week prednisone taper (PBO+20 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. 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% (29/32/6) 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 (0.0–350.0) 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.

Disclosure of Interest: None declared


SAT0530

CLINICAL FEATURES ASSOCIATION WITH HLA-B ALLELIC TYPES (B27, B51) IN KOREAN PATIENTS OF BEHCE'T'S DISEASE


Background: The recurrent oral ulcer frequently occur as a first clinical manifestation of Behçet’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-B27 (B27, B51) in spondyloarthropathy patients is also needed.


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SAT0529

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I. Smirnova, P. Novikov, S. Molesev, A. Zykov, T. Shvetsova. 1Medical center K+31, 2Sechenov First Moscow State Medical University; 3Lomonosov Moscow State University, Moscow, Russian Federation

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