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Efficacy and safety of Telitacicept combined with low-dose mycophenolate mofetil in IgA nephropathy

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Background and Aims: Currently, there is no specific agent blocking for IgA nephropathy. The KDIGO guideline recommends basic treatment with renin-angiotensin-aldosterone system (RAAS) antagonists. MMF can be used for Chinese patients. Telitacicept is a fusion protein composed of transmembrane activator and calcium modulating cyclophilin ligand interactor and fragment crystallizable portion of immunoglobulin G (IgG), which neutralizes the B lymphocyte stimulator and a proliferation-inducing ligand. Telitacicept (240 mg qw ih) treatment led to a clinically meaningful reduction in proteinuria in patients with IgAN in the present phase 2 clinical trial. This study intends to observe the efficacy of Telitacicept (160 mg qw ih) combined with low-dose MMF in the treatment of IgA nephropathy.

Method: Retrospective analysis involving all biopsy proven IgA nephropathy patients with complete clinical data in our department. After RAAS inhibitor treatment for 3 months, the patient’s urinary protein more than 0.75 g/24 h, he or she was given Telitacicept (160 mg qw) combined with Mycophenolate mofetil (1 g, twice a day) was treated for 6 months, and follow-up for 6-12 months. The quantification of 24-hour urinary protein and immunity functional, renal function was observed.

Results: 25 patients with IgA nephropathy confirmed by renal biopsy were enrolled, 14 males and 11 females, aged 34.32 ± 9.68 years’ old, 3 patients with Lee’s grade II, Grade III 17 patients, Grade IV 3 patients, and Grade V 2 patients. For Oxford classification, there were 3 cases with M0, 22 cases with M1 lesions, 20 cases with E0, 5 cases with E1 lesions, 1 case with S0, 24 cases with S1 lesions, 10 cases with T0, 15 cases with T1 lesions, and 17 cases with C0, 8 cases with C1 lesions. The patient’s urine protein quantification was 2.52 ± 1.82 g before treatment, after Telitacicept and MMF treatment for 2 months, the proteinuria was 1.05 ± 0.55 g (compared with that before treatment, P = 0.0004), and at 4 months, it was 0.71 ± 0.39 g (compared with that before treatment, P < 0.0001), 0.53 ± 0.31 g at 6 months (compared with than before treatment, P < 0.0001). And the 24-hour urine protein quantification of 13 patients was all lower than 0.5 g/24 hours. The renal function of all patients was stable during the observation period. The serum creatinine before treatment was 83.16 ± 21.85 μmol/L and it was 81.88 ± 19.48 μmol/L (P = 0.83) after 6 months. There were no patients with worsening renal function after treatment. Among them, the renal function of 3 patients was better than that after treatment. During follow-up period for 6- to 12-month, the patient did not develop any pulmonary infection requiring for hospitalization or other infections. Some patients experienced adverse reactions such as pain at the site of injection, but no patient discontinued treatment due to adverse reactions.

Conclusion: Telitacicept combined with low-dose mycophenolate mofetil is an alternative method for the treatment of IgA nephropathy. It is more effective than mycophenolate mofetil or Telitacicept use alone, and with fewer adverse reactions, especially with S or C lesions of Oxford classification. This is an observational retrospective study with a few cases, it’s worthy further randomized clinical study to prove.