Comparisons of the Efficacy of Two Rituximab-Simvastatin-Conjugated Nanoparticle Regimens in the Patients with Systemic Sclerosis Associated with Interstitial Lung Disease

Olga Koneva, Lidia P. Ananyeva, Lidmila Garzanova, Oxana Desinova, Olga Ovsyanikova, Maya Starovoytova, V.A. Nasonova Research Institute of Rheumatology, Moscow, Russian Federation

Background: Rituximab (RTM) is considered as a promising therapeutic agent for treatment of interstitial lung disease (ILD) in the patients with systemic sclerosis (SSc). However, the limited number of RTM-treated patients, heterogeneity of the studies in relation to main parameters, considerably different dose regimens, cumulative doses, and observation periods does not allow univocal conclusions on RTM efficacy or definitive recommendations on RTM use in the patients with SSc. The question whether to combine RTM with immunosuppressants (IS) or it is possible to use it as a single-agent therapy in the patients with SSc associated with ILD is still relevant.

Objectives: To compare the time courses of pulmonary function parameters and dermal fibrosis parameters during the use of RTM in combination with IS and as a single-agent therapy in the patients with SSc associated with ILD in the open-label prospective non-randomized study.

Methods: 90 patients with the confirmed SSc diagnosis and ILD evidence associated with ILD from the viewpoint of the poor effect and adverse effects of the currently available treatments. Research and development with adipose-derived stem cells (AdSCs) in immunosuppressive therapy have progressed for autoimmune diseases, and favorable outcomes have been reported. In recent years, the effectiveness of AdSCs in ILD model mice has been demonstrated (ref). The statin preparation has not only an anti-fibrotic action but also an action of promoting a cellular function including angiogenesis promoting action, an immunosuppressive action, an anti-inflammatory action, and the ability to reduce the atherogenic factor. The question was raised whether statins can be used as a single-agent therapy in the patients with SSc associated with ILD.

Results: In Groups A and B during the therapy significant decrease in mRSS (p=0.00034 and 0.000002 respectively) and EScSG (p=0.00011 and 0.000000 respectively), FVC increase (p=0.00017 and 0.000001, respectively), and stabilization of the DLCO were observed. The treatment groups did not differ significantly in the median FVC increments, clinically meaningful FVC and DLCO increments of decrements, and EScSG and mRSS time courses.

Conclusion: RTM administration both in combination with IS and as a single-agent therapy in the patients with SSc associated with ILD effectively alleviated skin induration and EScSG, improved or stabilized the pulmonary function parameters. The absence of statistically significant difference in the time course of evaluated parameters between the groups substantiate potential RTM use as a single-agent therapy that, this is most important for the patients with poor tolerability or contraindications to IS administration.

Disclosure of Interests: None declared


Notes: in Parameters column 1 = before treatment, 2 = after treatment; M ± SD = mean value and standard deviation; * = significant difference between the values measured before and after the treatment.

Conclusion: RTM administration both in combination with IS and as a single-agent therapy in the patients with SSc associated with ILD effectively alleviated skin induration and EScSG, improved or stabilized the pulmonary function parameters. The absence of statistically significant difference in the time course of evaluated parameters between the groups substantiate potential RTM use as a single-agent therapy that, this is most important for the patients with poor tolerability or contraindications to IS administration.

Disclosure of Interests: None declared