

Prevalence of Rituximab Efficacy Over Immunosuppressants in Therapy of Systemic Sclerosis

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Abstract : Abstract Objectives. Rituximab (RTX) shown a positive effect in the treatment of systemic sclerosis (SSc). But there is still not enough data on comparing the effectiveness of RTX with immunosuppressants (IS). The aim of our study was to compare changes of lung function and skin score in SSc between two groups of patients (pts) - on RXT therapy (prescribed after ineffectiveness of previous therapy with IS) and on therapy with IS only. Methods. This study included 103 pts received RTX as an addition to previous therapy (group 1) and 65 pts received therapy with IS and prednisolone (group 2). The mean follow-up period was 12.6 ± 10.7 months. In group 1 the mean age was 47 ± 12.9 years, female - 88 pts (84%), the diffuse cutaneous subset of the disease had 55 pts (53%). The mean disease duration was 6.2 ± 5.5 years. 82% pts had interstitial lung disease (ILD) and 92% were positive for ANA, 67% of them were positive for antitopoisomerase-1. All pts received prednisolone at a dose of 11.3 ± 4.5 mg/day, IS at inclusion received 47% of them. The cumulative mean dose of RTX was 1.7 ± 0.6 g. In group 2 the mean age was 50.8 ± 13.8 years, female-53 pts (82%), the diffuse cutaneous subset of the disease had 44 pts (68%). The mean disease duration was 8.8 ± 7.7 years. 81% pts had ILD and 88% were positive for ANA, 58% of them were positive for antitopoisomerase-1. All pts received prednisolone at a dose of 8.69 ± 4.28 mg/day, IS received 57% of them. Cyclophosphamide (CP) received 45% of pts. The cumulative mean dose of CP was 10.2 ± 15.1 g. D-penicillamine received 30% of pts. Other pts was on mycophenolate mofetil or methotrexate therapy in single cases. The pts of the compared groups did not differ in the main demographic and clinical parameters. The results are presented as delta (Δ) - difference between the baseline parameter and follow up point. Results. In group 1 there was an improvement of all outcome parameters: increased of forced vital capacity, % predicted - $\Delta FVC=4\%$ ($p=0.0004$); Diffusing capacity for carbon monoxide, % predicted remained stable ($\Delta DLCO=0.1\%$); improvement of the Rodnan skin score- $\Delta mRss=3.4$ ($p=0.001$); decrease of Activity index (EScSG-AI) - Δ Activity index= 1.7 ($p=0.001$). In group 2 the changes was insignificant: $\Delta FVC=-2.3\%$, $\Delta mRss=0.87$, Δ Activity index= 0.3 . But there was a significant decrease of DLCO: $\Delta DLCO=-5.1\%$ ($p=0.001$). Conclusion. The results of our study confirm the data on the positive effect of RTX in complex therapy in pts with SSc (decrease of skin induration, increase of FVC, stabilization of DLCO). Meantime, pts on IS and prednisolone therapy shown the worsening of lung function and insignificant changes of other clinical parameters. RTX could be considered as a more effective option in complex treatment of SSc in comparison with IS therapy

Keywords : immunosuppressants, interstitial lung disease, systemic sclerosis, rituximab

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