| Parameters | All group (n=37) | | p | Group A (n=23) | | p | Group B (n=14) | | p | P Between groups A and B |
|---|---|---|---|---|---|---|---|---|---|---|
| | point "1" | point "2" | | point "1" | point "2" | | point "1" | point "2" | | |
| Negative CT-dynamics, n/% | | 9/24.3 | | | 4/17.4 | | | 5/35.7 | | 0.008 |
| Positive CT-dynamics, n/% | | 13/34.2 | | | 6/42.9 | | | 7/30.4 | | 0.06 |
| Mean CT-score, points (M±σ) | 9.6±8.2 | 9.4±8.3 | | 0.7 | 4.1±3.9 | 0.5 | 18.07±5.6 | 18.1±6.1 | 1 | p1=0.000038 p2=0.000001 |
| "Ground-glass" score, points (M±σ) | 5.1±3.3 | 4.95±3.3 | 0.6 | 1.9±2.6 (median-0 [0;3]) | 1.3±2.1 (median-0 [0;2]) | 0.12 | 5.4±2.6 | 4.6±3.2 | 0.3 | p1=0.018 p2=0.013 |
| Reticular changes score, points (M±σ) | 7.4±3.7 | 7±3.4 | 0.4 | 2.6±2.4 | 2.7±2.3 | 0.7 | 7.9±2.4 | 7.6±1.98 | 0.3 | p1=0.0007 p2=0.0004 |
| Traction bronchiectasis index, points (M±σ) | 1.67±2.3 (median-0 [0;3]) | 2.0±2.6 (median-1 [0;3]) | 0.02 | 0.5±1.2 (median-0 [0;0]) | 0.7±1.3 (median-0 [0;1]) | 0.1 | 7.8±2.0 | 7.6±2.0 | 0.7 | p1=0.000000 p2=0.000000 |
| FVC, % of proper values (M±σ) | 94.2±19.5 | 94.6±16 | 1 | 92±18.9 | 91.9±19.6 | 0.95 | 89.2±21.5 | 90.3±14.2 | 0.23 | p1=0.7 p2=0.8 |
| DCL, % of proper values (M±σ) | 57.3±20.2 | 57.9±20.7 | 0.6 | 60.6±19.6 | 62.6±19.1 | 0.3 | 47.6±11.4 | 45.2±13.5 | 0.22 | p1=0.13 p2=0.02 |

** Between groups A and B*. Point "1"–at the time of inclusion in the study; point "2"–at the time of the last examination.

AB0728

## COMPARATIVE RESULTS OF LONG-TERM (FOR 36 MONTHS) USE OF RITUXIMAB AND IMMUNOSUPPRESSANTS IN PATIENTS WITH SYSTEMIC SCLERODERMA WITH INTERSTITIAL LUNG DISEASE IN REAL CLINICAL PRACTICE

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**Background:** Immunosuppressants (IS) is considered as a drug of choice for the treatment of interstitial lung disease (ILD) in the patients with systemic sclerosis (SSc). However, the IS use leads to rather limited and transient improvement of the pulmonary fibrosis. In this context the search for novel, more efficacious agents have been continued, such as attracting much attention rituximab (RTM).

**Objectives:** To compare the dynamics of pulmonary function parameters and skin fibrosis in patients with SSc associated with ILD, who received RTM and IS for 3 years in real clinical practice.

**Methods:** 158 pts with the SSc-ILD were enrolled into the study. All pts received low- and moderate-dose glucocorticoids regimens. **Group A** (n=100) **received IS's** (31/31% mycophenolate mofetil, 27/27% cyclophosphamide, 15/15% methotrexate; 27/27% other drugs; the patient's average age was 49.5±12.2 years, with female proportion 87%; SSc duration 8.6±7.2 years; diffused/localized forms 1/ 2.8). **Group B (n=58) received RTM a total dose** 3.0±1.2 g, 22 patients received RTM in combination with ISs (11/19% mycophenolate mofetil, 11/19% cyclophosphamide; average age 48.0±13.2 years, female proportion 86%, SSc duration 6.4±4.9 years, diffused/localized forms 1.5/1). The therapy duration in both groups was 36 months. The time courses of forced vital capacity (FVC), diffusive lung capacity (DLC), modified skin count (mRss, points), activity index (EScSG, points), HAQ were assessed in the study.

**Table 1.**

| Parameters | Group A n=100 | | Group B n=58 | | p |
|---|---|---|---|---|---|
| FVC1 M ± SD | 95.2±17.0 | P=0.3 | 76.8±20.7 | P=0.0003 | |
| FVC1 M ± SD | 96.5±18.9 | | 83.8±22.2 | | |
| Δ FVC %, SD'S [25%'S; 75%'S] | -0.7 [-5.8; 7,9] | | 5.6 [-1.9;14.8] | | 0.008 |
| DLCO 1, M ± SD | 62.6±19.9 | P=0.08 | 46.4±18.3 | P=0.6 | |
| DLCO 2, M ± SD | 60.1±17.4 | | 47.1±17.6 | | |
| Δ DLCO % | -1.7 [-5.9;3.3] | | 1.25 [-4; 7.05] | | 0.15 |
| mRss, 1 M ± SD | 5.6±5.3 | P=0.003 | 11.3±10.2 | P=0.000013 | |
| mRss, 2 M ± SD | 4.3±3.7 | | 5.5±4.8 | | |
| Δ mRss, SD'S [25%'S; 75%'S] | 0 [-2;0] | | -3 [-11;0] | | 0.000031 |
| HAQ1 | 0.86±0.5 | P=0.9 | 1.14±0.8 | P=0.01 | |
| HAQ2 | 0.86±0.6 | | 0.9±0.8 | | |
| EScSG 1, M ± SD | 1.64±1.2 | P=0.4 | 2.6± | P=0.0005 | |
| EScSG 2,M ± SD | 1.8±1.3 | | 1.4± | | |
| Dose of glucocorticoids 1, mg | 8.8±4.8 | P=0.16 | 11.4±4.0 | P=0.002 | |
| Dose of glucocorticoids 2, mg | 8.1±3.7 | | 9.1±2.9 | | |
| FVC increment by ≥10%, n/% | 16/16 | | 17/29.3 | | 0.04 |
| FVC decrement by ≥10% n/% | 14/14 | | 4/6.7 | | 0.18 |
| DLCO increment by ≥10%, n/% | 6/6 | | 5/8.6 | | 0.5 |
| DLCO decrement by ≥10% n/% | 14/14 | | 5/8.6 | | 0.3 |

*1 = before treatment, 2 = after treatment; M ± SD = mean value and standard deviation; * = significant difference between the vales measured before and after the treatment*

**Results:** In Groups A and B the therapy was associated with significant decrease in mRss and stabilization of the diffusive lung capacity. During the follow-up period in Groups A no change of the other studied parameters was observed. In Groups B the therapy was associated with significant decrease in HAQ and EScSG. Evaluation of FVC time course in Group B revealed significant FVC increase with median increment about 5.6%. In Group B 10% FVC increase was found in the third of the patients thus exceeding respective parameter in Group B (16%). The patient percentage with FVC decrease by ≥10% in group B was less common compared to group A. During RTM therapy it was possible to significantly reduce the dose of glucocorticoids. RTM and immunosuppressants administration for 36 months in the patients with SSc and ILD effectively alleviated skin induration and stabilized DLCO.

**Conclusion:** Only RTM significantly improved FVC and the patient's quality of life and decreased of the activity index. RTM demonstrated a steroid-saving effect. The study findings substantiate potential use of RTM as a first-line agent for the treatment ILD progressive phenotype in SSc. The immunosuppressants use as a single-agent therapy is more preferable in patients with less pronounced ILD.

**Disclosure of Interests:** None declared

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AB0729

## CLINICAL AND INSTRUMENTAL CHARACTERISTICS OF PATIENTS WITH SYSTEMIC SCLEROSIS IN DIFFERENT INTERVAL SEPARATED BY SCLERODERMA CLINICAL TRIALS CONSORTIUM DAMAGE INDEX (SCTC-DI) IN RUSSIAN COHORT PATIENTS.

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**Background:** Systemic sclerosis (SSc) is a complex disease having an incidence of 1-2 cases per 100,000. In SSc, inflammation leads to organ failure due to severe fibrosis of the skin and internal organs. At late stages, this disease is characterized by a profound decline in the quality of life and premature death [1]. The course of SSc is often one of progressive damage to multiple organs including the skin, joints, heart, lungs, gastrointestinal tract and kidneys. The scleroderma clinical trials consortium damage index (SCTC-DI): a new instrument to quantify organ damage in systemic sclerosis [2].

**Objectives:** To use the scleroderma clinical trials consortium damage index (SCTC-DI) for pts with systemic sclerosis and highlight pts with different disease severity in Russian cohort patients.

**Methods:** Data from 96 patients with systemic sclerosis (mean age was 51,3±12,2; 63% have limited subset of the disease; 88% were female) all fulfilling the ACR criteria for SSc. Functional lung tests, high-resolution CT (HRCT), echocardiography, SSc activity (by the European Scleroderma Study Group (EScSG) activity index), HAQ, SHAQ, the six minute walk test (6MWT), scleroderma clinical trials consortium damage index (SCTC-DI) were evaluated. Total scores of SCTC-DI were categorized into groups (low damage score<5, moderate damage score 6-12, high damage score ≥13). Other data collected including biological results (high-sensitivity C-reactive protein (hsCRP) and erythrocyte sedimentation rate (ESR). Statistical analysis: descriptive data are presented as means (±SD) or medians (with interquartile range [IQR]) for continuous variables, while categorical variables are expressed as counts and percentages. Univariate comparisons were made with 2-sample t tests.

**Results:** pts were divided into 3 groups in depend on total score of SCTC-DI. 77pts (80%) were into group 1 (with low damage score); 17 pts (18%) were into group 2 (with moderate damage score) and 2 pts (2%) were into group 3 (with high damage score). Baseline characteristics of the groups are presented in Table 1