Results: Among 72 (66 female) patients, mean (SD) age was 57.1 (11.1) years, modified Rodnan skin score 10.6 (10.5), SHAQ 0.64 (0.61) and 6MWT distance 473.5 (95.5) m. Mean BHT time was 35.05 (14.90) sec at the second time, and 41.11 (17.71) sec at the third time. The BHT time showed a statistically significant negative correlation with Borg scale (pretreatment test, r = 0.336, p = 0.002; post-test, r = 0.252, p = 0.034; Figure 1 and Table 1), while 6MWT showed a negative correlation with only post-test Borg scale (pretreatment test, r = 0.113 p = 0.343; post-test, r = 0.351 p = 0.002; Table 1). The BHT time was positively correlated with DLCO (%), r = 0.409, p < 0.001 and FVC (liters, r = 0.402, p < 0.001) (Table 1). We also found a statistically significant correlation between BHT time and SHAQ score (r = -0.451, p < 0.001; Table 1). However, EF and PASP by TTE showed no significant relationship with BHT time (EF, r = -0.108, p = 0.374; PASP, r = -0.246, p = 0.054; Table 1).

Background: Although interstitial lung disease (ILD) occurs in the majority of patients with systemic sclerosis (SSc), treatment options for this manifestation are empirical and at present consists of Cyclophosphamide (CyP) or Mycophenolate Mofetil (MMF). However, the immunosuppressants (IS) use leads to rather limited improvement of ILD and is associated with many adverse reactions. The search for novel, more efficacious agents has been continued, such as attracting much attention RTM. However, the limited number of RTM-treated patients, 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.

Objectives: To compare the impact of IS and RTM a single-agent therapy on SSc clinical manifestation and activity, and the safety of these agents in the open-label prospective non-randomized study.

Methods: 116 patients with the confirmed SSc diagnosis and ILD evidence based on MSCT findings were enrolled into the study. All patients received low and moderate-dose glucocorticoids regimens. Group A (n=35) received RTM as a single therapy agent for 13.3±2.3 months at total dose 1.35±0.5g (the patient’s average age was 45.0±15 years, with female proportion 80%; SSc duration 6.3±2.3 years; diffused/localized forms 13/1). Group B (n=36) received parenteral CyP for 12.6± months at total dose 10.6±5 g (the average age 47±12 years, females 92%, SSc duration 5.0±4.8 years, diffused/localized forms 16/1). Group C (n=45) received MMF for 12.6± months at a dose of 2 gms per day (the average age 49±13 years, females 91%, SSc duration 7.1±5 years, diffused/localized forms 1/13). The time courses of CVC, modified skin count (mRss, points), activity index (ESCsG, points) were assessed into the study.

Results: In Groups A, B and C the therapy was associated with significant decrease in mRss (p<0.02, 0.008, 0.007, respectively) and ESCsG (p=0.0007, 0.000165, 0.01, respectively).

Evaluation of FVC time course revealed significant FVC increase only in Groups A (p=0.002) and B (p=0.034), with median increment about 5%. In Groups A and B 10% FVC increase was found in the third of the patients thus exceeding respective parameter twice in Group C (p=0.015 and 0.008, respectively). The patient percentage with FVC decrease by ≥10% did not differ significantly between groups. The therapy was better tolerated in RTM-treated group: during RTM therapy adverse reactions emerged in lower proportion of the patients (4/11%) compared with CyP (19/53%, p=0.0000) and MMF-treated group (12/27%, p=0.5).

Conclusion: The BHT is a simple, safe, and less time-consuming test, reflective of pulmonary parameters and SHAQ, as compared with 6MWT. Our results suggest that the BHT might be a useful surrogate marker of cardiopulmonary capacity in SSc patients.

References:

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Table 1. Pearson’s correlation coefficients (r) for the relation between BHT and clinical parameters in comparison to 6MWT.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity Index 1</td>
<td>2.8±1.4</td>
<td>3.2±1.9</td>
<td>1.9±1.5</td>
</tr>
<tr>
<td>Activity Index 2</td>
<td>1.4±1.2</td>
<td>1.4±1.2</td>
<td>1.2±0.9</td>
</tr>
<tr>
<td>Skin count 1</td>
<td>11.5±5.5</td>
<td>11.2±7.9</td>
<td>7.5±6.9</td>
</tr>
<tr>
<td>Skin count 2</td>
<td>8.2±6.2</td>
<td>7.9±6.8</td>
<td>4.8±3.9</td>
</tr>
<tr>
<td>FVC increment by ≥10%, n/%</td>
<td>9/26</td>
<td>14/31</td>
<td>6/13.3</td>
</tr>
<tr>
<td>FVC decrement by ≥10% n/%</td>
<td>2/5.7</td>
<td>2/4.4</td>
<td>4/8.9</td>
</tr>
</tbody>
</table>

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

Conclusion: All agents effectively alleviated skin induration and ESCsG, but only RTM and CyP significantly improved FVC. The RTM single therapy was better tolerated compared to IS. The study findings substantiate potential use of RTM single therapy both as a first-line agent for ILD treatment in the patients with a progressive course of ILD damage SSc, and in the event of CyP ineffectiveness of poor tolerability. The MMF use is more preferable in patients with less pronounced ILD.

Disclosure of Interests: None declared.

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IMMUNOSUPPRESSANTS (CYCLOPHOSPHAMIDE AND MYCOPHENOLATE MOFETIL) VERSUS RITUXIMAB A SINGLE-AGENT THERAPY IN SCLERODERMA-RELATED INTERSTITIAL LUNG DISEASE: REAL CLINICAL PRACTICE

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Background: Rituximab (RTM) is considered as a promising therapeutic agent for treatment of With Interstitial Lung Disease (ILD) in the patients with systemic sclerosis (SSc). However, the limited number of RTM-treated patients, considerably...