Skin score, and whether prednisolone was safe with particular reference to renal function.

Methods: PRedSS set out as a Phase II, multicentre, double-blind randomised controlled trial, converted to open-label because of the Covid-19 pandemic. Patients were randomised to receive either moderate dose prednisolone (approximately 0.3mg/kg) or matching placebo (or no treatment during open-label) for 6 months. The co-primary endpoints were the Health Assessment Questionnaire Disability Index (HAQ-DI) and modified Rodnan skin core (mRSS) at 3 months. Over 20 secondary endpoints included patient reported outcome measures reflecting pain, itch, anxiety and depression, fatigue and helplessness. 72 participants randomised 1:1 were planned and anticipated to yield 60 evaluable, with over 80% power for each co-primary outcome in ANCOVA analyses [assumptions: HAQ-DI (α = 0.025, β = 0.6), mRSS (α = 0.025, β = 0.5, α = 8.2, β = 0.6)]. Mixed Models for Repeated Measures (week 6, month 3, month 6) were fitted with covariates trial arm, baseline score, anti-Scl-70 and their interactions with time point. Unstructured covariance matrix was assumed with the primary focus being the trial arm effect at 3 months.

Results: The study terminated early due to the Covid-19 pandemic and consequently did not meet the recruitment target of 72 patients. Thirty-five patients (Table 1) were randomised (17 to prednisolone and 18 to placebo/control, 25 subsequently did not meet the recruitment target of 72 patients. Thirty-five patients were randomised to receive either moderate dose prednisolone (approximately 0.3mg/kg) or matching placebo (or no treatment during open-label) for 6 months.

Baseline characteristics of patients by treatment allocation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Prednisolone (n=17)</th>
<th>Placebo (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>52.7 (14.0)</td>
<td>55.3 (12.7)</td>
</tr>
<tr>
<td>Female n (%)</td>
<td>10 (59)</td>
<td>9 (50)</td>
</tr>
<tr>
<td>Duration of skin thickening (years)</td>
<td>1.6 (0.8)</td>
<td>1.7 (0.8)</td>
</tr>
<tr>
<td>Anti-topoisomerase-1 n (%)</td>
<td>5 (29)</td>
<td>6 (33)</td>
</tr>
<tr>
<td>Anti-RNA polymerase III n (%)</td>
<td>6 (35)</td>
<td>8 (44)</td>
</tr>
<tr>
<td>HAQ-DI</td>
<td>16.8 (9.8)</td>
<td>17.0 (7.0)</td>
</tr>
<tr>
<td>mRSS</td>
<td>18.8 (7.9)</td>
<td>23.5 (8.6)</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation) unless stated otherwise.

Conclusions: PRedSS exemplified the challenges of running a clinical trial of an investigational medicinal product potentially associated with increased infection risk during the Covid–19 pandemic. Because PRedSS was terminated prior to target recruitment, it was underpowered, and any conclusions have to be extremely cautious. Although PRedSS suggested some benefit from moderate dose prednisolone, the small sample size indicates the need for a further randomised trial.

REFERENCES:

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FREQUENCY OF METABOLIC SYNDROME AND ITS RELATIONSHIP WITH DISEASE CHARACTERISTICS IN PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: Although the frequency of metabolic syndrome (MetS) has been found to increase in many rheumatological diseases such as rheumatoid arthritis, systemic lupus erythematosus, few studies have been conducted on the frequency of MetS in systemic sclerosis (SSc), and the results are inconsistent.

Objectives: In our study, we aimed to investigate the frequency of MetS in patients with SSc and its relationship with disease characteristics including organ involvement.

Methods: In a cross-sectional, single-center study, 76 patients who applied to our outpatient clinic between July and September 2021 were included in the study. MetS diagnoses were determined according to anthropometric measurements, lipid parameters, blood pressures, and NCEP ATP 3 criteria, and its relationship with SSc end-organ involvement and disease characteristics was examined.

Results: MetS was detected in 37 (48.7%) of 76 patients. Systolic and diastolic blood pressure, waist circumference, height, body mass index, LDL, triglyceride, and fasting blood glucose mean were found to be statistically significantly higher in patients with MetS (p<0.05). In addition, HDL was found to be significantly lower in patients with MetS diagnosis than in patients without MetS (p<0.05). While no significant relationship was found between MetS and SSc end-organ involvement, SSc disease activities (RAI, SCTC-DI), disease duration, a significant statistical relationship was found between MetS and modified Rodnan skin score (mRSS). It was found that patients with MetS had lower mRSS (p=0.019). According to ROC analysis, the mRSS cut-off point that predicted the presence of MetS was mRSS ≥11 (specificity: 84%, sensitivity: 45.95%, AUC: 0.656, p=0.014). No statistically significant correlation was found in the comparison with MetS risk factors for mRSS <11.

Conclusion: In our study, the frequency of MetS in patients with SSc was found to be lower than in the same age group in Turkey MetS prevalence studies. The frequency of MetS in our study is thought to be due to age and gender dominance in our study than SSc itself. Although mRSS was found to be significantly lower in patients with MetS, its sensitivity to predict MetS was found to be low. MetS is less common in patients with high mRSS; It is thought that cachexia due to inflammation, loss of appetite, and malnutrition due to GI involvement may have been effective.

REFERENCES:

Disclosure of Interests: None declared