SAT0273 PREDICTIVE VALUE OF THE REVISED EUROPEAN SCLERODERMA TRIALS AND RESEARCH GROUP ACTIVITY INDEX (EUSTAR-AI)

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Background: Disease activity as measured by the European Scleroderma Study Group Activity Index (EScrSG-AI) has been recently found to predict the development of damage over time in an early systemic sclerosis (SSc) cohort (2). The European Scleroderma Trials and Research Group Task Force for the Development of Revised Activity Criteria for SSc recently succeeded in identifying a preliminarily revised activity index (EUSTAR-AI) that had a greater construct validity than the EScrSG-AI (1) i.e. performing better in identifying patients with active disease (3).

Objectives: To assess in patients with SSc the predictive value of the EUSTAR-AI for disease severity accrual.

Methods: SSc patients from the EUSTAR database with a disease duration from the onset of the first non-Raynaud sign/symptom/5 years were first extracted. Patients were considered for the study if they presented the following features: a) availability of items included in the EUSTAR-AI, in the EScrSG-AI and in the Medsger severity scale at baseline and yearly for 2 consecutive years; b) availability of vital status at the last observation; c) availability of other disease features known to predict disease progression (male sex, clinical and serological subset).

To capture the disease activity variations over time, we calculated the EUSTAR-AI and the EScrSG-AI adjusted mean (area under the curve over time divided by time interval). Disease progression was based on the Medsger severity score at baseline and included accrual of a ≥1 summed severity score and of a ≥1 severity in each organ systems at the 2 year follow-up visit compared with the initial visit.

To explore specific determinants of disease progression, logistic regression analysis was carried out.

Results: A total of 549 patients satisfied the entry criteria. At univariate logistic regression analysis (among sex, age, clinical and serological subset, EScrSG-AI and EUSTAR-AI adjusted mean and baseline severity score), EScrSG-AI adjusted mean (OR 1.41 95% CI 1.20-1.67), antiScI70 antibody positivity (OR 1.72 95% CI 1.20-2.47), diffuse subset (OR 1.46 95% CI 1.01-2.10) and EUSTAR-AI adjusted mean (OR 1.41 95% CI 1.23-1.61) predicted disease severity accrual. Multivariate analysis revealed that the EUSTAR-AI adjusted mean was the best predictor of disease progression (Table1). Moreover, at multivariate analysis the EUSTAR-AI adjusted mean also predicted severity accrual of lung (OR 1.32), heart (OR 1.40), skin (OR 1.48) and peripheral vascular disease (OR 1.45).

Conclusion: The adjusted EUSTAR-AI has a distinct predictive value for disease progression and development of severe organ involvement in SSc and works better than EScrSG-AI.

REFERENCES

Disclosur of Interests: Serena Fasano: None declared, Veronica Giacone: None declared, Antonella Riccardi: None declared, Valentina Messiniti: None declared, ALESSANDRA VACC: None declared, Oliver Distler: Grant/research support from: Prof. Distler received research funding from Actelion, Bayer, Boehringer Ingelheim and Mitsubishi Tanabe to investigate potential treatments of scleroderma and its complications, Consultant for: Prof. Distler has/had consultancy relationship within the last 3 years with Actelion, AnaMar, Bayer, Boehringer Ingelheim, ChemomAb, espeR-are foundation, Genentech/Roche, GSK, Inventiva, Italfarmaco, Iqvia, Lilly, medac, Medimmune, Mitsubishi Tanabe Pharma, Pharmacyclics, Novartis, Pfizer, Sanofi, Serodapharm and UCB in the area of potential treatments of scleroderma and its complications. In addition, he has/had consultancy relationship within the last 3 years with A. Menarini, Amgen, Abbvie, GSK, Mepha, MSD, Pfizer and UCB in the field of arthritides and related disorders, Otylia Kowalka Bielecka Consultant for: “OK-B received consulting fees or other remuneration from Bayer, Boehringer Ingelheim, Inventiva, Medac, Novartis and Roche”, Yannick Allainore Consultant from: Inventiva, F Hoffman La-Roche, Sanofi, IMS, Pfizer, Consultant for: Actelion, Bayer, BMS, Boehringer, Roche, Sanofi, Gabriele Valentini Grant/research support from: MSD, Pfizer, Consultant for: MSD, Pfizer, biogen, Speakers bureau: MSD, amgen, biogen, Lilly, sanofi, pfizer.


SAT0274 THE EFFECT OF RITUXIMAB ON LUNG FUNCTION AND SKIN SCORE IN SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE. LONG-TERM OBSERVATION

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Background: There is a large clinical experience about the efficiency of rituximab (RTX) for the treatment of systemic sclerosis (SSc). There are several studies showing the decrease in skin induration and interstitial fibrosis in the lungs as the effect of therapy. However, there are not many long-term observations.

Objectives: To describe the efficacy of RTX on lung function and skin score in patients with systemic sclerosis-associated interstitial lung disease, in long-term follow-up.

Methods: This study included 71 patients (pts) with SSc. Data were collected prospectively. The mean follow-up period was 42 mo (12-72). Mean age was 46 years (17-66), female-59 (83%), diffuse cutaneous subset of the disease had 42 (59%), Scl-70 positivity-73% of pts. Duration of the disease was 5.6±4.4 yrs. All pts received concomitant treatment with low dose prednisolone and 45% - with immunosuppressants. The following indicators were evaluated: forced vital capacity,% predicted (FVC), diffusing capacity for carbon monoxide,% predicted (DLCO) and Rodnan skin score (mRss) over a periods of 12-18 months (point 1), 24-30 months (point 2), 36-42 months (point 3), 48-54 months (point 4) and 60-72 months (point 5) after the start of therapy. The results are presented in the form of mean values, delta, median, upper and lower quartile.

Table 1. Predictive features of severity progression by multivariate regression analysis

<table>
<thead>
<tr>
<th>Predictive factors</th>
<th>OR (IC 95%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.41 (1.23-1.61)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.32 (1.14-1.54)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.40 (1.15-1.70)</td>
<td>0.0005</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.03 (1.01-1.05)</td>
<td>0.0223</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.48 (1.21-1.82)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>0.97 (0.95-0.99)</td>
<td>0.0359</td>
</tr>
<tr>
<td>Adjusted mean EUSTAR-AI</td>
<td>1.45 (1.24-1.70)</td>
<td>&lt;0.0001</td>
</tr>
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Disclosure of Interests: None declared, Monica Deringer: None declared, Selina Kofler: None declared, Harald Sourij: None declared, Orazio: None declared, Martin Stradner Speaking at non-scientific meetings, giving expert evidence, membership of speaker’s bureau: Novartis, Roche, Lilly, BMS,Pfizer, Shirin, Winfried Graninger: Work done in the Austrian Federal Government within the COMET K1 Centre Program, Land Steiermark and Land Wien.