**Supplementary Table S1. Clinical and laboratorial characteristics of patients with primary Sjögren’s syndrome according to the status of medication.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Medication (+)**  **(N = 28)** | | | **Medication (-)**  **(N = 38)** | | | ***P*-value** |
| **Age, years** | 51.3 | ± | 10.5 | 47.7 | ± | 11.8 | 0.212† |
| **Disease duration** | 7.1 | ± | 3.9 | 3.6 | ± | 2.4 | <0.001 |
| **ESSPRI** | 4.2 | ± | 1.4 | 4.9 | ± | 1.8 | 0.088 |
| **ESSPRI-Dryness** | 5.7 | ± | 1.4 | 6.1 | ± | 2.0 | 0.441 |
| **ESSPRI-Fatigue** | 4.2 | ± | 2.0 | 5.3 | ± | 2.1 | 0.033 |
| **ESSPRI-Pain** | 2.7 | ± | 2.1 | 3.3 | ± | 2.4 | 0.290 |
| **ESS** | 5.9 | ± | 1.5 | 6.4 | ± | 1.9 | 0.223 |
| **Ocular-VAS** | 5.3 | ± | 1.6 | 5.0 | ± | 2.5 | 0.588 |
| **Oral-VAS** | 6.2 | ± | 2.1 | 7.2 | ± | 2.1 | 0.070 |
| **OSDI** | 43.7 | ± | 22.0 | 40.7 | ± | 23.3 | 0.918 |
| **PGA** | 5.3 | ± | 1.9 | 5.7 | ± | 2.2 | 0.431 |
| **ESSDAI** | 2.1 | ± | 2.2 | 5.7 | ± | 6.0 | 0.001 |
| **ClinESSDAI** | 1.5 | ± | 2.0 | 5.6 | ± | 6.8 | 0.001 |
| **ClintrialsESSDAI** | 1.5 | ± | 2.0 | 3.8 | ± | 4.6 | 0.006 |
| **Schirmer’ test positivity** | 22/28 | | (78.6) | 30/37 | | (81.1) | 1.000‡ |
| **OSS** | 7.2 | ± | 5.6 | 6.8 | ± | 6.6 | 0.829 |
| **tBUT** | 8.6 | ± | 3.7 | 9.0 | ± | 4.5 | 0.746 |
| **Unstimulated SFR (ml/min)** | 0.03 | ± | 0.05 | 0.03 | ± | 0.06 | 0.734 |
| **Stimulated SFR (ml/min)** | 0.35 | ± | 0.41 | 0.45 | ± | 0.61 | 0.461 |
| **Salivary gland scintigraphy** |  |  |  |  |  |  |  |
| **PG-UR** | 2.4 | ± | 0.8 | 2.6 | ± | 1.0 | 0.373 |
| **PG-EF (%)** | 35.8 | ± | 23.2 | 39.4 | ± | 19.9 | 0.502 |
| **SMG-UR** | 2.4 | ± | 1.0 | 2.4 | ± | 0.9 | 0.705 |
| **SMG-EF (%)** | 19.7 | ± | 18.6 | 20.7 | ± | 17.8 | 0.843 |
| **Focus score** | 1.4 | ± | 1.3 | 2.4 | ± | 2.0 | 0.046 |
| **ESR elevation** | 10/28 | | (35.7) | 25/38 | | (65.8) | 0.024‡ |
| **CRP elevation** | 1/28 | | (3.6) | 4/38 | | (10.5) | 0.385‡ |
| **IgG elevation** | 13/26 | | (50.0) | 25/38 | | (65.8) | 0.300‡ |
| **Anti-Ro antibody positivity** | 20/28 | | (71.4) | 25/37 | | (67.6) | 0.792‡ |
| **Anti-La antibody positivity** | 8/28 | | (28.6) | 11/37 | | (29.7) | 1.000‡ |

Data are described as the mean ± standard deviation (SD), or number of patients (%). *P* values are obtained using the Student’s *t*-test†, Mann–Whitney U test, or Chi-squared or Fisher’s exact test‡. ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; ESSPRI-Dryness, dryness domain of ESSPRI; ESSPRI-Fatigue, fatigue domain of ESSPRI; ESSPRI-Pain, pain domain of ESSPRI; ESS, EULAR sicca score; Ocular-VAS, visual analogue scale for ocular dryness; Oral-VAS; VAS for oral dryness; OSDI, ocular surface disease Index; PGA, patient’s global assessment; ESSDAI, EULAR Sjögren’s Syndrome Disease Activity Index; ClinESSDAI, Clinical ESSDAI; ClintrialsESSDAI, Clinical Trials ESSDAI ; OSS, ocular staining score; tBUT, tear Break-up time; SFR, salivary flow rate; PG, parotid gland; UR, uptake ratio; EF, ejection fraction; SMG, submandibular gland, ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

**Supplementary Table S2. Correlations between subjective and objective clinical disease activity indexes according to status of medication in primary Sjögren’s syndrome.**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Medication (+)**  **(N = 28)** | | | | |  | **Medication (-)**  **(N = 38)** | | | | |
|  | **ESSDAI** |  | **ClinESSDAI** |  | **ClinTrialsESSDAI** |  | **ESSDAI** |  | **ClinESSDAI** |  | **ClinTrialsESSDAI** |
|  | Spearman rho |  | Spearman rho |  | Spearman rho |  | Spearman rho |  | Spearman rho |  | Spearman rho |
| **ESSPRI** | 0.173 |  | 0.211 |  | 0.211 |  | 0.464\*\* |  | 0.496\*\* |  | 0.663\*\* |
| **ESSPRI-Dryness** | 0.250 |  | 0.332 |  | 0.322 |  | 0.026 |  | 0.025 |  | 0.207 |
| **ESSPRI-Fatigue** | 0.016 |  | 0.002 |  | 0.002 |  | 0.548\*\* |  | 0.516\*\* |  | 0.668\*\* |
| **ESSPRI-Pain** | 0.020 |  | 0.026 |  | 0.026 |  | 0.483\*\* |  | 0.563\*\* |  | 0.673\*\* |
| **ESS** | 0.302 |  | 0.361 |  | 0.361 |  | -0.014 |  | -0.026 |  | 0.149 |
| **Ocular-VAS** | -0.015 |  | 0.122 |  | 0.122 |  | -0.035 |  | -0.025 |  | 0.172 |
| **Oral-VAS** | 0.305 |  | 0.323 |  | 0.323 |  | -0.022 |  | -0.058 |  | 0.107 |
| **OSDI** | -0.048 |  | -0.152 |  | -0.152 |  | -0.206 |  | -0.233 |  | -0.233 |
| **PGA** | -0.091 |  | -0.050 |  | -0.050 |  | 0.405\* |  | 0.388\* |  | 0.518\*\* |

ESSDAI, EULAR Sjögren’s Syndrome Disease Activity Index; ClinESSDAI, Clinical ESSDAI; ClintrialsESSDAI, Clinical Trials ESSDAI; ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; ESSPRI-Dryness, dryness domain of ESSPRI; ESSPRI-Fatigue, fatigue domain of ESSPRI; ESSPRI-Pain, pain domain of ESSPRI; ESS, EULAR sicca score; Ocular-VAS, visual analogue scale for ocular dryness; Oral-VAS, VAS for oral dryness; OSDI, ocular surface disease index; PGA, patient’s global assessment. \**P* = <0.05, \*\**P* = <0.01

**Supplementary Table S3. Correlations between domains of ESSPRI and other PROs or objective clinical disease activity indexes in patients with primary Sjögren’s syndrome.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **ESSPRI-Dryness** | |  | **ESSPRI-Fatigue** | |  | **ESSPRI-Pain** | |
|  | Spearman rho | *P*-value |  | Spearman rho | *P*-value |  | Spearman rho | *P*-value |
| **ESSPRI** | 0.661 | <0.001 |  | 0.859 | <0.001 |  | 0.849 | <0.001 |
| **ESSPRI-Dryness** |  |  |  | 0.360 | 0.003 |  | 0.376 | 0.002 |
| **ESSPRI-Fatigue** | 0.360 | 0.003 |  | - | - |  | 0.636 | <0.001 |
| **ESSPRI-Pain** | 0.376 | 0.002 |  | 0.636 | <0.001 |  | - | - |
| **ESS** | 0.969 | <0.001 |  | 0.324 | 0.008 |  | 0.368 | 0.002 |
| **Ocular-VAS** | 0.799 | <0.001 |  | 0.289 | 0.019 |  | 0.208 | 0.094 |
| **Oral-VAS** | 0.811 | <0.001 |  | 0.241 | 0.052 |  | 0.328 | 0.007 |
| **OSDI** | 0.272 | 0.189 |  | 0.011 | 0.959 |  | 0.040 | 0.850 |
| **PGA** | 0.690 | <0.001 |  | 0.527 | <0.001 |  | 0.409 | <0.001 |
| **ESSDAI** | 0.160 | 0.198 |  | 0.395 | 0.001 |  | 0.310 | 0.011 |
| **ClinESSDAI** | 0.193 | 0.121 |  | 0.388 | 0.001 |  | 0.383 | 0.001 |
| **ClinTrialsESSDAI** | 0.293 | 0.017 |  | 0.461 | <0.001 |  | 0.440 | <0.001 |
| **OSS** | 0.333 | 0.017 |  | -0.182 | 0.200 |  | -0.099 | 0.490 |
| **tBUT** | -0.220 | 0.120 |  | 0.082 | 0.569 |  | 0.153 | 0.282 |
| **Unstimulated SFR (ml/min)** | -0.281 | 0.025 |  | 0.061 | 0.634 |  | -0.039 | 0.762 |
| **Stimulated SFR (ml/min)** | -0.263 | 0.037 |  | 0.104 | 0.419 |  | -0.033 | 0.797 |
| **Salivary gland scintigraphy** |  |  |  |  |  |  |  |  |
| **PG-UR** | -0.252 | 0.044 |  | 0.020 | 0.875 |  | -0.054 | 0.671 |
| **PG-EF (%)** | -0.227 | 0.071 |  | 0.136 | 0.283 |  | 0.097 | 0.448 |
| **SMG-UR** | -0.357 | 0.004 |  | -0.069 | 0.589 |  | -0.079 | 0.537 |
| **SMG-EF (%)** | -0.325 | 0.009 |  | -0.038 | 0.764 |  | -0.047 | 0.710 |
| **Focus score** | 0.261 | 0.050 |  | 0.006 | 0.962 |  | 0.086 | 0.525 |
| **ESR** | 0.156 | 0.210 |  | 0.365 | 0.003 |  | 0.142 | 0.256 |
| **CRP** | 0.133 | 0.289 |  | 0.430 | <0.001 |  | 0.222 | 0.073 |
| **IgG** | 0.209 | 0.097 |  | 0.297 | 0.018 |  | 0.116 | 0.363 |

ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; ESSPRI-Dryness, dryness domain of ESSPRI; ESSPRI-Fatigue, fatigue domain of ESSPRI; ESSPRI-Pain, pain domain of ESSPRI; ESS, EULAR sicca score; Ocular-VAS, visual analogue scale for ocular dryness; Oral-VAS, VAS for oral dryness; OSDI, ocular surface disease index; PGA, patient’s global assessment; OSS, ocular staining score; tBUT, tear break-up time; SFR, Salivary flow rate; PG, parotid gland; UR, uptake ratio; EF, ejection fraction; SMG, submandibular gland, ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

**Supplementary Table S4. Clinical and laboratorial characteristics of patients with primary Sjögren’s syndrome based on ESSPRI of 5.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **ESSPRI ≥ 5**  (N = 32) | | | **ESSPRI < 5**  (N = 34) | | | ***P*-value** |
| **Age, years** | 48.2 | ± | 10.5 | 50.2 | ± | 12.1 | 0.480† |
| **Disease duration** | 4.3 | ± | 2.8 | 5.9 | ± | 4.1 | 0.069 |
| **ESSPRI** |  |  |  |  |  |  |  |
| **ESSPRI-Dryness** | 6.9 | ± | 1.2 | 5.0 | ± | 1.7 | <0.001 |
| **ESSPRI-Fatigue** | 6.6 | ± | 1.2 | 3.3 | ± | 1.4 | <0.001 |
| **ESSPRI-Pain** | 4.6 | ± | 2.1 | 1.6 | ± | 1.4 | <0.001 |
| **ESS** | 7.2 | ± | 1.3 | 5.3 | ± | 1.7 | <0.001 |
| **Ocular-VAS** | 6.1 | ± | 1.6 | 4.2 | ± | 2.2 | <0.001 |
| **Oral-VAS** | 7.7 | ± | 1.6 | 5.9 | ± | 2.3 | <0.001 |
| **OSDI** | 45.7 | ± | 27.2 | 37.8 | ± | 17.2 | 0.379 |
| **PGA** | 6.7 | ± | 1.5 | 4.3 | ± | 1.8 | <0.001 |
| **ESSDAI** | 5.8 | ± | 6.1 | 2.5 | ± | 3.2 | 0.009 |
| **ClinESSDAI** | 5.8 | ± | 6.9 | 2.0 | ± | 3.5 | 0.007 |
| **ClintrialsESSDAI** | 4.5 | ± | 4.6 | 1.3 | ± | 2.0 | 0.007 |
| **Schirmer’s test positivity** | 29/32 | | (90.6) | 23/33 | | (69.7) | 0.061 |
| **OSS** | 6.9 | ± | 6.4 | 6.9 | ± | 6.2 | 0.988 |
| **tBUT** | 8.9 | ± | 4.1 | 8.9 | ± | 4.5 | 0.982 |
| **Unstimulated SFR (ml/min)** | 0.02 | ± | 0.03 | 0.04 | ± | 0.08 | 0.392 |
| **Stimulated SFR (ml/min)** | 0.37 | ± | 0.54 | 0.43 | ± | 0.53 | 0.682 |
| **Salivary gland scintigraphy** |  |  |  |  |  |  |  |
| **PG-UR** | 2.5 | ± | 0.9 | 2.5 | ± | 0.9 | 0.837 |
| **PG-EF (%)** | 35.9 | ± | 21.1 | 39.8 | ± | 21.5 | 0.714 |
| **SMG-UR** | 2.4 | ± | 0.9 | 2.4 | ± | 1.0 | 0.714 |
| **SMG-EF (%)** | 17.7 | ± | 17.5 | 22.8 | ± | 18.4 | 0.257 |
| **Focus score** | 2.2 | ± | 2.1 | 1.8 | ± | 1.6 | 0.448 |
| **ESR elevation** | 20/32 | | (62.5) | 15/34 | | (44.1) | 0.149‡ |
| **CRP elevation** | 5/32 | | (15.6) | 0/34 | | (0.0) | 0.023‡ |
| **IgG elevation** | 22/32 | | (68.8) | 16/32 | | (50.0) | 0.203‡ |
| **Anti-Ro antibody positivity** | 24/31 | | (77.4) | 21/34 | | (61.8) | 0.191‡ |
| **Anti-La antibody positivity** | 7/31 | | (22.6) | 12/34 | | (35.3) | 0.289‡ |

*P* values are obtained using the Student’s *t*-test†, Mann–Whitney U test, or Chi-squared or Fisher’s exact test‡. ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; ESSPRI-Dryness, dryness domain of ESSPRI; ESSPRI-Fatigue, fatigue domain of ESSPRI; ESSPRI-Pain, pain domain of ESSPRI; ESS, EULAR sicca score; Ocular-VAS, visual analogue scale for ocular dryness; Oral-VAS, VAS for oral dryness; OSDI, ocular surface disease index; PGA, patient’s global assessment; OSS, ocular staining score; tBUT, tear break-up time; SFR, Salivary flow rate; PG, parotid gland; UR, uptake ratio; EF, ejection fraction; SMG, submandibular gland, ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

**Supplementary Table S5. Correlations between age or disease duration and subjective or objective measures in primary Sjögren’s syndrome.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Age** | |  | **Disease duration** | |
|  | Spearman rho | *P*-value |  | Spearman rho | *P*-value |
| **ESSPRI** | -0.072 | 0.566 |  | -0.177 | 0.155 |
| **ESSPRI-Dryness** | 0.014 | 0.913 |  | -0.004 | 0.977 |
| **ESSPRI-Fatigue** | -0.160 | 0.200 |  | -0.271 | 0.028 |
| **ESSPRI-Pain** | -0.052 | 0.680 |  | -0.136 | 0.275 |
| **ESS** | 0.028 | 0.826 |  | -0.001 | 0.993 |
| **Ocular-VAS** | -0.004 | 0.972 |  | 0.009 | 0.946 |
| **Oral-VAS** | 0.025 | 0.841 |  | 0.012 | 0.924 |
| **OSDI** | -0.043 | 0.840 |  | 0.422 | 0.035 |
| **PGA** | 0.100 | 0.426 |  | 0.046 | 0.717 |
| **ESSDAI** | -0.323 | 0.008 |  | -0.189 | 0.128 |
| **ClinESSDAI** | -0.208 | 0.094 |  | -0.153 | 0.219 |
| **ClinTrialsESSDAI** | -0.226 | 0.068 |  | -0.101 | 0.417 |
| **OSS** | -0.020 | 0.891 |  | 0.270 | 0.055 |
| **tBUT** | -0.037 | 0.798 |  | -0.276 | 0.050 |
| **Unstimulated SFR (ml/min)** | -0.007 | 0.954 |  | -0.236 | 0.062 |
| **Stimulated SFR (ml/min)** | -0.011 | 0.932 |  | -0.147 | 0.249 |
| **Salivary gland scintigraphy** |  |  |  |  |  |
| **PG-UR** | 0.034 | 0.790 |  | -0.203 | 0.108 |
| **PG-EF (%)** | 0.100 | 0.432 |  | -0.285 | 0.022 |
| **SMG-UR** | 0.097 | 0.446 |  | -0.004 | 0.974 |
| **SMG-EF (%)** | 0.102 | 0.423 |  | 0.039 | 0.761 |
| **Focal score** | -0.130 | 0.335 |  | -0.091 | 0.502 |
| **ESR** | -0.298 | 0.015 |  | -0.325 | 0.008 |
| **CRP** | -0.167 | 0.181 |  | -0.203 | 0.103 |
| **IgG** | -0.414 | 0.001 |  | -0.195 | 0.122 |

ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; ESSPRI-Dryness, dryness domain of ESSPRI; ESSPRI-Fatigue, fatigue domain of ESSPRI; ESSPRI-Pain, pain domain of ESSPRI; ESS, EULAR sicca score; Ocular-VAS, visual analogue scale for ocular dryness; Oral-VAS, VAS for oral dryness; OSDI, ocular surface disease index; PGA, patient’s global assessment; OSS, ocular staining score; tBUT, tear break-up time; PGA, patient’s global assessment; ESSDAI, EULAR Sjögren’s Syndrome Disease Activity Index; ClinESSDAI, Clinical ESSDAI; ClintrialsESSDAI, Clinical Trials ESSDAI ; OSS, ocular staining score; tBUT, tear break-up time; SFR, salivary flow rate; PG, parotid gland; UR, uptake ratio; EF, ejection fraction; SMG, submandibular gland, ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.