Clinical Analysis of the Test Results of the Japanese Revised Criteria for Diagnosis of Sjögren’s Syndrome

Hiroshi Kimura¹ and Hideo Shojaku²

We investigated the test results from 73 patients who were diagnosed based on the Japanese revised criteria for the diagnosis of Sjögren’s syndrome (SjS). When a patient showed 2 positive results, he was diagnosed as having SjS. Twenty-six of 73 patients were definitively diagnosed as having SjS. Eleven patients had one positive test result only. Thirty-six had three negative results. The histopathologic test was performed on 11 patients, and all 11 had positive results. The oral test was performed on 23 patients, and positive results were obtained for 18. The ocular test was performed on 15 patients, and positive results were detected in 9. The serologic test was performed on 26 patients, and 14 patients showed positive results. In the combinations of the serologic test and the oral test, 9 patients were diagnosed as having SjS. In the combinations of the oral test and the histopathologic test, 7 patients were positively diagnosed. In the serologic test and the ocular test, 4 were positively diagnosed. In the ocular test and the histopathologic test, 3 were positively diagnosed. In the oral test and the ocular test, 2 were positively diagnosed. In the serologic test and the histopathologic test, 1 patient was positively diagnosed. When the patient showed a positive result on the first serologic test, one of the residual tests certainly showed a positive result. This study suggested a patient was definitively diagnosed as having SjS when the first serologic test showed a positive result. The predictive value positive (PVP) of the serologic test and the histopathologic test were both 100%. The PVP of the ocular test was 81.8% and that of the oral test was 66.7%. The PVP of the oral test was statistically different from that of the serologic and histopathologic tests. Our results strongly suggest that the diagnostic capability using the serologic test and the histopathologic test were superior to the oral test.

Keywords: test results, revised criteria for diagnosis, Sjögren’s syndrome

References
13) 道岸隆敏: 唾液腺シンチグラフィの診断, 核医学画像診断ハンドブック 改訂版一列腺機能と機能的な利用のために. (中崎憲一, 前谷清剛編). 278–279 頁, エルゼビア・ジャ

¹) Department of Otolaryngology, Saiseikai Toyama Hospital
²) Department of Otorhinolaryngology, Head & Neck Surgery, University of Toyama

Corresponding Author Address: Hiroshi Kimura
chavez@med.u-toyama.ac.jp
The Japanese Revised Criteria for Diagnosis of Sjögren’s Syndrome

1. A positive finding in at least 1 of the following two histopathologic examinations:
   A) Focus score $\geq 1$ on lip biopsy (focus defined as an agglomeration of at least 50 lymphocytes; focus defined as the number of foci per 4 mm$^2$ of glandular tissue)
   B) Focus score $\geq 1$ on lacrimal gland biopsy (focus defined as an agglomeration of at least 50 lymphocytes; focus defined as the number of foci per 4 mm$^2$ of glandular tissue)

2. A positive result in at least 1 of the following two oral items:
   A) Parotid sialography showing abnormal finding greater than or equal to Stage 1 (small punctate; $<1$ mm in diameter)
   B) Decreased salivary secretion demonstrated with the chewing gum test ($\leq 10$ mL in 10 minutes) or Saxon test ($\leq 2$ g in 2 minutes) and salivary scintigraphy showing a reduction in salivary gland function

3. A positive result in at least 1 of the following two ocular items:
   A) Schirmer’s test ($\leq 5$ mm in 5 minutes) and Rose bengal test ($\geq 3$ according to van Bijsterveld’s scoring system)
   B) Schirmer’s test ($\leq 5$ mm in 5 minutes) and positive result on ocular dye test

4. Presence of at least 1 of the following serum autoantibodies:
   A) Antibodies to Ro/SS-A antigens
   B) Antibodies to La/SS-B antigens

The presence of 2 out of 4 items established a definitive diagnosis of Sjögren’s Syndrome.

The order and the results of the tests that performed each group

<table>
<thead>
<tr>
<th>Test</th>
<th>Cases (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>serologic test (+) → oral test (+)</td>
<td>9 cases (34.6%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (+) → ocular test (+)</td>
<td>3 cases (11.5%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (+) → oral test (−) → ocular test (+)</td>
<td>1 case (3.9%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (+) → ocular test (+)</td>
<td>2 cases (7.7%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (+) → oral test (−) → ocular test (−) → histopathologic test (+)</td>
<td>1 case (3.9%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (+) → ocular test (−) → histopathologic test (+)</td>
<td>7 cases (26.9%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (+) → ocular test (−) → histopathologic test (−)</td>
<td>3 cases (11.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>B group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (+) → ocular test (−) → histopathologic test (−)</td>
<td>9 cases (31.8%)</td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (−) → ocular test (+) → histopathologic test (−)</td>
<td>2 cases (18.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>C group (histopathologic test was not performed)</strong></td>
<td>cases</td>
<td></td>
</tr>
<tr>
<td>serologic test (−) → oral test (−) → ocular test (−)</td>
<td>36 cases</td>
<td></td>
</tr>
</tbody>
</table>

(+): positive test result, (−): negative test result, →: Test was performed in the order of the arrows.