Reassessment of the Classification of the Severity in Idiopathic Pulmonary Fibrosis Using SF-36 Questionnaire

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Abstract

Objective To investigate whether or not the newly revised classification of the severity of idiopathic interstitial pneumonia (IIP) is appropriate with respect to quality of life (QOL).

Methods The association between the subscale of Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and pulmonary function or serum marker was analyzed using Pearson’s correlation coefficient. The association between the subscale of SF-36 and the previous or newly revised classification of the severity of IIP was analyzed using Spearman’s rank correlation test.

Patients Forty patients with idiopathic pulmonary fibrosis (IPF) were enrolled.

Results The mean deviation value scores for 7 items, excluding bodily pain (BP) in SF-36 were below the national reference values. % vital capacity (VC) was correlated with the 7 items excluding BP. However, neither serum LDH nor KL-6 values were correlated with any item in SF-36. According to the new or previous classification of the severity, severity was correlated with physical function, limitation of role functioning related physical problems and general health (GH); the correlation coefficient with the new one was slightly higher than the previous one. Based on these results, we established a unique draft on the classification of the severity. %VC <70% was added as an item for the newly revised classification in our draft. In our draft, there was rank correlation between the 7 items, excluding BP, in SF-36 and severity.

Conclusion With respect to QOL, the newly revised classification of the severity of IIP was not satisfactory, but the hypoxemia during exercise in patients with resting PaO2 >80 Torr and reduction of VC were found to be important factors.

Key words: SF-36, QOL, IPF, classification of the severity

Introduction

Idiopathic pulmonary fibrosis (IPF) has undergone important redefinition in the last several years, based on revised histopathologic classification criteria (1). IPF is the most frequent type among the types of idiopathic interstitial pneumonia (IIP), but patients with IPF have a poor prognosis (median survival of 2.8±4.0 years), because no therapy has been demonstrated to be efficacious. Thus, management of patients with IPF should be directed towards the improvement of quality of life (QOL), treat the impaired pulmonary function and prolong the survival time.

In Japan, the classification of the severity of IIP was revised in Autumn 2003 (2). In this new classification, hypoxemia during exercise was considered on the basis of a standard classification, in which the severity was determined by resting PaO2 (Table 1). The classification of severity is essentially prepared based on the prognosis of disease and the treatment response; however, it should reflect health-related QOL for patients if possible. We investigated whether the newly revised classification was appropriate with respect to QOL.

Subjects and Methods

The subjects were 40 patients with IPF among the patients with IIP who were treated at the outpatient clinic in our hospital. In our survey on QOL, a general health-related ques-

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tionnaire, Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), was sent and collected. We selected IPF patients without other respiratory diseases or cardiovascular diseases. This study was approved by the Ethics Committee of Jichi Medical School, and patients gave written, informed consent before study entry. The SF-36 questionnaire consists of 8 subscales, 1) physical function (PF), 2) limitation of role functioning related to physical problems (RP), 3) bodily pain (BP), 4) general health perception (GH), 5) vitality (VT), 6) social function (SF), 7) limitation of role functioning related to emotional problems (RE), and 8) mental health (MH), and comprises 36 questions. Scales 1) to 4) represent QOL regarding physical respect, and scales 5) to 8) represent QOL regarding mental respect. These 8 items were calculated as the serial variable scale (perfect mark: 100 points) using the fixed scoring program. The association between these results on QOL and the new/previous classification of severity in each patient was analyzed using Spearman’s rank correlation test. The association between the lung function test (%VC, FEV1.0 %, and %DLCO) and the serum levels of markers (LDH and KL-6) was analyzed using Pearson’s correlation coefficient. \( p<0.05 \) was regarded as significant.

**Results**

The 40 patients with IPF consisted of 28 males and 12 females, with a mean age of 66.6±6.7 years. Surgical lung biopsy facilitated histopathological diagnosis in 13 patients, whereas IPF was clinically diagnosed in accordance with the ATS/ERS consensus statement in the remaining 27 patients (3). Concerning the laboratory data, the mean %VC, FEV1.0 %, %DLCO, LDH, and KL-6 values were 78.6±25.5%, 80.3±9.5%, 43.3±18.6%, 498±197 mU/ml, and 1,395±879 U/ml, respectively. According to the new classification of severity, the grade was evaluated as I in 16 patients, II in 4 patients, III in 10 patients, and IV in 10 patients. According to the previous classification of severity, the grade was evaluated as I in 16 patients, II in 14 patients, III in 2 patients, and IV in 8 patients.

The mean deviation value scores for the 7 items, excluding BP, in the SF-36 questionnaire were below the national reference values (4), suggesting that QOL was reduced in the patients with IPF in both physical and mental respect. In particular, the mean deviation values of PF and RP were 37.7 and 39.5, respectively, markedly low (Fig. 1). The correlation between each subscale in the SF-36 questionnaire and the lung function test or serum markers was investigated using Pearson’s correlation coefficient. %VC correlated with the 7 items excluding BP. %DLCO correlated with the 4 items excluding BP, GH, VT, and MH. However, neither LDH nor KL-6 was correlated with any item (Table 2).

We analyzed the correlation between each subscale and the severity using Spearman’s rank correlation. According to the new/previous classification of severity, the correlation coefficient with the new classification of severity was higher than that with the previous classification of severity (Table 3).

Based on these results, we established a unique draft on the QOL severity, and similarly investigated it, since among the lung function test parameters, %VC was correlated with each subscale in the SF-36 questionnaire: %VC <70% was added as an item for evaluating the severity, and in the new classification of severity, the reduction of SpO2 during a 6-
Table 3. Correlation between the Subscale of SF-36 and the Severity Using Spearman's Rank Correlation

<table>
<thead>
<tr>
<th>Previous classification</th>
<th>Revised classification</th>
<th>Our draft</th>
</tr>
</thead>
<tbody>
<tr>
<td>PF</td>
<td>–0.429**</td>
<td>–0.624**</td>
</tr>
<tr>
<td>RP</td>
<td>–0.438**</td>
<td>–0.598**</td>
</tr>
<tr>
<td>BP</td>
<td>–0.265</td>
<td>–0.213</td>
</tr>
<tr>
<td>GH</td>
<td>–0.379*</td>
<td>–0.487**</td>
</tr>
<tr>
<td>VT</td>
<td>–0.157</td>
<td>–0.365*</td>
</tr>
<tr>
<td>SF</td>
<td>–0.188</td>
<td>–0.333*</td>
</tr>
<tr>
<td>RE</td>
<td>–0.238</td>
<td>–0.524**</td>
</tr>
<tr>
<td>MH</td>
<td>–0.179</td>
<td>–0.327*</td>
</tr>
</tbody>
</table>

**p<0.01, *p<0.05.

Table 4. Our Draft of the Classification of the Severity of Idiopathic Interstitial Pneumonia

<table>
<thead>
<tr>
<th>Previous severity</th>
<th>SpO2&lt;90% during exercise</th>
<th>%VC&lt;70%</th>
<th>Our draft</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (PaO2 ≥ 80 Torr)</td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>II (80 &gt; PaO2 ≥ 70)</td>
<td></td>
<td></td>
<td>II</td>
</tr>
<tr>
<td>III (70 &gt; PaO2 ≥ 60)</td>
<td></td>
<td></td>
<td>III</td>
</tr>
<tr>
<td>IV (60 &gt; PaO2)</td>
<td></td>
<td></td>
<td>IV</td>
</tr>
</tbody>
</table>

Discussion

The classification of the severity of IIP is unique. This classification was established to determine the object range in the national research business on treatment for specific diseases (2). In Europe and the United States, the clinical-radiological-physiologic (CRP) score, which is evaluated from clinical findings, thoracic imaging findings, and lung function findings (5), and the composite physiologic index (CPI) score, which is evaluated from lung function findings, have been established to predict the prognosis of IPF and indicate lung transplantation (6); however, these scores are not routinely used. This may be because the CRP score is complex, and because the formula for calculating the CPI score is difficult. In this respect, the classification in Japan is simple, and may be commonly used.

The previous classification of the severity of IIP in Japan was established based on the finding that resting PaO2 was associated with the prognosis of IIP (7); however, the new classification was established considering hypoxemia during exercise. A recent study reported that hypoxemia during exercise was associated with the prognosis of IIP (8). In patients with IIP, dyspnea on effort is often observed; in particular, this disorder is marked in patients with IPF. In this study, we investigated whether the new severity classification involving desaturation during exercise reflected QOL.

In previous studies, the SF-36 and WHOQOL-100 questionnaires regarding general health-related QOL and the St. George respiratory questionnaire (SGRQ), which is specific to the disease, were useful for evaluating QOL for patients with IPF, although there is no IPF-specific questionnaire regarding QOL (9–11). In this study using the SF-36 questionnaire, scores for the 7 items, excluding BP, in the patients with IPF were lower than the Japanese national reference values, suggesting the reduction of physical and mental QOL. These items were correlated with %VC, and some items were correlated with %DLco. However, these items were not correlated with LDH or KL-6. In rank correlation with the classification of severity, the correlation coefficient with the new severity classification (draft) was higher than that with the previous severity classification; however, only 3 items were correlated, suggesting that the two classifications are not satisfactory with respect to QOL.

Therefore, we prepared an original draft based on the two classifications. Initially, in the new classification, desaturation during exercise is considered in grade-II or higher patients; however, we also investigated desaturation during exercise in grade-I patients, because based on our experience, the PaO2 value during exercise is often decreased to less than 60 Torr despite a resting PaO2 value of 80 Torr or more, in patients with IPF. Since there was a correlation between %VC (a parameter of lung function) and each parameter in the SF-36 questionnaire, %VC < 70% was added as an item. With this draft, 7 of the 8 items were correlated with QOL (rank correlation).

These results suggest that the reduction of SpO2 during exercise and %VC are important with respect to QOL, as demonstrated for resting PaO2. Recently, it has been reported that both VC at baseline and the rate of serial decrease in VC were prognostic factors for IPF (12–14). One of indicators of longer survival among patients with IPF was shorter symptomatic period (≤ 1 yr) with less dyspnea, relatively preserved lung function. However, QOL itself was not mentioned as a...
factor of prognosis in the ATS/ERS consensus statement (3).
As a future issue, a multi-center study should be conducted, as the results of this study were obtained from a small number of patients in a single hospital. In addition, it should be investigated whether or not our draft reflects the prognosis.

References