The Influence of an Inhaled Steroid on Quality of Life in Patients With Asthma or COPD

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Relatively little is known about the influence of inhaled corticosteroids on general well-being (quality of life) in patients with asthma or COPD. In a 4-year prospective controlled study, we examined the influence of beclomethasone dipropionate (BDP), 400 μg, two times daily, on quality of life in 56 patients with asthma or COPD in comparison with the effects of BDP on symptoms and lung function. During the first 2 years, patients received only bronchodilator therapy with salbutamol or ipratropium bromide. During the third and fourth years, additional treatment with BDP was given. Fifty-six patients (28 with asthma, 28 with COPD) with an annual decline in the forced expiratory volume in 1 s (FEV₁) of at least 80 mL/yr in combination with at least two exacerbations per year during bronchodilator therapy alone participated. Quality of life was assessed at the start and after 2 and 4 years by means of the Inventory of Subjective Health (ISH) and the Nottingham Health Profile (NHP). Although BDP significantly improved the course of lung function (FEV₁) (p<0.0001), it did not improve the ISH score or the six dimensions of the NHP neither in asthma nor in COPD. Beclomethasone dipropionate temporarily decreased respiratory symptoms during months 4 to 6 of BDP treatment in patients with asthma (p<0.01) and during months 7 to 12 in patients with COPD (p<0.05). A weak correlation was found both cross-sectionally and longitudinally between (change in) symptoms and quality of life on the one hand, and the (change in) FEV₁ on the other. It was concluded that BDP did not improve the general well-being of patients with asthma or COPD as measured by these generic health instruments. However, BDP significantly improved the course of lung function and temporarily decreased the severity of symptoms. It seems probable that changes in quality of life would have been better detected by use of a disease-specific health instrument. Such an instrument was not available at the start of the study. Another possible explanation for these observations is that patients soon get used to different levels of lung function and learn to live with their disease. It is advised that disease-specific health instruments are used in future intervention studies and that quality of life is measured frequently during the early phase of the intervention, eg, once every month.

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Key words: asthma; beclomethasone dipropionate; COPD; inhaled corticosteroid; quality of life

T
reatment with inhaled corticosteroids has become increasingly important in asthma and (to a smaller degree) in COPD.1-4 Airway inflammation is an important pathophysiologic mechanism in asthma and perhaps also in COPD.5,6 Several short-term studies during some months7-10 and a few long-term studies during 1 or 2 years11-13 in asthma have shown that inhaled steroids are able to improve lung function, nonspecific bronchial responsiveness, symp-

toms, exacerbations, and can reduce the need for bronchodilator therapy. There is less unanimity about the effects of corticosteroids in patients with COPD.14 A meta-analysis of short-term studies with systemic corticosteroids,15 a recent short-term trial,3 and a retrospective long-term study4 suggested that corticosteroids are potentially beneficial in COPD.

To our knowledge, no controlled studies have been published on the effects of inhaled steroids on quality of life in patients with asthma or COPD. Recently, in an uncontrolled study, Juniper et al16 showed that quality of life was improved in patients who responded to an inhaled steroid. It is generally agreed that improving the health of patients is an important goal of therapeutic intervention.17

Patients with asthma and COPD may suffer from
breathlessness, exercise limitation, anxiety and depression, and problems related to social activities. The quality of life in patients with asthma or COPD was worse than in subjects of the general population. However, cross-sectional relationships between objective measurements of the severity of the disease (as forced expiratory volume in 1s (FEV1)) and quality of life have been shown to be poor, even when disease-specific questionnaires are used. As quality of life is an important outcome measurement for the patients themselves, it is important to know whether treatment with inhaled corticosteroids not only improves the clinical outcome measures of asthma or COPD but also the quality of life of patients with these diseases.

We studied the influence of an inhaled corticosteroid (beclomethasone dipropionate, BDP) on the quality of life in 56 patients (28 with asthma, 28 with COPD) in a prospective controlled study. The influence of BDP on quality of life was compared with the effects on symptoms and lung function. We did not use disease-specific questionnaires as these instruments were not available at the start of the study.

METHODS

Patients

Fifty-six patients (28 with asthma, 28 with COPD) with an annual decline in FEV1 of at least 80 mL/yr in combination with at least two exacerbations per year participated in this 4-year study. The criteria for diagnosis of asthma or COPD were based on the standards of the American Thoracic Society. The study was approved by the Medical Ethics Committee of the University of Nijmegen. All patients gave informed consent.

Study Design and Treatment

At the start of the 4-year intervention study, the patients were randomly allocated to one of the two parallel treatment regimens: continuous (four times daily) or on demand (only dry powder inhalations during periods of complaints) bronchodilator therapy. In the third and fourth year, the 56 patients were additionally treated with BDP, 400 µg, two times daily. Outcome measures during treatment with bronchodilators alone (first 2 years) were compared with those during additional BDP therapy (third and fourth years of study) in a self-controlled design, which is known to produce equally valid results as the parallel study design.

Measurements

Baseline Characteristics: At the start of the study, smoking behavior, allergy, lung function (FEV1 and FEV1/inspiratory vital capacity (IVC)), reversibility, diurnal peak-flow rate index, and bronchial responsiveness to histamine were assessed.

Reversibility was assessed by the increase in FEV1, 1 h after the administration of salbutamol, 400 µg, and ipratropium bromide, 80 µg, and it was expressed as a percentage of the predicted value of FEV1. The diurnal peak-flow rate index was determined by the absolute difference between the weekly measured evening and morning peak flow (same day and time of day) divided by the highest value of that day for a period of 4 weeks. Bronchial responsiveness to histamine was measured according to the method of Cockcroft et al and expressed as the provoking concentration of histamine that produced a 20% fall in FEV1 (PC20 value).

Outcome Measures: Quality of life was measured by completing two questionnaires, viz., the Dutch version of the Nottingham Health Profile (NHP) and the Inventory of Subjective Health (ISH). The NHP is a generic, self-administered questionnaire designed to measure perceived physical, emotional, and social health problems. The emphasis is on the respondent’s subjective perception of his or her health status. The NHP contains 38 statements relating to 6 dimensions: physical mobility (6 statements), pain (8 statements), social isolation (5 statements), emotional reactions (9 statements), energy (3 statements), and sleep (5 statements). The statements were taken from interviews with patients suffering from various acute or chronic diseases, and from other health questionnaires like the Sickness Impact Profile. All statements are formulated in such a way that they can be answered by yes or no. McKenna et al derived the weights from a sample of both patients and healthy subjects using Thurstone’s method of perceived health problems. Separate NHP dimension scores are presented as a profile, not integrated into an overall score. Although the NHP was originally developed as a survey instrument to measure perceived health status in a population, it has been used extensively in evaluation studies and is claimed to be sensitive to change in disease severity. The NHP has proved to be reliable and can be administered easily, with small demands on patient time and effort. The higher the score, the more physical complaints are reported. The ISH is a generic, commonly used Dutch scale that contains 21 questions related to subjective physical complaints like tiredness, chest and heart problems, gastric problems, indigestion, headache, etc. Most complaints can be grouped according to the organ system to which they are referred. The remaining ones relate to the overall physical condition. The ISH statements were taken partly from the Cornell Medical Index and completed with statements from expert-interviews about the influence of physical stress on health. The internal consistency and reliability of the ISH are strong and answers do not appear to be influenced by social desirability. The overall ISH score is made up by the number of affirmative answers. The more physical complaints are reported, the higher the score. Quality of life was assessed at the start and after 2 and 4 years of study.

Respiratory symptoms were assessed by means of two questionnaires. First, the questionnaire of the Medical Research Council (MRC) (Dutch version) was used at the start and after 2 and 4 years of study. A total score (MRC-symptom score) of 0 to 8 was determined from the answers to eight different questions. Second, patients made weekly recordings of severity of cough, phlegm, and dyspnoea on a scale of 0 to 4. The separate scores together made up the total symptom score.

The FEV1 was assessed by means of the Microspiro HI-298 (Chest Corporation, Japan).

Analysis

No period or carryover effects were present in this self-controlled trial. Regression-to-the-mean appeared to explain only a small, negligible part of the improvements in FEV1 during BDP therapy.

The annual decline in FEV1 during bronchodilator therapy alone was estimated by linear regression of FEV1 in the course of time. Because of a nonlinear change in FEV1 during BDP treatment, the FEV1 values at the end of BDP treatment were compared with those at the start. The changes in the quality of life scores before and during BDP treatment were statistically compared by the Wilcoxon matched-pairs signed-ranks test (because the distribution was not normal), changes in FEV1 by the unpaired Student’s t test. Correlations between the change in quality of life and MRC-score on the one hand and the change in
Table 1—Clinical Characteristics of the Patients With Asthma and COPD at the Start of the 4-Year Intervention Study*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Asthma</th>
<th>COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>Age, yr</td>
<td>49 (12)</td>
<td>52 (10)</td>
</tr>
<tr>
<td>Sex, M/F</td>
<td>12/16</td>
<td>16/12</td>
</tr>
<tr>
<td>Pack-years</td>
<td>18 (14)</td>
<td>23 (17)</td>
</tr>
<tr>
<td>Smokers, ±</td>
<td>14/14</td>
<td>19/9</td>
</tr>
<tr>
<td>Cigarettes/day</td>
<td>4.2 (6.7)</td>
<td>10.0 (9.2)</td>
</tr>
<tr>
<td>Allergy, ±</td>
<td>4/14</td>
<td>0/4/24</td>
</tr>
<tr>
<td>FEV1, % pred</td>
<td>67 (17)</td>
<td>70 (16)</td>
</tr>
<tr>
<td>FEV1/IVC, %</td>
<td>57 (16)</td>
<td>63 (18)</td>
</tr>
<tr>
<td>Reversibility FEV1, % pred</td>
<td>14 (9)</td>
<td>7 (4)</td>
</tr>
<tr>
<td>Diurnal PEFR index, %</td>
<td>12 (8)</td>
<td>9 (5)</td>
</tr>
<tr>
<td>PC2O2 (mg/mL)</td>
<td>0.81</td>
<td>6.2</td>
</tr>
<tr>
<td>MRC symptom score</td>
<td>4.9 (1.8)</td>
<td>5.5 (1.7)</td>
</tr>
<tr>
<td>NHP score</td>
<td>6.3 (4.6)</td>
<td>9.5 (4.6)</td>
</tr>
</tbody>
</table>

* Differences between asthma and COPD were statistically compared by the unpaired Student’s t test for normally distributed variables, the $\chi^2$ test for dichotomous variables, and the Mann-Whitney U test for continuous not-normally distributed variables. SD between parentheses.

p<0.05.

p<0.001.

Allergy was defined as at least one positive test out of seven RAST.

§§IVC=inspiratory vital capacity.

PEFR=peak expiratory flow rate.

FEV1 on the other were calculated both before and during BDP therapy (longitudinal analysis). Besides, correlations among quality of life, symptoms, and lung function were assessed cross-sectionally (between-patient analysis).

Clinical characteristics of asthmatics and patients with COPD were statistically compared by the unpaired Student’s t test for normally distributed variables, the $\chi^2$ test for dichotomous parameters, and the Mann-Whitney U test for continuous, not normally distributed variables.

RESULTS

Baseline Characteristics

At the start of the 4-year study, asthmatics were characterized by less past and current smoking, a higher percentage of allergy, a higher reversibility, and a more severe bronchial hyperresponsiveness than patients with COPD (Table 1). Quality of life as assessed by the ISH score was worse in patients with asthma than in patients with COPD (Table 1).

Of the 56 patients, 48 completed treatment with BDP. Reasons for dropping out were as follows: refusal to use corticosteroids (one with asthma, one with COPD); bronchial carcinoma (one with COPD); chronic heart failure (one with COPD); persistent oral candidiasis and dysphonia (two with COPD); and personal (nonmedical) reasons (one with asthma, one with COPD).

Quality of Life of Study Population in Comparison With a Random Sample of the Population

Compared with data in the general population, quality of life at the start of our study appeared to be impaired in the asthmatics and patients with COPD (Fig 1). With the exception of the emotional reaction score and the sleep score of the NHP, the quality of life scores in our patients with asthma or COPD were, on average, two to three times higher than in the general population (Fig 1).

The influence of BDP on Quality of Life, Symptoms, and Lung Function

In Table 2, the changes in quality of life, MRC-symptom score, and FEV1 during the 2-year study period before the use of BDP and during BDP treatment are shown. No significant changes in the quality of life and symptom scores were found in patients with asthma either before treatment with BDP or during BDP therapy (all p values >0.17) (Table 2). Also, when the changes in quality of life scores before BDP treatment were compared with those during BDP therapy, no significant improvements were observed in patients with asthma (all p values >0.48). In patients with COPD, however, the MRC symptom score, the emotional reaction score, and the social isolation score of the NHP improved significantly before BDP treatment despite a substantial worsening of the FEV1 (Table 2). During BDP therapy, no significant changes in quality of life were found in patients with COPD.

In patients with asthma, the severity of weekly recorded symptoms showed a decrease of 17% during the first 3 months of treatment with BDP compared with the period before BDP was given (p<0.01) (Fig 2). During the rest of the treatment period, no significant improvements were found for the weekly symptom score. In patients with COPD, the severity of weekly recorded symptoms was only significantly reduced during months 7 to 12 of BDP treatment (13%, p<0.05) (Fig 2).

Both in patients with asthma and COPD, the course of lung function improved by BDP treatment. The FEV1 deterioration of —160(SEM 20) mL/yr before BDP differed from the change of +10(23) mL/yr during BDP (paired Student’s t test, p<0.0001). This effect was more evident in asthmatics (—173 vs +38 mL/yr) than in patients with COPD (—146 vs −23 mL/yr).
**Longitudinal Correlation Between the Change in Quality of Life or Symptoms and the Change in Lung Function**

In general, there was only a weak correlation within patients between the change in quality of life or MRC symptom scores on the one hand and the change in FEV₁ on the other, both in asthma and COPD (Table 3). The only statistically significant findings were those of the energy score of the NHP. In patients with asthma, the change in the energy score was related to the change in FEV₁ during bronchodilator therapy alone (r=0.44, p<0.05). In patients with COPD, the change in energy score was related to the change in FEV₁, during additional BDP treatment (r=-0.46, p<0.05).

**Cross-Sectional Correlation Among Quality of Life, Symptoms, and Lung Function**

When the quality of life and MRC symptom scores were related to the FEV₁ at the start, after 2 and af-

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**Table 2—Changes in Quality-of-Life Scores, MRC Symptom Scores, and Lung Function Before and During the Use of BDP**

<table>
<thead>
<tr>
<th></th>
<th>Before BDP</th>
<th>p</th>
<th>During BDP</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change in</td>
<td></td>
<td>Change in</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISH</td>
<td>-0.27 (0.49)</td>
<td>0.59</td>
<td>-0.68 (0.66)</td>
<td>0.31</td>
</tr>
<tr>
<td>NHP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td>+5.5 (4.0)</td>
<td>0.18</td>
<td>+0.4 (4.8)</td>
<td>0.94</td>
</tr>
<tr>
<td>Pain</td>
<td>-1.5 (3.4)</td>
<td>0.66</td>
<td>+0.5 (2.5)</td>
<td>0.85</td>
</tr>
<tr>
<td>Emotional reaction</td>
<td>+1.2 (4.2)</td>
<td>0.78</td>
<td>+0.2 (3.1)</td>
<td>0.94</td>
</tr>
<tr>
<td>Sleep</td>
<td>-0.10 (3.8)</td>
<td>0.98</td>
<td>-3.0 (3.7)</td>
<td>0.43</td>
</tr>
<tr>
<td>Social isolation</td>
<td>+2.7 (4.1)</td>
<td>0.51</td>
<td>+0.5 (3.1)</td>
<td>0.87</td>
</tr>
<tr>
<td>Physical mobility</td>
<td>+4.3 (3.0)</td>
<td>0.17</td>
<td>+0.5 (2.5)</td>
<td>0.84</td>
</tr>
<tr>
<td>MRC symptom score</td>
<td>+0.12 (0.37)</td>
<td>0.75</td>
<td>+0.24 (0.31)</td>
<td>0.45</td>
</tr>
<tr>
<td>FEV₁ mL/yr</td>
<td>-173 (22)</td>
<td>0.0001</td>
<td>+38 (30)</td>
<td>0.22</td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISH</td>
<td>+1.2 (0.6)</td>
<td>0.065</td>
<td>-1.3 (0.9)</td>
<td>0.18</td>
</tr>
<tr>
<td>NHP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td>+6.8 (4.9)</td>
<td>0.18</td>
<td>-3.4 (6.1)</td>
<td>0.59</td>
</tr>
<tr>
<td>Pain</td>
<td>+2.0 (5.1)</td>
<td>0.69</td>
<td>-6.7 (4.7)</td>
<td>0.18</td>
</tr>
<tr>
<td>Emotional reaction</td>
<td>+7.3 (2.5)</td>
<td>0.01</td>
<td>-2.4 (2.4)</td>
<td>0.34</td>
</tr>
<tr>
<td>Sleep</td>
<td>-2.6 (4.3)</td>
<td>0.55</td>
<td>-0.8 (7.3)</td>
<td>0.91</td>
</tr>
<tr>
<td>Social isolation</td>
<td>+4.4 (2.0)</td>
<td>0.04</td>
<td>-0.3 (3.6)</td>
<td>0.94</td>
</tr>
<tr>
<td>Physical mobility</td>
<td>+1.1 (2.4)</td>
<td>0.84</td>
<td>-2.2 (2.4)</td>
<td>0.38</td>
</tr>
<tr>
<td>MRC symptom score</td>
<td>+1.14 (0.40)</td>
<td>0.009</td>
<td>-0.25 (0.33)</td>
<td>0.46</td>
</tr>
<tr>
<td>FEV₁ mL/yr</td>
<td>-146 (36)</td>
<td>0.0006</td>
<td>-23 (35)</td>
<td>0.52</td>
</tr>
</tbody>
</table>

*SEM between parentheses. A negative change in quality of life and MRC score implies a deterioration; a positive sign, an improvement.
that BDP significantly improved the course of lung function, while there was no evidence that the quality of life measured by generic instruments was changed. BDP diminished the severity of symptoms only significantly for some months during the first year of BDP treatment. During the rest of the treatment period, no influence on symptoms was found either in the weekly recorded symptom score or in the 2-yearly measured MRC symptom score. The substantial decline in lung function with bronchodilator therapy alone was not accompanied by a significant worsening of quality of life in this period. In fact, some of the scores even improved significantly in this part of the trial in patients with COPD. This may be explained by an “in care” effect because of participation in the trial. All these findings together may suggest that patients soon get used to different levels of airway obstruction and learn to live with their disease. Their perception of the severity of their disease may be limited.17 Perhaps we could have found a positive effect of BDP on quality of life if we had measured this variable frequently in the first year of BDP, like for symptoms. It seems advisable that quality of life is measured frequently during the early phase of the intervention, e.g., once every month.

Apart from the frequency, there is some reason to doubt that generic health instruments as NHP and ISH are able to detect changes in quality of life of patients with asthma. In the present study, these instruments have been shown to be able to detect an impaired subjective well-being when compared with the general population. Comparable observations

Table 3—Correlation Between the Changes in Quality of Life Scores, the MRC Symptom Scores, and the Changes in FEV1 Before and During the Use of BDP (Within-Subject Analysis)

<table>
<thead>
<tr>
<th></th>
<th>Before BDP</th>
<th>p</th>
<th>During BDP</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISH</td>
<td>+0.11</td>
<td>0.59</td>
<td>-0.33</td>
<td>0.10</td>
</tr>
<tr>
<td>NHP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td>+0.44</td>
<td>0.023</td>
<td>+0.11</td>
<td>0.60</td>
</tr>
<tr>
<td>Pain</td>
<td>-0.07</td>
<td>0.72</td>
<td>-0.02</td>
<td>0.91</td>
</tr>
<tr>
<td>Emotional reaction</td>
<td>+0.35</td>
<td>0.076</td>
<td>-0.34</td>
<td>0.066</td>
</tr>
<tr>
<td>Sleep</td>
<td>-0.34</td>
<td>0.09</td>
<td>+0.26</td>
<td>0.20</td>
</tr>
<tr>
<td>Social isolation</td>
<td>+0.30</td>
<td>0.14</td>
<td>-0.17</td>
<td>0.42</td>
</tr>
<tr>
<td>Physical mobility</td>
<td>+0.35</td>
<td>0.077</td>
<td>+0.20</td>
<td>0.34</td>
</tr>
<tr>
<td>MRC symptom score</td>
<td>-0.06</td>
<td>0.75</td>
<td>+0.23</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISH</td>
<td>-0.19</td>
<td>0.39</td>
<td>-0.14</td>
<td>0.57</td>
</tr>
<tr>
<td>NHP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td>-0.18</td>
<td>0.41</td>
<td>-0.46</td>
<td>0.039</td>
</tr>
<tr>
<td>Pain</td>
<td>-0.05</td>
<td>0.81</td>
<td>-0.23</td>
<td>0.33</td>
</tr>
<tr>
<td>Emotional reaction</td>
<td>+0.11</td>
<td>0.63</td>
<td>-0.18</td>
<td>0.44</td>
</tr>
<tr>
<td>Sleep</td>
<td>-0.20</td>
<td>0.22</td>
<td>-0.15</td>
<td>0.54</td>
</tr>
<tr>
<td>Social isolation</td>
<td>-0.22</td>
<td>0.32</td>
<td>+0.18</td>
<td>0.44</td>
</tr>
<tr>
<td>Physical mobility</td>
<td>+0.30</td>
<td>0.18</td>
<td>-0.03</td>
<td>0.89</td>
</tr>
<tr>
<td>MRC symptom score</td>
<td>-0.04</td>
<td>0.55</td>
<td>+0.32</td>
<td>0.14</td>
</tr>
</tbody>
</table>
were done in other studies with patients with hyper­tension, myocardial infarction, coxarthrosis, stroke and asthma. However, this does not mean that these instruments are able to detect differences in quality of life of asthmatic patients during, for example, a therapeutic intervention. It was recently shown that the Sickness Impact Profile (a generic questionnaire with partly the same questions as the NHP) could not detect changes in quality of life, while a more specific questionnaire could detect differences. Similar observations were done in other recent studies. A disease-specific health instrument has the advantage of covering specific aspects of the clinical disorder under study that are not relevant for a generic well-being scale. Examples of disease-specific quality of life scales of asthma or COPD have only recently become available and experience with these scales is therefore limited. Unfortunately, disease-specific questionnaires were not available at the start of the present study.

A comparison of the ISH and NHP scores in our patients with asthma and COPD with data from the general population revealed that patients experience their disease as important for their general well-being. Quality of life seemed impaired in patients with asthma and COPD when compared with the general population, although this simple comparison must be interpreted with caution. Most of the quality of life scores were two to three times higher in the patients of this study than in samples of the general population. Patients with asthma or COPD may suffer from breathlessness, exercise limitation, anxiety and depression, and problems related to social activities. Quality of life may be more disturbed in patients with COPD than in asthmatics. In our study, quality of life as assessed by the ISH was worse in patients with COPD than in patients with asthma. This difference was not found for the six dimensions of the NHP. In patients with COPD, obstruction as well as respiratory complaints are of a sustained, chronic character. In patients with asthma, the degree of airflow limitation varies considerably in the course of time and symptom-free intervals may alternate with periods of cough, wheezing, and dyspnea. The ISH is particularly directed at chronic physical complaints and it is therefore logical that patients with COPD had a higher ISH score than asthmatics.

We investigated the correlation between the quality of life scores, MRC symptom score and the FEV₁ both cross-sectionally and longitudinally. In asthma as well as in COPD, the correlations between lung function and quality of life scores were weak with only two (opposite) significant correlations for the energy score of the NHP. In general, correlations within subjects (longitudinal analysis) were slightly higher than between subjects (cross-sectional analysis). Many other studies found a low correlation between all kinds of quality of life scales and the lung function level. It has been suggested that the attitude to health or disease interferes with the relation between lung function and the results of psychometric tests. This general attitude toward health or disease may be the reason that a lower lung function level is not necessarily accompanied by a lower experienced quality of life.

We conclude that treatment with BDP (in comparison with bronchodilator treatment alone) did not improve the general well-being of patients with asthma or COPD as measured by generic instruments despite a positive influence of BDP on the course of lung function and a temporary reduction in severity of symptoms in these diseases. Neither the substantial decline in lung function during bronchodilator therapy alone nor the improvement in the course of lung function during BDP therapy was accompanied by corresponding changes in the generic quality of life scores. An explanation for these findings may be the disability of the generic instruments to detect differences and that patients soon get used to different levels of lung function and learn to live with their disease. We recommend that quality of life in future intervention studies is measured by disease-specific health instruments. During the early phase of the intervention, quality of life must be measured frequently, eg, once every month.

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