Rhinitis, rhinosinusitis and quality of life in children

Respiratory allergy (allergic rhinitis and asthma) is a high-prevalence disease that affects an average of 10–15% of the general population (1). Thus, allergic asthma and rhinitis are probably the most common immune-mediated disorders. The prevalence of respiratory allergy, especially rhinitis, is constantly increasing, as clearly demonstrated by large population-based epidemiological studies. The reason for the increasing prevalence is still a matter of debate and some intriguing hypotheses (including the ‘hygiene hypothesis’) have been proposed (2, 3). What is clear is that a dysregulation of the immune response occurs in respiratory allergy, depending on numerous factors (i.e. genetic background, maternal factors, infections, environment) (4). This is the reason why an integrated therapeutic approach is unanimously proposed (5). In particular, some drugs such as antihistamines and topical steroids are highly effective in controlling symptoms and inflammation, whilst immunotherapy affects the response to allergens in the early stages (6).

In parallel to the development of the basic knowledge and of therapeutic strategies, it has become progressively clear that allergic rhinitis can alter the self-perceived health status, pose limitations in everyday activities and affect the working and school productivity (7, 8). As a consequence, a new classification of rhinitis, essentially based on the duration of the disease and its impact on the well-being, was proposed. The inflammatory involvement of the mucosa of paranasal sinuses (infectious or not) is almost always associated with rhinitis (dysfunction of the ostiomeatal complex), so the term rhinosinusitis has been proposed as the most accurate, and nasal polyposis has been included in this category as well (9).
The operational definition of rhinosinusitis includes some typical symptoms (congestion, nasal discharge, facial pressure/pain, loss of smell) plus the endoscopic or tomographic evidence of polyps, ostiomeatal discharge or involvement of the sinusal mucosa. Rhinosinusitis is conventionally termed as chronic for a duration >12 wk.

The self-perceived effects of an illness on well-being are encompassed by the term quality of life (QoL) (10). QoL has rapidly been recognized as a crucial parameter for evaluating diseases and treatments themselves. Numerous ‘instruments’ (questionnaires) to measure the impact of a given disease (including respiratory allergy) have been developed and validated in recent years, and more and more attention is currently paid to this aspect in clinical trials.

What is QoL and how do we measure it?

QoL (or better health-related quality of life, HRQL) is ‘the functional effects of an illness and its therapy upon a patient, as perceived by the patient himself’ (11). It is easy to understand that such a definition covers a broad spectrum of subjective aspects of illness, and that QoL is at least in part independent of specific symptoms of a disease. In fact, assessing the patient’s subjective point of view offers a more comprehensive description of the impact of the disease and its therapy on everyday life (12). This is of special relevance in patients suffering from chronic diseases, when the primary goal of treatment is to achieve the highest level of well-being.

It can be stated that ‘physicians measure and patients perceive.’ While health status is defined by physicians, usually by means of objective measures, the impact of a disease on QoL is assessed by the patient himself by means of questionnaires (more properly defined ‘instruments’), composed by a variable number of questions (or ‘items’). Depending on the purpose of the evaluation, two types of instruments can be used: generic or specific questionnaires. Generic questionnaires are applicable to all health conditions, and therefore, they allow a comparison of patients suffering from different diseases as well as ill and healthy subjects. There are several validated generic questionnaires (13–17) (Table 1) and, among them, the most widely used in patients with respiratory allergy are the expanded and brief versions of the Medical Outcome Study Short Form (known as SF-36, SF-20 and SF-12). Specific questionnaires are restricted to a particular disease or to a specific function (e.g. sexuality) or problem (e.g. pain). At variance with generic questionnaires, the specific ones explicitly consider the symptoms or the limitations of a given disease. Thus, these tools do not allow comparison between different diseases, but are very useful to evaluate the same patients at different times (e.g. before and after treatment). Numerous instruments are currently available to evaluate the HRQL in rhinitis and asthma, as summarized in table 2.

Despite the simplicity of the concept of QoL, the development and the validation process of a questionnaire is a matter of great complexity, where numerous statistical, ethical and methodological problems must be solved (18). Moreover, once a questionnaire has been prepared, it must be tested for reproducibility, consistency and validity (19, 20) in large samples of patients.

### Rhinosinusitis and quality of life in children

The history of HRQL in the field of respiratory allergy (and allergic diseases, in general) is chronologically brief but the literature is quite rich, thus testifying to the interest in this topic (21, 22). Since the introduction of the first rhinoconjunctivitis questionnaire (23), many instruments have been validated and standardized for measuring HRQL in children, adolescents and adults with rhinitis (or asthma) (24–31) as summarized in Table 2. Of note, the pediatric versions of the questionnaires are constructed to be completed either by parents or the children themselves, according to age (26, 30). In the last years, it has become clear that allergic rhinitis and asthma are strictly associated and represent two clinical aspects of a unique immunologic disorder (32). Based on this observation, a specific instrument

### Table 1. Generic questionnaires

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Author</th>
<th>No. of items</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical outcome study. Short Form 36 (SF-36)</td>
<td>Ware</td>
<td>36</td>
<td>Med Care 1992: 30: 473–83</td>
</tr>
<tr>
<td>Sickness impact profile (SIP)</td>
<td>Bergner</td>
<td>136</td>
<td>Med Care 1981: 19: 787</td>
</tr>
<tr>
<td>Nottingham health profile (NHP)</td>
<td>Hunt</td>
<td>45</td>
<td>J Epidemiol Comm Health 1980: 34: 281</td>
</tr>
<tr>
<td>15-D health-related Qol</td>
<td>Sintonen</td>
<td>15</td>
<td>Ann Med 2001: 33: 328</td>
</tr>
<tr>
<td>Satisfaction profile (SAT-P)</td>
<td>Majani</td>
<td>32</td>
<td>Int J Ment Health 1999: 28: 77</td>
</tr>
</tbody>
</table>
designed for patients with comorbid rhinitis and asthma was also introduced to explore the impact of both diseases (33).

Many clinical trials confirmed that the impact of rhinitis on QoL in adults and children is real and measurable (34–37) with both generic and specific instruments. This is not surprising if we look at the disease from the patient’s point of view. From a subjective perspective, patients with allergic rhinitis experience troublesome nasal symptoms (i.e. rhinorrea, congestion, sneezing, and itching) and have frequently associated ocular signs and symptoms (i.e. redness, itching, puffy leads, tearing), headache, fatigue and lack of concentration. As a result, many patients refer problems in physical activities, sleep, mood, and social relationship. Allergic rhinitis/asthma has been shown to reduce working ability in adults (38, 39), also in children the learning is impaired and school performance is globally reduced (40, 41). This effect of rhinitis on learning is because of a direct interference of symptoms and, indirectly, to sleep disturbance and consequent daily fatigue. Concerning rhinosinusitis, there are few QoL instruments, such as the Rhinosinusitis Disability Index (42), a five-item instrument designed for children with sinonasal symptoms (43) and another recent specific questionnaire, which was reported to perform well also in acute disease (44). Overall, the data on QoL in rhinosinusitis (45, 46) are noticeably few with respect to allergic rhinitis. This is probably because of the fact that rhinosinusitis is often an acute infectious event and less frequently it is chronic and long-lasting. Anyway, these studies consistently showed that rhinosinusitis also impairs self-perceived well-being in children (43, 47). Finally, data on the impairment of QoL are available also for nasal polyposis, which is typically a chronic condition (48).

The QoL questionnaires, both generic and specific, were also used to assess the effects of drugs and other treatments, and it was shown that an effective therapy of allergic rhinitis usually improve the health-related QoL (49–52). This is true also in the pediatric age, where several studies were conducted with leukotriene modifiers (53), topical steroids (54–56), antihistamines (57–59) and immunotherapy (60). All these studies also confirm that a proper treatment in children leads, in association with symptomatic improvement, to a better QoL. Concerning rhinosinusitis, there are few studies in children focusing on QoL, because the treatment of chronic sinusitis is essentially based on surgical approaches (61–63).

### Practical problems with QoL

After many years of studies with HRQL in allergic diseases, some interesting aspects have emerged. One of the most important observations is that QoL and clinical/objective measurements are not fully interchangeable. For instance, there are studies documenting a clinical or functional improvement induced by antihistamines or bronchodilators, not accompanied by detectable changes in the HRQL (64, 65). In other studies, the clinical evaluation did not discriminate between two different treatments whereas QoL did (66, 67). Thus, QoL scales measure something different from the classical measures (symptom scores, pulmonary function, nasal airway resistance) and should integrate those measure in clinical studies.

Another relevant methodological aspect is the choice between generic and specific instruments in clinical trials, as the two types of instruments measure different aspects (68). There are few

### Table 2. Specific questionnaires for rhinitis and asthma

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Author</th>
<th>Items</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini asthma quality of life questionnaire</td>
<td>Juniper</td>
<td>15</td>
<td>Eur Respir J 1999: 14: 32</td>
</tr>
<tr>
<td>Pediatric asthma quality of life</td>
<td>Juniper</td>
<td>23</td>
<td>Qual Life Res 1996: 5: 35–46</td>
</tr>
<tr>
<td>Life activities asthma questionnaire</td>
<td>Creer</td>
<td>72</td>
<td>J Asthma 1992: 29: 393</td>
</tr>
<tr>
<td>Rhinasthma</td>
<td>Baiardini</td>
<td>30</td>
<td>Allergy 2003</td>
</tr>
</tbody>
</table>
direct comparisons, and one of these, in chronic bronchitis, clearly favored the specific questionnaires (69). In the case of rhinitis, specific instruments seem to have better discriminative and evaluative properties (70) than the generic assessments and generic questionnaires may not be able to detect the impact of mild disease (71). On the other hand, generic questionnaires allow to compare different populations, and also ill and healthy subjects. To date, the best solution would be of using in association a generic and a specific questionnaire. Finally, QoL questionnaires explore the impact of diseases over long periods (not <2 wk). Therefore, the instruments may not be sensitive to rapid changes in health status, such as those induced by drugs.

Conclusions

Health-related quality of life has gained great attention and relevance in the field of respiratory allergy, as well as in most fields of clinical medicine. The impact of the disease (rhinitis and asthma) on well-being has been clearly documented, as well as the effects of the different treatments. Thus, it is universally agreed that HRQL should be included as mandatory supportive outcome in all clinical trials. This is particularly true for respiratory allergy that is often chronic and the effects of which can be appreciated by questionnaires. Surprisingly, there are few data on rhinosinusitis and QoL, whereas many trials, mainly in adults, evaluated QoL aspects in rhinitis and asthma. On the other hand, it has become also clear that HRQL cannot totally replace the traditional and objective outcomes, such as pulmonary function in asthma or symptom scores in rhinitis. Further data are needed on the QoL aspects, also related to treatment, in children.

Acknowledgments

This work has been partially supported by ARMIA (Associazione Ricerca Malattie Immunologiche e Allergiche).

Conflicts of interest

The authors have declared no conflicts of interest.

References


70. Juniper EF, Thorpmpson AK, Roberts JN. Can the standard gamble and rating scale be used to measure quality of life in rhinoconjunctivitis? Comparison with the RQLQ and SF-36 Allergy 2002: 57: 201–6.