Improvement in quality of life for patients with tree pollen-related rhinoconjunctivitis and asthma after ultra short course specific immunotherapy (uSCIT) Pollinex Quattro (PQ)

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Introduction

Seasonal allergic rhinitis and asthma have a major impact on quality of life (QoL) for affected individuals.[1,2] When treating these patients, it is therefore important to consider both the severity of symptoms and their effect on general well-being, and the ability to perform daily activities.

The Rhinoconjunctivitis and Asthma Quality of Life questionnaires (RQLQ and AQLQ, respectively)[3] provide the means for quantifying changes in these areas.

Objectives

The aim of this multicentre study was to evaluate the influence of tree-pollen uSCIT adjuvanted with monophosphoryl lipid A (MPL®) on QoL of patients with allergic rhinoconjunctivitis or rhinoconjunctivitis and asthma.

Methods

A total of 131 patients with tree pollen-related rhinoconjunctivitis or rhinoconjunctivitis and allergic asthma (53 patients) were enrolled into this multicentre trial. Inclusion criteria were a rhinoconjunctivitis severity score of ≥3 and an asthma severity score of 1 or 2

Baseline severity scores for rhinoconjunctivitis were derived from a questionnaire that asked subjects with rhinoconjunctivitis with or without concomitant asthma about the effects of their allergy symptoms in the previous pollen season.

The following QoL aspects were graded from 0 (not at all) to 3 (a great deal):

- impairment of daily activities (including sport and leisure)
- disturbance of work or school life
- the presence of troublesome symptoms
- impairment of normal sleep

Asthma severity was scored according to the German national asthma guidelines.[4]

Patients received four pre-seasonal uSCIT injections, containing a mixture of tree pollen allergoids and MPL. Injections were administered according to the standard schedule in four weekly doses of 300, 800, 2000, and 2000 standardized units.

RQLQs and AQLQs were completed by patients at three time points: before treatment (relating to the previous pollen season), during and at the end of the pollen season following treatment.

The timing and duration of the pollen season were determined by analysing the pollen count in a pollen trap in Treuenbrietzen. All but one of the study centres was located within close proximity of the pollen trap.

The Quality of Life Questionnaires

This version of the RQLQ and AQLQ[5] has been specifically adapted for use in the Bencard Allergie GmbH & Allergy Therapeutics Ltd study "Specific immunotherapy with Pollinex® Quattro" Interdisciplinary Study Group Treuenbrietzen/Potsdam.

The RQLQ

The RQLQ assessed QoL in relation to problems related to carrying out daily activities, sleep problems, non-nose and eye symptoms, practical problems, nasal symptoms, eye symptoms and emotional well-being. Each domain was graded from 0 (not troubled) to 6 (extremely troubled).

The AQLQ

In addition to questions on general symptoms, the AQLQ assessed QoL in relation to activities (strenuous, moderate, social, and workrelated), emotional well-being (for example, frustration as a result of asthma, fear of getting out of breath), and problems related to environmental factors, for example dust and air pollution. Global effects of treatment and adverse events were also recorded by the physician.

Overall scores

The overall scores for the change in RQoL and AQoL mid-season and end-of-season were derived from the subscores and represented the overall mean score of the questionnaires.

Results

Patients

Of the 131 patients enrolled in the trial, 127 completed the treatment. The median age of enrolled patients was 40 years (age range 10-72). Just over half (57%) of the patients were female.

The severity of rhinoconjunctivitis and asthma symptoms in enrolled patients at baseline is shown in Figures 1 and 2, respectively.

Figure 1. Severity of rhinoconjunctivitis at baseline

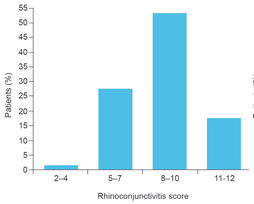
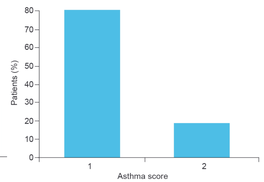


Figure 2. Severity of asthma at baseline



Tree pollen count

The pollen counts for May to June 2007 are shown in Figure 3.

Figure 3. Tree pollen count May - June 2007

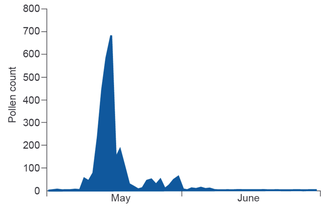
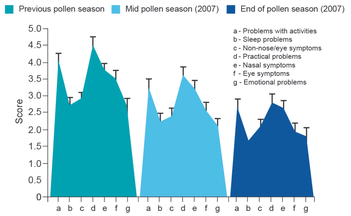


Figure 4. Change in rhinoconjunctivitis QoL subscores following uSCIT therapy

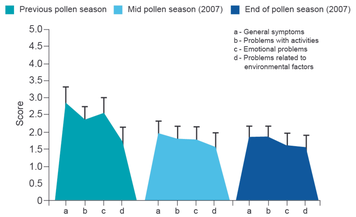


Efficacy

Change in quality of life

There was an improvement in the overall RQoL scores following treatment with uSCIT, with the mid-season score showing a reduction of 0.7 ($p < 0.0001$) and the end-of-season score a reduction of 1.2 ($p < 0.0001$).
The subscore analysis showed an improvement in all areas of the questionnaire as shown in Figure 4.
There was also an improvement in the overall AQoL scores following treatment with uSCIT, with the mid-season score showing a reduction of 0.7 ($p = 0.0012$) and the end-of-season score a reduction of 0.7 ($p = 0.0012$). The subscore analysis showed an improvement in all areas of the questionnaire as shown in Figure 5.

Figure 5. Change in asthma QoL subscores following uSCIT Therapy



Change in symptoms

The majority of patients with rhinoconjunctivitis (80.9%) and asthma (64.1%) experienced an improvement of their symptoms compared with the pollen season before treatment, as assessed by the physician, and reduced use of anti-allergy medication was reported by 42.7% of patients.

Safety

The reasons for stopping treatment were a lack of cooperation (2 patients), an intermittent illness (1 patient), and failing to attend the clinic at the appropriate times (1 patient).
Local adverse events were experienced by 28 patients (21.4%). Of the local adverse reactions reported, 86.4% were graded as mild or moderate.
Systemic reactions were experienced by four (3.1%) patients: rhinitis (mild), common cold (mild), itching around the mouth (mild), and dizziness. No serious and no anaphylactic reactions were reported.

Discussion

This multicentre study demonstrated a clear improvement in the overall scores in all QoL areas evaluated after treatment with pre-seasonal uSCIT.

There were also improvements in rhinoconjunctivitis and asthma symptoms, with 42.7% of patients needing less concurrent anti-allergy medication after treatment.

The level of patient acceptance of therapy was high and the number of adverse events recorded was low. No serious events or anaphylactic episodes were reported.

This study supports the use of pre-seasonal uSCIT in the treatment of seasonal allergic rhinitis and asthma, in terms of positive effects on quality of life, symptom relief, and a good safety and tolerability profile.

Conclusions

This multicentre study showed the efficacy and tolerability of preseasonal uSCIT with MPL-adjuvanted tree pollen allergoids.

The self-administered QoL questionnaires were demonstrated to be valid tools for efficacy and safety evaluation of uSCIT therapy.

Investigators and study centres

Dr E Benke (Brandenburg), Dr A Erdmann (Jüterbog), Dr A-P Erdmann (Luckenwalde), Dr G Fiedler (Weißenfels), Dr S Hofmann (Potsdam), Dr B Jasch (Rathenow), Dr U Kallien (Königs), Dr S Knuppe-Andree (Potsdam), Dr H-J Lüdcke (Potsdam), Dr K Lohse (Beelitz), Dr U Rabe (Treuenbrietzen), Dr J Hanfland (Bonn).

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