

ORIGINAL PAPER

Evaluation of the quality of life after individualized homeopathic treatment for seasonal allergic rhinitis. A prospective, open, non-comparative study

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Background: Quality of life (QoL) is an important outcome measure in the treatment of seasonal allergic rhinitis (SAR), a condition for which homeopathy is frequently used.

Objective: The assessment of the effect of homeopathic medical prescriptions with the Rhino-conjunctivitis Quality of Life Questionnaire (RQLQ) in the treatment of SAR.

Methods: A prospective, open, non-comparative study was conducted in Belgium. Patients aged between 14 and 68 years with SAR were treated by one of seven homeopathic physicians. Patients completed the RQLQ at baseline and again after three and four weeks of homeopathic treatment.

Results: Seventy-four patients were screened, of whom 46 met the study eligibility criteria (average age 36 years, 70% female). The mean RQLQ score at baseline was 3.40 (± 0.98). After three and four weeks of homeopathic treatment it had fallen to 1.97 (± 1.32) ($P = 0.0001$), and 1.6 (± 1.28) ($P = 0.0001$), respectively.

Conclusions: After homeopathic treatment, patients reported an alleviation of their symptoms of allergic rhinitis as reported in the RQLQ. A formal Randomized Clinical Trial (RCT) is indicated. *Homeopathy* (2009) 98, 11–16.

Keywords: homeopathy; allergic rhinitis; quality of life

Introduction

Allergic rhinitis is a global health problem, affecting between 10% and 40% of the world's population.^{1,2} In industrialized countries it is the most common allergic condition affecting about 20% of the population.³ The prevalence of hay fever (seasonal allergic rhinitis) has increased for many decades but appears to have stabilised in recent years.⁴ Current guidelines of the European Academy of

Allergy and Clinical Immunology (EAACI) Working Party on the Management of Rhinitis and Allergic Rhinitis and its Impact on Asthma (ARIA) initiative state that antihistamines are the first-line therapy for allergic rhinitis.^{5,6}

In a recent ARIA update on complementary and alternative medicine for rhinitis and asthma, homeopathy in rhinitis was described in good-quality trials. Passalacqua⁷ reported some positive results, but a number of negative studies were also found. Because of conflicting results, it is not possible to provide evidence-based recommendations for homeopathy in the treatment of allergic rhinitis, and further trials are needed.

Rationale for the study

In Germany and Switzerland allergic rhinitis is one of the most common diagnoses treated by homeopathic doctors.^{8,9}

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Allergic rhinitis is also a frequent reason for seeing a homeopathic doctor in Belgium, although allergic rhinitis is not so frequent in Belgian general practice (30th–40th place).¹⁰

Homeopathy can be divided into at least four different types, which should be differentiated in any discussion of the topic. In addition to isopathy (using a dilution of an allergen),* there are clinical homeopathy (using the same remedy for people with a similar condition), complex homeopathy (using fixed combinations of remedies for people with similar conditions) and individualized homeopathy, which are the most widely used approach for chronic diseases.¹¹ Central to the latter is a detailed description of the patient's physical, emotional, and mental symptoms,¹² used to make a correct homeopathic prescription. The result is that most patients receive different prescriptions even if their medical diagnosis is similar.

This pilot study was intended to evaluate the effect of an individualized homeopathic prescription in the treatment of seasonal allergic rhinitis (SAR) by means of the Rhino-conjunctivitis Quality of Life Questionnaire (RQLQ) after three and four weeks treatment. This study was originally considered as a preliminary to a Randomized Clinical Trial (RCT) comparing standard conventional therapy with homeopathy (non-inferiority study). The RCT was never performed because sponsorship was withdrawn.

Methods

Study design

This was an observational, prospective, open, non-comparative multicentre study conducted during the spring 2006 allergic rhinitis season. Eligible patients from seven general practitioners in Belgium were recruited. All recruiting physicians had at least 15 years experience of individualized homeopathy. The severity of the allergy-related symptoms was measured by means of the Total 5 Symptoms Score (T5SS). The T5SS score was used only as criteria for inclusion and not as an outcome measure. Patients completed the RQLQ at their initial visit and after three and four weeks of treatment with individualized homeopathy.

Patient population

Patients were eligible for the study if they were between 14 and 68 years of age with symptoms of SAR, a T5SS score of at least 6 out of 15 for the last 24 h or and a T5SS score of at least 15 out of 60 on four days during the last week. Additionally, one of the IgE RAST tests for pollen (trees, grasses and weeds) had to be positive.

Patients who used antihistamine drugs for the last 14 days were excluded. Patients with asthma requiring daily treatment with other drugs than an inhaled β -2-agonist on an "as required" basis were excluded.

All patients with allergic rhinitis who met the inclusion criteria were enrolled in the study.

*One sort of pollen or a mix of pollen is diluted and dynamised conform with the rules of Good Manufacture Practice (GMP) for homeopathy.

Instruments

Health-related Quality of Life (HRQL): The RQLQ^{13,14} is a standard and established method of evaluating HRQL in allergic rhinitis. It is valid,¹³ reliable and correlates with disease status and treatment response.^{14,15} The RQLQ was developed to measure the problems of adults experience as a result of their nose and eye symptoms. The measure consists of 28 questions addressing seven domains (activity limitations, sleep problems, non-nose/eye symptoms, practical problems, nose symptoms, eye symptoms, emotional function), as well as a total symptom score, the average of the seven domains representing overall QoL. Patients were asked to recall their experience and give their responses on a 7-points Likert scale (0 = no impairment, 6 = extreme impairment). Rhinitis-specific changes are estimated from mean scores of each domain. Higher scores indicate poorer HRQL. The instrument has been linguistically and culturally translated into multiple languages, including French and Dutch. The RQLQ was completed each week to reflect the condition of the previous week. Mean changes in score from the RQLQ above 0.5 were considered of clinical importance.¹⁶

T5SS score: The T5SS evaluates local nose and eye symptoms (rhinorrhoea, sneezing, nasal congestion, and nasal and ocular itching). Rhinitis symptoms are evaluated by means of a 4-points Likert scale from 0 (absent) to 3 (severe) for each symptom and reflect the condition over the previous 24-h period.

Physicians assessment of symptom severity: Physicians assessed patients' symptoms by means of a 6-point Likert scale (-1 = worse, 4 = cured).

Analyses

Study end-point: Changes in overall RQLQ score from baseline and after three and four weeks of treatment served as the primary study end-points. Secondary end-points included changes from baseline in the seven individual domains of the RQLQ, changes from baseline in the physician's assessment of patient's symptoms by means of the 6-points Likert scale. The confidence of the physician about the appropriateness of the homeopathic prescription and sufficient symptoms during history taking at the initial visit were also recorded and analysed.

The rubrics¹ of the homeopathic repertory and homeopathic remedies used were recorded. Temporary aggravation after the start of treatment was noted. The firm which provided the homeopathic medicine was recorded.

Statistical methods: All statistical tests were two-sided with statistical significance declared at the 0.05 probability level. Paired *t*-tests were performed between baseline and three weeks of treatment, baseline and four weeks of treatment, and between three and four weeks of treatment. The SPSS program was used for statistical calculations. A kappa test was performed to correlate the results of the RQLQ score with the physician's assessment.

¹A rubric is the file in the homeopathic repertory that matches the best with the symptom expressed by the patient.

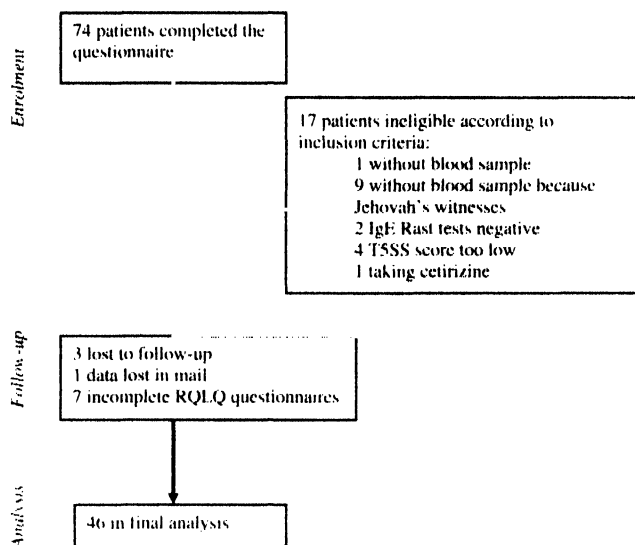


Figure 1 Flow of participants through the study.

Results

Sample

Seventy-four patients were screened for the study. Seventeen patients didn't meet the inclusion criteria. Blood sample was not taken erroneously from one patient. Nine patients were Jehovah's witnesses and refused the blood test. Two patients had negative IgE Rast tests. In four patients the T5SS score was too low for inclusion. One patient completed the RQLQ at the initial visit while taking cetirizine (Figure 1).

Of the patients who were eligible for the study three patients were lost to follow-up. Data of one patient were lost in the mail. Seven patients presented incomplete RQLQs. Thus for the final analyses 46 patients were available. They were treated by five homeopathic physicians, who enrolled 18, 15, 7, 4 and 2 patients. Patients of two physicians were not enrolled in the study for reasons above mentioned.

Patients were between 14 and 68 years of age. The mean age of patients was 36 (± 13.5) years and 70% were female. Twenty percent of patients were new to the practice of the physician.

HRQL

The highest RQLQ score at baseline was 5.50, the lowest 1.21, the mean was 3.40 (± 0.98) at baseline.

After three and four weeks of treatment, patients reported significant improvement in the HRQL. After three weeks of homeopathic treatment it was 1.97 (± 1.32) ($P = 0.0001$) and after four weeks of treatment 1.6 (± 1.28) ($P = 0.0001$) (Figure 2).

Patients reported an improvement of 38% after three weeks of homeopathic treatment (1.32 (SE = 0.2)) in HRQL. After four weeks of homeopathic treatment the improvement was 52% (1.79 (SE = 0.2)). The difference

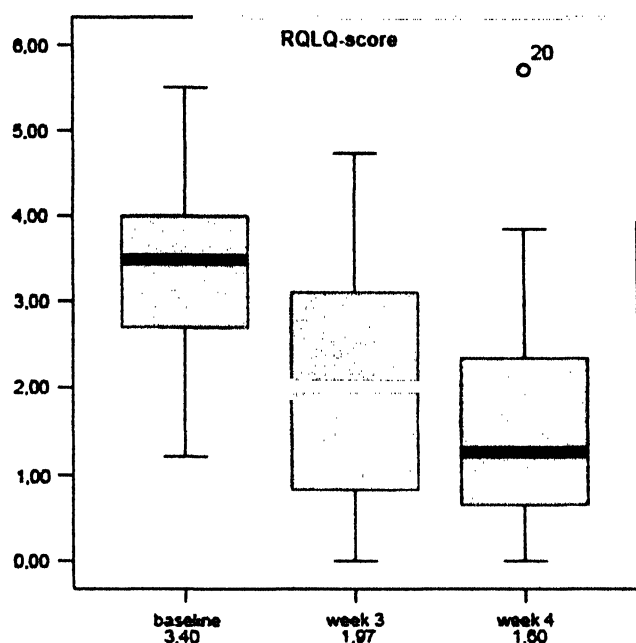


Figure 2 RQLQ scores (mean and SD) at baseline and after 3 and 4 weeks treatment $P < 0.01$ at 3 and 4 weeks vs. baseline.

between three and four weeks of treatment is not statistically significant ($P = 0.075$) (Figure 3).

Likewise, in the other sub-sections of the RQLQ, a statistically significant difference between baseline and three and four weeks' treatment was found ($P = 0.0001$). The difference between three and four weeks' treatment was statistically significant for general symptoms ($P = 0.045$) and for nose symptoms ($P = 0.049$) only (Figures 4 and 5).

Physicians' assessment of symptom severity

The physicians' assessment of the patients' condition after four weeks homeopathic treatment was: the condition of 4% of patients was worse, 9% unchanged, 4% a little better, 25% better, 44% much better and 4% cured (Figure 6).

Comparing the result from the 6-points Likert scale with the result in the RQLQ obtained after four weeks' treatment, correlation 51% ($\text{kappa} = 0.009$).

Homeopathic medication

The 10 most frequently used homeopathic remedies were *Sulphur* (13%), *Pulsatilla* (8%), *Medorrhinum* (6%), *Tuberculinum aviaire* (5%), *Natrum muriaticum*, *Phosphorus*, *Sepia* (each 4%), *Arundo*, *Calcarea phos.*, *Thuya* (each 3%).

Dilutions and frequency of administration of the homeopathic medication were not recorded. When symptoms weren't better after the first week, patients received a second, and third homeopathic medicine if necessary.

In total 96 homeopathic medicines were used, a mean of two medicines per patient.

Homeopathic rubrics (symptoms)

In total, 219 rubrics of the homeopathic repertory were used for the 46 patients, some of these were used more

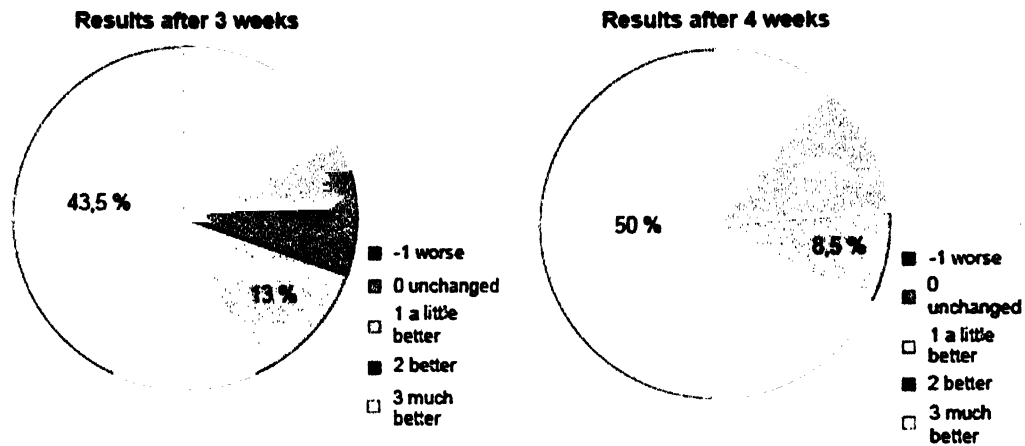


Figure 3 Patient assessed change at 3 and 4 weeks.

than once, a total of 193 rubrics was used, a mean of 4.7 rubric per patient. Sixty-four (29%) belonged to one of 59 different "MIND" rubrics.

In total 63 rubrics with symptoms of allergic rhinitis (29%) comprising 47 individual rubrics. The rubric "hay fever" was used five times and "EYE, itching, inner canthi" eight times.

Ninety-two other rubrics (42%) were used, comprising 87 different ones (Figure 7).

Physician confidence in prescription

For 22% of patients, the physician was not sure about the appropriateness of the prescribed therapy. He or she was sure for 65% of patients and very sure for 11%. For one patient the data were missing.

Sufficient information during history taking

For 85% of patients, the homeopathic physician found he had sufficient information during history taking to enable a correct homeopathic prescription. In 11% of patients, he found he had too little information; for one patient there was too much information. For one other patient the data were missing.

Medicine suppliers

Fifty-nine percent of the homeopathic drugs dispensed were manufactured by Unda[®], 11% by Dolisos[®].

Discussion

The loss of patients between screening and analysis was due to a poor communication between principal investigator and local investigators. One investigator didn't know that a third questionnaire was asked after four weeks. The blood samples with positive IgE Rast test were an inclusion criterion thus, Jehovah's witnesses were not eligible.

The 52% improvement in QoL is in line with improvements seen in two large-scale studies in Germany⁸ (50% for $n=3981$) and the United Kingdom¹⁷ (50.7% for $n=4627$) for all diseases not just allergic rhinitis. There is a good correlation between the physicians assessment of symptom severity and the result of the RQLQ score.

We did not distinguish between intermittent and persistent allergic rhinitis. All patients with intermittent allergic rhinitis (symptoms present less than four consecutive weeks a year) will be better after four weeks without any treatment. Patients who consult a homeopathic physician for allergic rhinitis usually have been suffering for a long time and from severe symptoms as the high level of the RQLQ score at baseline indicates.

This study cannot be conclusive because there is no control group. Neither the physician, nor the patient was blinded.

We cannot conclude that the degree of certainty of the physician about the appropriateness of the homeopathic prescription of a homeopathic remedy and the physician's impression whether he had sufficient information about the patient's condition influenced the outcome.

In individualized homeopathy each patient receives an individual homeopathic medicine tailored to their personal complaints. The mental and emotional symptoms are given priority in prescribing, followed by the homeopathic medicine. The general and peculiar symptoms and finally

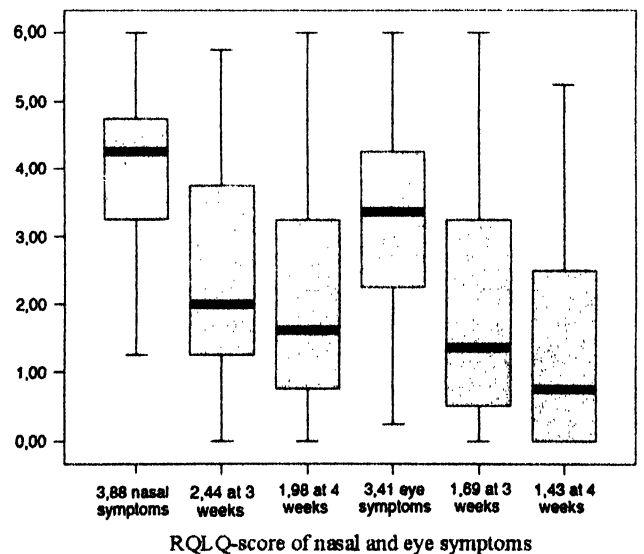
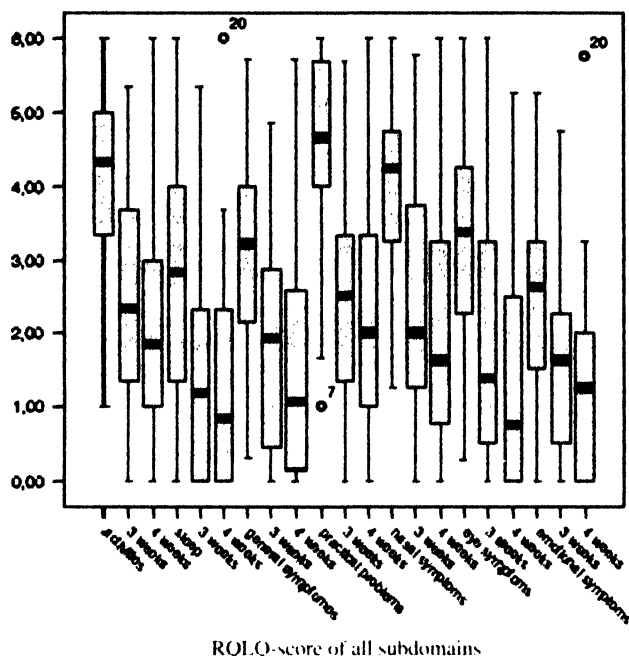


Figure 4 RQLQ nose and eye symptoms at baseline, 3 and 4 weeks.



RQLQ-score of all subdomains

Figure 5 RQLQ scores for all sub-domains at baseline, 3 and 4 weeks.

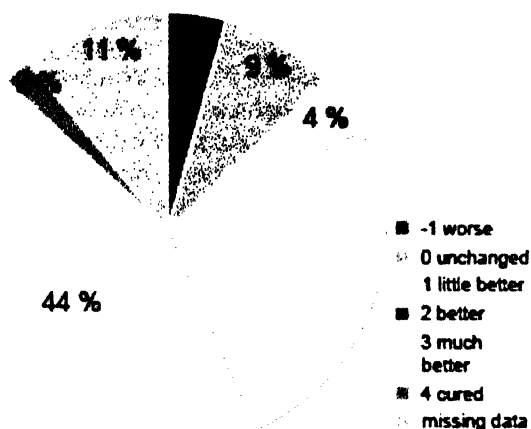


Figure 6 Physician's assessment of symptom severity.

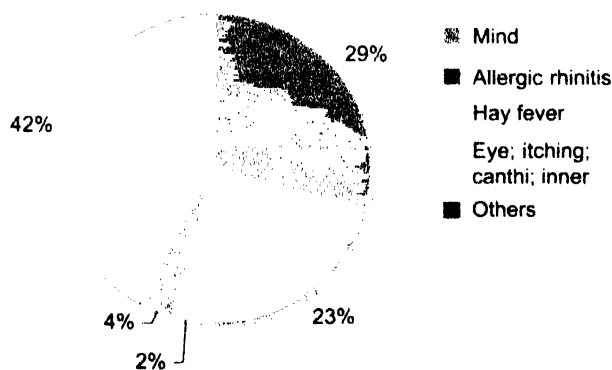


Figure 7 Rubrics used.

the local symptoms (the allergic rhinitis symptoms) are taken into account.

Hence, many different homeopathic medicines are used to treat the same disease.

We didn't examine the way the consultation was conducted or the time of the consultation.

Conclusion

The RQLQ has a quantitative and clinical relevance to evaluate the homeopathic treatment of allergic rhinitis. However, it is not possible to draw a conclusion on the effect of the homeopathic treatment. This would require an RCT. To evaluate the effect of homeopathic treatment for allergic rhinitis an RCT should be performed.

Conflict of interest

There were no conflicts of interest.

Funding source

The cost of the study was covered with the proceeds of the congress "Het congres der lage landen" in 2006. No other parties were involved.

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