



Levocetirizine improves health-related quality of life and health status in persistent allergic rhinitis[☆]

G. Walter Canonica^{a,*}, Jean Bousquet^b, Geneviève Van Hammée^c,
Claus Bachert^d, Stephen R. Durham^e, Ludger Klimek^f, Joaquim Mullol^g,
Paul B. Van Cauwenberge^d, the XPERT study group

^aAllergy & Respiratory Diseases Clinic, DIMI, Genoa University, Pad. Maragliano, L.go R. Benzi 10, 16132 Genoa, Italy

^bService des Maladies Respiratoires, Hôpital Arnaud de Villeneuve, 34295 Montpellier Cedex 5, France

^cUCB S.A. Global Health Outcomes Research, Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium

^dDepartment of Oto-Rhino-Laryngology, Ghent University Hospital, De Pintelaan 185, B-9000, Ghent, Belgium

^eNational Heart and Lung Institute, Royal Brompton Hospital, Imperial College School of Medicine, Dovehouse Street, London, SW3 6LY, UK

^fCenter for Allergy and Rhinology, An den Quellen 10, D-65183 Wiesbaden, Germany

^gUnitat de Rinologia Servei de Otorinolaringologia, Hospital Clínic c/ Villarreal, 170 08036 Barcelona, Spain

Received 24 November 2005; accepted 31 March 2006

KEYWORDS

Health-related
quality of life;
Levocetirizine;
Persistent allergic
rhinitis;
RQLQ;
SF-36

Summary

Background: Allergic rhinitis is a chronic respiratory disorder with a detrimental impact on health-related quality of life (HRQOL) and health status. Enhancement and maintenance of patient function and well-being are therefore considered as essential.

Objective: To determine whether long-term treatment with levocetirizine 5 mg improves HRQOL and health status in persistent allergic rhinitis (PER) patients assessed with RQLQ and SF-36 scales over a 6-month period.

Methods: The Xyzal[®] in PER Trial (XPERTTM) was a multi-center, double-blind, parallel-group study. A total of 551 patients were randomized to receive levocetirizine 5 mg or placebo once daily for 6 months and assessed for symptoms, HRQOL (Rhinoconjunctivitis Quality of Life Questionnaire: RQLQ) and health status (SF-36). Sensitivity of the RQLQ and SF-36 to disease severity was tested to ensure

[☆]This study was supported by UCB Farchim, Chemin de Croix Blanche, Bulle, Switzerland.

*Corresponding author. Tel: +39 010 3538931/+39 010 3538933; fax: +39 010 3538904.

E-mail address: canonica@unige.it (G. Walter Canonica).

their suitability for use in PER patients. Treatment effect was assessed by means of repeated measures analyses.

Results: Over the 6-month treatment period, levocetirizine showed statistically significant improvements over placebo in HRQOL ($P < 0.001$ for all RQLQ domains and overall scores) and health status ($P \leq 0.004$ for SF-36 physical and mental summary scores; $P < 0.05$ for all SF-36 scales). The relative improvement of levocetirizine over placebo exceeded the predefined clinically meaningful threshold of 30% for all RQLQ scores and the improvement from baseline was 3 times the established MID for RQLQ.

Conclusion: The RQLQ and SF-36 could be used to measure HRQOL and health status in PER patients. Long-term treatment with levocetirizine provides sustained improvement of HRQOL and reduces disease burden in PER patients.

© 2006 Published by Elsevier Ltd.

Introduction

Allergic rhinitis (AR) is a common chronic respiratory disease affecting 10–40% of the population worldwide.^{1,2} Its prevalence has been increasing regularly for many years, doubling within 10 years.³ AR is a disease of bothersome symptoms, such as rhinorrhea, sneezing, nasal congestion, itching of the nose and/or conjunctivitis and is often associated with comorbid disorders including asthma, chronic sinusitis, otitis media, and lower respiratory tract infection.⁴ The management of allergic rhinitis involves reducing the causes (allergen avoidance, immunotherapy) and controlling the manifest symptoms (pharmacotherapy).^{5,6} The first-line treatment for the control of symptoms is administration of H₁-receptor antagonists.⁷

AR may significantly impair patient's health-related quality of life (HRQOL), a component of overall quality of life that reflects the impact of disease and treatment on patient's physical and emotional functioning and well-being.^{8–10} It has been recognized as an essential outcome measure that complements clinical assessments to support treatment decisions.^{11,12} Since AR can adversely affect daily activities, sleep patterns, mental and social functioning, work and school-related performance, which consequently result in substantial social and economic costs,^{13–15} the enhancement and maintenance of patients' HRQOL are considered as essential in the treatment of AR.

AR was traditionally classified as seasonal (SAR) and perennial (PAR) allergic rhinitis based on time of exposure. This classification, however, did not entirely correspond to the patients' pattern of AR symptoms as patients with perennial symptoms quite often also have seasonal exacerbations and additionally, not all patients with PAR have symptoms present during the whole year.¹⁶ To meet these concerns, the World Health Organization Initiative on Allergic Rhinitis and its Impact on

Asthma (ARIA, 2001) suggested a new classification of AR as "intermittent" (IAR) or "persistent" (PER) based on the frequency and duration of symptoms.¹⁷ Persistent corresponds to symptoms present for more than 4 days a week and for more than 4 weeks, suggesting the presence of chronic inflammation whereas intermittent corresponds to symptoms present less than 4 days a week or for less than 4 weeks. This classification has been recently validated.^{18,19}

Until recently, the effect of an H₁-antihistamine on HRQOL and health status was not studied in AR patients diagnosed according to the newly defined ARIA classification. The Xyzal[®] in Persistent Rhinitis Trial (XPRT[™]) was the first large study investigating the effects of a modern H₁-antihistamine in the treatment of PER, as defined by ARIA, over a 6-month period.²⁰ The study compared the impact of levocetirizine 5 mg, a potent new-generation antihistamine, and placebo on efficacy, safety, HRQOL (measured using the Rhinoconjunctivitis Quality of Life Questionnaire: RQLQ) and health status (measured using the Medical Outcomes Survey Short Form 36: SF-36). This study showed that treatment with levocetirizine led to significant symptom relief and provided a fast and sustained improvement of the HRQOL and health status in patients with PER. However, since the primary aim of the XPRT study was to evaluate the effect of treatment on symptoms and HRQOL after 4 weeks' treatment, the individual RQLQ domains and the SF-36 scales were not presented over the entire study period.²⁰

An important aspect of assessments that are repeated over time, however, is that they may be dependent on each other. It has been suggested that repeated assessments over time should be subjected to analysis using a longitudinal modeling approach.²¹ Furthermore, when questionnaires are used for the first time in a newly defined patient population, the sensitivity of the questionnaires in

Download English Version:

<https://daneshyari.com/en/article/4212149>

Download Persian Version:

<https://daneshyari.com/article/4212149>

[Daneshyari.com](https://daneshyari.com)