Allergol Immunopathol (Madr). 2014;42(2):102–108

Allergologia et immunopathologia

Sociedad Española de Inmunología Clínica, Alergología y Asma Pediátrica

www.elsevier.es/ai

ORIGINAL ARTICLE

Profile of patients treated with omalizumab in routine clinical practice in Spain

J. Ancochea[a], T. Chivato[b], P. Casan[c], C. Picado[d], L. Herráez[e,*], J. Casafont[e]

[a] *Hospital de la Princesa, Madrid, Spain*
[b] *Hospital Central de la Defensa, Madrid, Spain*
[c] *Instituto Nacional de Silicosis-Hospital Universitario Central de Asturias, Facultad de Medicina, Oviedo, Spain*
[d] *Hospital Clínic, Universitat de Barcelona, Barcelona, Spain*
[e] *Departamento Médico, Novartis farmacéutica S.A. Barcelona, Barcelona, Spain*

Received 31 May 2012; accepted 26 October 2012
Available online 23 December 2012

KEYWORDS
Uncontrolled severe allergic asthma;
Anti-IgE;
Omalizumab;
Effectiveness;
Observational study

Abstract
Background: Omalizumab is indicated in patients with severe allergic asthma not controlled by high-dose inhaled glucocorticoids and long-acting beta-agonists. Few data are available on the profile of patients treated with this drug in routine clinical practice in Spain.
Objective: To describe the profile of patients with severe allergic asthma treated with omalizumab and the course of the disease after a period of treatment.
Methods: Retrospective, multicentre study, recording the data on patients of either sex and ≥12 years with uncontrolled severe allergic asthma, previously treated with omalizumab. Data were evaluated in relation to pulmonary function, symptoms, quality of life, and concomitant anti-asthma treatment before the prescription of omalizumab and at the time of the study visit.
Results: 214 patients were evaluable (mean age = 48.2 ± 17.7 years; mean age at the time of diagnosis = 26.6 ± 16.5 years). 90.7% had experienced exacerbations the year before receiving omalizumab, and the mean total IgE level was 273 ± 205.4 IU/ml. The mean monthly dose was 380.5 ± 185.4 mg. Compared with the baseline situation, differences were observed after treatment with omalizumab in mean FEV_1 (62.7 ± 15.9% vs. 70.8 ± 18.7%), in the proportion of patients requiring oral corticosteroids (47.7% vs. 14.0%), and in the ACQ and AQLQ scores. 32.7% of the patients received doses not recommended by the Summary of Product Characteristics (SPC).
Conclusions: Profile of asthmatic patients treated with omalizumab predominantly corresponds to uncontrolled severe asthma cases, in accordance with SPC's indications. The results of the study suggest a favourable clinical course similar to that observed in other studies.

* Corresponding author.
E-mail address: Lys.herraez@novartis.com (L. Herráez).

0301-0546/$ - see front matter © 2012 SEICAP. Published by Elsevier España, S.L. All rights reserved.
http://dx.doi.org/10.1016/j.aller.2012.10.010

Introduction

Asthma is a chronic pulmonary inflammatory disease affecting approximately 300 million people worldwide.[1] The mortality risk in asthmatic patients increases with the clinical severity of the condition – the latter being a predictor of mortality independently of the number of admissions to hospital.[2,3]

The Global Initiative for Asthma (GINA) 2008[4] guidelines recommend stepwise therapy according to the severity of the disease, taking into account that for good disease control, special emphasis on the prevention of exacerbations, hospitalisations and symptoms is required.

Despite the available treatments and recommendations of the different guidelines, many asthma patients are inadequately controlled,[5–8] even after receiving high doses of inhaled corticosteroids in combination with other anti-asthma drugs. In Spain, approximately 70% of all asthmatic patients are poorly controlled, and 10% are totally uncontrolled, according to the results of the Study of the Control of Asthma in Spain (ESCASE).[9] A recent European study[10] has shown that approximately 50% of all patients with severe asthma had not reached the treatment objectives recommended by the GINA.[4]

Considering the inadequate control of asthma, and knowing that approximately 50–80% of all patients with severe asthma present an immunoglobulin E (IgE)-mediated allergic component that modulates the cascade triggering the allergic inflammatory reaction,[10–12] omalizumab was developed as a monoclonal antibody. It binds to circulating IgE (anti-IgE), inhibiting the binding of IgE to FcεRI on mast cells and basophiles by binding to an antigenic epitope on IgE that overlaps with the site to which FcεRI binds, preventing the mentioned inflammatory reaction.[13] Different clinical trials have demonstrated the efficacy of omalizumab,[14–19] with a reduction in the number of exacerbations and hospital admissions, as well as improvement in the quality of life of patients with persistent moderate or severe asthma. Accordingly, the GINA 2008[4] guidelines include treatment with omalizumab as an adjuvant to inhaled corticosteroids plus long-acting β_2-agonists.Due to the recently obtained marketing authorisation in Spain, there are not enough data to establish the characteristics of the patients receiving treatment with omalizumab and its use in routine clinical practice – the existing information being limited to a few case series.[20–22]

Thus, the present study was designed to describe the profile of patients with severe allergic asthma treated with omalizumab in routine clinical practice, and to establish the course of the disease after a period of time receiving the drug.

Materials and methods

Study design and population

The RIGE study is a retrospective, multicentre study involving the participation of 60 specialists in pneumology and allergology from all over Spain.

During five months, data were collected on patients of both sexes and aged 12 years or older, who had received at least one dose of omalizumab. Another inclusion criterion was that patients had to be included according to SPC. In all cases, written informed consent was obtained from the patient or legal representative or tutor (in the case of minors). Patients who had participated in a clinical trial with omalizumab or other anti-asthma drugs in the year prior to inclusion were excluded, as well as those patients who had a situation that limited their participation in the study. A sample size of 221 patients provided a precision of $\pm$5.0% to estimate the factors determining the continuity of treatment with omalizumab in patients with severe allergic asthma, with a 95% confidence interval (95% CI). Assuming 10% of patients would not be valid for the analysis, the number of patients to be recruited was 246.

The study was approved by the Ethics Committee of the Barcelona Clinic Hospital, Barcelona, Spain and notified to the Spanish Agency for Medicines and Medical Devices (AEMPS). Written informed consent was obtained from all patients before their entry into the study.

Data collection

The following patient information was collected from the medical records on a retrospective basis: biodemographic data (age, sex, weight, height), clinical history of asthma (personal and family disease antecedents, date of diagnosis, presence of exacerbations), data related to treatment with omalizumab (dose, frequency and duration of treatment), IgE levels and pneumoallergen skin prick tests.

To evaluate the patient's course, data corresponding to the period before the prescription of omalizumab and at the time of the study visit were collected, as well as information on pulmonary function (forced vital capacity (FVC), forced expiratory volume in one second (FEV_1) and peak expiratory flow (PEF)), concomitant drug treatment for asthma, symptomatology (symptoms, Asthma Control Questionnaire (ACQ) score),[23] and quality of life (Asthma Quality of Life Questionnaire (AQLQ) score).[24] In addition, an evaluation was made of the degree to which patient life was affected by the disease, according to investigator criterion (rated as not at all, a little, quite a lot, or a lot). A global evaluation was also made of the efficacy of the treatment, based on the Global Evaluation of Treatment Efficacy (GETE). For the patients who discontinued treatment with omalizumab prior to their participation in the study, the post-treatment information considered was that at the time of withdrawal.

Treatment with omalizumab

Study was done on whether the patients included in the study had been prescribed the treatment according to the indications of the SPC of omalizumab, was evaluated based on a positive skin prick test, the presence of diurnal and nocturnal symptoms, whether concomitant therapy was provided with inhaled corticosteroids and β_2-agonists, and the FEV_1. Study was also done on whether the dose level received corresponded to the doses recommended by SPC, which is defined by IgE levels and body weight.