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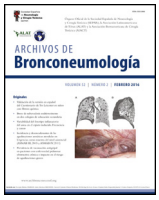

Original Article

Comparison of Costs and Clinical Outcomes Between Hospital and Outpatient Administration of Omalizumab in Patients With Severe Uncontrolled Asthma☆

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ABSTRACT

Objectives: To compare clinical outcomes and costs between two administration strategies of omalizumab treatment.
Method: We evaluated two cohorts of patients with uncontrolled severe asthma over a 1-year period. Patients received the treatment in the primary care center in Hospital A and conventional hospital administration in Hospital B.
Results: We studied 130 patients, 86 in Hospital A and 44 in Hospital B, 30 men (24%) and 100 women (76%), age 50±15 years, FEV1% 67±22%, body mass index (BMI) 28±6 kg/m^2, 639±747 UI IgE/mL, followed for 24±11 months (12–45), Asthma Control Test (ACT) score 12±4 and Asthma Control Questionnaire (ACQ) 3±2. There were no significant pretreatment differences between the groups in hospital admissions and emergency room visits in the previous year, nor in proportion of patients receiving oral steroids. Evaluations were performed at baseline and after 12 months of treatment, revealing significant differences in ACT (P<.001), ACQ (P<.001), improvement in FEV1% (P<.001), reduction in total admissions (P<.001), days of hospitalization (P<.001), emergency room visits (P<.001), cycles and doses of oral steroids (P<.001) compared to the previous year. Hospitalization costs, emergency room visits, unscheduled visits to primary care and to the pulmonologist were significantly reduced in each hospital and on the whole, but administration and travel costs were 35% lower in the ambulatory strategy adopted in Hospital A.
Conclusion: The administration of omalizumab in ambulatory health centers achieved the same clinical results as a hospital administration strategy, but with lower costs.

Comparación de costes y resultados clínicos entre la administración hospitalaria o ambulatoria de omalizumab, en pacientes con asma grave no controlada

Palabras clave:
Asma grave no controlada
Omalizumab
Costes
Administración ambulatoria

RESUMEN

Objetivos: Evaluar los resultados clínicos y los costes de 2 estrategias de administración de omalizumab.
Método: Se compararon, de forma retrospectiva, 2 cohortes de pacientes con asma grave no controlada: una, procedente del hospital A, en la que el tratamiento se administró en un centro de salud, y otra, procedente del Hospital B, con administración hospitalaria convencional.
Resultados: Se estudió a 130 pacientes, 86 en A y 44 en B, 30 hombres (24%) y 100 mujeres (76%), edad 50 ± 15 años, FEV1% 67 ± 22%, índice de masa corporal (IMC) 28 ± 6 kg/m^2, IgE 639 ± 747 UI/mL, seguimiento de 24 ± 11 meses (12-45), Asthma Control Test (ACT) 12 ± 4 y Asthma Control Questionnaire (ACQ) 3 ± 2, sin diferencias significativas basales entre ambas cohortes en ingresos hospitalarios ni visitas

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a urgencias en el año previo, ni en número de pacientes con esteroides orales. Al comparar la situación basal y tras los 12 meses de tratamiento, se observaron diferencias significativas en ACT (p < 0,001), ACQ (p < 0,001) y mejoría en el FEV1% (p < 0,001), reducción en número de ingresos (p < 0,001), días de hospitalización (p < 0,001), visitas a urgencias (p < 0,001), ciclos y dosis de esteroides p < 0,001) respecto al año previo, tanto individualmente como en conjunto. Los costes de hospitalización, visitas a urgencias, visitas no programadas a Primaria y al neumólogo se redujeron significativamente en ambos hospitales, pero los costes de administración y desplazamiento fueron un 35% inferiores con la pauta ambulatoria en A.
Conclusión: La administración ambulatoria de omalizumab en los centros de salud consigue los mismos resultados clínicos que una pauta de administración hospitalaria, con menores costes.

Introduction

Estimates suggest that in at least 5% of cases, asthma is severe and uncontrolled.[1,2] The Spanish asthma management guidelines (GEMA) define severe uncontrolled asthma (SUA) as asthma that cannot be controlled despite administration of combined high-dose inhaled corticosteroids+long-acting beta-agonists (ICS+LABA) for 1 year, or oral corticosteroids for 6 months.[3] Patients with a history of severe asthma have a 6-fold risk of a fatal outcome 3 years after hospital discharge. Furthermore, these patients have a higher risk of disease-related hospitalization, poor quality of life, high costs related to their disease, and mortality.[1–4] Nevertheless, severe cases often remain undetected by both primary care and specialist physicians, because being, as they are usually are, confined to specialist asthma units,[5] physicians working outside this context need not be skilled in their diagnosis.

Pharmacological asthma therapy has remained practically unchanged for many years. The first anti-IgE monoclonal antibody (omalizumab) has been available in Spain since 2006, and is indicated for SUA. Patients with severe asthma have a higher risk of morbidity and mortality, and absorb most of the asthma healthcare budget (70% of the total funds allocated to the Finnish asthma program, for example).[6] Omalizumab has been shown to be effective in the management of severe asthma. Dose and dosing frequency of this drug is calculated from the patient's pretreatment IgE levels (IU/ml) and body weight (kg). Doses range from 75 to 600 mg omalizumab every 15 or 30 days, adjusted to serum IgE.[7–9]

Although omalizumab can be administered in outpatient clinics, in Spain it is usually administered in a hospital, and the administration strategy is adapted to the specific setting, such as day clinics, pharmacy services, or pulmonology units. The method of administration and need for trained personnel add to the cost of the drug and increase the burden on the patient, who must bear the expense of traveling to the hospital to receive treatment. However, the effectiveness of outpatient vs. in-hospital administration, and the difference in cost between these strategies is as yet unknown.

The aim of this study was to compare the clinical outcomes and costs associated with omalizumab treatment in SUA patients in 2 tertiary hospitals. In one hospital, the drug was administered on an outpatient basis in a primary care center, and in the other it was administered in the day hospital.

Method

Type of Study

Retrospective, population-based cohort study.

Duration

Twelve months.

Setting

Asthma units of the Pulmonology Departments of the Hospital Universitario San Juan in Alicante (hospital A) and the Consorcio Hospital General Universitario in Valencia (hospital B).

Population

Patients with SUA included in an omalizumab treatment program in both centers, whose data was entered into a database, and who fulfilled the following criteria:

- Age > 18 years.
- IgE > 100 IU/ml.
- Positive skin prick and/or positive specific IgE to airborne allergens.
- SUA criteria, treated with high-dose inhaled corticosteroids and a long-acting beta-agonist in combination with other drugs, such as oral leukotriene inhibitors and/or long-acting muscarinic antagonists and/or theophylline and/or steroids.[3]
- Uninterrupted administration of omalizumab for at least 12 months.

Primary Endpoint

- To compare the economic cost of 2 different omalizumab administration strategies: day hospital and primary care center.

Secondary Endpoints

- To compare outcomes in both hospitals, in terms of exacerbations, hospitalization, lung function, and savings in medication following treatment with omalizumab for at least 12 months.
- To compare the number and characteristics of exacerbations, hospitalizations, lung function, and savings both before and after administration of omalizumab for at least 12 months in each hospital.

Administration Strategy

Strategy A. The drug was dispensed by the hospital pharmacy in a cooling pouch and collected by the patient. Both oral and written instructions were given for administration of the drug (including the first dose) in the nurse's treatment room in the patient's local primary care center.

Strategy B. The drug was dispensed by the hospital pharmacy and administered in the day clinic according to established protocols.