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Eligibility for treatment with omalizumab in Italy and Germany

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Summary
Omalizumab is an add-on therapy for patients with uncontrolled severe allergic asthma. In Europe, patients must fulfil a number of additional criteria to become eligible for omalizumab therapy, creating a challenge for epidemiology studies to quantify the potential patient pool. Thus, and in the absence of robust data, the number of omalizumab-eligible patients has remained unclear.

To assess eligible patient numbers, a chart-audit design approach was employed to measure epidemiology variables based on patient-level data. 770 patient charts were reviewed in designated towns in Germany and Italy, in collaboration with >200 primary care physicians (PCPs) and respiratory specialists (RS). This study sample represents >50% and >70% of local RS in these designated towns of Germany and Italy, respectively.

Of patient charts evaluated, 4 patients were currently receiving omalizumab. A further 31 patients (12 PCP; 19 RS) were evaluated as omalizumab-eligible (i.e. fulfilled all product label criteria) but were not receiving the drug. Extrapolating to a national level, this yields >6500 eligible patients in Germany, and >3200 in Italy. Furthermore, this study sample revealed a significant number of PCPs treating uncontrolled severe asthma patients without referral to RS; these patients are not consistently evaluated for FEV_1, aero-allergen sensitivity, a qualitative understanding of severe exacerbations, and day and night-time symptoms.

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This study suggests that significant numbers of omalizumab-naïve severe allergic asthma patients in Germany/Italy are eligible for omalizumab therapy. Despite proven benefits in uncontrolled severe allergic asthma, adjunctive omalizumab therapy is underutilized.

Introduction

It has been estimated that approximately 300 million people worldwide have asthma, resulting in a high burden of morbidity and mortality [1,2]. Although mild and moderate asthma can usually be controlled with inhaled corticosteroids (ICSs) and, if necessary, long-acting β_2-agonists (LABAs), many patients with severe asthma remain inadequately controlled [1,3].

The overall prevalence of asthma in Europe has been estimated to range from 5 to 18%, with approximately 20% to 30% of these patients having severe asthma [1,2]. An estimated 20% of patients with severe asthma have inadequately controlled disease [4]. In Europe, the prevalence of uncontrolled asthma among patients receiving ICSs has been estimated to range from 20 to 67% [5].

Options for patients who require additional therapy alongside an ICS and LABA include omalizumab, a humanized anti-immunoglobulin E (IgE) monoclonal antibody which is approved in the European Union (EU) as an add-on therapy for selected patients with uncontrolled severe persistent allergic asthma [6]. Omalizumab has a well-established efficacy and safety profile in patients with inadequately controlled severe allergic asthma [7–13].

Patients in Europe must fulfil a number of additional criteria to become eligible for omalizumab therapy. In particular, patients must have severe, persistent, allergic asthma with baseline IgE concentrations and bodyweights that fall within the limits set out in the approved asthma dosing tables for omalizumab. Patients must also have inadequately controlled asthma despite treatment with an ICS and LABA. Although the overall burden of asthma in Europe has been evaluated in several studies [5,14,15], epidemiological studies have not, to date, provided robust data to quantify the potential population of severe allergic asthma patients with unmet needs who could potentially benefit from omalizumab treatment.

To address this lack of information, we employed a retrospective medical record-audit approach to measure epidemiology variables based on patient-level data to assess the number of patients who could potentially benefit from omalizumab treatment ("omalizumab-eligible patients") in Italy and Germany.

Methods

To identify patients potentially eligible for omalizumab treatment we analysed retail and hospital sales data of high-dose ICS/LABA within regions of Italy and Germany. A potential candidate for omalizumab would be receiving treatment with high-dose ICS/LABA combination, therefore high-dose ICS/LABA was used as a surrogate to identify these patients.

Region selection

A region in a country consisted of a number of territorial divisions: in Germany a territorial division was a grouping of pharmacies (nanobrick) and their surrounding territories; in Italy the divisions were based on local health authorities (these definitions are national healthcare subdivisions and territorial breakdown units of the health ministry in Italy, and of the sick funds in Germany).

To identify 'extremes' of prescribing habits, the retail and hospital sales of high-dose ICS/LABA products were first deciled in each country and then the two sets of sales data (retail and hospital) were matched together by the territories in each country. Two regions were subsequently selected in Italy and Germany to represent two "extremes" of prescribing dynamics in asthma patients. For the first extreme, a region in each country was selected that fell into the top three deciles for retail sales but the bottom three deciles for hospital sales: this represented a region with high-prescribing primary care physicians (PCPs) (based on high retail and low hospital sales of ICS/LABA) indicating that a high proportion of patients (on high-dose ICS/LABA) were cared for in the primary care setting rather than under the care of a respiratory or hospital specialist: referral to a respiratory or hospital specialist was low. For the second extreme, a region in each country was selected that fell into the bottom three deciles for retail sales but the top three deciles for hospital sales: this represented a region with high-prescribing respiratory or hospital specialists (based on low retail and high hospital sales of ICS/LABA) indicating that a high proportion of patients (on high-dose ICS/LABA) were under the care of a respiratory or hospital specialist rather than in a primary care setting: referral to a respiratory specialist or hospital was high.

To illustrate that the regions chosen in each country were representative of the extreme situations, high-dose ICS/LABA sales were analysed for each country including all their territorial divisions. In Italy, one region was in the North West (Piacenza) and one region was in the centre of the country (Pescara), each with a total population of at least 250,000. High-prescribing PCP numbers were normalised per head of population; high-prescribing hospital specialist numbers were normalised per number of hospital beds. In Germany, one region combined two administrative districts in Hessen and Brandenburg (Giessen and Cottbus/Frankfurt an der Oder); the second region combined three administrative districts in Nordrhein-Westfalen (Recklinghausen/Lünen-Kamen/Hamm); each had a population of at least 850,000.

The regions were also selected according to the following criteria and with the same normalisation procedures applied as in Italy, namely per head of population in the territorial division for the office-based prescriptions

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