Severe asthma patients (SA) represent a low percentage (5-10%) within the global asthmatic population. However, they represent the most affected group of patients on their quality of life, associated morbidity, and resources consumption. Asthma has become a worldwide public health concern, of increasing magnitude and prevalence. Economic burden of SA is considerable in terms of direct and indirect costs. Pharmacological therapies represent the main component of direct medical expenses, due to other factors –to the introduction and availability in recent years of more expensive options, such as biological therapies with monoclonal antibodies (moAb). This fact insists on the importance of evaluating the costs and results of the different therapeutic options through economic assessments, which ensure the sustainability of our health system.

In Spain, four CEA studies have been published in real life on the use of omalizumab for the treatment of patients with severe asthma. The first two studies were performed on small samples of patients. Both studies show –with design limitations, such as performing retrospective studies and having a small number of patients– that omalizumab therapy presented a moderate incremental cost-effectiveness ratio (ICER) [between € 462.08 and € 5423.13], evaluated by the number of exacerbations avoided and a three-point increase in the ACT, evaluated in euros of 2015 and 2016 respectively. They have also shown very similar results for the ICER, both for calculating avoided exacerbation, and the three-point increase in the ACT, evaluated in euros of 2015 and 2016 respectively. They have also shown very similar results for the ICER, both for calculating avoided exacerbation, and the three-point increase in the ACT, evaluated in euros of 2015 and 2016 respectively.

The incorporation of other moAb such as mepolizumab into the therapeutic arsenal of severe asthma further complicates medical decision making and resource management, which determines the need for economic and budgetary impact evaluation (BIE) of this drug. The first study carried out in Spain by García Mochón following this line of work investigates the introduction of mepolizumab as a therapy for IgE mediated or not IgE mediated severe refractory eosinophilic asthma in unmonitored adult patients. Their high doses of inhaled corticosteroids (ICS) and adrenergic long-acting agonists (LABA) and/or systemic corticosteroids (SC) are being quantified from the National Health System's (NHS) perspective to calculate direct costs in 2018 euros for a period of 3 years (2018-2020).

The study population included patients older than 12 years with severe refractory asthma to the therapy in Spain. Through Spain’s National Statistics Institute (NSI) data, the percentages of severe refractory asthma patients under abovementioned therapy who were diagnosed with eosinophilic asthma were included, obtaining a QALY cost of € 50,239.98. In a study by Entrenas, 220 patients with severe allergic asthma under omalizumab therapy were analyzed, belonging to the communities of Andalusia and Extremadura. The ICER was calculated, and the results of one year prior to, and one year following omalizumab’s introduction were compared. Last studies, despite their limitations, both agree on the introduction of omalizumab for severe asthma therapy in clinical practice contributing to a decrease in direct and indirect costs. They have also shown very similar results for the ICER, both for calculating avoided exacerbation, and the three-point increase in the ACT, evaluated in euros of 2015 and 2016 respectively.

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eosinophils a greater relative efficacy and a very sensitive reduction of costs (12,744.2-19,451.6), clearly showing in the subgroup analysis by level of susceptibility population), the costs for avoided exacerbation are €5,085 (95% CI: 12,744.2-19,451.6), for patients with greater than or equal to 500/µL eosinophil plasma levels, as indicated in the therapeutic positioning report14.

The data set forces us to reflect on the situation of selecting the type of moAb, from the pharmacoeconomic and sustainability perspective. There is no solid evidence on a marker or set of markers that help the choice of one drug over another for a patient with asthma and eosinophilic component, outside the justified clinical situation. Nor do we have a direct comparison between omalizumab and mepolizumab. On the other hand, previous studies—which can include the subgroup analysis of the pivotal cost-effectiveness studies of mepolizumab10—show that patients with a greater baseline eosinophilic component obtain greater benefit, which makes mepolizumab to be used as a priority—the only justified exceptional nature—in patients with non-IgE mediated severe refractory eosinophilic asthma, in patients with greater than or equal to 500/µL eosinophil plasma levels, as indicated in the therapeutic positioning report14.

Bermopo15 describes the mepolizumab evaluation process by the National Institute for Health and Care Excellence (NICE), and shows similar results to those obtained in García Mochón’s work12 in cost per QALY for a greater than or equal to 300/µL eosinophil count. Other studies that perform CLA of added mepolizumab to the standard therapy16, and that determine the incremental cost per QALY in a lifetime horizon, conclude that in their environment (United States of America), this cost exceeds the coverage thresholds used, even in the case of respondents to mepolizumab. Therefore, these authors16, as in the work of García Mochón12, suggest that health authorities should consider negotiating significant discounts on mepolizumab prices. The economic evaluation, in a limited resources context, should make the clinician reflect on the most efficient treatment in this profile of patients with severe refractory asthma to conventional treatment.

Bibliography