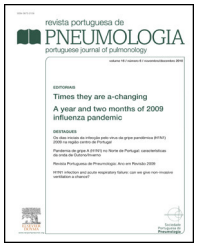
Rev Port Pneumol. 2015;21(3):111–112

revista portuguesa de
PNEUMOLOGIA
portuguese journal of pulmonology
www.revportpneumol.org



EDITORIAL

Omalizumab: a treatment for severe asthma in real life?

In 2015, asthma remains an important health problem. It is costly: first as a chronic disorder it represents a significant burden for the patients and their relatives; secondly due to management of disease including controller medications and what is required for acute exacerbations i.e.: hospitalizations and days off work Overall, while mortality has certainly decreased, most of our current treatments are still primarily symptom based and do not alter with the natural history of the disease. Meanwhile, severe asthma remains a challenge, as most patients with this type of asthma remain uncontrolled despite a real diagnosis, a fair compliance and an important need of existing therapies with known side effects.

Total IgE has been linked to asthma in epidemiological studies and was considered to be associated with an allergic phenotype of the disease. More recently, it has been shown to be a part of the high TH2 group of potential biomarkers, such as eNO and blood eosinophils, in predecting future risk including recurrent exacerbations. IgE and IgE receptors play a part in the pathophysiology of asthma by activating various effector cells even in non- allergic situations. Very recently an epigenome association with total IgE was reported, and methylated genes encoding for eosinophil products were connected in a reproducible way. The results were confirmed by isolated eosinophils from patients with high eosinophilia and asthma. This type of study will certainly point towards new types of mechanisms, which will allow a more personalized way to treat asthma.[1]

Omalizumab has been shown in several well-performed studies to decrease the exacerbation rate in severe uncontrolled allergic asthma.[2] It has been used with success to treat mild asthma and allergic rhinitis and to prevent seasonal exacerbations in patients with a broad range of severity.[3] Randomized control studies are helpful to demonstrate the efficacy and safety of new drugs. They are the bottom line of marketing in westernized countries. They sustain the different guidelines, but even though most of the recommendations are based on randomized control studies, most of the patients with severe asthma are not qualified to enter RCP studies.[4] Therefore large pragmatic trials with real life conditions are currently more popular. These trials will try to demonstrate efficiency and include a large numbers of patients. They will enroll patients with less strict criteria, closer a real clinical situation and allow a longitudinal follow-up with pertinent outcomes.[5,6]

In this issue of the journal, taking advantage of the EXperience study,[7] our Portuguese colleagues have considered 62 patients from their own country to demonstrate an overall 60% satisfaction with the treatment, with a fair control of asthma including daily symptoms and exacerbations. The treatment improves health related quality of life but has little impact on lung function. This study describes an interesting observation and confirms the larger study from Grimaldi Bensoussa et al, reporting the real improvement seen in the initial Innovate study.[8] The number of severe exacerbations and the need for oral corticosteroid upsurges were significantly decreased in this real life study of omalizumab treated patients as compared to the reference arm. We can postulate that omalizumab is a well-established treatment in Europe for severe asthma. It is advocated by the GINA guidelines and the ATS/ERS task force on severe asthma, however as a specific biotherapy it requires more investigation.[9] It would be worth knowing if we can confirm its efficacy in non-allergic severe asthma.[10] We are all fighting to improve antecipation of the response to the intervention. At present, we need specific biomarkers with an impact on future risk. Last of all, it is important to assess the potential for these interventions to go along with asthma remission, but recent studies are not very encouraging. Omalizumab is the first efficient and safe biotherapy for severe asthma with the potential to be used in this disease. We should continue to question how it works and to report efficiency data from large real life cohort studies.

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