# EFFECTIVENESS AND SAFETY OF OMALIZUMAB IN THE TREATMENT OF SEVERE UNCONTROLLED ASTHMA

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## BACKGROUND AND IMPORTANCE

New biological anti-asthmatic therapies have been recently developed. In the absence of comparative studies among these therapies, there is a need to provide a better understanding of their behaviour in the real world. Omalizumab is the first monoclonal antibody for the add-on treatment of severe allergic asthma (SAA).

## AIM AND OBJECTIVES

To evaluate the effectiveness and safety of omalizumab in SAA.

## MATERIAL AND METHODS

Retrospective observational study of all patients with SAA who started on Omalizumab since 2009.

Through pharmacy recordings and the electronic clinical record, we collected:

- Demographic variables.
- Treatment data [mean dose at baseline and changes along the treatment, treatment duration until last medical review (LMR), need for oral corticosteroids (CO)].
- Forced expiratory volume in the first second (FEV1).
- Scores in the asthma control test (ACT).
- Adverse drug reactions (ADR).
- Reasons for treatment discontinuation.

## RESULTS

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| **46 patients** | **Demographic variables** | 63% women<br>Median age 45 years (range 10-74)]. | | |
| | **Treatment data** | Mean dose (baseline): 536±264 mg<br>Treatment duration util LMR: 34±17 | | |
| | **Efectiveness** | **FEV1** | FEV1 baseline (mean value): 65± 17% | FEV1>80% was reached in 58,7% (27/46) of patients. (Median FEV1=90%) |
| | | | FEV1 week 16: 77±18% | 26% (12/46) of patients increased FEV1 ( an average of 13%) although FEV1 >80% was not reached. |
| | | | FEV1 until LMR: 80±20% | 15.3% (7/46) of patients, it decreased an average of 11% comparing to baseline. |
| | | **ACT questionnaire** | Only 37% (17/46) of questionnaires were recorded. | Total control (ACT> 25): 23.5% (4/17)<br>Good control (ACT = 20-24): 29.4% (5/17)<br>Poor control (ACT <20): 47.1% (8/17) |
| | | **Oral corticosteroid (CO):** | At the beginning of the treatment, 67.3% (31/46) of patients required daily administration of CO and after omalizumab, only 10.8%. | |
| | **Safety** | **Adverse drug reactions (ADR)** | 28% (13/46) of patients suffered any ADR. | |
| | | **Stopped treatment (15 patients)** | Inefficacy (n = 5)<br>ADR (n = 5)<br>Non-compliance (n = 1),<br>Clinical improvement (n=4; after an average of 24 months treatment duration.) | |

## CONCLUSION AND RELEVANCE

Omalizumab improves lung function in patients with SAA, eliminating the use of CO and with an acceptable safety profile. We noticed that there is a need to improve the registration of some clinical parameters in order to ensure an adequate therapy monitoring that will help to gain knowledge of the role of each of these therapies.

Conflict of interest: Nothing to disclose.