

# Biologicals in the Treatment of Severe Asthma: Effectiveness, Safety and Economic Impact Using Hospital Real-World Data

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## INTRODUCTION

Anti-IgE (omalizumab), anti-IL5 (mepolizumab and reslizumab) and anti-IL5 receptor (benralizumab) treatments are available for severe allergic and eosinophilic asthma. Clinical trials studies have shown beneficial effects in oral corticosteroid use and asthma exacerbations. Real-life studies offer the opportunity of obtaining outcomes suitable in clinical practice, as controlled trials do not mirror the real patients' population observed in clinical practice.

## OBJECTIVES

The aim of this retrospective study was to evaluate the effectiveness, safety and costs of biological therapy in asthma using hospital real-world data.

## METHODS

In Centro Hospitalar e Universitário São João (CHUSJ), to monitor asthma biological therapy, an on-line form was set up and sent to the prescribers to be filled 12 months after the start of the treatment. Data was collected from 2007 until May 2021.

The number of exacerbations requiring hospitalisation and/or emergency department visit, the use of oral corticosteroids, the forced expiratory volume in 1 second (FEV1) and Asthma Control Test (ACT) score before and 12 months after the beginning of biological therapy were compared. The suspected adverse drug reactions were also collected. To calculate the economic impact of these treatments data from Pharmacy Information System was used. Statistical analysis was performed using IBM®SPSS® Statistics 27<sup>th</sup> version.

## RESULTS

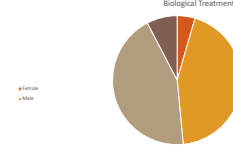
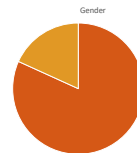
A total of 66 patients, 82% female and with the mean age of 51,9 (SD=11,2), were included in our study. The percentage of biological treatments were distributed as followed: 44% in Omalizumab, 44% in Mepolizumab, 8% in Reslizumab and 4% in Benralizumab.

Twelve months prior to biological therapy, 45% and 86% used oral corticoid therapy or did cycles of corticoid therapy (> 3 days), respectively. The mean daily OC dose (prednisolone dose equivalent) 13,7 mg with a maximum of 60,0 mg and a minimum of 12,0 mg, and the mean of OC courses was 3,34 (SD= 1,96). After the biological treatment started it was observed a decrease in the mean daily OC dose of 8,28 mg (p value<0,001) and in the mean number of OC cycles of 2,06 (p value <0,001).

Before treatment started 80% of the patients needed ER attention and 21% were hospitalised due to asthma exacerbation. During the period of 12 months of biological treatment both percentages of ER visits and hospitalisations decreased significantly to 28.2% (95%CI 10,9-45,5) and 17,3% [95% CI 5,7- 28,9] respectively.

## PATIENTS INCLUDED

| Age  |        |
|------|--------|
| N    | 66     |
| Mean | 51,89  |
| SD   | 11,224 |
| Min  | 16     |
| Max  | 74     |



## TREATMENTS

| Biological Treatment |    |       |
|----------------------|----|-------|
|                      | N  | %     |
| Benralizumab         | 3  | 4,5   |
| Mepolizumab          | 29 | 43,9  |
| Omalizumab           | 29 | 43,9  |
| Reslizumab           | 5  | 7,6   |
| Total                | 66 | 100,0 |

## ADVERSE DRUG REACTIONS

### Suspected Adverse Drug Reaction to Biologicals

|                      | N  | %     |
|----------------------|----|-------|
| Alopecia             | 1  | 1,5   |
| Anaphylatic reaction | 1  | 1,5   |
| Back pain            | 1  | 1,5   |
| Blur vision          | 1  | 1,5   |
| Headache             | 2  | 3,0   |
| Hirsutism            | 1  | 1,5   |
| Local                | 1  | 1,5   |
| Nausea               | 2  | 3,0   |
| Nausea and vomiting  | 1  | 1,5   |
| No ADR               | 44 | 66,7  |
| Oral pain            | 1  | 1,5   |
| Pruritus             | 5  | 7,6   |
| Somnolence           | 2  | 3,0   |
| Vomiting             | 1  | 1,5   |
| Weight gain          | 2  | 3,0   |
| Total                | 66 | 100,0 |

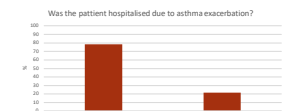
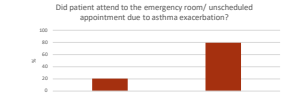
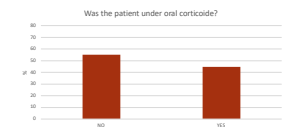
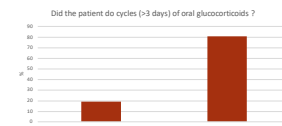
## CONCLUSIONS

Results with biological therapies in real-life clinical setting are comparable to those reported in clinical trials. Biological therapy reduces oral corticosteroid use and the number of exacerbations requiring hospitalisation and/or emergency department visit without important adverse effects associated

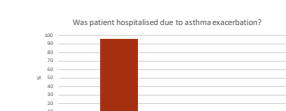
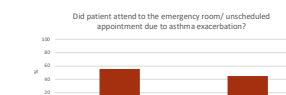
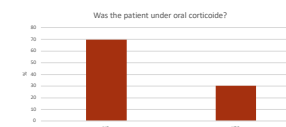
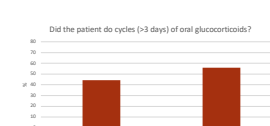
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2. Expert Rev Clin Immunol. 2019 Sep;15(9):951-958
3. Asthma Res Pract. 2020 May 13;6:2
4. [SPC NUCALA](#)
5. [SPC XOLAIRE](#)
6. [SPC FASENRA](#)
7. [SPC CINQAERO](#)

## BEFORE BIOLOGICAL THERAPY



## AFTER BIOLOGICAL THERAPY



## RESULTS (CONT.)

The median of ACT score was 12,0 (VAR=34,9) and the mean value of FEV1 was 1,9 (SD=0,6) and 12 months after the start of the biological, the median ACT score was 22,00 (VAR=21,1) and the mean FEV1 was 2,0 (SD =0,8) having the difference no statistical significance.

Apart from one case of anaphylactic reaction 20 minutes after the administration of the suspected drug (mepolizumab), the adverse drug reactions (ADR) collected were not serious. Pruritus (8%), nausea (5%), vomiting (3%), somnolence (3%), weight gain (3%) and headache were the most frequent ADR described.

The mean cost associated with the treatment with: omalizumab (first introduced in CHUSJ) was 1 024,23 € / month (SD=644,47 €), mepolizumab (second introduced in CHUSJ) was 1 145,10 € / month (SD=555,47 €), reslizumab (only 5 treatments) was 828,41€/month (SD=244,58 €) and benralizumab (only 3 treatments) was 1 692,49 €/month (SD=444,51€).