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SHORT COMMUNICATION

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## Efficacy of tezepelumab in patients with severe allergic asthma in clinical practice

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### Abstract

**Introduction:** Tezepelumab is a human monoclonal immunoglobulin G2λ antibody that targets the cytokine thymic stromal lymphopoietin (TSLP). In clinical trials, tezepelumab has been shown to reduce the annualized asthma exacerbation rate in patients with both high and low levels of T2 inflammation biomarkers.

**Methods:** This is a prospective, multicenter study of RE-ASGRAMUR (Register of Severe Asthma of the Region of Murcia) conducted under routine clinical practice conditions. We analyzed exacerbations, changes in lung function (pre-bronchodilator FEV1), asthma control (ACT), and quality of life (mini AQLQ). In addition, T2 biomarkers, including blood eosinophils and exhaled nitric oxide (FeNO), were analyzed.

**Results:** We present a series of 38 patients with severe allergic asthma who received treatment with tezepelumab. More than half of these patients had previously shown inadequate responses to other biologic therapies. Following treatment, the annualized rate of

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exacerbations decreased markedly from a baseline mean of 2.2 to 0.28, representing an 86.8% reduction. The Asthma Control Test (ACT) score improved by an average of 5.2 points, while the mini Asthma Quality of Life Questionnaire (miniAQLQ) score increased by 1 point. Pulmonary function also improved significantly, with a mean increase of 170 mL in FEV<sub>1</sub>. Furthermore, type 2 inflammatory biomarkers, including blood eosinophil counts and fractional exhaled nitric oxide (FeNO), showed a significant reduction.

**Conclusions:** Tezepelumab is an effective treatment for severe allergic asthma, improving exacerbations, disease control, quality of life, and lung function.

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## Introduction

Tezepelumab is a human monoclonal immunoglobulin G2 $\lambda$  antibody that targets the cytokine thymic stromal lymphopoietin (TSLP), preventing its binding to the receptor and reducing the immune stimuli that TSLP can trigger in different asthma endotypes. Tezepelumab decreases downstream biomarkers of inflammation, including blood and airway eosinophils, FeNO, IgE, IL-5, and IL-13.<sup>1</sup>

In clinical trials, tezepelumab has been shown to reduce the annualized asthma exacerbation rate in patients with both high and low levels of T2 inflammation biomarkers. However, the effect was greater in those with high levels, and it has also been shown to improve asthma control, quality of life, and lung function, while reducing airway hyperresponsiveness.<sup>2,3</sup>

TSLP plays a central role in allergen-triggered airway responses and in the persistent airway inflammation observed in allergic asthma. During allergic inflammation, TSLP activates Th2 cells, which subsequently promote the release of IL-4, IL-5, and IL-13. The combined action of IL-4 and IL-13 stimulates T-cell proliferation, drives B-cell maturation into plasma cells, and induces class switching toward IgE antibodies. At the same time, IL-5 and IL-13 together promote eosinophilic inflammation, increase mucus production, and contribute to the formation of mucus plugs in the airways.<sup>4</sup> By blocking TSLP, tezepelumab inhibits these pathogenic pathways in allergic asthma, and clinical trials have demonstrated its efficacy in patients with severe allergic asthma.<sup>5,6</sup>

Recently, real-world data have been reported,<sup>7,8</sup> and we have published 3-month and 6-month results of tezepelumab treatment in patients with severe asthma.<sup>9,10</sup> However, data on the effectiveness of tezepelumab in allergic asthma remain limited; this study aimed to evaluate the real-life effects of tezepelumab in patients with severe allergic asthma.

## Methods

We report the results of an observational, prospective, multicenter study conducted by the Registry of Severe Asthma of the Region of Murcia (RE-ASGRAMUR) under routine clinical practice conditions in 9 centers in Murcia, Spain. The study was carried out ethically in accordance with the World Medical Association Declaration of Helsinki.

All patients provided written informed consent, and the Research Ethics Committee approved the study (approval No. E.O. 2021-77).

We included patients diagnosed with severe uncontrolled asthma according to the American Thoracic Society (ATS)/European Respiratory Society (ERS) criteria. Allergic asthma was defined as a clinical history of asthma symptoms triggered by exposure to relevant aeroallergens, together with sensitization to the corresponding aeroallergens confirmed by skin testing and/or positive specific IgE.

Patients received at least 6 months of tezepelumab treatment, administered at a dose of 210 mg every 4 weeks.

We analyzed exacerbations, changes in lung function (pre-bronchodilator FEV<sub>1</sub>), asthma control (ACT), and quality of life (miniAQLQ). In addition, T2 biomarkers, including blood eosinophils and exhaled nitric oxide (FeNO), were evaluated.

A descriptive analysis of the study variables was conducted. Absolute frequencies and percentages were used for qualitative variables, while mean, standard deviation, median, interquartile range, and minimum and maximum values were calculated for quantitative variables. The normality of quantitative variables was assessed using the Kolmogorov-Smirnov test, and the Student's t-test for paired samples was applied to compare baseline data with data at 6 months.

## Results

We present a series of 38 patients diagnosed with severe allergic asthma. Three patients discontinued treatment: one due to loss of follow-up, one due to treatment failure, and one because of adverse effects, including nausea, internal burning, and severe ocular and nasal itching. All three patients had previously experienced failure with other biologic therapies.

Thirty-five patients received at least 6 months of treatment with tezepelumab. All patients were treated with high doses of inhaled corticosteroids and long-acting  $\beta$ 2-agonists (LABA); 29 patients (83%) also received long-acting muscarinic antagonists (LAMA), and 24 patients (69%) were treated with montelukast.

The baseline characteristics of the patients are shown in [Table 1](#). The mean age was 53.2 years (range, 18-80), and 57% were women. Rhinitis was present in 31% of patients, and nasal polyposis in 14%.

The mean number of exacerbations in the previous year was 2.2; seventeen patients required an ED visit, and four required hospital admission. Patients were poorly controlled, with a mean ACT score of 11.59, and had impaired quality of life, with a mean miniAQLQ score of 3.09. Notably, eighteen patients had previously experienced failure with another biologic therapy.

The results after tezepelumab treatment are presented in Table 2. The mean number of exacerbations decreased from 2.2 to 0.28 (annualized rate), and no patient required an ED visit or hospital admission. Significant improvements were observed in ACT score, AQLQ score, and FEV1, along with significant reductions in eosinophils and FeNO.

## Discussion

We observed a marked reduction in asthma exacerbations after 6 months of tezepelumab treatment, with the mean

number decreasing from 2.2 to 0.28—an 86.8% reduction, which is higher than the rates recently reported by Gates et al.<sup>7</sup> and in the PASSAGE study<sup>8</sup> (76% in the overall cohort and 80% in allergic patients).

This decrease in exacerbations is slightly higher than that observed in a series of 57 patients with and without allergy (85.6%).<sup>10</sup> This reduction highlights the favorable response to tezepelumab in patients with severe allergic asthma and underscores the importance of blocking TSLP in this population.

We would like to highlight these positive results in a series of patients, more than half of whom had previously failed another biologic treatment. This finding is consistent with other recently published series,<sup>7,11</sup> suggesting that by blocking TSLP early in the inflammatory cascade, tezepelumab disrupts multiple downstream inflammatory pathways, which may account for its effectiveness in patients who have failed other biologics that target only a single pathway. It lowers blood eosinophil counts and reduces fractional exhaled nitric oxide (FeNO) and IgE levels by decreasing the production of IL-5, IL-13, and IL-4. In addition, tezepelumab may directly modulate mast cell activity, a key driver of allergic responses. Collectively, these effects likely explain its success in treating severe allergic asthma.<sup>12</sup>

Treatment improved asthma control in our patients, with an increase in ACT score of 5.22 points, exceeding the minimal important difference (MID) of 3 points. The quality of life score, as measured by the miniAQLQ, also improved by 1 point, surpassing the MID of 0.5 points. Regarding lung function, we observed an increase of 170 mL (5.21%) in FEV1. These findings are consistent with the improvements in lung function and patient-reported outcomes reported in clinical trials of severe allergic asthma.<sup>13</sup>

Finally, we observed significant decreases in T2 biomarkers, including eosinophils and FeNO, consistent with the results reported in real-world series.<sup>7,11</sup>

To the best of our knowledge, this is the first published study on the efficacy of tezepelumab in patients with severe allergic asthma. Overall, we observed an excellent response after 6 months of treatment, characterized by a significant reduction in asthma exacerbations. Improvements were also seen in asthma control, quality of life, and pulmonary function. These findings are particularly relevant, as more than half of the patients had previously failed another biologic therapy.

**Table 1** Baseline patient characteristics.

Parameter	N = 35
Women n (%)	20 (57)
Age (mean ± SD)	53.2 ± 12.9
BMI (mean ± SD)	31.2 ± 6.8
Age onset symptoms (mean ± SD)	34 ± 16
Rhinitis, n (%)	11 (31)
Polyposis, n (%)	5 (14)
Eosinophils (mean ± SD)	472 ± 634
IgE (mean ± SD)	269 ± 401
FeNO (mean ± SD)	29.3 ± 29
ACT (mean ± SD)	11.59 ± 3.65
AQLQ (mean ± SD)	3.09 ± 1.11
Exacerbations (mean ± SD)	2.2 ± 2.23
≥ 1 ED visit n (%)	17 (48.6)
≥ 1 Hospital admission n (%)	4 (11.4)
FEV1 ml (mean ± SD)	2046 ± 617
FEV1 % (mean ± SD)	67.53 ± 15
Prior treatment with a biologic agent	18 (51.4)
Omalizumab, n (%)	5 (14.3)
Mepolizumab, n (%)	2 (5.7)
Benralizumab, n (%)	6 (17.1)
Dupilumab, n (%)	5 (14.3)

**Table 2** Results.

N=35	Previous	6 months	Mean difference	P
Exacerbations	2.2 ± 2.23	0.28 ± 1.1	1.91 ± 2.32	0.00001
ED visits	1.4 ± 1.86	0	1.4 ± 1.86	0.0001
ACT	11.59 ± 3.65	16.81 ± 5.33	5.22 ± 5.09	0.00001
AQLQ	3.09 ± 1.11	4.09 ± 1.57	1 ± 1.46	0.0012
FEV1, %	67.53 ± 15	72.74 ± 17	5.21 ± 8.84	0.0019
FEV1, ml	2046 ± 617	2217 ± 724	170 ± 302	0.0027
Eosinophils	472 ± 634	154 ± 143	318 ± 630	0.0086
FENO	29.3 ± 29	22.4 ± 26	6.9 ± 13	0.0093

## Author Contributions

Juan Carlos Miralles-López and José Valverde-Molina designed the study and wrote the manuscript. Virginia Pérez-Fernández performed the informational analysis. All the authors contributed to data collection, and all read and approved the final manuscript.

## Conflict of Interest

Juan Carlos Miralles López has received consultancy fees from AstraZeneca and speaker fees from Novartis, GSK, AstraZeneca, Sanofi, Chiesi, and Gebro. Yulia Petryk has received speaker fees from AstraZeneca, Sanofi, and Chiesi. Juan José Cortés Collado has received speaker fees from AstraZeneca, Sanofi, and GSK. Francisco Javier Bravo Gutiérrez has received speaker fees from Novartis, Ferrer, GSK, AstraZeneca, Sanofi, and Chiesi. Rubén Espinosa Andújar has received speaker fees from GSK, AstraZeneca, Sanofi, FAES, and Chiesi. Manuel Castilla-Martínez has received consultancy fees from GSK and AstraZeneca and speaker fees from Novartis, GSK, AstraZeneca, Sanofi, and Chiesi. Sheila Cabrejos-Perotti has received speaker fees from Sanofi. María Jesús Avilés-Inglés has received speaker fees from Chiesi. Inmaculada Ibarra Calabuig has received speaker fees of Roxall, Hall allergy, Asacpharma, Immunotek, Diater, Sanofi, and Allergy Therapeutics. Miguel Henrique Reyes Cotes has received speaker fees from GSK and AstraZeneca. Manuel José Pajarón-Fernández has received speaker fees from GSK. María Loreto Alemany-Francés has received speaker fees from Novartis, GSK, AstraZeneca, and Chiesi. José Valverde Molina has received consultancy fees from AstraZeneca and speaker fees from Novartis, GSK, AstraZeneca, Sanofi, and GEBRO. The remaining authors declare that they have no conflicts of interest.

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