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Response to benralizumab in patients with severe eosinophilic asthma

Respuesta a benralizumab en pacientes con asma grave eosinofílica

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Abstract

Background: Severe asthma represents a significant public health challenge, and monoclonal antibodies such as benralizumab represent an effective therapeutic option for achieving disease control.
Objective: To evaluate the effectiveness of benralizumab in patients with severe eosinophilic asthma by assessing changes in fractional exhaled nitric oxide (FeNO), peripheral blood eosinophils, symptom control, forced expiratory volume in 1 second (FEV1), and exacerbation rates six months after treatment initiation.
Materials and methods: A prospective observational study was conducted in 11 patients with severe uncontrolled eosinophilic asthma. Clinical outcomes (ACT), quality of life (mini-AQLQ), FEV1, exacerbations, and biomarkers of blood eosinophils and FeNO were assessed at baseline and six months.
Results: After six months of benralizumab therapy, > 90% of patients showed significant improvement in quality of life (mini-AQLQ, $p < 0.05$), and 72.7% achieved better asthma control (ACT, $p < 0.05$). Exacerbations decreased by 66.9% ($p < 0.05$). Blood eosinophils decreased by 97.5% ($p < 0.05$), FeNO by 57% ($p < 0.05$), and FEV1 increased by 27.7% ($p < 0.05$).
Conclusions: Benralizumab demonstrated significant clinical and inflammatory benefits in this cohort, improving biomarkers, lung function, exacerbation rates, and patient-reported outcomes, supporting its effectiveness in real-world management of severe eosinophilic asthma.

Resumen

Introducción: el asma grave representa un importante desafío para la salud pública, y los anticuerpos monoclonales como el benralizumab ofrecen una opción terapéutica eficaz para el control de la enfermedad.
Objetivo: evaluar la efectividad del benralizumab en pacientes con asma eosinofílica grave mediante la valoración de los cambios en el óxido nítrico exhalado fraccionado (FeNO), eosinófilos en sangre periférica, control de síntomas, volumen espiratorio forzado en el primer segundo (FEV1) y tasas de exacerbaciones seis meses después del inicio del tratamiento.
Material y métodos: se realizó un estudio observacional prospectivo en 11 pacientes con asma eosinofílica grave no controlada. Se evaluaron los desenlaces clínicos (ACT), la calidad de vida (mini-AQLQ), el FEV1, las exacerbaciones y los biomarcadores eosinófilos en sangre y FeNO al inicio y a los seis meses.
Resultados: tras seis meses de tratamiento con benralizumab, más del 90% de los pacientes mostró una mejoría significativa en la calidad de vida (mini-AQLQ, $p < 0.05$) y el 72.7% alcanzó un mejor control del asma (ACT, $p < 0.05$). Las exacerbaciones disminuyeron en un 66.9% ($p < 0.05$). Los eosinófilos en sangre se redujeron en un 97.5% ($p < 0.05$), el FeNO en un 57% ($p < 0.05$) y el FEV1 aumentó en un 27.7% ($p < 0.05$).
Conclusiones: el benralizumab demostró beneficios clínicos e inflamatorios significativos en esta cohorte, mejorando los biomarcadores, la función pulmonar, las tasas de exacerbaciones y los desenlaces reportados por los pacientes, lo que respalda su efectividad en el manejo en vida real del asma eosinofílica grave.

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Introduction

Asthma represents a major public health burden, with significant clinical and economic consequences for both patients and healthcare systems.[1] It is a chronic respiratory disease affecting approximately 315 million individuals worldwide, with an estimated 3–10% presenting with severe disease. Severe asthma is defined as disease that remains uncontrolled despite adherence to guideline-recommended therapy at steps 4 or 5 of the Global Initiative for Asthma (GINA), with optimal management of modifiable factors.[2]

Due to the clinical, pathophysiological, and therapeutic heterogeneity of asthma, classification into phenotypes has been proposed.[3] The main severe asthma phenotypes include:

• Type 2-high (Th2-high): characterized by eosinophilia and typically responsive to biologic therapy.

• Non-Type 2 (non-Th2): associated with neutrophilic inflammation and corticosteroid resistance.

• Mixed phenotype: demonstrating overlapping features of both Th2-high and non-Th2 inflammation.[4]

Biologic therapy is recommended in patients with uncontrolled severe asthma who continue to experience persistent symptoms and/or exacerbations despite optimized standard treatment.[5] The choice of biologic agent is guided by the patient's predominant phenotype and biomarker profile. Benralizumab, approved for the treatment of eosinophilic asthma, is a humanized monoclonal antibody that targets the interleukin-5 receptor α (IL-5Rα) expressed on eosinophils and basophils, inducing apoptosis and near-complete depletion of these cells.[6,7]

Monitoring treatment response through inflammatory biomarkers is crucial to optimize the use of biologics, achieve disease control, and reduce unnecessary healthcare utilization.

Materials and methods

An observational, prospective, and analytical study was conducted at the Unidad Médica de Alta Especialidad (UMAE) No. 01, Bajío, of the Instituto Mexicano del Seguro Social (IMSS) in León, Guanajuato, Mexico. The protocol was approved by the Local Research Ethics Committee (registration: R-2022-1001-027) and carried out in accordance with the principles of the Declaration of Helsinki.

Adults (≥ 18 years) with a diagnosis of uncontrolled severe asthma with an eosinophilic phenotype were included. This was defined as peripheral blood eosinophilia ≥ 150–300 cells/μL.[8,9] Patients were followed by the Allergy Department during 2022 and met Global Initiative for Asthma (GINA) criteria for severe uncontrolled asthma despite optimized step 4–5 treatment, including high-dose inhaled corticosteroids plus long-acting β_2-agonists, with persistent symptoms and/or a history of ≥ 2 exacerbations requiring systemic corticosteroids in the previous year. These patients were therefore considered candidates for benralizumab therapy.

Patients with other chronic respiratory diseases (e.g., chronic obstructive pulmonary disease, pulmonary fibrosis, or bronchiectasis), those with acute respiratory infections within three months prior to enrollment, and those who did not complete the 6-month follow-up were excluded.

The primary objective of this study was to evaluate whether benralizumab reduces fractional exhaled nitric oxide (FeNO) levels after six months of treatment. Secondary objectives included assessing its effects on peripheral blood eosinophil counts, pulmonary function measured by forced expiratory volume in one second (FEV1), asthma control using the Asthma Control Test (ACT),[10] health-related quality of life using the Mini Asthma Quality of Life Questionnaire (miniAQLQ),[11] and the number of exacerbations recorded during follow-up.

Clinical data were collected from electronic medical records and direct clinical evaluations. Demographic variables (age and sex), inflammatory biomarkers (peripheral eosinophil counts and FeNO), clinical questionnaires (ACT and mini-AQLQ), spirometry parameters (FEV1), and the number of exacerbations—defined as events requiring systemic corticosteroids, emergency department visits, or hospitalization—were recorded. All outcomes were assessed at baseline (prior to benralizumab initiation) and after six months of therapy.

The ACT is a validated, self-administered five-item questionnaire designed to assess asthma control over the previous four weeks. The total score ranges from 5 to 25, with higher scores indicating better control. It uses a 5-point Likert scale (1–5), including two items on asthma symptoms, one on rescue medication use, one on activity limitation, and one on patient perception of control. The ACT is widely used in clinical practice, endorsed by the Global Initiative for Asthma (GINA) 2024 guidelines,[12] and is freely available for non-commercial research and clinical use.

The miniAQLQ is a disease-specific, 15-item self-administered instrument validated in both paper and electronic formats. It assesses functional impairment across four domains: symptoms, activity limitation, emotional func-

tion, and environmental stimuli. Patients are instructed to recall their experiences during the previous two weeks and respond on a 7-point scale, where 7 indicates no impairment and 1 indicates severe impairment. The miniAQLQ is freely available for academic and non-commercial research.

Pulmonary function (FEV1) was measured by spirometry in accordance with the American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines.[13] Fractional exhaled nitric oxide (FeNO) was assessed according to ATS clinical practice recommendations.[14]

Quantitative variables were expressed as mean ± standard deviation or as median with interquartile range, depending on the distribution assessed with the Kolmogorov-Smirnov test. Qualitative variables were expressed as absolute frequencies and percentages. Comparisons between baseline and post-treatment values were performed using the Wilcoxon signed-rank test for quantitative variables and the McNemar test for dichotomous qualitative variables. A p-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics v25.0 (IBM Corp.) and Microsoft Excel 2016.

Results

A total of 11 patients initiated benralizumab therapy, of whom 8 (72.7%) were women, with a mean age of 53.1 years (range: 44.1–62.0). After six months of treatment, significant improvements were observed across all evaluated parameters (table I). Asthma control, defined as an ACT score ≥ 20, was achieved in 8 patients (72.7%) ($p < 0.05$). Health-related quality of life improved in all participants: 10 patients (90.9%) reported a marked improvement, whereas 1 patient (9.1%) reported a moderate improvement.

Regarding inflammatory biomarkers, peripheral blood eosinophil counts decreased by 97.5% ($p < 0.05$), and fractional exhaled nitric oxide (FeNO) levels declined by 57% ($p < 0.05$). Pulmonary function, measured by FEV1, improved by 27.7% ($p < 0.05$), and the number of exacerbations was reduced by 66.9% compared with baseline ($p < 0.05$).

Discussion

Given the central role of inflammatory biomarkers in guiding and optimizing biologic therapy, the evaluation of treatment response in severe eosinophilic asthma increasingly relies on objective thresholds that reflect minimal clinically important differences, defined as a 20–40% reduction in exacerbations, a ≥ 3-point improvement in ACT, a ≥ 20% reduction in FeNO, a ≥ 200 mL increase in FEV1, and a ≥ 50% decrease in peripheral blood eosinophils.[15]

In pivotal trials such as SIROCCO and CALIMA, benralizumab reduced exacerbation rates by 36–51% and improved FEV1 by 106–159 mL compared with placebo.[16,17] The phase 3b randomized ANDHI trial demonstrated a 49% reduction in exacerbation risk over 24 weeks, together with clinically meaningful improvements in symptoms and lung function.[18] Similarly, the ZEPHYR-2 real-world study reported sustained reductions in annualized exacerbation rates across eosinophil subgroups, including patients switching from other biologics.[19] Another real-world analysis showed ≥ 50% reductions in oral corticosteroid use and exacerbations in over 80% of patients, alongside significant improvements in lung function, asthma control, and eosinophil suppression, with higher baseline eosinophils predicting greater benefit.[20]

Benralizumab discontinuation after achieving remission has been explored in a limited number of studies. Current evidence suggests that clinical remission is generally maintained while biologic therapy is continued; however, data on sustained remission following benralizumab withdrawal remain scarce. Consequently, there is no consensus supporting the systematic discontinuation of biologic therapy in

Table I Response to benralizumab therapy

Parameter	Baseline	6 months	*p*-value
FeNO (mean ± SD)	107.27 ± 56.45	46.09 ± 14.77	0.003
ACT score (mean ± SD)	10.9 ± 3.1	21 ± 4.21	0.003
Asthma controlled by ACT (%)	0 (0%)	8 (72.7%)	0.08
Mini-AQLQ (mean ± SD)	3.14 ± 1.26	5.66 ± 1.19	0.003
Blood eosinophils (median/IQR)	1383 (42.6-2809)	33.63 (7.5-74.8)	0.003
FEV1 (mean ± SD)	58.36 ± 15.45	83.09 ± 14.23	0.013
Exacerbations (mean ± SD)	3.63 ± 1.85	1.09 ± 1.51	0.003

FeNO: Fractional exhaled nitric oxide; ACT: Asthma Control Test; mini-AQLQ: Mini Asthma Quality of Life Questionnaire; FEV1: forced expiratory volume in 1 second

patients with severe asthma, even among those who have achieved clinical remission. Treatment decisions should therefore be individualized and guided by sustained disease control, biomarker suppression, exacerbation history, and close clinical follow-up.[21]

The time required to achieve clinical remission with benralizumab appears to extend beyond the initial treatment phases. Available real-world evidence suggests that remission is most frequently attained after sustained therapy, typically between 9 and 12 months of treatment, with remission rates increasing and remaining stable during long-term follow-up (2–4 years) in patients with severe eosinophilic asthma. In this context, clinical remission—commonly defined as the absence of exacerbations, discontinuation of maintenance of oral corticosteroids, and adequate symptom control—has been reported in a substantial proportion of patients after one year of continuous therapy. In the XALOC-2 real-world study, approximately 27% of patients achieved composite clinical remission criteria at 56 weeks of benralizumab treatment, highlighting that remission is generally a medium- to long-term outcome rather than an early treatment endpoint.[22]

Notably, the magnitude of the effects observed in our cohort—including marked reductions in eosinophils and FeNO, together with meaningful improvements in FEV1, asthma control, and exacerbation frequency—exceeded what is typically reported in controlled trials. This robust response may reflect the selection of patients with highly active type 2 inflammation, characterized by elevated baseline biomarkers and a relatively homogeneous clinical phenotype. Patients with higher initial eosinophil and FeNO levels are known to derive greater benefit from IL-5-targeted therapy, which supports our findings.[23,24]

Improvements in asthma control (ACT ≥ 20 in 72.7% of patients) and quality of life (marked improvement in mini-AQLQ in 90.9% of patients) highlight the relevance of benralizumab not only on physiological parameters but also on patient-centered outcomes, particularly in individuals dependent on oral corticosteroids, whose long-term use carries substantial adverse effects.[25]

The inflammatory biomarkers assessed, including blood eosinophils and FeNO, play a key role in predicting and monitoring response. The reduction in FeNO reflects effective suppression of airway eosinophilic inflammation and is consistent with recent evidence showing that early declines in FeNO during anti-IL-5 therapy are associated with higher rates of clinical remission, supporting its role as a biomarker to guide biologic management.[26,27] Comprehensive patient assessment, including ACT scores, exacerbation burden, lung function, and quality of life at 3–4 months after treatment initiation, allows early identification of responders and timely adjustment of therapy.[28]

Significant improvements in lung function and reductions in exacerbations underscore the clinical relevance of benralizumab, as these outcomes are closely linked to morbidity, hospitalizations, and healthcare utilization. The magnitude of exacerbation reduction in our cohort (66.9%) supports the effectiveness of benralizumab in real-world clinical practice and further highlights the potential utility of biomarker-guided monitoring to inform treatment continuation and adjustments. Nonetheless, these findings should be interpreted with caution, as the magnitude of benefit may be influenced by selection bias toward patients with prominent type 2 inflammation, regression to the mean, and unmeasured concomitant interventions.

From a health economics perspective, although benralizumab represents a high-cost therapy, its use has been associated with significant reductions in exacerbations, emergency department visits, and hospitalizations, as well as decreased exposure to oral corticosteroids, potentially offsetting both direct and indirect healthcare costs. In the absence of biologic therapy, patients with severe eosinophilic asthma often remain dependent on high-dose inhaled or systemic corticosteroids, which are associated with substantial long-term adverse effects, including osteoporosis, diabetes mellitus, hypertension, adrenal suppression, and an increased risk of infections. Severe asthma exacerbations are a major driver of healthcare utilization and costs, particularly due to hospital admissions, underscoring the clinical and economic value of therapies that effectively reduce exacerbation rates.[25]

Limitations

This study is limited by its small sample size and single-center design, which restrict generalizability. The lack of a control group prevents causal inference, and the six-month follow-up does not capture long-term outcomes. Additionally, only selected biomarkers were assessed, and patient-reported outcomes may be subject to recall bias. Larger, multicenter, and controlled studies are needed to validate these findings and further optimize benralizumab therapy.

Conclusions

Benralizumab treatment was highly effective in patients with severe eosinophilic asthma, leading to significant reductions in peripheral eosinophils, FeNO, and exacerbation frequency, as well as improvements in lung function (FEV1), asthma control, and quality of life at six months. These out-

comes exceed the minimal clinically important differences and highlight the importance of selecting patients based on eosinophilic phenotype and inflammatory biomarkers to optimize therapeutic response. Larger multicenter studies are warranted to validate these results and generalize their applicability to broader severe eosinophilic asthma populations.

Despite its higher upfront cost, benralizumab provides substantial clinical advantages over conventional therapy, resulting in improved disease control, fewer exacerbations, and a reduced burden of corticosteroid-related morbidity in patients with severe eosinophilic asthma.

We express our gratitude and dedicate this work to the memory of Dr. Rafael Luna Montalbán, an outstanding internist and infectious disease specialist at the Hospital de Especialidades del Centro Médico Nacional del Bajío, whose tireless work in medicine, teaching, and research left a profound mark on our training. His vocation, commitment, and human quality continue to serve as an example and constant inspiration to all of us.

Conflict of interest disclosure: The authors have completed and sent the Spanish-translated form of the Declaration for Potential Conflicts of Interest of the International Committee of Medical Journal Editors, and no conflicts of interest were reported related to this article.

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