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A Super-Responder Case with Asthma, Chronic Rhinosinusitis and Nasal Polyposis Successfully Treated with Benralizumab

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ABSTRACT

BACKGROUND: Benralizumab is a humanized, afucosylated anti-eosinophil monoclonal antibody that binds with high affinity and specificity to the alpha subunit of the human interleukin 5 receptor (IL-5Rα). Benralizumab is primarily indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma. This monoclonal antibody is increasingly recognized with a therapeutic effect in other entities in which activated eosinophils and basophils have a pivotal role in disease course.

CASE REPORT: We herein report a case with nasal polyposis and asthma who was treated with benralizumab with an excellent response, characterized by absence of asthma crisis or rhinosinusitis, without the need of oral steroids, and with a low dose of inhaled medications.

CONCLUSION: In conclusion, this case suggests that benralizumab may be considered earlier as a remission induction therapy in patients with asthma and other allergic comorbidities.

KEYWORDS: Benralizumab; Monoclonal antibody; Interleukin-5 receptor (IL-5Rα); Asthma; Rhinosinusitis; Eosinophils; Basophils; Steroids.

RESUMEN

ANTECEDENTES: Benralizumab es un anticuerpo monoclonal humano dirigido contra los eosinófilos, que se enlaza con alta afinidad y especificidad a la subunidad alfa del receptor de la interleucina 5 humana (IL-5Rα). Está indicado como tratamiento de mantenimiento complementario en pacientes adultos con asma eosinofílica grave. Cada vez es más reconocido por su efecto en otras alteraciones, en las que los eosinófilos y basófilos activados desempeñan un papel importante en la evolución de la enfermedad.

REPORTE DE CASO: Paciente masculino de 52 años con poliposis nasal y asma, con excelente respuesta al tratamiento con benralizumab, caracterizada por la ausencia de crisis asmáticas y episodios de rinosinusitis, sin necesidad de prescripción de corticosteroides por vía oral y con dosis baja de medicación inhalada.

CONCLUSIÓN: Este caso sugiere que benralizumab es una opción valiosa para lograr la remisión clínica en pacientes cuidadosamente seleccionados con asma y otras comorbilidades alérgicas.

PALABRAS CLAVE: Benralizumab; Anticuerpo monoclonal; Receptor de interleucina-5 (IL-5Rα); Asma; Rinosinusitis; Eosinófilos; Basófilos; Corticoides.

INTRODUCTION

Nasal polyposis is essentially a chronic inflammatory disease.[1] Several studies focusing on the inflammatory process have linked functional abnormalities of immune system cells, such as macrophages, dendritic cells, and stem cells, to the persistence of inflammation, while other studies have shown how the inflammatory milieu affects cell activity and differentiation in nasal polyposis driven by a Th2 immune response.[2]

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Benralizumab is a humanized, afucosylated monoclonal antibody directed against the alpha subunit of the interleukin-5 receptor (IL-5Rα), which is expressed on eosinophils and basophils, conferring specificity for eosinophil-driven disease.[3-5] It is currently approved as an add-on maintenance treatment for adults with severe eosinophilic asthma inadequately controlled with high-dose inhaled corticosteroids and additional controllers.[3]

Several biological agents are available for type 2 inflammatory airway disease, and the choice among them depends on the predominant comorbidities and the underlying inflammatory endotype.[6,7] Omalizumab, an anti-IgE antibody, is primarily indicated in allergic asthma but has a more limited role in chronic rhinosinusitis with nasal polyps.[8,9] Dupilumab, which blocks the IL-4Rα subunit shared by the IL-4 and IL-13 pathways, has shown efficacy in both severe asthma and nasal polyposis.[10] Among the anti-IL-5 axis agents, mepolizumab and reslizumab neutralize circulating IL-5, whereas benralizumab targets the IL-5 receptor α subunit directly, producing a rapid and near-complete depletion of eosinophils.[11]

A growing body of evidence suggests that benralizumab might be a treatment option in patients with disease entities featuring eosinophilia as a major pathophysiological component.[12-14] Moreover, it is increasingly recognized that several hypereosinophilic syndromes share common pathogenic roots that might be suitable for anti-IL-5Rα therapies.[15,16]

In Mexico, there is a lack of epidemiological studies and registries helping to understand the actual burden of nasal polyps and other chronic inflammatory conditions. Moreover, there are no local academic recommendations that guide therapeutic decisions in difficult or infrequent cases. Efforts have been made to change this landscape, starting with case series illustrating clinical decisions in peculiar case scenarios. Herein, we describe a case of a patient with asthma and chronic rhinosinusitis with nasal polyps who was treated with benralizumab, demonstrating an excellent response from the outset and achieving long-term stabilization.

CASE REPORT

A 52-year-old man was referred to our institution with a diagnosis of difficult-to-treat eosinophilic asthma and nasal polyps. The patient had a history of allergy to non-steroidal anti-inflammatory drugs (NSAIDs) and asthma since childhood, with three prior surgical resections of nasal polyps. There was no family history of similar diseases or conditions. In 2018, the patient presented with a mild exacerbation of asthma, for which a short course of oral corticosteroids was prescribed along with antibiotics, resulting in an adequate response. Skin prick allergy tests performed with weight/volume allergen extracts at a 1:10 concentration tested positive for dog antigens, *Chenopodium album*, *Poa*, *Fraxinus*, *Prosopis*, and *Ligustrum*.

Clinical evolution and interventions

As summarized in the chronological evolution in Table 1, in July 2019, the patient was diagnosed with rhinosinusitis and an asthma exacerbation, which were treated with levofloxacin and high-dose inhaled corticosteroids. Two additional episodes of bacterial sinusitis were identified in November 2019 and February 2020, and six other asthma exacerbations were diagnosed between June 2020 and July 2021, requiring short courses of oral corticosteroids. In September 2021, another episode of sinusitis was identified, associated with the presence of nasal polyps in the frontal sinuses (**Figure 1A and B**).

Table 1.
Chronology of clinical events and therapeutic interventions.

Date / Period	Clinical event / Diagnosis	Management / Response
Childhood – 2017	Asthma and Nasal Polyposis	3 Surgical resections
2018	Mild asthma exacerbation	Oral steroids / antibiotics (Adequate response)
July 2019	Rhinosinusitis + asthma exacerbation	Levofloxacin / High-dose ICS
Nov 2019 – Feb 2020	Two episodes of bacterial sinusitis	Antibiotics and standard care

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Date / Period	Clinical event / Diagnosis	Management / Response
June 2020 – July 2021	Six asthma exacerbations	Repeated short-term oral steroids
September 2021	Sinusitis with frontal sinus polyps	Medical management
February 2022	Severe asthma attack (FEV_1 62%, 22% reversibility)	Criteria met for biological therapy
May 2022	Initiation of biological therapy	Start of Benralizumab
2022 – 2024	No exacerbations (Clinical stability)	Benralizumab

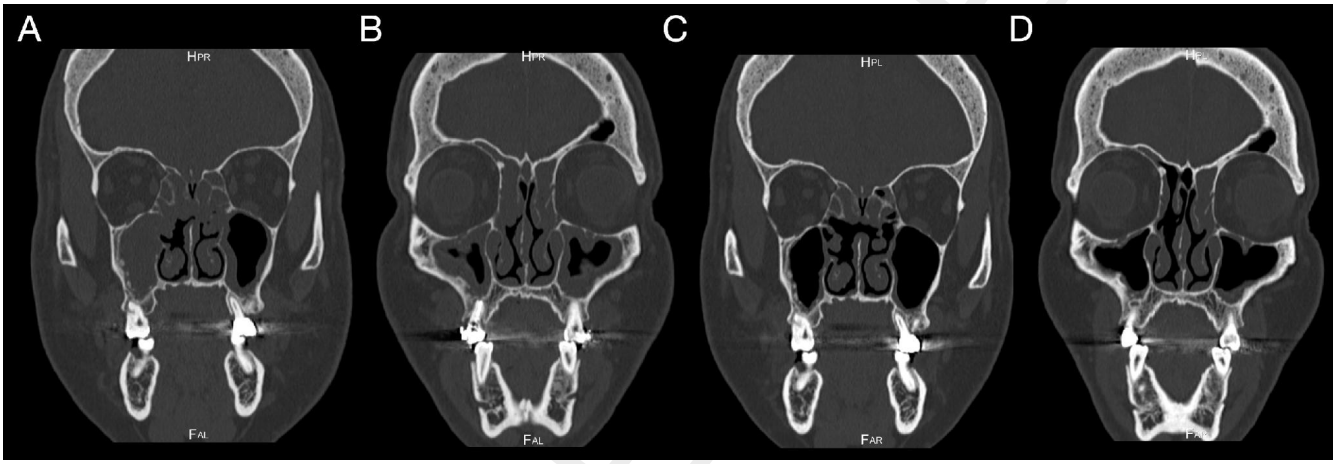


Figure 1. Computed tomography showing nasal polyps before (A and B) and at 12-month follow-up with benralizumab therapy (C and D).

There was a brief period of 5 months of relative stability until February 2022, when he experienced a severe asthma attack (FEV_1: 62%, with improvement to 75% after bronchodilator administration, representing 22% reversibility; IgE: 63 IU/mL). At this point, the patient met the criteria for severe uncontrolled asthma, defined by more than two exacerbations within a year requiring oral corticosteroids, treatment with high-dose inhaled corticosteroids, and an FEV_1 of 62% with 22% reversibility. Given this severity, combined with his eosinophil-mediated comorbidities (recurrent nasal polyposis with three prior surgical resections and NSAID intolerance), he was considered a candidate for early biological therapy. Subcutaneous benralizumab was started on May 12, 2022 (30 mg once every 4 weeks for the first three doses, and once every 8 weeks thereafter).

Outcomes and follow-up

In the following 24 months, no asthma or sinusitis exacerbations were identified under combination therapy with benralizumab, inhaled budesonide/formoterol b.i.d., and mometasone b.i.d. This clinical stability was accompanied by significant radiological clearance of the nasal polyps observed at the 12-month follow-up (**Figure 1C and D**). This regimen has been successfully maintained since benralizumab initiation. No adverse events related to benralizumab were reported by the patient throughout the follow-up period.

DISCUSSION

The primary aim of asthma management is to maintain long-term asthma control with the minimum effective dose of medication using a step-up pharmacological approach. Before adding second-line medications, patients are started on low-dose inhaled corticosteroids, with dose adjustments based on clinical response. Long-term use of oral corticosteroids is regarded as a last resort due to the severe adverse effects associated with this drug class. Benralizumab is a humanized, afucosylated, anti-interleukin-5 receptor α monoclonal antibody that induces nearly complete depletion of eosinophils via enhanced antibody-dependent cell-mediated cytotoxicity.[4,5,17,18] When benralizumab binds to basophils and eosinophils, it

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facilitates their interaction with NK cells, ultimately leading to apoptosis. Because eosinophils play a key role in airway inflammation, blocking these cells exerts a potent anti-inflammatory effect. Therefore, benralizumab is indicated for adult patients with severe eosinophilic asthma as add-on maintenance therapy.[3] In the pivotal CALIMA and SIROCCO trials, benralizumab demonstrated superiority over placebo at 56 and 48 weeks, respectively, in reducing the annualized exacerbation rate in patients with elevated eosinophil counts.[19-21]

The present case can be categorized as a super-responder based on the sustained absence of exacerbations and the elimination of oral corticosteroid use following treatment initiation, aligning with the clinical criteria proposed by Kavanagh et al., who first described super-responders to benralizumab as patients without clinical exacerbations and without the need for oral corticosteroids to manage asthma.[22] Later, Miralles-López et al. noted that super-responders to benralizumab were typically older, presented with higher baseline eosinophil counts, had comorbid nasal polyposis, and had less severe disease prior to therapy, helping to establish that patients with severe eosinophilic asthma are suitable candidates for benralizumab treatment.[23]

Therefore, our case further illustrates the importance of prompt recognition of patients with asthma and eosinophil-mediated allergic comorbidities who may be at risk for poor responses to standard therapy.[13,24,25] Over time, prolonged trials with ineffective regimens may result in increased healthcare resource utilization and life-threatening exacerbations,[26] along with a higher incidence of adverse effects linked to repeated or long-term courses of oral corticosteroids and antibiotics.[27-29] Moreover, cases with significant comorbidities, such as the one presented here, underscore the potential value of evaluating therapies targeted at the IL-5 axis at earlier disease stages. Nevertheless, as these observations are derived from a single case, they should be considered hypothesis-generating, and controlled studies are needed to determine whether earlier intervention provides clinical benefits before the disease progresses to a harder-to-manage state.[13,25,30]

It is important to note that this report is limited to a single patient, so these findings should not be broadly generalized. Additionally, the excellent response observed is defined by clinical parameters, such as the reduction in asthma attacks and the elimination of oral corticosteroid use, since serial blood eosinophil counts were not available for longitudinal monitoring. The absence of these biomarker measurements is a limitation of this retrospective report, and the therapeutic response should therefore be interpreted on clinical grounds. While these limitations exist, the patient's clear clinical stabilization provides relevant evidence for the use of benralizumab in similar clinical scenarios.

The clinical course observed in this patient contrasts with the natural history expected under conventional management. Despite three prior surgical resections and repeated courses of inhaled and oral corticosteroids, the patient continued to experience recurrent sinonasal disease and asthma exacerbations. In patients with chronic rhinosinusitis with nasal polyps managed with corticosteroids alone, polyp recurrence and the need for revision surgery are frequent.[25] The sustained absence of exacerbations and the elimination of oral corticosteroid courses after the initiation of benralizumab therefore represent a clinically meaningful departure from the previous trajectory.

These observations are particularly relevant in the Mexican context, where access to biological therapies remains limited and unevenly distributed.[31] The lack of local registries and academic recommendations means that decisions regarding the timing of biological therapy are often made on a case-by-case basis. In this setting, reports such as the present one may help to inform clinical judgment and to support a timely consideration of anti-IL-5 receptor therapy in carefully selected patients with severe eosinophilic asthma and eosinophil-mediated comorbidities.

Furthermore, the patient presented with asthma, nasal polyposis, and NSAID allergy, a triad strongly suggestive of Aspirin-Exacerbated Respiratory Disease (AERD, or Samter's Triad). However, this diagnosis was not formally evaluated through provocation challenges, which adds complexity to the retrospective interpretation of the case.

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Future real-world studies should also include analyses of anti-drug antibodies potentially associated with long-term benralizumab exposure; however, this factor may not be as determinant as previously hypothesized.[29] Novel anti-IL-5Rα indications may be explored in future cases with comorbid eosinophilic asthma to better elucidate the clinical benefit of benralizumab in stabilizing comorbid conditions beyond inadequately controlled asthma.

CONCLUSION

In conclusion, our case suggests that benralizumab could be a valuable option to explore in patients with difficult-to-treat eosinophilic asthma, particularly when other eosinophil-mediated allergic comorbidities are present. These findings highlight the need for further studies to evaluate the impact of earlier biological intervention in similar clinical profiles.

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Patient consent

Written informed consent for the publication of this case report and any accompanying images was obtained from the patient.

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