Submitted: 26 November, 2024 Accepted: 21 March, 2025 Published: 08 August, 2025 DOI:10.22514/sv.2025.107

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ORIGINAL RESEARCH

Benralizumab in severe eosinophilic asthma

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Abstract

Background: Severe asthma is a significant cause of morbidity, and biologic therapies may offer benefits for some patients. Benralizumab, a monoclonal antibody, targets the interleukin-5 receptor (IL-5R) on eosinophils, preventing IL-5 from binding to its receptor. This action inhibits the differentiation and maturation of eosinophils in the bone marrow, making benralizumab a promising treatment for severe eosinophilic asthma. Following its marketing approval in Turkey in October 2023, this study aims to share initial clinical experience with benralizumab in treating severe eosinophilic asthma. **Methods**: A retrospective review was conducted on the medical records of 30 adult patients diagnosed with severe eosinophilic asthma, including both biologic-naive patients and those previously treated with biologics. These patients were initiated on benralizumab between 01 November 2023 and 01 October 2024, and their clinical data, including asthma control test scores, St. George's Respiratory Questionnaire scores, eosinophil counts, pulmonary function forced expiratory volume 1, frequency of asthma attacks, and oral corticosteroid use, were collected before and after benralizumab initiation. **Results**: We observed that despite the presence of comorbidities, significant clinical improvements were observed within four weeks of starting benralizumab, with measurable effects as early as one month. **Conclusions**: Benralizumab based recoveries were consistent across multiple outcome measures, including asthma control, quality of life, and pulmonary function.

Keywords

Severe eosinophilic asthma; Benralizumab; Quality of life; Asthma attacks; FEV1

1. Introduction

Asthma is a chronic and heterogeneous disease, characterized by variable symptoms and persistent airway inflammation. Classifying asthma by phenotype and endotype can provide valuable insights into treatment strategies by identifying the underlying mechanisms. Asthma endotypes are primarily categorized into two groups: high-type 2 inflammation and low-type 2 inflammation [1, 2], and severe asthma is defined as asthma that remains uncontrolled despite optimized treatment with high-dose inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA), or worsens when high-dose therapy is reduced [3]. It is estimated that 3–10% of individuals with asthma suffer from severe asthma [4].

In Turkey, the prevalence of severe asthma has been reported to be 7% in a single-center study and 12% in a multicenter study conducted at a tertiary hospital [5, 6]. Eosinophilic asthma, which is associated with the high-type 2 inflammation endotype, is characterized by frequent exacerbations, poor symptom control and progressive lung function decline. The cytokine interleukin-5 (IL-5) plays a central role in the differentiation, activation and survival of eosinophils, making it a key driver of eosinophilic asthma [7]. The presence of eosinophilia is directly linked to poor disease control and an increased risk of asthma exacerbations [8].

However, severe eosinophilic asthma is often resistant to standard treatments such as ICS and oral corticosteroids (OCS), which may be due to the excessive secretion of IL-5 that overwhelms the anti-inflammatory effects of corticosteroids [9]. Benralizumab is a monoclonal antibody that targets the IL-5 receptor alpha (IL-5Rα), and works by depleting eosinophils through both direct receptor binding and antibody-dependent cell-mediated cytotoxicity (ADCC) to ensure rapid and effective eosinophil depletion in both the blood and tissue [10].

Clinical trials have demonstrated that benralizumab significantly reduces the frequency of severe asthma exacerbations, decreases the use of OCS, improves lung function (as measured by FEV1), and enhances overall symptom control [11–14]. In addition to these findings, real-world studies have shown that biologic therapies, such as benralizumab, are associated with notable improvements in health-related quality of life for patients with severe asthma [15]. One commonly used tool to assess quality of life in respiratory disease patients, including those with asthma, is the St. George's Respiratory Questionnaire (SGRQ). The SGRQ evaluates general health, daily

functioning and overall well-being, providing a comprehensive measure of the impact of asthma on patients' lives [16, 17].

Severe asthma, especially with frequent exacerbations, is associated with increased morbidity and mortality, highlighting the need for effective treatments. Recent advancements in biologic therapies have significantly improved the management of severe asthma, offering new therapeutic options for patients with refractory disease. Therefore, this study aims to evaluate the efficacy, safety and impact of benralizumab on both clinical outcomes and quality of life in patients with severe eosinophilic asthma.

2. Methods

2.1 Patient selection

This study included 30 adult patients with severe eosinophilic asthma who received benralizumab treatment at the immunology and allergy clinic of our tertiary healthcare center between 01 November 2023 and 01 October 2024. All patients underwent treatment according to the Global Initiative for Asthma (GINA) step 5 guidelines [4]. The study inclusion criteria were as follows: patients aged over 18 years, receiving high-dose ICS plus long-acting beta2 agonists (LABA), an eosinophil count of $\geq$300 cells/μL, and either two or more asthma attacks per year requiring emergency room visits (with at least 3 days of OCS use) or one or more hospitalizations due to asthma attacks. The exclusion criteria included patients with active autoimmune diseases, malignancies or pregnancy. Patients with prior exposure to biological agents were also eligible for inclusion in the study.

Herein, eosinophil counts were measured at the time of treatment initiation and checked at least twice to account for possible suppression by OCS or high-dose ICS. Additionally, historical eosinophil data were reviewed via the national online health system to confirm the diagnosis of eosinophilic asthma.

2.2 Study design

In Turkey, benralizumab is approved as an additional maintenance treatment for adults with severe eosinophilic asthma who are already using high-dose ICS and one or more additional control agents (*e.g.*, LABA). Patients must also have had at least two exacerbations in the previous year, requiring a minimum of three days of systemic corticosteroid treatment, and a blood eosinophil count of $\geq$300 cells/μL. Benralizumab was administered subcutaneously (30 mg) every 4 weeks for the first three doses, followed by 30 mg every 8 weeks thereafter.

Data collected for this study included the presence of concurrent nasal polyps, non-steroidal anti-inflamatory drug (NSAID) sensitivity, baseline blood eosinophil levels, total immunoglobulin E (IgE) levels, number of asthma attacks, OCS use, emergency room visits and hospitalizations due to exacerbations.

Atopy was assessed via skin prick testing and/or specific IgE testing. Pulmonary function tests, asthma control tests (ACT) and SGRQ scores were also recorded. The SGRQ is composed of three sections: Symptoms (8 questions), Activity (16 questions), and Impact (26 questions). The scores are calculated using a scoring algorithm, where individual section scores and the total score range from 0 (no impairment) to 100 (maximum impairment) [16]. The same data were collected 4 weeks after the initiation of benralizumab treatment. A flow chart for the patient selection process is shown in Figs. 1,2.

2.3 Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) 25.0.1 (IBM Co., New York, NY, USA). The normality of numerical variables was assessed using the Kolmogorov-Smirnov test. Normally distributed data were expressed as mean $\pm$ standard deviation, while non-normally distributed data were presented as median (quartile 1 (Q1)–quartile 3 (Q3)). Categorical variables were presented as frequencies and percentages. Paired *t*-tests were used to compare dependent groups, while independent *t*-tests were used to compare two independent groups, and one-way analysis of variance (ANOVA) was used to compare more than two independent groups. The Chi-square test was applied for categorical variables. A p-value of < 0.05 was considered statistically significant.

3. Results

The study included 30 patients, of which 15 (50%) were male and 15 (50%) were female, with a mean age of 54.1 $\pm$ 11.7 years. Among the patients, 17 (56.7%) had a history of atopy and 15 (50%) had nasal polyps. Eighteen patients (60%) had not previously received any biologic therapy. Of the 12 patients who had prior biologic treatment, 3 (10%) had been treated with omalizumab, 3 (10%) with mepolizumab and 6 (20%) had received both omalizumab and mepolizumab. In the year prior to starting benralizumab, the mean number of hospitalizations was 0.33 $\pm$ 0.66, the mean number of emergency room visits was 3.4 $\pm$ 3.5, and the mean frequency of systemic corticosteroid use was 3.9 $\pm$ 3.24. The study cohort's demographic and clinical characteristics are summarized in Table 1.

The duration of benralizumab treatment varied across patients, with 24 patients having received at least three doses. One patient had been on treatment for nearly a year. Regardless of nasal polyposis status or the number of prior asthma attacks, statistically significant improvements were observed in both the SGRQ and ACT scores for all patients, as well as in atopic and non-atopic groups separately. The changes in respiratory function and quality of life parameters after 4 weeks of benralizumab treatment are shown in Table 2.

To determine the eosinophil threshold value, the 15 patients with the highest eosinophil count were compared to the 15 patients with the lowest eosinophil count. The cutoff value was identified as 925 cells/μL. Both groups showed significant improvements in the total and subgroup scores of the SGRQ following treatment. These improvements are detailed in Table 3. Importantly, no adverse effects related to benralizumab, including allergic reactions, were reported during the study.

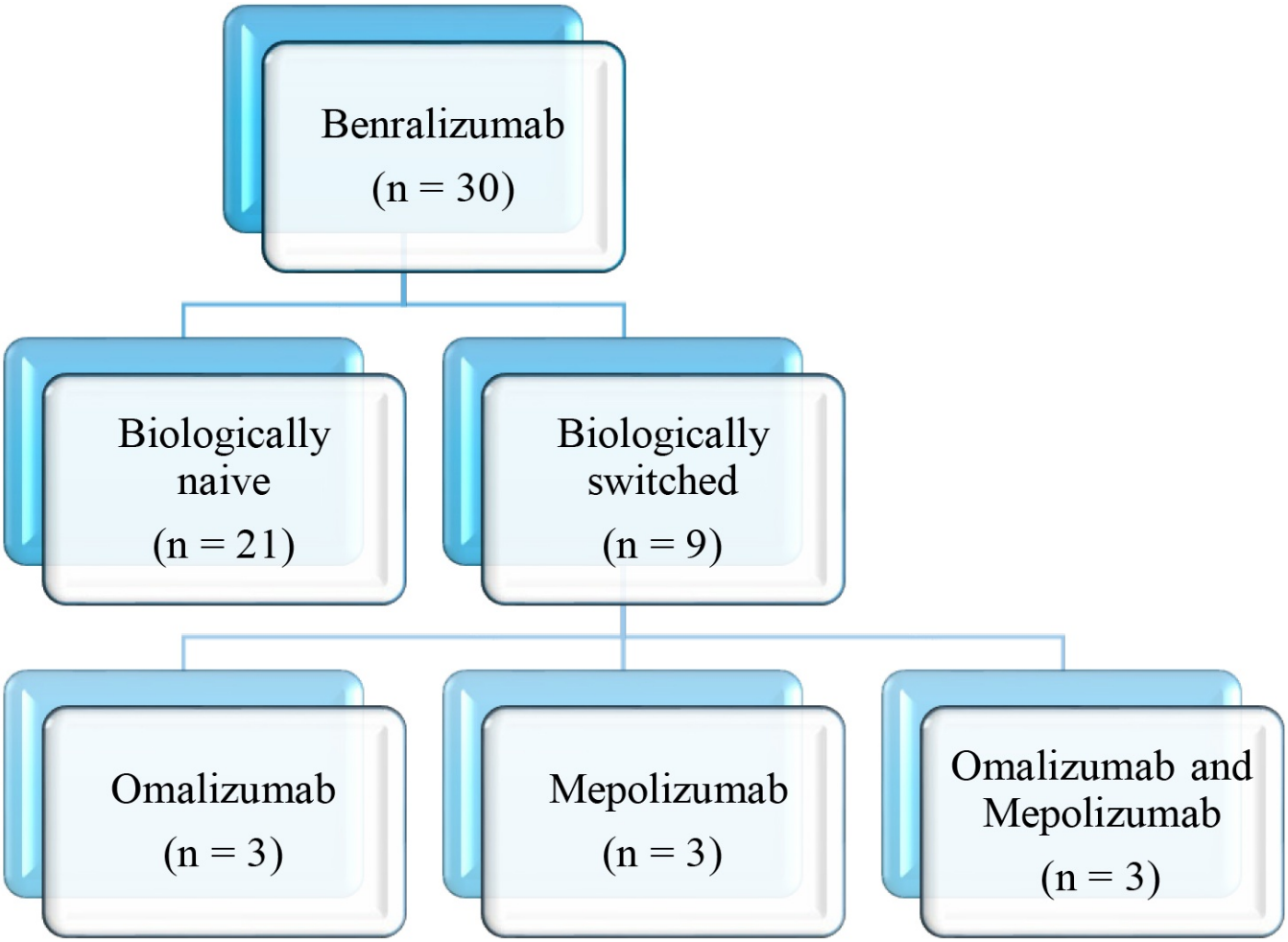

FIGURE 1. Flow chart of the study patients and grouping.

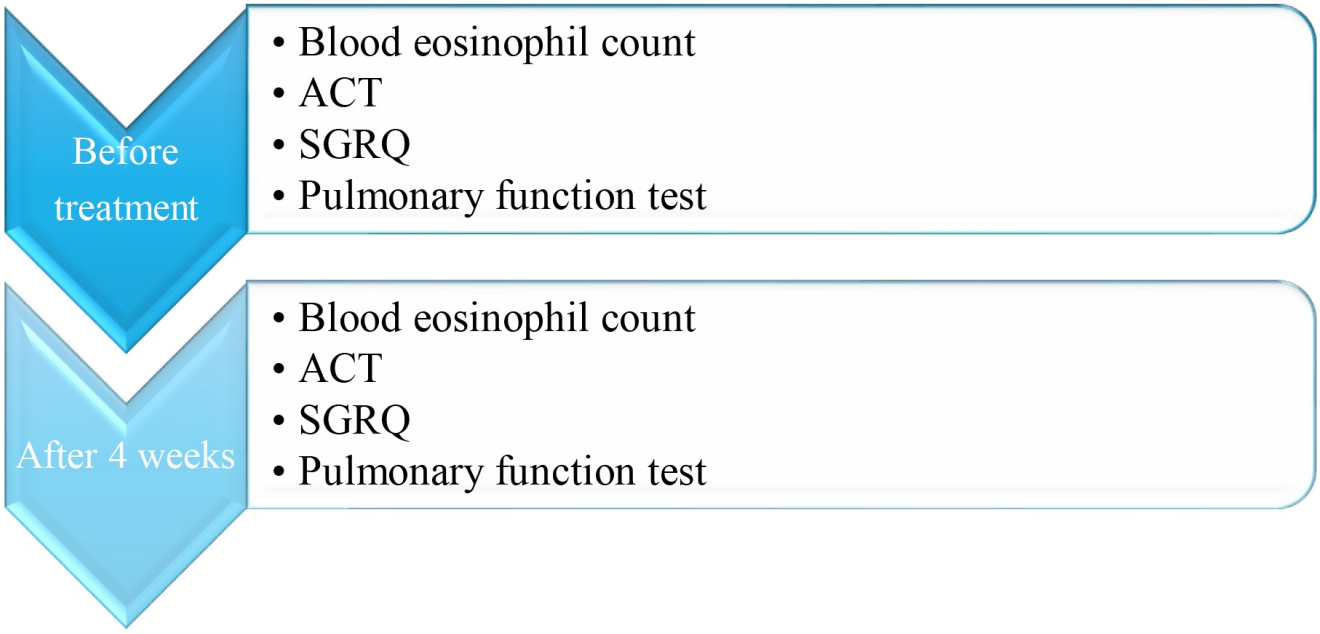

FIGURE 2. Parameters recorded and assessed. ACT: Asthma Control Test; SGRQ: St George's Respiratory Questionnaire.

TABLE 1. Demographic and clinical characteristics of the included patients.

Parameters	Values
Age, yr (mean ± SD)	54.1 ± 11.7
OCS usage in a year (times)	3.9 ± 3.24
Number of hospitalizations in a year (mean ± SD)	0.33 ± 0.66
Number of emergency applications in a year (mean ± SD)	3.4 ± 3.5
Gender, n (%) Male/Female	15 (50%)/15 (50%)
Atopy, n (%)	17 (56.7%)
Nasal polyposis, n (%)	15 (50%)
NSAID sensitivity, n (%)	8 (26.7%)
Prior biological agent use, n (%)	
Omalizumab	3 (10%)
Mepolizumab	3 (10%)
Both omalizumab and mepolizumab	6 (20%)

SD: Standard deviation; OCS: Oral corticosteroid; NSAID: Nonsteroidal anti-inflammatory drugs. Before treatment, the patients had a mean eosinophil count of 885.0 ± 398 cells/μL, a mean forced expiratory volume in 1 second (FEV1) of 1.7 ± 0.8 liters and a mean ACT score of 11.0 ± 3.8.

TABLE 2. Changes in variables before and after 4 weeks of benralizumab treatment.

Parameters	Before treatment	After 4 weeks of treatment	*p*-value
Eosinophil Cells (cells/μL)	885.00± 398.10	1.33 ± 4.34	<0.001
FEV1 (L)	1.7 ± 0.84	2.2 ± 0.99	<0.001
FVC (L)	2.40 ± 1.11	2.90 ± 1.30	0.028
FEV1/FVC (%)	66.9 ± 12.7	72.0 ± 11.9	0.292
SGRQ score	75.00 ± 14.15	31.58 ± 16.94	<0.001
Symptom	84.32 ± 10.52	41.84 ± 23.52	<0.001
Activity	77.75 ± 18.58	36.31 ± 19.66	<0.001
Impact	70.49 ± 17.18	27.85 ± 22.02	<0.001
ACT score	11.0 ± 3.8	20.3 ± 2.2	<0.001

μL: Microliter; FEV1: Forced expiratory volume 1; L: Liter; FVC: Forced vital capacity; SGRQ: St. George's Respiratory Questionnaire; ACT: Asthma control test.

TABLE 3. Eosinophil cutoff value and changes in St. George's respiratory questionnaire scores.

Variables	Before treatment				After 4 weeks of treatment				*p*-value
	Total	Symptom	Activity	Effects	Total	Symptom	Activity	Effects	
Eos >925 cells/μL	76.10	85.17	77.74	72.34	30.31	38.51	34.82	19.53	<0.001
Eos <925 cells/μL	73.90	83.49	77.76	68.65	32.87	45.17	37.80	24.66	<0.001

μL: Microliter.

4. Discussion

In this study, we observed significant improvements in respiratory function, asthma control, and quality of life in 30 patients with severe eosinophilic asthma, observed just four weeks after the initiation of benralizumab treatment.

Previous studies have demonstrated that benralizumab is both effective and safe in the management of severe eosinophilic asthma. The most commonly reported adverse events during treatment include worsening asthma, nasopharyngitis, upper respiratory tract infections and local skin reactions at the injection site. However, in our cohort, no systemic or local adverse events were observed. Pooled *post-hoc* analyses of benralizumab clinical trials have shown that patients with elevated blood eosinophil counts, frequent exacerbations, poor lung function, oral OCS dependence, adult-onset asthma, and nasal polyposis tend to exhibit improved clinical outcomes with benralizumab therapy [12–14, 18–21]. In line with these findings, our study observed statistically significant improvements in ACT scores, FEV1, blood eosinophil counts, and quality of life at four weeks of treatment, consistent with a similar patient

profile. Notably, in the trial phase 3 SIROCCO and CALIMA studies, benralizumab was shown to significantly reduce exacerbations and improve FEV1 in patients with blood eosinophil counts $\geq$300 cells/μL after 16 weeks of treatment [11, 12]. An interesting and distinctive feature of our study is that we observed comparable results in a much shorter time frame—just 4 weeks after treatment initiation.

The observed reduction in eosinophil levels in our patients was closely correlated with clinical improvements. Specifically, the mean FEV1 increased from 1.7 L to 2.2 L (459 mL) after 4 weeks, a change that was statistically significant. In a similar study by Padilla *et al.* [22], an improvement in FEV1 of 291 mL was reported, making the 459 mL improvement observed in our study particularly remarkable. Blood eosinophil count is widely regarded as the most reliable biomarker for predicting the efficacy of benralizumab, with other patient characteristics and biomarkers also being explored as potential predictors of treatment response [18, 23–26]. In our study, the reduction in eosinophil count over 4 weeks was paralleled by improvements in both quality of life and FEV1, further validating eosinophil count as a key biomarker for predicting therapeutic response.

Benralizumab efficacy in our cohort was demonstrated irrespective of atopy, allergic sensitivities, IgE levels [27–31], and fungal sensitivities [32]. This finding aligns with previous reports indicating that the therapeutic effects of anti-IL-5 treatments in patients with severe eosinophilic asthma are generally independent of IgE levels and atopic characteristics. One study further suggested that patients with positive skin prick tests experienced significant improvements in asthma exacerbation frequency, ACT scores and daily short-acting beta2-agonist (SABA) use, compared to those with negative skin prick tests [31]. In our study, 56.7% of patients were atopic, and we found that benralizumab provided statistically significant improvements in ACT, SGRQ total and subgroup scores, as well as FEV1, at week 4 in both atopic and non-atopic patients. These findings are consistent with the literature, which also reports significant benefits of benralizumab across both atopic and non-atopic asthma subgroups.

One of the most striking findings of our study is the improvement in quality of life in all patients, regardless of atopy, nasal polyps or eosinophil count. Statistically significant improvements were observed in both the ACT and SGRQ scores for all the 30 patients. This is consistent with a similar study in the literature, where 77% of patients achieved clinically significant improvements in ACT scores, and 79% in SGRQ scores following benralizumab treatment. Importantly, these improvements were observed irrespective of baseline blood eosinophil counts, comorbidities, previous exacerbation history or maintenance OCS use [33].

Our limitation is that the number of patients is low since benralizumab has been used in our country since October 2023. Moreover, since the drug was started at variable times in the last 1 year, our long-term data is not yet sufficient.

5. Conclusions

In this study, we observed significant improvements in asthma control, quality of life, and FEV1 in all patients after the first dose of benralizumab. Notably, these improvements were observed independently of various factors, such as eosinophil levels, presence of nasal polyps, atopy, frequency of asthma exacerbations, and OCS dependency, suggesting that benralizumab may provide substantial clinical benefits across diverse subgroups of patients with severe eosinophilic asthma.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and anayzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

GO, LC, SD, HB—study designed. NYA and ME—participated in data collection. GO, LC, ME and NYA—performed statistical analysis; provided critical feedback and helped shape the research; analysis and manuscript; discussed the results and contributed to the final manuscript. LC—wrote the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Ethics Committee of Adana City Training and Research Hospital (Approval: No. 6/195, dated: 10 October 2024). The study adhered to Good Clinical Practice guidelines and the Declaration of Helsinki. Informed consent was obtained from all participants prior to their inclusion in the study.

ACKNOWLEDGMENT

We would like to thank Omer Ozer for his support in statistical analysis.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: Leyla Cevirme, Güzin Ozden, Nurullah Y. Akcam, Merve Erkoc, Susamber Dik, Hakan Basir. Benralizumab in severe eosinophilic asthma. Signa Vitae. 2025; 21(8): 9-14. doi: 10.22514/sv.2025.107.