






# Real-life effectiveness of mepolizumab on remission and chronic rhinosinusitis with nasal polyps in severe eosinophilic asthma

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## Abstract

**Aim:** This study aimed to assess the effectiveness of mepolizumab in enhancing asthma control, achieving clinical remission, and alleviating upper airway symptoms in patients with severe eosinophilic asthma (SEA) with comorbid nasal polyps and/or chronic rhinosinusitis (CRS). Additionally, it aimed to identify clinical and laboratory predictors of remission. The findings are based on real-world data from a single center.

**Methods:** This retrospective, single-center, real-world study included 99 patients diagnosed with SEA. Patients were categorized into three groups based on the presence or absence of nasal polyps and CRS. Treatment response was evaluated using the asthma control test (ACT), spirometry, laboratory biomarkers, computed tomography (CT) scores, and nasal polyp scores. Remission was defined as the absence of asthma exacerbations and systemic corticosteroid use, along with improvements in both forced expiratory volume in 1 second (FEV<sub>1</sub>) and ACT scores.

**Results:** After 12 months of mepolizumab therapy, there were significant improvements in FEV<sub>1</sub> values, asthma exacerbation frequency, systemic corticosteroid requirements, and nasal symptom scores. The overall remission rate was 30.6%. Patients with higher baseline FEV<sub>1</sub> and no prior exposure to omalizumab were more likely to achieve remission.

**Conclusions:** This real-world evidence suggests that mepolizumab provides meaningful clinical, functional, and radiological improvements in patients with SEA, regardless of comorbid nasal polyps or CRS. Furthermore, the study highlights independent predictors associated with treatment-induced remission in this population.

## Keywords

severe asthma, mepolizumab, nasal polyps, chronic rhinosinusitis, remission



## Introduction

Severe eosinophilic asthma (SEA) is a chronic airway disorder that often remains refractory to conventional treatments and is characterized by recurrent exacerbations and impaired quality of life. SEA frequently coexists with comorbid conditions such as chronic rhinosinusitis (CRS), nasal polyps (NPs), gastroesophageal reflux (GER), and atopic dermatitis (AD) [1].

CRS with NPs (CRSwNP) is among the most prominent upper airway comorbidities, present in approximately 40–60% of patients with severe asthma. It is regarded as a manifestation of lower airway inflammation. In these patients, symptom control is more difficult to achieve, treatment responses are reduced, and quality of life is further compromised [2, 3].

Mepolizumab is a humanized monoclonal antibody targeting interleukin-5 (IL-5), approved for reducing exacerbation frequency and improving symptom control in patients with SEA by suppressing eosinophilic inflammation [4, 5]. As multiple biologics have become available for treating severe asthma [6], the clinical relevance of switching between agents has gained importance [7]. Notably, approximately 30% of patients with severe asthma fulfill the eligibility criteria for all four currently approved biologics, and nearly 75% are eligible for at least two [8, 9].

Mepolizumab is also recommended by current guidelines for patients with NPs, as it has demonstrated efficacy in reducing polyp burden, alleviating upper airway symptoms, and improving clinical and radiological outcomes [10–12].

In parallel with advances in treatment, the concept of remission in asthma management has gained increasing attention. Clinical remission is generally defined by the absence of symptoms, elimination of systemic corticosteroid use, no exacerbations, and improvement in pulmonary function. However, the patient- or disease-related factors that predict remission remain incompletely understood [13–16].

This real-world study aimed to evaluate the clinical effectiveness of mepolizumab in patients with SEA and comorbid CRSwNP or CRSsNP (CRS without NPs). Additionally, we sought to determine the rate of remission and identify potential predictors associated with achieving remission after 12 months of treatment.

## Materials and methods

### Study design

This retrospective, observational, single-center real-world study included patients diagnosed with SEA with CRSwNP/CRSsNP. Patients were followed at the Tertiary Care Allergy and Clinical Immunology Clinic between 2021 and 2023 and received mepolizumab treatment. The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of KTO Karatay University Hospital (IRB No. 2023/031).

### Study population

A total of 99 patients with a confirmed diagnosis of SEA were included. The diagnosis was established in accordance with the 2024 Global Initiative for Asthma (GINA) guidelines [1] and confirmed by a specialist in allergy and clinical immunology based on clinical history, spirometry demonstrating reversible airflow limitation, and/or bronchodilator response testing. All patients received uninterrupted monthly subcutaneous mepolizumab therapy (100 mg) for at least 12 months. Inclusion criteria required a baseline blood eosinophil count  $\geq 150$  cells/ $\mu\text{L}$  and at least two asthma exacerbations requiring systemic corticosteroids in the preceding 12 months. Patients were stratified into three subgroups according to ear, nose, and throat (ENT) examination and paranasal sinus computed tomography (CT) findings obtained prior to initiating mepolizumab, irrespective of previous oral corticosteroid (OCS) exposure. This ensured classification based on pre-treatment sinonasal status, without confounding effects of corticosteroids or biologics. Subgroup definitions were as follows:

1. SEA with both CRS and NP (CRSwNP);
2. SEA with CRS but without NP (CRSsNP);
3. SEA without CRS or NP (non-CRS).

## Data collection

Demographic and clinical data were retrospectively extracted from patient records, including age, sex, height, weight, body mass index (BMI), asthma duration, and duration of mepolizumab therapy. Information on allergen sensitization status, smoking history, and comorbid allergic conditions such as allergic rhinitis or AD was also obtained. ENT findings and radiological data (NPs, CRS), aspirin sensitivity, and details of both prior and current asthma treatments were recorded. ENT examination and CT findings were obtained prior to mepolizumab initiation to avoid corticosteroid-induced changes in sinonasal status.

Clinical parameters were evaluated for the 12 months before and after mepolizumab initiation, including asthma exacerbation frequency, unplanned emergency department visits, and daily OCS dose. Pulmonary function parameters—particularly forced expiratory volume in 1 second (FEV<sub>1</sub>)—and asthma control test (ACT) scores were recorded at baseline, at Month 4, and at Month 12 following the initiation of treatment (see Table 1). The validated and reliable Turkish version of the ACT was used in this study [17]. Asthma control was categorized based on ACT scores: scores of 20 or higher indicated well-controlled asthma, scores between 15 and 19 reflected partially controlled asthma, and scores below 15 were considered poorly controlled [18].

**Table 1. Asthma control assessment.**

Evaluation aspects	Clinical description (past 4 weeks)	Score definition (1–5)
Activity limitation	The extent to which asthma interfered with work, school, or home activities.	1 = All of the time 2 = Most of the time 3 = Some of the time 4 = A little of the time 5 = None of the time
Shortness of breath	Frequency of shortness of breath episodes.	1 = More than once a day 2 = Once a day 3 = 3–6 times a week 4 = Once or twice a week 5 = Not at all
Nocturnal symptoms	Frequency of being awakened at night or early morning due to asthma symptoms (wheezing, coughing, chest tightness, shortness of breath).	1 = 4 or more nights a week 2 = 2–3 nights a week 3 = Once a week 4 = Once or twice 5 = Not at all
Rescue medication use	Frequency of rescue inhaler or nebulizer use (e.g., albuterol).	1 = 3 or more times per day 2 = 1–2 times per day 3 = 2–3 times per week 4 = Once a week 5 = Not at all
Overall asthma control	Patient's self-assessment of asthma control.	1 = Not controlled at all 2 = Poorly controlled 3 = Somewhat controlled 4 = Well controlled 5 = Completely controlled

Evaluation: sum the scores for all questions (25–20: well-controlled; 19–15: partial control; < 15: poorly controlled).

## Definition of remission and severe exacerbation

Remission was defined as the absence of asthma exacerbations and systemic corticosteroid use throughout the 12-month treatment period, accompanied by an improvement in FEV<sub>1</sub> compared to baseline and an ACT score of 20 or higher at Month 12. Severe exacerbation was defined as a worsening of asthma symptoms requiring OCS therapy for at least three consecutive days.

## Evaluation criteria

Multiple clinical and laboratory parameters were evaluated before and after treatment. Pulmonary function was assessed via FEV<sub>1</sub> (predicted%) measurements at baseline, Week 16, and Month 12. Peripheral blood eosinophil counts were recorded at baseline, Week 4, Week 16, and Month 12. Daily OCS dosage, the number of asthma exacerbations, and ACT scores were documented at each follow-up visit. Sinonasal symptoms and radiological findings were assessed using the Sino-Nasal Outcome Test-22 (SNOT-22) and paranasal sinus CT imaging, both at baseline and at the 12-month follow-up (see [Table 2](#)).

**Table 2. Sino-Nasal Outcome Test-22 (SNOT-22).**

Symptom	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem as bad as it can be
1. Need to blow the nose	0	1	2	3	4	5
2. Sneezing	0	1	2	3	4	5
3. Runny nose	0	1	2	3	4	5
4. Cough	0	1	2	3	4	5
5. Post-nasal discharge (dripping at the back of your nose)	0	1	2	3	4	5
6. Thick nasal discharge	0	1	2	3	4	5
7. Ear fullness	0	1	2	3	4	5
8. Dizziness	0	1	2	3	4	5
9. Ear pain/pressure	0	1	2	3	4	5
10. Facial pain/pressure	0	1	2	3	4	5
11. Difficulty falling asleep	0	1	2	3	4	5
12. Waking up at night	0	1	2	3	4	5
13. Lack of a good night's sleep	0	1	2	3	4	5
14. Waking up tired	0	1	2	3	4	5
15. Fatigue during the day	0	1	2	3	4	5
16. Reduced productivity	0	1	2	3	4	5
17. Reduced concentration	0	1	2	3	4	5
18. Frustrated/restless/irritable	0	1	2	3	4	5
19. Sad	0	1	2	3	4	5
20. Embarrassed	0	1	2	3	4	5
21. Sense of taste/smell	0	1	2	3	4	5
22. Blockage/congestion of the nose	0	1	2	3	4	5
Total SNOT-22 score						

Higher scores on the SNOT-22 survey items suggest worse patient functioning or symptom severity (total score range: 0–110). Adapted with permission from [\[31\]](#). © Copyright-2013 American College of Allergy, Asthma & Immunology.

Radiological improvement in CRS was evaluated using paranasal sinus CT; a reduction of  $\geq 6$  points in the Lund-Mackay CT score (LMS) was considered clinically meaningful ([Table 3](#)). For patients who underwent ENT evaluation, endoscopic findings were assessed using the nasal polyp score (NPS), with a reduction of  $\geq 1$  point regarded as a significant improvement ([Table 4](#)). Informed consent was obtained from all participants prior to study enrollment.

**Table 3. Lund-Mackay CT assessment (LMS).**

Paranasal sinuses
<ul style="list-style-type: none"><li>• Maxillary (0, 1, 2)</li><li>• Anterior ethmoid (0, 1, 2)</li><li>• Posterior ethmoid (0, 1, 2)</li><li>• Sphenoid (0, 1, 2)</li><li>• Frontal (0, 1, 2)</li><li>• Ostiomeatal complex (0 or 2 only)</li></ul>
0: With no abnormalities; 1: partial opacification; 2: total opacification. LMS: Lund-Mackay CT score. Adapted with permission from [32]. © Copyright-2010 Springer-Verlag Berlin Heidelberg.

**Table 4. Endoscopic nasal polyp score.**

Polyp score by each nostril	Polyp size
Score 0	No polyps
Score 1	Small polyps in the middle meatus not reaching below the inferior border of the middle concha
Score 2	Polyps reaching below the lower border of the middle turbinate
Score 3	Large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle concha
Score 4	Large polyps causing almost complete congestion/nasal obstruction of the inferior meatus
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## Statistical analysis

All statistical analyses were performed using SPSS software version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were presented as frequencies and percentages. For between-group comparisons, an independent samples *t*-test or one-way ANOVA was used for continuous variables, and the chi-square test was applied for categorical variables. A *p*-value of  $< 0.05$  was considered statistically significant.

## Results

### Baseline characteristics

A total of 99 patients were included in the study. Among them, 72.7% were female, with a mean age of  $48.7 \pm 13.6$  years. The median BMI was  $28.6 \text{ kg/m}^2$  (range: 25–31.2), and the mean duration of asthma was  $13.5 \pm 7.6$  years. The average duration of mepolizumab treatment was 26.7 months. Aspirin sensitivity was observed in 42.4% of patients, while 71.7% were non-atopic. Prior use of another biologic agent before mepolizumab initiation was reported in 42.4% of cases. The pre-treatment eosinophil percentage was 9.35% (range: 5.6–13), and the absolute eosinophil count was 885 cells/ $\mu\text{L}$  (range: 522.5–1,192 cells/ $\mu\text{L}$ ) (Table 5). According to ENT examinations and paranasal CT imaging performed before treatment, 54 patients had both pansinusitis and NP, 12 had pansinusitis alone, 9 had localized sinusitis, and 3 had isolated NP.

**Table 5. Baseline socio-demographic characteristics, medical history, and laboratory characteristics.**

Parameters	Total (N = 99) %
Sex, <i>n</i> (%) female	72 (72.7)
Smoking status, <i>n</i> (%) non-smoker	79 (79.8)
BMI	28.6 (25–31.2) $\text{kg/m}^2$
Disease duration, years	10 (7–15)
Skin prick test result, <i>n</i> (%)	
• No atopy	71 (71.7)
• Mite	11 (11.1)
• Mold	6 (6.1)
• Pollen	8 (8.1)

**Table 5. Baseline socio-demographic characteristics, medical history, and laboratory characteristics. (continued)**

Parameters	Total (N = 99) %
• Multiple allergens	3 (3)
Additional disease, <i>n</i> (%)	20 (20.2)
Aspirin sensitivity, <i>n</i> (%)	42 (42.4)
Additional allergic disease, <i>n</i> (%)	33 (33.3)
Prior omalizumab treatment before mepolizumab treatment, <i>n</i> (%)	42 (42.4)
Asthma control, <i>n</i> (%)	
• None	71 (71.7)
• Partial	28 (28.3)
Pre-treatment FEV <sub>1</sub> (L)	68 (51–80)
Pre-treatment FEV <sub>1</sub> (%predicted)	2.07 (1.61–2.48)
PNSCT, <i>n</i> (%)	
• Normal	21 (21.2)
• Pansinusitis + nasal polyp	54 (54.5)
• Pansinusitis	12 (12.1)
• Nasal polyp	3 (3)
• Sinusitis	9 (9.1)
HRCT, <i>n</i> (%) normal	61 (61.6)
Eosinophil percentage	9.35% (5.6–13)
Eosinophil count	885 (522.5–1,192 cells/μL)
Blood total IgE level	160 (67–390)
ECP	65.4 (40–150)

Categorical variables are presented as a number (percentage). Continuous variables are expressed as median (interquartile range, IQR). BMI: body mass index; PNSCT: paranasal sinus computed tomography; HRCT: high resolution computed tomography; FEV<sub>1</sub>: forced expiratory volume in 1 second; FEV<sub>1</sub> (%predicted): percent predicted FEV<sub>1</sub>; IgE: immunoglobulin E; ECP: eosinophil cationic protein.

## Treatment outcomes

### Pre- and post-treatment clinical findings

Significant clinical improvements were observed following 12 months of mepolizumab therapy. The mean FEV<sub>1</sub> increased from 2.07 ± 0.80 L at baseline to 2.25 ± 0.71 L at Month 12 (*p* = 0.001), indicating a marked improvement compared to pre-treatment values. The annual frequency of exacerbations significantly decreased from 4 (range: 2–5) at baseline to 1 (range: 0–2) at Month 12 (*p* < 0.001). Daily OCS use was also significantly reduced, from 16 ± 11.3 mg at baseline to 2.0 ± 6.5 mg at Month 12 (*p* < 0.001). Similarly, ACT scores improved significantly from 14.4 ± 3.9 at baseline to 21.4 ± 3.7 at Month 12 (*p* < 0.001). Asthma response was achieved in 82.8% of patients after one year of mepolizumab treatment, with 70.7% classified as having well-controlled asthma (*n* = 70) and 12.1% as partially controlled (*n* = 12).

### Improvements in NP and CRS

Among patients with NPs and/or CRS, notable improvements in sinonasal outcomes were observed. The LMS significantly decreased from 18 (6–23) to 9 (4–16) (*p* < 0.001). The median endoscopic NPS declined from 5 (6–3) to 2 (4–2) (*p* < 0.001). In parallel, SNOT-22 scores also showed a significant improvement, decreasing from 47 (42.5–67) at baseline to 23 (12–54) at Month 12, as shown in [Table 6](#).

**Table 6. Pre- and post-treatment comparison of clinical and laboratory findings in all patients.**

Parameters N = 99	Pre-treatment	Month 1	Month 4	Year 1	<i>p</i> value
FEV <sub>1</sub>	68 (51–80)	/	80 (61.5–88)	83.5 (68.7–92)	< 0.001
FEV <sub>1</sub> (L)	2.07 (1.61–2.48)	/	2.17 (1.63–2.2)	2.23 (1.67–2.7)	/
Number of emergency service visits	4 (2–5)	/	/	1 (0–2)	< 0.001
OCS use (mg)	12 (8–16)	0 (0–4)	/	0 (0–8)	< 0.001



**Table 6. Pre- and post-treatment comparison of clinical and laboratory findings in all patients. (continued)**

Parameters <i>N</i> = 99	Pre-treatment	Month 1	Month 4	Year 1	<i>p</i> value
Frequency of attacks	4 (2–6)	/	/	1 (0–1.5)	< 0.001
Eosinophil count	885 (522–1,192)	70 (40–130)	80 (40–140)	90 (50–197)	< 0.001
Eosinophil percentage	9.35 (5.67–13.0)	0.7 (0.40–1.50)	0.9 (0.42–1.60)	1.1 (0.7–2.2)	< 0.001
IgE level	160 (67.8–390)	139.5 (68–243)	123 (61–243)	131 (56–276)	0.173
ECP	65.4 (40–150)	31 (23–60)	24.75 (14.6–46.3)	28.2 (17–45.7)	< 0.001
ACT	14 (12–17)	20 (18–23)	23 (21–24)	24 (18–25)	< 0.001
ACQ	1.4 (1.1–1.8)	0.9 (0.6–1.1)	0.7 (0.4–0.9)	0.9 (0.5–1.1)	< 0.001
NPS	5 (6–3)	/	/	2 (4–2)	< 0.001
LMS	18 (6–23)	/	/	9 (4–16)	< 0.001
SNOT-22	47 (42.5–67)	/	/	23 (12–54)	< 0.001

FEV<sub>1</sub>: forced expiratory volume in 1 second; OCS: oral corticosteroid; IgE: immunoglobulin E; ECP: eosinophil cationic protein; ACT: asthma control test; ACQ: asthma control questionnaire; NPS: nasal polyp score; LMS: Lund-Mackay CT score; SNOT-22: Sino-Nasal Outcome Test-22. /: indicates data not collected or unavailable for this timepoint. For eosinophil count, eosinophil percentage, IgE level, ECP, ACT, and ACQ, *p*-values indicate within-group comparisons between baseline and each follow-up timepoint (Week 4, Week 16, and Month 12). For FEV<sub>1</sub>, FEV<sub>1</sub> (L), number of emergency service visits, OCS use (mg), NPS, LMS, and SNOT-22, *p*-values represent comparisons between baseline and Month 12. Continuous variables are presented as median (interquartile range, IQR).

### Subgroup analysis by nasal comorbidities

Patients were divided into three groups based on nasal comorbidities. The rate of aspirin sensitivity was 55.4% in Group 1, 33.3% in Group 2, and 20.0% in Group 3. The mean age of the overall population was 49 years. The mean BMI was 29.53 kg/m<sup>2</sup> and differed significantly among the groups (*p* < 0.01), being 27.36, 30.75, and 30.48 kg/m<sup>2</sup> in Groups 1, 2, and 3, respectively. Improvements in FEV<sub>1</sub> (percent predicted), ACT scores, asthma control questionnaire (ACQ) scores, blood eosinophil counts (both absolute and percentage), and serum eosinophil cationic protein (ECP) levels were observed across all groups: Group 1 (CRSwNP), Group 2 (CRSSNP), and Group 3 (non-CRS). Nasal symptom scores were assessed only in patients with sinonasal disease (Groups 1 and 2). In Group 1, SNOT-22 scores significantly decreased from 66 (range: 38–96) to 45 (range: 10–90); NPS declined from 5 (range: 6–3) to 2 (range: 4–2); and LMS decreased from 22 (range: 6–24) to 15 (range: 2–24), with all *p*-values < 0.001. In Group 2, although patients did not have NPs, significant improvements were still observed: SNOT-22 scores decreased from 34 (range: 12–53) to 14 (range: 4–33), and LMS scores declined from 13 (range: 0–22) to 7 (range: 0–10). Since patients in Group 3 did not have CRS or NPs, nasal symptom scores were not applicable in this group (see Table 7).

When comparing the three subgroups, in patients with severe asthma and concomitant NPs plus pansinusitis, blood eosinophil count and percentage were significantly higher compared to those with either CRS alone or severe asthma without sinonasal disease, as expected (*p* = 0.010 for eosinophil count, *p* = 0.004 for eosinophil percentage). In contrast, no statistically significant differences were observed between the groups regarding other clinical parameters, including FEV<sub>1</sub> (%), ACT score, OCS use, asthma exacerbation rate, and ACQ scores (*p* > 0.05).

### Remission and associated factors

Remission analysis at Month 12 was conducted in 85 patients, of whom 26 (30.6%) achieved remission. There were no significant differences between the remission and non-remission groups in terms of demographic, allergic, or sinonasal characteristics. However, remission was associated with higher baseline FEV<sub>1</sub> and forced vital capacity (FVC) values, fewer emergency department visits and exacerbations, and the absence of prior omalizumab use (Table 8).

Table 7. Changes in groups' parameters by nasal comorbidities of patients with SEA after biological treatment.

Group	Group 1 (n = 57) SEA with NPs and CRS					Group 2 (n = 21) SEA with CRS but no NPs					Group 3 (n = 21) SEA only (without CRS or NP)				
Parameters	Before treatment	4 week	16 week	Month 12	p	Before treatment	4 week	16 week	Month 12	p	Before treatment	4 week	16 week	Month 12	p
FEV <sub>1</sub> (% predicted)	68 (48.5–83.5)	/	82 (40–110)	87 (41–113)	< 0.001	60.5 (53–74)	/	69 (48–88)	72 (27–102)	0.087	74 (51–82.7)	/	78 (46–100)	76.5 (37–95)	0.355
FVC	78 (63.5–90.7)	/	89 (47–118)	96 (49–118)	< 0.001	75.5 (60–80)	/	78 (37–92)	77 (41–107)	0.129	80 (54–89)	/	82 (51–105)	82 (42–98)	0.876
FEV <sub>1</sub> /FVC	85 (78–92)	/	91 (58–110)	92 (73–113)	0.008	84 (74–92)	/	84 (69–108)	88 (62–108)	0.196	91.5 (82–96)	/	94 (71–112)	95.5 (58–108)	0.41
FEV <sub>1</sub> (lt)	2.22 (1.7–2.7)	/	/	2.34 (0.82–4.10)	< 0.001	1.71 (1.3–2.2)	/	/	1.92 (1.5–2.3)	0.036	1.82 (1–2.1)	/	/	1.94 (1.3–2.4)	0.034
Eo (count)	1,000 (650–1,465)	80 (35–190)	80 (30–150)	100 (65–200)	< 0.001	640 (570–1,030)	70 (60–100)	95 (57–137)	80 (60–175)	< 0.001	440 (315–840)	40 (35–80)	40 (30–100)	65 (40–152)	< 0.001
Eo (%)	10.3 (7.1–15.8)	1 (0.4–1.9)	0.8 (0.5–1.6)	1.25 (0.7–2.2)	< 0.001	8.2 (6.2–11.3)	1 (0.7–1.2)	1.2 (0.6–1.9)	1.2 (0.9–2.2)	< 0.001	4.6 (3.1–9.9)	0.55 (0.4–1.2)	0.6 (0.3–1.1)	0.8 (0.5–1.8)	< 0.001
Number of emergency service visits	4 (2–6)	/	/	0 (0–2)	< 0.001	3 (2.5–4)	/	/	0 (0–2)	< 0.001	2 (2–4)	/	/	1 (0–2)	0.001
OCS use (mg)	16 (8–26)	0 (0–8)	/	0 (0–4)	< 0.001	8 (8–16)	0 (0–4)	/	0 (0–4)	0.002	8 (8–19)	0 (0–4)	/	0 (0–4)	0.135
Frequency of attacks	4 (2–6)	/	/	1 (0–1.5)	< 0.001	3 (3–5)	/	/	1 (0–2)	< 0.001	3 (2–4)	/	/	1 (1–1.2)	< 0.001
SNOT-22	66 (38–96)	/	/	45 (10–90)	< 0.001	34 (12–53)	/	/	14 (4–33)	< 0.001	/	/	/	/	/
NPS	5 (6–3)	/	/	2 (4–2)	< 0.001	/	/	/	/	/	/	/	/	/	/
LMS	22 (6–24)	/	/	15 (2–24)	< 0.001	13 (0–22)	/	/	7 (0–10)	< 0.001	/	/	/	/	/

SEA: severe eosinophilic asthma; CRS: chronic rhinosinusitis; FEV<sub>1</sub>: forced expiratory volume in 1 second; FEV<sub>1</sub> (%predicted): percent predicted FEV<sub>1</sub>; FVC: forced vital capacity; OCS: oral corticosteroid; Eo: eosinophil; NPS: nasal polyp score; LMS: Lund-Mackay CT score; SNOT-22: Sino-Nasal Outcome Test-22. /: indicates data not collected or unavailable for this timepoint. The p-value indicates the comparison between the baseline and Year 1 group; the bolded p-values indicate statistically significant results (p < 0.05).



**Table 8. The univariate regression analysis was conducted to compare patients who achieved remission and those who did not, in order to identify independent factors associated with remission.**

Parameters	Univariate regression analysis		
	Average	95% CI	p value
Prior omalizumab use	0.290	0.106–0.795	<b>0.016</b>
Baseline FEV <sub>1</sub> (%)	1.031	1.002–1.061	<b>0.038</b>
Baseline FVC (%)	1.035	1.005–1.066	<b>0.022</b>
Number of emergency service visits before treatment	0.759	0.600–0.958	<b>0.021</b>
Pre-treatment number of attacks	0.753	0.596–0.952	<b>0.018</b>
Pre-treatment ACT score	1.211	1.028–1.427	<b>0.022</b>
Pre-treatment ACQ score	0.280	0.096–0.814	<b>0.019</b>
Pre-treatment IgE level	0.999	0.998–1.001	0.284
Pre-treatment eosinophil count	1.000	1.000–1.001	0.207
Presence of atopy	0.464	0.152–1.415	0.177

FEV<sub>1</sub>: forced expiratory volume in 1 second; FVC: forced vital capacity; ACT: asthma control test; ACQ: asthma control questionnaire; IgE: immunoglobulin E. *p*-values indicate the association between each variable and remission status in univariate logistic regression, the bolded values indicate statistically significant results ( $p < 0.05$ ).

Multivariate regression analysis was performed using variables that were statistically significant in the univariate analysis ( $p < 0.05$ ) and not collinear. Models constructed with non-collinear parameters revealed that prior use of omalizumab was associated with a lower likelihood of achieving remission, whereas higher baseline percentages of FEV<sub>1</sub> and FVC were significantly associated with an increased probability of remission (Table 9).

**Table 9. The multivariate regression analysis was conducted to further assess the independent predictors of remission, also comparing the remission and non-remission groups.**

Parameters	Multivariate regression analysis		
	Average	95% CI	p value
<b>Model-1*</b>			
Number of emergency service visits before treatment	0.717	0.550–0.934	<b>0.014</b>
Pre-treatment eosinophil count	1.001	1.000–1.001	0.099
<b>Model-2**</b>			
Pre-treatment FEV <sub>1</sub> (%)	1.038	1.005–1.073	<b>0.025</b>
Prior omalizumab use	0.331	0.113–0.967	<b>0.043</b>
<b>Model-3***</b>			
Pre-treatment FEV <sub>1</sub> (%)	1.035	1.003–1.069	<b>0.033</b>
Prior omalizumab use	0.306	0.106–0.885	<b>0.029</b>
<b>Model-4****</b>			
Pre-treatment FVC (%)	1.035	1.002–1.069	<b>0.038</b>
Prior omalizumab use	0.302	0.104–0.877	<b>0.028</b>
<b>Model-5*****</b>			
Pre-treatment FVC (%)	1.032	1.000–1.065	<b>0.047</b>
Prior omalizumab use	0.282	0.098–0.808	<b>0.018</b>

*p*-values represent independent associations between selected variables and remission status after adjustment in multivariate logistic regression. Variables that were statistically significant in the univariate analysis and not collinear were included in the multivariate models. Bolded *p*-values indicate statistical significance ( $p < 0.05$ ). FEV<sub>1</sub>: forced expiratory volume in 1 second; FVC: forced vital capacity.

## Regression analysis of factors influencing remission

Univariate regression analysis (Table 8) demonstrated that higher baseline FEV<sub>1</sub> and FVC percentages, fewer emergency department visits, fewer exacerbations, and absence of prior omalizumab use were significantly associated with remission. Multivariate regression analysis (Table 9) identified two independent predictors of remission. A higher baseline FEV<sub>1</sub> percentage was significantly associated with

an increased likelihood of remission ( $p = 0.014$ ). Additionally, patients without a history of omalizumab use prior to initiating mepolizumab therapy were more likely to achieve remission ( $p = 0.02$ ). In contrast, no significant associations were found between remission status and the presence of NP, CRS, or nonsteroidal anti-inflammatory drug-exacerbated respiratory disease (NERD) ( $p > 0.05$ ).

## Discussion

Although several real-world studies have evaluated the clinical efficacy of mepolizumab in patients with SEA, few have focused specifically on remission outcomes in the presence of coexisting CRSwNP. Moreover, most existing data are derived from multicenter or Western cohorts. Our study contributes novel insights by presenting single-center, real-life evidence from Türkiye—a country where access to biologics, phenotype distribution, and treatment approaches may differ from other settings. Additionally, this study is among the few that have investigated the impact of prior biologic exposure, particularly omalizumab, on the likelihood of achieving remission with subsequent mepolizumab therapy. These features increase both the regional relevance and clinical applicability of our findings and help address a notable gap in the current literature.

This study demonstrated that mepolizumab treatment in patients with SEA leads to significant clinical and laboratory improvements—not only in asthma-related outcomes but also in comorbid conditions such as CRS and NP. Furthermore, it showed that mepolizumab may contribute to achieving remission, a concept gaining increasing importance in asthma management and now recognized in current international guidelines. A subset of patients in our cohort successfully achieved this therapeutic goal. We evaluated 12-month outcomes in 99 patients with SEA who received mepolizumab therapy. Asthma symptom control improved substantially, as evidenced by a 10-point increase in ACT scores and a 0.5-point reduction in ACQ scores ( $p < 0.001$ ). Following treatment, only 17.2% of patients had uncontrolled asthma. Studies have shown increases in ACT scores ranging from 5.00 to 8.53 and reductions in ACQ scores from  $-0.5$  to  $-0.8$ , confirming the symptom-reducing effect of mepolizumab [19–22].

Another key finding is the steroid-sparing effect of mepolizumab. A systematic review showed that corticosteroid use decreased or even ceased during treatment in many patients with severe asthma [4, 18]. Our findings are consistent, showing a progressive decline in OCS use from a median of 12 mg (range: 4–40 mg) at baseline to 0 mg (range: 0–8 mg) at Month 12. Asthma exacerbations requiring systemic steroids also decreased from 4 to 1 per year ( $p < 0.001$ ). These results align with studies reporting reductions from 4.16 to 1.41, 2.80 to 0.90, and 3.14 to 0.85 events per year [23, 24]. Eosinophils are granulated innate immune cells responsible for type 2 inflammation and play a major role in the pathogenesis of both asthma and NP. Their levels are especially elevated in patients with severe asthma and coexisting NP. While IL-5 is not essential for eosinophil development, it is crucial for their differentiation and survival in peripheral tissues. Mepolizumab significantly reduces eosinophils by targeting IL-5 [25]. In our study, significant reductions were observed at Weeks 4, 16, and 56 ( $p < 0.001$ ). FEV<sub>1</sub> increased from 68 to 83.5% of predicted values, corresponding to a 160 mL volume gain. These outcomes are consistent with Israel et al. [4], who reported FEV<sub>1</sub> increases ranging from 150 to 400 mL in both retrospective and prospective studies.

We divided patients into three subgroups based on the presence of CRSwNP. When comparing these subgroups, patients with severe asthma and concomitant NPs plus pansinusitis exhibited significantly higher blood eosinophil counts and percentages compared to those with either CRS alone or severe asthma without sinonasal involvement ( $p = 0.010$  for eosinophil count,  $p = 0.004$  for eosinophil percentage). In contrast, no statistically significant differences were observed between the groups in terms of other clinical parameters, including FEV<sub>1</sub> (%), ACT score, OCS use, asthma exacerbation rate, and ACQ scores ( $p > 0.05$ ). These findings suggest that while the degree of eosinophilic inflammation may vary depending on sinonasal comorbidity, the clinical and functional benefits of mepolizumab treatment appear to be consistent across different patient profiles [5].

Our study also evaluated the impact of mepolizumab on CRSwNP. In the SYNAPSE study, Fokkens et al. [26] reported a mean baseline NPS of 5.5, with most patients experiencing a  $\geq 1$ -point reduction after 52 weeks. Mepolizumab improved sinonasal symptoms and reduced the need for repeated sinus surgery and systemic steroids [26, 27]. In our study, the NPS decreased by 3 points, and among 57 patients with CRSwNP, SNOT-22 dropped by 21 points, the Lund-Mackay score by 7 points. Eosinophil counts also declined from 1,000 to 100 cells/ $\mu$ L. These findings align with Domínguez-Sosa et al. [11], who showed reductions in NPS (4 to 1), SNOT-22 (–63), and OCS use in 53 of 55 patients. Our data support the efficacy of mepolizumab in CRSwNP independent of asthma or NERD, consistent with Bachert et al. [28].

One of our key aims was to evaluate remission—defined by absence of symptoms, no OCS use, no exacerbations, and improved pulmonary function [10]. Among 85 evaluable patients, 30.6% achieved remission, consistent with REALITI-A findings (33%) and a systematic review reporting rates between 28.6 and 43.2% [10, 29]. Importantly, even among non-remission patients, many demonstrated substantial improvements in FEV<sub>1</sub> and ACT scores. This supports the relevance of “partial remission” or partial response as a meaningful therapeutic endpoint. Recognizing these improvements is essential in real-world clinical practice, as rigid remission definitions may overlook patients who benefit significantly from treatment.

We also explored predictors of remission. Higher baseline FEV<sub>1</sub> and FVC, and absence of prior omalizumab use, were significantly associated with achieving remission. Omalizumab is the first biologic approved for asthma and has been available in Türkiye since 2008, while mepolizumab became available in 2019 [6]. In our cohort, 42.4% had received omalizumab previously. These included both atopic and non-atopic eosinophilic asthma patients, some treated off-label with consent. Patients often switched to mepolizumab due to poor response, increased exacerbation frequency, systemic steroid dependency, or persistent sinonasal symptoms. Several real-world studies have reported that switching between biologics may be less effective in patients who previously failed to respond [8]. Our findings suggest that prior biologic exposure may alter immune responsiveness and reduce the likelihood of remission with subsequent treatments. Moreover, patients with higher baseline pulmonary function may represent a less severe phenotype with lower airway remodeling and inflammation, thus more likely to achieve remission [30].

This study has several important limitations. First, its retrospective and single-center design may limit the generalizability of the findings to broader populations or different healthcare settings. Second, although data were collected on several clinical variables—such as BMI, GER disease (GERD), proton pump inhibitor (PPI) use, prior endoscopic sinus surgery (ESS), and cardiovascular comorbidities—these factors were not significantly associated with remission and were therefore not analyzed in detail. Additionally, due to institutional constraints and the retrospective nature of the study, certain key parameters could not be assessed. Specifically, fractional exhaled nitric oxide (FeNO) and small airway resistance (R5–R20) measurements were not available during the study period and thus were excluded from the analysis. Similarly, data on sleep apnea were not routinely recorded in patient files and could not be evaluated. These limitations may have hindered a more comprehensive evaluation of potential predictors of remission. It should also be noted that prior systemic corticosteroid use may have affected sinonasal imaging findings and phenotype classification, which represents a potential limitation when conducting retrospective subgroup analyses. Despite these limitations, the study remains valuable as it reflects real-world clinical practice. Future prospective, multicenter studies with broader access to objective biomarkers and functional assessments are warranted to validate and expand upon our findings.

In conclusion, our findings demonstrate that mepolizumab provided significant clinical benefits in patients with SEA, regardless of the presence of CRSwNP. Over 12 months, improvements were observed in ACT and ACQ scores, LMS, endoscopic NPS, OCS use, exacerbation frequency, hospitalization rates, and blood eosinophil counts, starting from the first dose. At one year, 30.6% of patients achieved full asthma remission based on predefined criteria. However, a substantial proportion of patients who did not meet full remission still experienced clinically meaningful improvements in FEV<sub>1</sub> and ACT scores, indicating that

partial responders also benefit significantly from treatment. Recognizing partial response as a distinct therapeutic outcome may enhance the interpretation of treatment success in real-world settings. Furthermore, higher baseline FEV<sub>1</sub> and absence of prior omalizumab use were independently associated with higher remission rates, suggesting better outcomes in biologic-naïve patients. This highlights the potential impact of treatment history on biologic efficacy and supports the need for individualized treatment strategies. Despite the absence of a control group—a limitation of our study—the consistent improvements observed support the effectiveness of mepolizumab in real-world practice. Future randomized controlled trials with larger cohorts and comparator arms are warranted to validate these results and further guide biologic use in SEA.

## Abbreviations

ACQ: asthma control questionnaire

ACT: asthma control test

AD: atopic dermatitis

BMI: body mass index

CRS: chronic rhinosinusitis

CRSsNP: chronic rhinosinusitis without nasal polyps

CRSwNP: chronic rhinosinusitis with nasal polyps

CT: computed tomography

ENT: ear, nose, and throat

FEV<sub>1</sub>: forced expiratory volume in 1 second

FVC: forced vital capacity

GER: gastroesophageal reflux

IL-5: interleukin-5

LMS: Lund-Mackay CT score

NERD: nonsteroidal anti-inflammatory drug-exacerbated respiratory disease

NPs: nasal polyps

NPS: nasal polyp score

OCS: oral corticosteroid

SEA: severe eosinophilic asthma

SNOT-22: Sino-Nasal Outcome Test-22

## Declarations

### Author contributions

EA: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Validation, Visualization, Writing—original draft, Writing—review & editing. MD: Conceptualization, Investigation, Writing—original draft, Writing—review & editing. AB: Supervision. All authors read and approved the submitted version.

### Conflicts of interest

The authors declare that they have no conflicts of interest.

## Ethical approval

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki, and the study protocol was approved by the Institutional Review Board of KTO Karatay University Hospital (IRB No. 2023/031).

## Consent to participate

Informed consent to participate in the study was obtained from all participants.

## Consent to publication

Not applicable.

## Availability of data and materials

The data of this manuscript could be available from the corresponding author upon reasonable request.

## Funding

Not applicable.

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