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Sinonasal outcomes in patients with chronic rhinosinusitis with nasal polyps and severe asthma treated with mepolizumab: A real-life study

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Abstract
Mepolizumab is a monoclonal antibody targeting interleukin-5 that has been approved for the treatment of severe eosinophilic asthma (SEA) and chronic rhinosinusitis with nasal polyps (CRSwNP). This study aims to evaluate the sinonasal outcomes and safety of mepolizumab in patients with CRSwNP and SEA. This retrospective, real-life study included 19 patients aged 18 years and older who received 100 mg of subcutaneous mepolizumab every 4 weeks for at least 12 months. Sinonasal symptom severity, rhinorrhea, nasal congestion/obstruction, postnasal drip, and loss of smell were assessed using the visual analog scale (VAS). Disease-specific quality of life was assessed using the sino-nasal outcome test-22 (SNOT-22). The history of endoscopic sinus surgery (ESS) was evaluated for each patient. Asthma-related outcomes included the asthma control test (ACT), number of exacerbations, and daily systemic corticosteroid dose. Evaluations were conducted at baseline, 6 months (t6), and 12 months (t12). Adverse events were also recorded. The median age was 49 years (min-max: 29-63), and 57.9% of patients were female. Compared with baseline, significant improvements were observed in all VAS parameters and total/subdomain SNOT-22 scores at both t6 and t12. The number of asthma exacerbations and systemic corticosteroid doses decreased significantly. No patient required ESS during the follow-up period. Only two patients experienced mild injection-related side effects. Mepolizumab treatment has resulted in significant improvement in sinonasal symptoms and quality of life. These findings support the use of mepolizumab as a safe and effective option in selected patients with CRSwNP and concomitant SEA.

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Introduction

Chronic rhinosinusitis (CRS) is an inflammatory condition characterized by the presence of symptoms such as nasal obstruction/congestion, nasal discharge (anterior and/or posterior nasal drip), facial pain/pressure, and a reduced/lost sense of smell.[1] CRS is classically divided into two phenotypes: with nasal polyps (CRSwNP) and without nasal polyps. A European cohort study by The Global Allergy and Asthma European Network found that 49.6% of CRSwNP patients were accompanied by asthma.[2] In addition, the presence of nasal polyps in asthma patients is also associated with asthma severity. Nasal polyps are more frequent and associated with a more severe radiologic burden in patients with severe asthma.[3,4]

CRSwNP and asthma share many similarities with respect to the underlying pathophysiologic mechanisms that cause the disease. Type 2 inflammation is the most common form of this phenomenon. Type 2 inflammation is eosinophilic airway inflammation mediated by type 2-related cytokines such as Interleukin-4 (IL4), Interleukin-5 (IL-5), and Interleukin-13 (IL-13), with circulating and/or local Immunoglobulin E (IgE) production.[5,6] From this common perspective, local corticosteroids are the mainstay of therapy to achieve optimal disease control for both CRSwNP and asthma.[1,7] The European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) 2020 report recommends primarily saline spray/irrigation, intranasal corticosteroid administration, and review of treatable personal characteristics/comorbidities in the treatment of CRS. Short-term systemic steroid therapy is also recommended in patients with CRSwNP, but serious side effects of systemic corticosteroids may occur.[1,8] Sinonasal surgery remains an important therapeutic option in patients with CRSwNP who do not achieve adequate disease control with medical treatment. In cases where symptom control is not attained even after endoscopic sinus surgery (ESS), the use of biologic agents should be considered as an alternative treatment strategy.[9] Biologic agents targeting IL-4/IL-13 (dupilumab), IL-5 (mepolizumab), and IgE (omalizumab) are approved treatment options for CRSwNP.[9-12]

Mepolizumab is a humanized IgG1/k class monoclonal antibody that binds to IL-5 and blocks its association with the IL-5 receptor alpha.[13] It was first approved for severe eosinophilic asthma (SEA), then for eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome. Finally, in 2021, it received Food and Drug Administration (FDA) approval for CRSwNP following the SYNAPSE study.[14] Because of limited access to biologic agents for patients diagnosed solely with CRSwNP under the public health insurance policies in Türkiye, this study aimed to evaluate real-world outcomes in patients with CRSwNP accompanied by SEA. The primary objective of this study was to evaluate the effect of mepolizumab on nasal symptom severity and sinonasal disease-related quality of life in patients with CRSwNP and SEA. The secondary objective was to evaluate the effect of mepolizumab on the need for surgical intervention for nasal polyps and its safety profile.

Materials and Methods

Patient characteristics and study design

This retrospective real-life study includes 19 patients over the age of 18 who received 100 mg of subcutaneous mepolizumab every 4 weeks for at least 12 months between November 2020 and February 2025. All patients were severe eosinophilic asthmatics with CRSwNP.

Demographic data including age (at the first mepolizumab application visit), gender, body mass index (BMI), comorbid systemic and allergic diseases, atopy status (according to skin prick test and/or serum-specific IgE (IU/mL) test results), and smoking history were obtained from the patient file. Age at asthma diagnosis, age at nasal polyp diagnosis, baseline blood eosinophil count (cells/μl), and baseline total IgE levels (IU/mL) were recorded. Patients' history of ESS before the initiation of mepolizumab and the number of surgical procedures, if any, were recorded. Surgical history was also evaluated at 6 month and 12 months of mepolizumab treatment.

Patients reported outcomes

Visual analog scale (VAS) (0 minimum–10 maximum) scores were recorded to assess the severity of symptoms of rhinorrhea, nasal congestion, postnasal drip, and loss of smell.

Sinonasal outcome test-22 (SNOT-22) scores were recorded to assess the quality of life associated with sinonasal disease. For this purpose, the form of SNOT-22, which has been previously proven to be valid and reliable in Turkish, was used.[15] In this scoring system, "no problem" is scored as 0 points while "problem as bad as it can be" is scored as 5 points and the total score is between 0 and 110. An increase in scores corresponded to a decline in quality of life. SNOT-22 scores for nasal, otologic/fascial pain, sleep, and emotional function subscales were also evaluated. The patients' self-administered VAS and SNOT-22 scores were extracted from medical records at baseline, and subsequently at 6 and 12 months following initiation of mepolizumab treatment.

Asthma-related outcomes

Asthma control was assessed using the asthma control test (ACT), which considers daytime and nighttime symptoms, use of rescue medication, and limitations in daily activities over the past 4 weeks.[7] The presence of asthma exacerbation was also evaluated. An asthma exacerbation was defined as a worsening of respiratory symptoms requiring systemic corticosteroid use for at least three consecutive days. ACT scores, the number of asthma exacerbations, and systemic corticosteroid doses prior to mepolizumab initiation, as well as at the 6th and 12th months of treatment, were obtained from patient medical records.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics for categorical variables were presented as frequencies and percentages, and group comparisons were conducted using the Chi-square test. The Kolmogorov–Smirnov test was used to assess the normality of data distribution.

Changes in repeated measures across baseline, 6 months, and 12 months were analyzed using the Friedman test, and post-hoc pairwise comparisons were performed using the Wilcoxon signed-rank test.

Ethic statement

Ethics approval for the study was obtained from the ethics committee of Ankara Atatürk Sanatoryum Training and Research Hospital (Approval No: 2024-BÇEK/250, dated March 12, 2025).

Results

Patients' demographic characteristics

A total of 19 patients, including 11 women (57.9%), with a median (min–max) age of 49 (29–63) were included in the study. The median BMI was 26.8 (23.4–38.2). Around 52.6% of the patients were atopic. The median age at diagnosis of asthma was 31 years (15–46), while the median age at diagnosis of nasal polyps was 33 years (16–53). Baseline eosinophil count median was 500 cells/μl (90–1180), and total IgE median was 213 kU/l (38.5–2477). Thirteen patients had a prior history of ESS. Other demographic and clinical characteristics of the participants are presented in Table 1.

Patient-reported outcomes

VAS

VAS scores were collected at three time points: baseline, t6, and t12 following the initiation of mepolizumab treatment. For rhinorrhea, the median (min–max) VAS scores decreased from 7 (010) at t0 to 6 (1–9) at t6 and 0 (0–8) at t12. Nasal congestion showed a marked reduction from 10 (6–10) at t0 to 5 (3–10) at t6 and 0 (0–9) at t12. Postnasal drip scores declined from 10 (6–10) to 5 (3–10) and 2 (0–10). Similarly, loss of sense of smell changed from 10 (0–10) at t0 to 6 (0–10) at t6 and 2 (0–10) at t12. Statistically significant improvements were observed for all four symptoms ($p< 0.001$ each), demonstrating consistent clinical benefit of mepolizumab in reducing symptom severity over the 12-month period.

When the VAS scores for loss of smell were analyzed separately, it was found that one patient exhibited an increase in the score from t0 to t12. In eight patients, the score remained persistently high (10 at both T0 and T12), indicating no improvement. The remaining nine patients showed a decrease in VAS scores. A comparison between patients whose VAS scores improved (n=9) and those whose scores remained unchanged or worsened (n=9) revealed that a history of ESS was significantly more common in the nonimproved group ($\chi^2 = 4.000$, $p = 0.046$). There were no statistically significant differences between the two groups in terms of age, sex, BMI, smoke history, baseline eosinophil and total IgE count, age at asthma diagnosis, and age at nasal polyp diagnosis.

SNOT-22

A significant improvement was observed in SNOT-22 scores following mepolizumab treatment. The median (min–max) baseline score was 67 (29–101), which decreased to 35 (10–68) at 6 months, and further to 12 (0–72) at 12 months ($\chi^2 = 34{,}207$ $p < 0.001$). These findings indicate a consistent improvement in sinonasal symptoms following treatment.

Table 1 Demographic and clinical characteristics of the patients.

Characteristics	Values
Sex, female, n (%)	11 (57.9)
Age [years], median (min–max)	49 (29–63)
Body mass index, kg/m², median (min–max)	26.8 (23.4–38.2)
Atopy (skin prick test/serum-specific IgE), n (%)	10 (52.6)
Age at asthma diagnosis, [years], median (min–max)	31 (15–46)
Age at nasal polyp diagnosis, [years], median (min–max)	33 (16–53)
Smoking story, n (%)	
Never smoked	12 (63.1)
Ex smoker	7 (36.8)
Current smoker	0
Baseline serum eosinophil [cells/μl], median (range)	500 (90–1180)
Baseline total IgE [kU/l], median (range)	213 (38.5–2477)
History of endoskopic sinus surgery, n (%)	
Yes	13 (68.4)
No	6 (31.6)

IgE: Immunoglobulin E

Significant reductions were observed across all SNOT-22 subdomains, including nasal, otologic/fascial, sleep, and emotional subdomains. Detailed subscale outcomes are presented in Table 3.

ESS

Six patients had no prior history of sinus surgery. Eight patients had undergone sinus surgery once, three patients had undergone the procedure twice, and two patients had undergone it thrice. None of the patients underwent ESS during the study period up to the t6 and t12 time points ($\chi 2$ = 26,000, p=0,000).

Asthma outcomes

The results showed a statistically significant decrease in the number of asthma exacerbations from baseline to t6 and

Table 2 Visual analog scale (VAS) scores at baseline, 6 months (t6), and 12 months (t12) after initiation of mepolizumab treatment (n=19).

VAS Parameter	Time Point	Mean ± SD	Min	Max	25th Pctl	Median (50th)	75th Pctl	Friedman χ^2	p-value
Rhinorrhea	t0	6,8±3,2	0	10	5	7[a]	10	28,737	<0.001
	t6	5,1±2,5	1	9	3	6[b]	7,0		
	t12	2,1±3,0	0	8	0	0[c]	4,0		
Nasal Congestion	t0	9,2±1,2	6	10	8	10[a]	10	35,547	<0.001
	t6	5,6±1,8	3	10	4	5[b]	7		
	t12	2,2±2,9	0	9	0	0[c]	5		
Postnasal Drip	t0	8,8±1,5	6	10	8	10[a]	10	33,091	<0.001
	t6	5,6±2,1	3	10	4	5[b]	7		
	t12	3,0±3,5	0	10	0	2[c]	5		
Loss of Sense of Smell	t0	8,6±2,7	0	10	8	10[a]	10	12,359	<0.001
	t6	6,5±3,2	0	10	4	6[b]	10		
	t12	5,0±4,5	0	10	0	2[c]	10		

The Friedman test was applied to assess changes over time, and pairwise post-hoc comparisons were conducted using the Wilcoxon signed-rank test. Statistically significant differences were observed between time points with different superscript letters (a vs. b, b vs. c, and a vs. c), whereas no significant difference was found between groups sharing the same superscript.

Table 3 Sinonasal outcome test-22 (SNOT-22) scores at baseline, 6 months (t6), and 12 months (t12) after initiation of mepolizumab treatment (n=19)

Variables	Time Point	Mean ± SD	Min	Max	25th Pctl	Median (50th)	75th Pctl	Friedman χ^2	p-value
SNOT-22 Total	t0	68,5±18,6	29	101	60	67[a]	83	34,107	<0.001
	t6	36,8±14,8	10	68	28	35[b]	43		
	t12	18,5±18,5	0	72	7	12[c]	31		
SNOT-22 Nasal	t0	29,7±6,5	18	39	24	31[a]	36	37,000	<0.001
	t6	17,7±7,2	4	36	13	17[b]	22		
	t12	7,4±8,4	0	27	0	5[c]	14		
SNOT-22	t0	11,4±2,8	8	19	9	11[a]	12	25,671	<0.001
Otological/Fascial	t6	6,9±2,6	4	14	5	6[b]	8		
	t12	5,0±5,3	0	23	1	5[c]	6		
SNOT-22 Sleep	t0	21,5±12,1	0	45	12	20[a]	32	24,371	<0.001
	t6	9,8±6,3	0	24	7	9[b]	13		
	t12	5,1±6,7	0	23	0	3[c]	6		
SNOT-22	t0	5,3±2,8	1	10	2	5[a]	8	0,000	<0.001
Emotional	t6	2,3±1,6	0	6	1	2[b]	3		
	t12	0,95±1,7	10	6	0	0[b]	1		

The Friedman test was applied to assess changes over time, and pairwise post-hoc comparisons were conducted using the Wilcoxon signed-rank test. Statistically significant differences were observed between time points with different superscript letters (a vs. b, b vs. c, and a vs. c), whereas no significant difference was found between groups sharing the same superscript.

Table 4 Asthma control test scores, number of asthma exacerbations, and systemic corticosteroid doses at baseline, 6 months (t6), and 12 months (t12) after initiation of mepolizumab treatment (n = 19).

Variables	Time Point	Mean ± SD	Min	Max	25th Pctl	Median (50th)	75th Pctl	Friedman χ^2	p-value
Asthma Control Test Scores	t0	23,8±2,2	16	25	23	25	25	2,467	0,291
	t6	24,7±0,5	23	25	25	25	25	0,291	
	t12	24,1±1,6	20	25	23	25	25		
Number of Asthma Exacerbations	t0	2,0±1,6	0	5	1	2[a]	3	26,936	<0.001
	t6	0,11±0,31	0	1	0	0[b]	0	0,000	
	t12	0,16±0,37	0	1	0	0[b]	0		
Systemic Corticosteroid Doses (methylprednisolone-equivalent)	t0	6,1±9,4	0	40	2	4[a]	4	26,080	<0.001
	t6	1,1±1,9	0	8	0	0,571[b]	1,142		
	t12	0,3±1,0	0	4	0	0,000[c]	0,000		

The Friedman test was applied to assess changes over time, and pairwise post-hoc comparisons were conducted using the Wilcoxon signed-rank test. Statistically significant differences were observed between time points with different superscript letters (a vs. b, b vs. c, and a vs. c), whereas no significant difference was found between groups sharing the same superscript.

t12 ($p < 0.001$), but no significant difference in ACT scores was observed at the three time points ($p = 0.291$). The median daily dose of systemic corticosteroids (expressed in methylprednisolone-equivalent) was significantly reduced over the study period

Adverse effect

Except for one patient who reported pain at the injection site and another patient who experienced pain, redness, and swelling at the injection site, no other side effects related to mepolizumab were reported by patients in the study population.

Discussion

This retrospective, observational, real-life study evaluated the clinical outcomes of 19 patients with asthma-related CRSwNP during the first year of mepolizumab treatment. A significant reduction in sinonasal symptom scores and a notable improvement in the quality of life were observed. Furthermore, none of the patients required ESS during the first 12 months of mepolizumab treatment.

According to the EPOS/EUFOREA Biologics in CRSwNP 2023 report, type 2 inflammation is defined as tissue eosinophil ≥10/hpf, or blood eosinophil ≥150 cells/mL, or total IgE ≥100 kU/L.[9] Patients in our study had a baseline eosinophil count of 500 (min–max: 90–1180) cells/μL. Three patients had eosinophil counts below 150, which we attribute to their steroid-dependent management because of comorbid conditions. Based on this report, we conclude that all patients included in our study exhibited evidence of type 2 inflammation. Biological agents have been a good alternative in patients with recurrent severe CRSwNP after surgery who also have asthma comorbidity.[1] Mepolizumab has been approved for the treatment of severe asthma and CRSwNP, which are diseases associated with type 2 inflammation. Although its clinical benefit has been demonstrated in randomized controlled trials, the results of treatment in real-life settings are extremely important.[14,16]

The negative impact of CRSwNP on patients' quality of life has been previously demonstrated.[17] Several randomized controlled trials have shown that mepolizumab treatment leads to a significant reduction in SNOT-22 scores. In two separate trials, SNOT-22 improvements were reported following administration of mepolizumab at doses of 100 mg every 4 weeks for 52 weeks, and 750 mg every 4 weeks for 25 weeks, respectively.[14,16] Similarly, in the real-world RINOSUR study, a 52-week follow-up of patients receiving 100 mg of mepolizumab every 4 weeks resulted in a significant reduction in SNOT-22 scores by 53 points (74.5 ± 39 vs. 21.5 ± 35.5; $p < 0.001$).[18] Domínguez-Sosa et al. also demonstrated a substantial improvement in sinonasal-related quality of life, reporting a median SNOT-22 score reduction of −63 points (95% CI: −68 to −58; $p < 0.001$) in 55 patients with CRSwNP treated with mepolizumab 100 mg every 4 weeks over a 6-month period.[19] In our study, the total SNOT-22 score decreased by 55 points after 12 months of follow-up, and this reduction was statistically significant. In addition, all subdomain scores showed significant improvement. This significant improvement in disease-specific quality of life aligns with findings from previous randomized controlled trials and real-world studies.[14,16,18,19]

In our study, a consistent and statistically significant improvement was observed in all sinonasal symptoms, including rhinorrhea, nasal congestion, postnasal drip, and loss of smell. These findings are in line with previously published data in the literatüre.[16,19] Among the evaluated symptoms, the least improvement was noted in olfactory function. In spite of statistical significance, 8 out of 18 patients did not report any improvement in their sense of smell. In these patients, the VAS score for loss of smell remained at 10 at baseline, t6 and t12 time points indicating persistent loss of smell throughout the follow-up period. An

increase in VAS scores related to loss of smell was observed in one patient. When patients with no improvement or worsening in olfactory VAS scores (n=9) were compared to those with improved scores (n=9), the group with improved olfactory function had a lower frequency of previous ESS (x^2=4.000, p=0.046). This finding may suggest that patients with more severe nasal polyposis are more likely to require ESS and may therefore experience less symptom improvement with mepolizumab treatment.

Depending on the surgical procedure, concomitant medical therapy, severity of nasal polyposis, and time elapsed since surgery, studies have shown that up to 60% of nasal polyps may recur. Asthma and aspirin sensitivity have also been identified as major factors associated with recurrence.[20,21] Postoperative recurrence remains a major challenge in the clinical management of patients with nasal polyposis. In a study involving 118 patients who had undergone sinonasal surgery, nasal polyp recurrence was observed in 60% of cases, with a median time to recurrence of 12 months. Notably, the presence of comorbid asthma and allergic conditions was significantly associated with an increased risk of recurrence and the need for revision surgery.[20] Similarly, in a cohort of 363 patients diagnosed with CRSwNP, the recurrence rate after ESS was reported as 35% at 6 months and 38% at 12 months; previous surgical history and polyposis severity were identified as significant predictors.[22] The immunological mechanisms underlying recurrence are also becoming increasingly well understood. In a study, tissue IL-5, IL-5 receptor alpha, and eosinophilic cationic protein levels were found to be significantly higher in patients who underwent revision surgery because of nasal polyps. In addition, elevated tissue IL-5 levels were identified as a predictor for revision surgery.[23] Type 2 inflammation and the presence of IL-4, IL-5, and IL-13 cytokines have also been demonstrated in the development of CRSwNP.[5,6] Mepolizumab is a monoclonal antibody developed against IL-5, which targets the disease mechanism by suppressing eosinophilic inflammation. In our current study, none of the 13 patients treated with mepolizumab and with a history of ESS underwent revision surgery during the 12-month follow-up. It is noteworthy that none of the 13 patients underwent revision surgery in spite of all of them having concomitant asthma and 6 of them having Samter's triad. In additon, none of the remaining six patients required primary ESS. This finding supports the notion that IL-5-targeted therapy may reduce the need for surgery and lower the long-term risk of recurrence, particularly in patients with CRSwNP accompanied by asthma and eosinophilic inflammation. Two randomized controlled trials found that mepolizumab 100 mg/4 weeks and 750 mg/4 weeks reduced the need for ESS, and this result was supported by real-life studies conducted with mepolizumab 100 mg/4 weeks.[14,16,18,19,24] The results of our study are consistent with existing literature data. However, factors such as the surgical procedure performed, the time elapsed since the last surgery, and the severity of nasal polyps, which affect recurrence, were not evaluated in the study. Therefore, it is advisable to interpret the results with caution.

In our study, injection-related adverse events were observed in only two patients. A recent analysis of the FDA Adverse Event Reporting System database found that mepolizumab was associated with fewer adverse events in the treatment of CRSwNP than in asthma. The presence of comorbid asthma and older age were identified as factors that increased the likelihood of adverse events in patients with CRSwNP. These findings suggest that the safety profile of mepolizumab may vary depending on the clinical indication.[25] Overall, our results support the safety and tolerability of mepolizumab in patients with CRSwNP.

The beneficial effects of mepolizumab on severe asthma—such as improvement in ACT scores, reduction in asthma exacerbations, and decreased need for daily systemic corticosteroids—have been well-documented in previous studies.[26,27] The findings of our study regarding asthma exacerbation frequency and systemic steroid use are consistent with the existing literature. The absence of a statistically significant improvement in ACT scores may be attributed to the small sample size and the relatively high baseline ACT scores of our patients at the initiation of treatment. These factors likely limited the potential for measurable improvement over the follow-up period.

The primary limitations of this study are its small sample size, lack of control group, and retrospective design. As a result of the retrospective nature, key clinical parameters such as CRS exacerbations, paranasal sinus computed tomography findings, blood eosinophil levels, and pulmonary function test results could not be assessed during the course of mepolizumab treatment. These limitations should be carefully considered when interpreting the study findings. Future trials with larger sample sizes are needed to provide more definitive and generalizable conclusions.

Conclusion

Biological agents should be considered when conventional treatment strategies for CRSwNP fail to achieve adequate disease control and prevent polyp recurrence. Mepolizumab therapy in CRSwNP patients with type 2 inflammation accompanied by asthma resulted in a significant reduction in sinonasal symptom scores and significantly improved disease-related quality of life. It may reduce the need for ESS in this patient group and has a low risk of serious side effects. These findings suggest that mepolizumab may be an effective and safe treatment option in selected CRSwNP patients.

Author's Contribution

All authors contributed equally to this article.

Conflict of Interest

The authors declare no potential conflicts of interest with respect to research, authorship, and/or publication of this article.

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