Effectiveness of mepolizumab in eosinophilic asthma and chronic rhinosinusitis with nasal polyps

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Rhinology 64: 5, 0 - 0, 2026
https://doi.org/10.4193/Rhin26.207

Received for publication:
March 23, 2026
Accepted: June 2, 2026

Associate Editor:
Ahmad Sedaghat

Dear Editor:

Chronic rhinosinusitis with nasal polyps (CRSwNP) is a chronic inflammatory disease affecting 2–4% of the population which has a significant impact on quality of life. Approximately 40% to 60% of people with CRSwNP also have eosinophilic asthma, reflecting the unified airway concept characterised by type 2 inflammation driven by interleukin (IL)-4, IL-5 and IL-13 [(1)].

Management of CRSwNP includes topical nasal corticosteroids (OCS), oral OCS, and endoscopic sinus surgery. However, up to 60% of patients have recurrent polyps after surgery [(2)].

Mepolizumab is a humanised immunoglobulin G1 (IgG1) monoclonal antibody targeting IL-5 that reduces eosinophil in the tissue and plasma and has demonstrated efficacy as a treatment of severe eosinophilic asthma (SEA) and CRSwNP [(3)].

The objective of this study was to evaluate the real-world effectiveness of mepolizumab, administered over 12 months, in patients with uncontrolled SEA and concomitant CRSwNP.

We designed a retrospective, single-centre cohort study. The inclusion and follow-up period spanned from January 2020 to December 2025.

Inclusion criteria were patients with age eighteen years or older, confirmed diagnosis of CRSwNP by nasal endoscopy and/or computed tomography (CT) of paranasal sinuses according to the Spanish Consensus on the Management of CRSwNP [(4)], diagnosis of uncontrolled SEA according to the Spanish Asthma Management Guidelines criteria [(5)] and treatment with mepolizumab 100 mg every 4 weeks for at least 12 months.

Exclusion criteria were Incomplete data in electronic medical records, loss to follow-up during the first month after treatment initiation, discontinuation of mepolizumab in the first four weeks for reasons unrelated to inefficacy or adverse effects.

Response to treatment was assessed at 12 months with the EXACTO multidimensional 10-point scale [(6)], which covers four domains: exacerbations (absence), asthma control (ACT ≥ 20), OCS (withdrawal or reduction > 50%), and lung function (FEV1 ≥ 80% or improvement > 10%). We classified participants as super responders (10 points), good responders (7–9 points), partial responders (3–6 points), or non-responders (0–2 points). Additionally, we used the FEOS score (FEV1, Exacerbations, OCS, Symptoms) to assess the overall clinical response [(7)].

The study was approved by the Drug Research Ethics Committee of Elda University General Hospital (code 2023/04).

The cohort included 95 patients with a mean age of 57 ± 13 years, of whom 72% were women. The mean follow-up duration was 800 ± 248 days (approximately 26 months). There was a high burden of comorbidities: 40% atopy with sensitisation to one or more aeroallergens, 43% nonsteroidal anti-inflammatory drug (NSAID)-exacerbated respiratory disease (N-ERD), 35% atopic dermatitis, 25% food allergy, 18% obesity (body mass index ≥ 30 kg/m2), 9% bronchiectasis, 6% allergic bronchopulmonary aspergillosis, 3% previously diagnosed obstructive sleep apnoea, and 3% ischemic heart disease.

Following the initiation of mepolizumab, there was a significant and sustained improvement in all upper and lower airway parameters (Table 1). Additionally, we observed a progressive reduction in the size of nasal polyps over the follow-up visits.

At baseline, 19 participants (20%) required maintenance OCS for asthma control, with a mean dose of 20 ± 10 mg/day of prednisone-equivalent. After 12 months of treatment, only 6 participants continued OCS treatment (68.5% reduction in corticosteroid dependent patients), with a mean dose of less than 5 mg/day of prednisone (decrease more than 75% in the mean dose).

At baseline, 76 participants (80%) had needed rescue cycles of systemic corticosteroids during the previous year for worsening nasal polyposis, with an average of three cycles per participant.

Table 1. Evolution of upper and lower airway parameters after starting mepolizumab 100mg.

	Mean value ± standard deviation				
Variable	**Baseline**	**3 months**	**6 months**	**12 months**	**P value**
Exacerbations (annual rate)	3.2 ± 1.8	1.2 ± 0.9	0.5 ± 0.7	0.3 ± 0.6	< 0.001
ACT (points)	13 ± 1	18 ± 3	21 ± 3	22 ± 3	< 0.001
FEV1 (% predicted)	76 ± 22	78 ± 17	80 ± 16	82 ± 16	< 0.05
FeNO (ppb)	42 ± 18	28 ± 14	22 ± 10	18 ± 8	< 0.001
Eosinophils (cells/µL)	520 ± 280	110 ± 85	60 ± 45	40 ± 30	< 0.001
SNOT-22 (points)	52 ± 14	35 ± 12	24 ± 10	18 ± 9	< 0.001
Nasal Polyp Score (points)	6.2 ± 1.8	4.1 ± 1.5	2.8 ± 1.3	1.9 ± 1.2	< 0.001
Nasal obstruction VAS (0–10)	8.2 ± 1.5	5.1 ± 2.0	3.5 ± 1.8	2.8 ± 1.9	< 0.001
Nasal secretion VAS (0–10)	7.5 ± 1.8	4.8 ± 1.9	3.2 ± 1.7	2.5 ± 1.6	< 0.001
Facial pain VAS (0–10)	5.8 ± 2.4	3.5 ± 2.1	2.2 ± 1.8	1.5 ± 1.3	< 0.001
Loss of smell VAS (0–10)	8.8 ± 1.2	5.9 ± 2.3	4.1 ± 2.0	3.2 ± 2.1	< 0.001

Abbreviations: ACT, Asthma Control Test (values: 0 to 25); FeNO, fractional exhaled nitric oxide; FEV1, forced expiratory volume in one second; SNOT-22 (values: 0 to 110), 22-item Sino-Nasal Outcome Test; VAS, visual analogue scale. The p-value is calculated from the baseline to a period of 12 months.

During follow-up, only 29 participants (30.5%) required any rescue cycles (61.8% reduction), with an average of one cycle per participant (66.7% reduction).

Evaluation with the EXACTO scale at 12 months showed that 54.7% of patients met the criteria for complete response and another 30.5% showed a good response. The mean FEOS score after treatment was 76 ± 15 points reflecting an optimal response to biological treatment.

The safety profile of mepolizumab was excellent throughout follow-up. No serious adverse drug events were reported.

Our findings are consistent with real-world evidence demonstrating long-term improvements in SNOT-22 scores, quality of life, and nasal symptoms, as well as a reduction in exacerbations. These results confirm the long-term benefits of mepolizumab for the unified airway [3,8,9].

Furthermore, our results on the improved visual analogue scale (VAS) for smell are consistent with the post-hoc analysis of the randomised, double-blind, placebo-controlled, parallel-group, phase 3 SYNAPSE trial, where mepolizumab demonstrated the ability to restore olfactory function in patients with CRSwNP [10].

Our study has limitations inherent to its retrospective, single centre and observational design. Furthermore, there was no systematic endoscopic and CT evaluation at the end of follow-up. Nevertheless, this study has several strengths. We used real-world data with an average follow-up of one year and we conducted a multidimensional assessment using the EXACTO scale and validated instruments such as SNOT-22 and ACT.

Conclusion

Mepolizumab is a treatment with sustained effectiveness in people with uncontrolled severe eosinophilic asthma and CRSwNP, achieving high rates of clinical response and control of both diseases with a favourable safety profile.

Authorship contribution

Acquisition, analysis, and interpretation of data: EC, IB, JLL, MA, MAB, CC, PF, VE and ML. Drafts and revisions during the writing process: EC, IB. Final approval of the article before submission to Rhinology: All authors have read and agreed to the published version of the manuscript.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Drug Research Ethics Committee of Elda University General Hospital (protocol code 2023/04). All study participants gave their informed consent for the use of their data.

Availability of data and materials

All data generated or analysed during this study are included in this published article.

Conflict of interest

The authors declare no conflicts of interest.

Funding

This research received no external funding.

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