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Brief Communication

Real-World Effectiveness and Safety of Mepolizumab in Severe Eosinophilic Asthma: Insights From the Korean Severe Asthma Registry (KoSAR)

So-Young Park [1†] **Daegeun Lee** [1†] **Joo-Hee Kim** [2] **Youngsoo Lee** [3] **Ga-Young Ban** [4] **Da Woon Sim** [5] **Jae-Woo Kwon** [6] **So Ri Kim** [7] **Woo-Jung Song** [8] **Heung-Woo Park** [9] **Yoon-Seok Chang** [10] **Young-Il Koh** [5] **Byung-Jae Lee** [11] **Hae-Sim Park** [3] **You Sook Cho** [8] **Sang-Heon Kim** [12*]

[1]Division of Pulmonary, Allergy and Critical Care Medicine, Department of Internal Medicine, Chung-Ang University Gwangmyeong Hospital, Gwangmyeong, Korea
[2]Division of Pulmonary Medicine, Department of Internal Medicine, Hallym University Sacred Heart Hospital, Hallym University Medical School, Anyang, Korea
[3]Department of Allergy and Clinical Immunology, Ajou University School of Medicine, Suwon, Korea
[4]Division of Pulmonary, Allergy and Critical Care Medicine, Department of Internal Medicine, Hallym University Gangdong Sacred Heart Hospital, Seoul, Korea
[5]Department of Allergy and Clinical Immunology, Chonnam National University Hospital, Chonnam National University Medical School, Gwangju, Korea
[6]Division of Allergy and Clinical Immunology, Department of Internal Medicine, Gangwon National University Hospital, Chuncheon, Korea
[7]Department of Internal Medicine, Research Center for Pulmonary Disorders, Chonbuk National University Medical School, Jeonju, Korea
[8]Department of Allergy and Clinical Immunology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea
[9]Division of Allergy and Clinical Immunology, Department of Internal Medicine, Seoul National University, Seoul, Korea
[10]Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea
[11]Division of Allergy, Department of Internal Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea
[12]Division of Pulmonary Medicine and Allergy, Department of Internal Medicine, Hanyang University Hospital, Hanyang University College of Medicine, Seoul, Korea

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Correspondence to
Sang-Heon Kim, MD, PhD
Division of Pulmonary Medicine and Allergy, Department of Internal Medicine, Hanyang University Hospital, Hanyang University College of Medicine, 222 Wangsimni-ro, Seongdong-gu, Seoul 04763, Korea.
Tel: +82-2-2290-8336
Fax: +82-2-2290-8364
Email: sangheonkim@hanyang.ac.kr

[†]So-Young Park and Daegeun Lee contributed equally to this work.

ORCID iDs
So-Young Park
https://orcid.org/0000-0002-5224-3077
Daegeun Lee
https://orcid.org/0000-0001-5843-8927
Joo-Hee Kim
https://orcid.org/0000-0002-1572-5149
Youngsoo Lee
https://orcid.org/0000-0001-8918-9353

ABSTRACT

Mepolizumab, an interleukin-5 antagonist, is globally recognized for its efficacy in randomized controlled trials for the treatment of severe eosinophilic asthma. The present study explored its real-world effectiveness and safety in a Korean cohort, filling a critical gap in current research. This multi-center retrospective study used data from the Korean Severe Asthma Registry, involving 67 patients treated with mepolizumab for uncontrolled severe asthma between September 2017 and July 2022. We assessed the effects of treatment on acute exacerbations, oral corticosteroid (OCS) maintenance dose, lung function, and quality of life. The notable findings included a marked reduction in the proportion of patients experiencing acute exacerbations, with 73.0% of patients reporting no exacerbations during the 6-month treatment period. At baseline, 31.8% of patients had reported no exacerbations over the prior 12 months. The OCS maintenance doses also decreased substantially, with only 3.2% of patients requiring OCS after 6 months. Additionally, there was an improvement in lung function. No severe adverse reactions were reported in this study, highlighting the safety of

Ga-Young Ban
https://orcid.org/0000-0002-7961-742X
Da Woon Sim
https://orcid.org/0000-0002-9723-0720
Jae-Woo Kwon
https://orcid.org/0000-0003-1639-3606
So Ri Kim
https://orcid.org/0000-0002-6074-9158
Woo-Jung Song
https://orcid.org/0000-0002-4630-9922
Heung-Woo Park
https://orcid.org/0000-0002-6970-3228
Yoon-Seok Chang
https://orcid.org/0000-0003-3157-0447
Young-Il Koh
https://orcid.org/0000-0002-5100-9473
Byung-Jae Lee
https://orcid.org/0000-0001-6940-0836
Hae-Sim Park
https://orcid.org/0000-0003-2614-0303
You Sook Cho
https://orcid.org/0000-0001-8767-2667
Sang-Heon Kim
https://orcid.org/0000-0001-8398-4444

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mepolizumab. This study confirmed that mepolizumab reduced exacerbations and OCS use, with additional improvements seen in asthma control, lung function, and patient-reported quality of life. These real-world findings support broader applications and reinforce the need for further research to optimize treatment strategies. Despite certain limitations, such as the small sample size and retrospective design, this study significantly contributes to the understanding of the real-world efficacy and safety of mepolizumab.

Keywords: Asthma; biologics; mepolizumab

INTRODUCTION

Mepolizumab, an interleukin-5 antagonist monoclonal antibody, has become a key treatment option for managing severe eosinophilic asthma.[1,2] Based on the outcomes of randomized controlled trials (RCTs), mepolizumab is designed to mitigate asthma exacerbations, decrease the need for maintenance doses of oral corticosteroids (OCSs), and improve lung function by targeting eosinophilic inflammation.[1,3,4] While RCTs support its efficacy, real-world studies are essential to understand its impact across diverse patient populations and clinical conditions.[5,6] Following the approval of various therapeutic biologics for severe asthma, based on the results of RCTs, numerous studies analyzing the real-world effects of these medications across diverse races and environments have been published globally to date. Notably, many of these studies have demonstrated superior efficacy compared with the outcomes reported in RCTs. In real-world studies, mepolizumab has been shown to reduce the incidence of acute exacerbations, decrease the use of systemic steroids, and lower healthcare utilization in patients with severe eosinophilic asthma.[7-9] In Korea, mepolizumab was approved by the Korean Ministry of Food and Drug Safety in 2015 and has been covered by the national health insurance since November 2023. Therefore, studies on the efficacy and safety of mepolizumab in the Korean healthcare system are warranted. To provide such information, we utilized data from the Korean Severe Asthma Registry (KoSAR), a multi-center severe asthma cohort in Korea, to analyze the effectiveness and safety of mepolizumab in a real-world setting.

MATERIALS AND METHODS

Patients and study design

This multi-center, retrospective study included patients who received mepolizumab for uncontrolled severe asthma between September 2017 and July 2022 in 25 medical centers affiliated with KoSAR-BIO.[10] The baseline for the study was set as the first day of biologic administration, and follow-up data were collected at 1 month intervals on each subsequent day of administration. Informed consent was obtained from all participants. The study was performed in accordance with the Declaration of Helsinki, and the protocols were approved by the Institutional Review Board of Hanyang University Hospital (HYUH-202010015).

Treatment outcomes and responder evaluation

The baseline characteristics of all patients were collected. Additionally, to evaluate the effects of biologics, the number of acute exacerbations, OCS maintenance dose, lung function, asthma control test (ACT), and quality of life score (Quality of Life Questionnaire for Adult Korean Asthmatics [QLQAKA] and EuroQol-visual analog scale [EQ-VAS])[11] were

evaluated on a monthly basis. Acute exacerbation was defined as an unscheduled outpatient visit, emergency room visit, hospitalization, admission to the intensive care unit, or burst administration of systemic steroids ≥ 15 mg for more than 3 days.

Define clinical remission

In this study, remission was defined at the final treatment point as meeting the following criteria: 1) Exacerbation-free; 2) OCS-free; 3) ACT score ≥ 20; and 4) Improvement of forced expiratory volume in 1 second (FEV1) by at least 100 mL from baseline. Patients who satisfied all 4 criteria were classified as Complete Clinical Remission (C-CR). Those meeting 3 criteria were categorized as Clinical Remission (CR). Patients satisfying at least one criterion were classified as Partial Remission (PR), and those meeting none were labeled as Non-Remission (NR).

Criteria for adverse reactions

Data on the adverse reactions that occurred during mepolizumab administration were collected. The severity of these reactions was categorized as mild, moderate, or severe. A mild reaction was defined as the occurrence of symptoms that did not interfere with daily life and allowed the patient to continue treatment. Moderate severity was defined as requiring dose reduction or temporary adjustment due to interference with daily activities. Severe reactions were defined as side effects that required discontinuation of the drug.[12] These adverse reactions were recorded after each dose administration.

Statistical analyses

All statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA) and R software (R Project for Statistical Computing, Vienna, Austria; www.r-project.org/). For descriptive statistics, continuous variables are presented as the mean ± standard deviations or median with interquartile ranges (IQR), and as counts of events (%) for categorical variables. One-way analysis of variance or the Kruskal–Wallis test was used to compare the means of more than 2 groups for parametric and nonparametric data, respectively. To assess the effects of biologics on paired comparisons, parametric data were analyzed using the paired *t*-test and nonparametric data were compared using the Wilcoxon signed-rank test. Missing data were handled by imputation. Statistical significance was defined as 2-sided $P < 0.05$.

RESULTS

Clinical characteristics of patients

We enrolled 67 patients from the KoSAR who had received mepolizumab treatment. Most patients received medication fewer than 6 doses of mepolizumab during the follow-up period, and the number of patients who received medication for more than 1 year was less (**Fig. 1**). The baseline characteristics of the patients are presented in **Table**. The mean age of patients was 52.6 years. The proportion of women was 44.3% and the average body mass index was 24.4 kg/m^2. The most common smoking status was never smoker (53.3%). The mean age of asthma onset was 41.1 years. At the time of registration, the asthma control status was identified as uncontrolled (45.2%), partly controlled (21.4%), or controlled (33.3%). The average number of acute exacerbations in the previous year was 3.0 ± 5.9. The mean ACT, QLQAKA, and EQ-VAS scores were 16.2, 56.8, and 62.7, respectively. Approximately 80% of patients had allergic rhinitis, 55% had chronic sinusitis as a comorbidity, and 13.3% had nasal polyps. Lung function was confirmed with an average FEV1 of 62.8 ± 13.3%, forced vital

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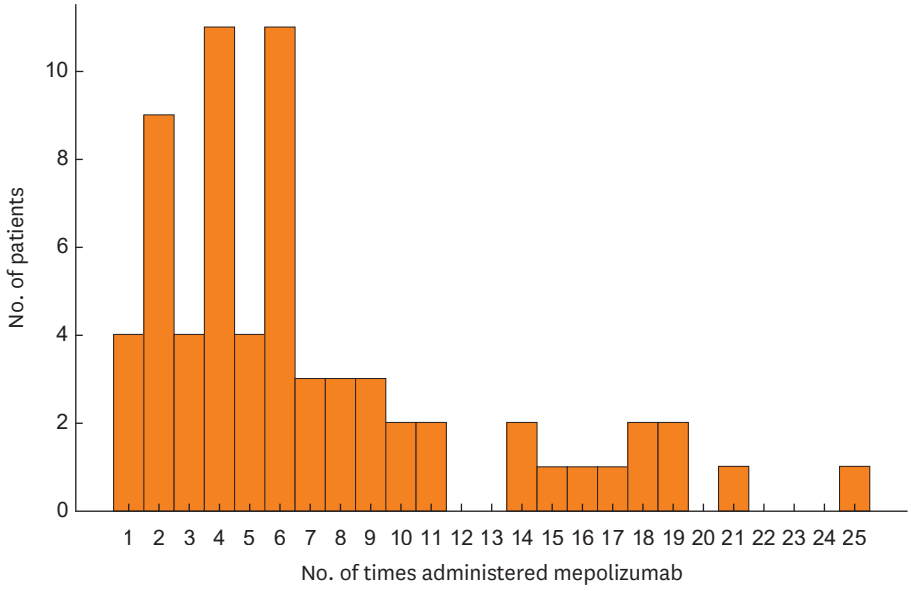

Fig. 1. The distribution of patients according to the number of times they were administered mepolizumab. Most patients received treatment for less than 1 year (up to 12 administrations).

capacity (FVC) of 75.5 ± 11.7%, and FEV1/FVC ratio of 66.3 ± 12.8%. The fractional exhaled nitric oxide was 64.8 ± 58.6 ppb. The blood eosinophil count was 854 (IQR, 1,204.2) cells and total immunoglobulin E was 294.8 IU/mL. The average dose of inhaled corticosteroids, in terms of budesonide equivalents, was 876 mcg. Approximately 19% of patients received maintenance OCSs at median dose of 3.8 mg/day.

Mepolizumab effectiveness: severe exacerbation, OCS maintenance, and pulmonary function

Owing to the insufficient number of patients who received mepolizumab treatment for 12 months, the analysis was conducted using data from the first 6 months of treatment. At baseline, 20 patients (31.8%) had not experienced any acute exacerbations in the previous year. During the 6 months of mepolizumab treatment, a higher proportion of patients (46 patients, 73%) were observed to be free from acute exacerbations (**Fig. 2A**). We conducted a subgroup analysis based on the number of doses administered, dividing the patients into groups who received treatment for less than 3 months and those who continued treatment for up to 6 months. In both groups, a reduction in acute exacerbations was observed compared to before treatment (**Fig. 2B**). Additionally, the number of patients requiring OCS maintenance therapy tended to decrease, which is generally considered desirable due to its potential side effects. Initially, 12 patients (19.1%) underwent OCS maintenance therapy at baseline. The number tended to decrease to 9 patients (14.3%) after one month and further decreased to 2 patients (3.2%) after 6 months of mepolizumab treatment (**Fig. 3A**). Among these, only 2 patients who received mepolizumab for 3 months or less remained on OCS maintenance, and both discontinued OCS within that period. The maintenance dose of steroids decreased from 3.8 (IQR, 2.5–7.6) mg/day at baseline to 1.6 (IQR, 0.8–3.0) mg/day after 3 months, and then slightly increased to 2.1 (IQR, 1.6–2.7) mg/day after 6 months (**Fig. 3B**). The baseline average FEV1 was 1,980 mL, which increased to 2,994 mL after 6 months of mepolizumab treatment and was statistically significant (P = 0.044) (**Fig. 4**).

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Table. Baseline clinical characteristics of patients

Characteristics	Mepolizumab (n = 67)
Age (yr)	52.6 ± 12.1
Female	27 (44.3)
BMI (kg/m^2)	24.4 ± 3.6
Smoking	
Never smoker	32 (53.3)
Ex-smoker	26 (43.3)
Current smoker	2 (3.3)
Asthma onset age (yr)	41.1 ± 14.7
Asthma control	
Uncontrolled	19 (45.2)
Partly controlled	9 (21.4)
Controlled	14 (33.3)
Asthma exacerbations over the past year	3.0 ± 5.9
ACT score	16.2 ± 5.9
QLQAKA	56.8 ± 15.4
EQ-VAS	62.7 ± 24.3
Comorbidities	
Allergic rhinitis	50 (79.4)
Atopic dermatitis	6 (9.5)
Allergic conjunctivitis	7 (11.1)
Chronic rhinosinusitis	33 (55.0)
Nasal polyps	8 (13.3)
Pulmonary function test	
FEV1 (%)	62.8 ± 13.3
FEV1 (mL)	1,980.4 ± 689.5
FVC (%)	75.5 ± 11.7
FVC (mL)	3,002.2 ± 898.9
FEV1/FVC (%)	66.3 ± 12.8
FeNO (ppb)	64.8 ± 58.6
Blood eosinophil (cells/μL)*	854 (IQR, 1,204.2)
Total IgE (IU/mL)*	294.8 (IQR, 283.5)
Medication	
Inhaled corticosteroids (μg/day)†	876 ± 644.8
OCS maintenance	12 (19.1)
OCS maintenance dose (mg/day)*	3.8 (IQR, 5.1)

Values are presented as mean ± standard deviation or number (%).
BMI, body mass index; ACT, asthma control test; QLQAKA, Quality of Life Questionnaire for adult Korean Asthmatics; EQ-VAS, Euro Quality of life Visual Analogue Scale; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; FeNO, fractional exhaled nitric oxide; IQR, interquartile range; IgE, immunoglobulin E; OCS, oral corticosteroid.
*Nonparametric method (Kruskal–Wallis test); †Budesonide equivalent dose.

Mepolizumab effectiveness: quality of life, asthma control, and changes in blood eosinophil counts

Before the administration of mepolizumab, mean ACT score was 16.2 ± 5.9. After 1 month, the ACT score significantly increased to 21.9 ± 4.9, and remained improved at 20.3 ± 1.8 points after 6 months (**Fig. 5A**). The median QLQAKA score at baseline was 56.8 (IQR, 17.0), which increased to 72.0 (IQR, 23.0) after 1 month and further to 74.0 (IQR, 9.5) at 6 months, representing a statistically significant improvement from baseline (**Fig. 5B**). The median eosinophil count at baseline was 854.1 (IQR, 1,204.2) cells/μL. After 1 month of mepolizumab treatment, it significantly decreased to 158.0 (IQR 362.1) cells/μL ($P < 0.001$). By 6 months, the median further declined to 95.4, (IQR, 748.4) cells/μL, underscoring the substantial and sustained efficacy of the treatment in reducing the eosinophil levels (**Fig. 6**).

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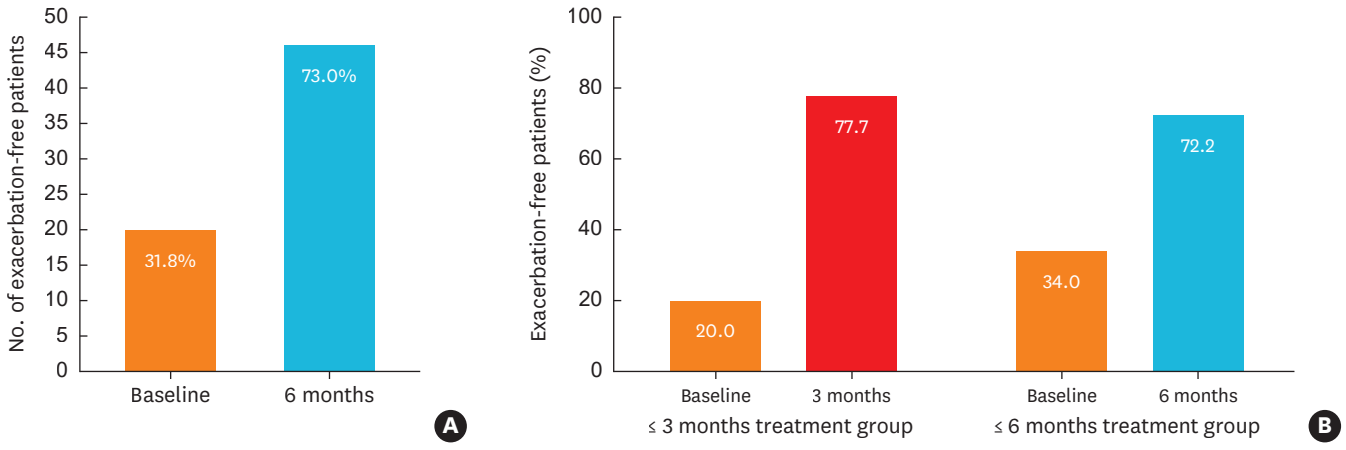

Fig. 2. Comparison of the proportion of patients who did not experience any acute exacerbations. (A) The proportion of total patients who had not experienced any acute exacerbations was 31.8% (20 patients) at baseline, and 73% (46 patients) were observed to be exacerbation-free during 6 months of mepolizumab treatment. (B) Subgroup analysis comparing patients who received mepolizumab for ≤ 3 months and ≤ 6 months. In the ≤ 3-month group, the proportion of exacerbation-free patients rose from 20.0% at baseline to 77.7% during treatment, and in the ≤ 6-month group, from 34.0% to 72.2%, respectively. Baseline exacerbation data were collected over a 12-month period, whereas treatment-phase data cover only 6 months, which may limit direct comparability.

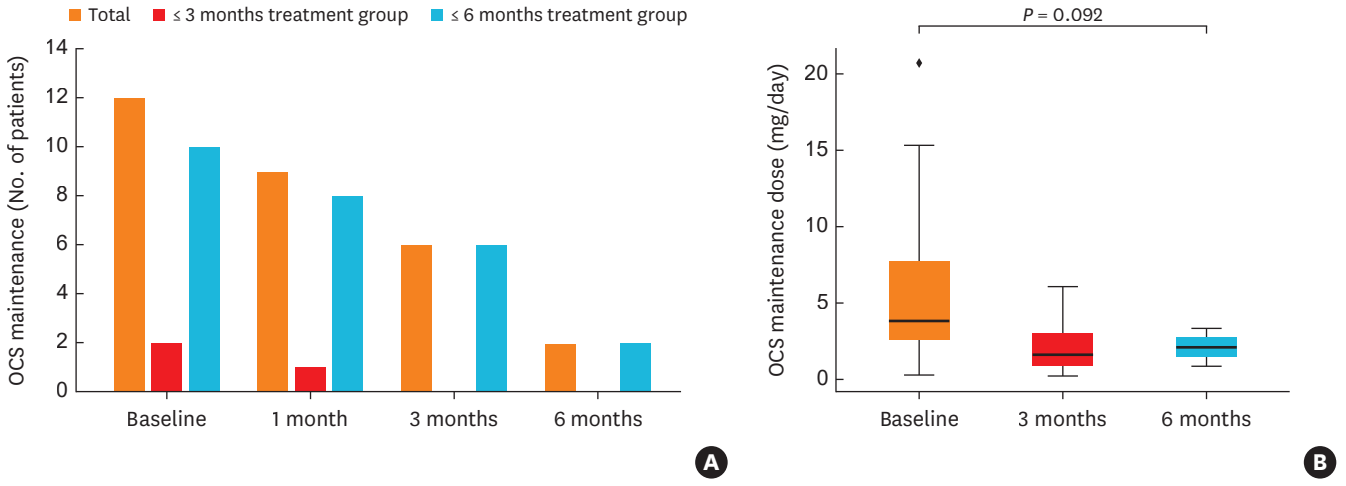

Fig. 3. Changes in OCS maintenance status and dosage (n = 63, patients included in analysis). (A) Proportions of patients receiving OCS maintenance therapy at baseline, 1, 3, and 6 months. Subgroup analysis compares the proportions between the ≤ 3 months treatment group and the ≤ 6 months treatment group. (B) Trends in maintenance OCS dosage at baseline, 3 months, and 6 months.
OCS, oral corticosteroid.

Mepolizumab effectiveness: CR

Among patients treated with mepolizumab, 2 (3.0%) were classified as NR, 23 (34.3%) as CR, and the remaining 42 (62.7%) as PR. No patients met all 4 criteria for C-CR.

Adverse reactions

No severe adverse events were reported during the study. Five side effects were reported, of which 4 were classified as mild and one as moderate. The moderate adverse reaction was myalgia, whereas the 4 mild cases included headache, symptoms of upper respiratory tract infection, indigestion, and localized itching.

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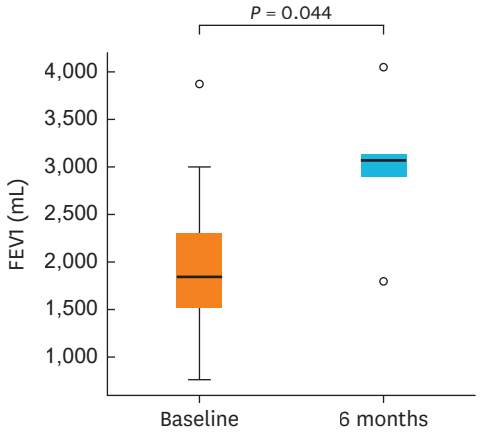

Fig. 4. Changes in lung function after 6 months of mepolizumab treatment (n = 28). The baseline average FEV1 was 1,980 mL, which increased to 2,994 mL after 6 months of mepolizumab treatment (*P* = 0.044).
FEV1, forced expiratory volume in 1 second.

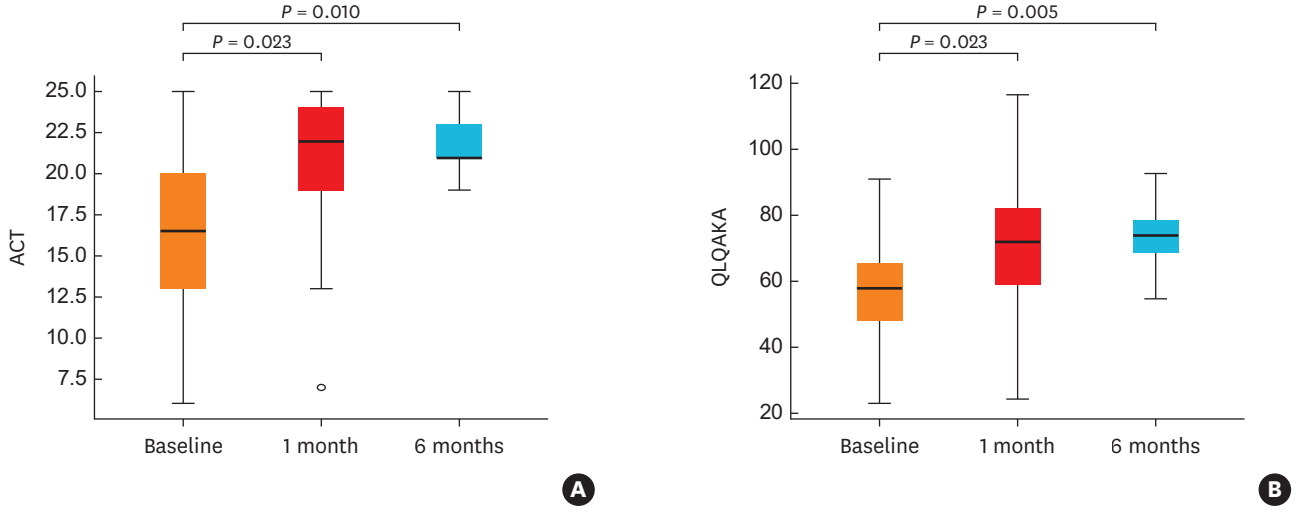

Fig. 5. Asthma control and quality of life improvement. (A) The graph shows changes in asthma control scores (n = 63), and (B) represents changes in quality of life (n = 21). Both parameters showed statistically significant improvement during the 6-month treatment period.
ACT, asthma control test; QLQAKA, Quality of Life Questionnaire for adult Korean Asthmatics.

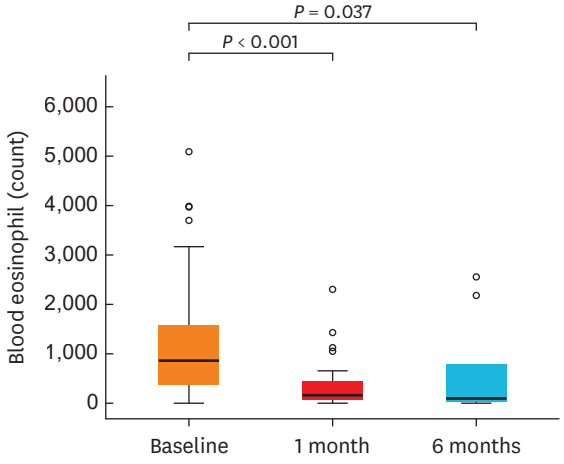

Fig. 6. Changes in eosinophil counts following mepolizumab treatment (n = 60). Compared to the baseline, the median values at both 1 month and 6 months significantly decreased, demonstrating that the treatment is effective in reducing eosinophil counts.

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DISCUSSION

This study analyzed the real-world efficacy of mepolizumab in Korean patients with severe asthma. Mepolizumab effectively reduced exacerbations, OCS maintenance doses, and eosinophil counts, while improving asthma control, lung function, and quality of life. However, since this study period preceded national insurance coverage for mepolizumab, financial burden may have contributed to the fact that most patients received treatment for less than one year. Although recent approval for reimbursement may improve accessibility, stringent criteria could still limit patient eligibility.

In this study, 73% of patients experienced no exacerbation during 6 months. The results from another multi-center study conducted in Korea showed that during 1 year of mepolizumab treatment, approximately 56.7% of patients reported no acute exacerbations.[13]

The use of OCS as a continuous maintenance therapy in patients with severe asthma increases mortality and causes long-term complications.[14,15] However, approximately 20%–30% of patients with severe asthma continue to receive OCSs.[16,17] Biologics have been proven in RCTs to decrease the need for OCS maintenance in patients with type 2 (T2)-high phenotypes.[3,4,18] In other real-world studies of mepolizumab, the maintenance dose of OCS was reduced by 52% following treatment.[8] Similar real-world studies have found that 47.8% of patients were able to discontinue this treatment, and the mean daily dose was decreased by 59.9%.[7] In the present study, we observed that the maintenance dose of OCS was reduced by approximately 67%, and significantly, over 80% of patients discontinued OCS maintenance altogether.

Lung function improved, with FEV1 increasing by 1,000 mL in 6 months, which should be interpreted with caution given the small sample size. Significant improvements in quality of life and asthma control appeared within a month, aligning with previous RCTs and real-world studies.[19,20] After mepolizumab administration, the eosinophil counts significantly decreased within one month, and by 6 months, the blood eosinophil counts consistently decreased to < 100. Moreover, mepolizumab has proven long-term safety.[21-23] No severe adverse reactions were observed in the present study.

The present study had several limitations. First, the small number of patients and variability in the number of doses administered presented challenges in the comparative analysis of certain parameters. Second, the retrospective analysis of data collected in the cohort led to some missing data. Additionally, as this study reflects real-world practice, inherent heterogeneity and complexity were unavoidable due to factors such as financial burden and inconsistent treatment adherence, which are less common in RCTs. Third, the number of acute exacerbations at baseline was collected over the previous 12 months, whereas the post-treatment period covered only 6 months. As data on exacerbations in the 6 months prior to treatment were not available, direct comparison using equivalent time frames was not feasible.

Despite these limitations, this study is the first to report the effectiveness of mepolizumab in a real-world setting among Korean patients with severe asthma. Mepolizumab has been proven highly effective in patients with severe asthma in Korea, reducing the incidence of acute exacerbations, decreasing the need for OCS maintenance, and improving lung function and quality of life. For patients exhibiting a T2-high phenotype, receiving this treatment is important to minimize the side effects and improve long-term prognosis. Future studies should explore the long-term therapeutic effects and cost-effectiveness of these drugs.

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