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## Evaluating the effectiveness and safety of mepolizumab in elderly patients with severe asthma: insights from the REDES study

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### ABSTRACT

**Objective:** Asthma and severe asthma are problems affecting all age groups, but asthma is frequently undiagnosed in the elderly, due to the poor perception of airflow limitation, lack of fitness, and presence of multiple comorbidities. Even so, the proportion of patients with severe asthma aged  $\geq 65$  is significant, and data on efficacy of asthma medications in the elderly are sometimes limited. We report here the effectiveness and safety of mepolizumab (an IL-5 inhibitor) in elderly ( $\geq 65$  years) patients.

**Methods:** The REDES study was an observational, multicenter study of the effectiveness and safety of mepolizumab 100 mg SC every 4 weeks in 318 severe asthma patients in Spain. This post-hoc analysis compares the effectiveness and safety of patients  $\geq 65$  years old to patients  $< 65$  years after 12 months of mepolizumab treatment.

**Results:** 27% of patients were  $\geq 65$  years old, compared with 73% of patients  $< 65$  years. Elderly patients showed a trend toward less frequent comorbid nasal polyps ( $p=0.06$ ) and a lower proportion of atopic sensitization (as detected by prick test or specific IgE) ( $p=0.02$ ). Similar improvements were noted in ACT score ( $p<0.0001$ ), comparable exacerbation reductions ( $p<0.0001$ ), and lung function parameters ( $p<0.04$  in elder group and  $p<0.0001$  in younger elder group), although an apparent greater reduction of OCS daily dose was observed in elder patients ( $p=0.0002$ ). No new safety signals were reported in the elderly population.

**Conclusions:** This study further supports mepolizumab as an effective and well tolerated therapy in the difficult to treat population of elderly patients with severe asthma.

### ARTICLE HISTORY

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Real-world; difficult to treat; effectiveness; IL-5; comorbidities; fitness

### Introduction

Asthma remains a complex heterogeneous syndrome encompassing a series of respiratory manifestations associated with chronic airway inflammation and, in spite of the increasing availability and research in this particular area of medicine, the majority of the burden of asthma morbidity is avoidable (1).

Asthma and severe asthma are problems affecting all age groups, but asthma is frequently undiagnosed in the elderly, due to the poor perception of airflow limitation, lack of fitness, and presence of multiple comorbidities. Asthma costs may be higher as well among these patients, as they suffer from frequent hospitalizations and use multiple medications (1).

In Spain, the population of patients with asthma managed by secondary care are, on average, 51 years

old, and those with severe asthma, 57 years old. One in every three patients with severe asthma is  $\geq 65$  years old, according to the PAGE study (2). However, data on efficacy of asthma medications in the elderly are sometimes limited, as these patients are often excluded from clinical trials (1).

As age-related physiological and immunological changes (e.g. lung function decline) complicate asthma management and affect treatment effectiveness in elderly patients, the data on the safety and effectiveness of biologic therapies in these patients is still limited (3,4).

The aim of our study is to report the effectiveness and safety of mepolizumab (an IL-5 inhibitor) in elderly ( $\geq 65$  years) patients in a post-hoc analysis of the real-world REDES study (5).

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## Methods

The REDES study was a retrospective, real-world, multicenter, cohort study of the effectiveness and safety of mepolizumab 100 mg SC every 4 weeks for 12 months, that enrolled patients with severe eosinophilic asthma from 24 Spanish hospitals. Patients enrolled were  $\geq 18$  years old, had a clinical diagnosis of severe asthma, and had initiated mepolizumab  $\geq 12$  months before study inclusion. The primary endpoint was the change in the annual rate of clinically significant asthma exacerbations, and secondary endpoints included average OCS daily maintenance dose, pre- and post-bronchodilator spirometric tests, changes in Asthma Control Test (ACT), and blood eosinophil counts. The results in the overall study population have been previously reported (5).

The REDES study was performed in line with the guiding principles of the Declaration of Helsinki and order SAS/3470/2009. Approval of the study protocol was granted by the ethics committee of Hospital La Princesa, Madrid, Spain (5). Separate ethics approval was not required for this analysis.

This analysis compares the clinical and sociodemographic features, and the effectiveness and safety of mepolizumab in elderly patients from the REDES study ( $\geq 65$  years old) compared with patients  $< 65$  years old after 12 months of mepolizumab therapy.

Differences between groups were analyzed as per the following: for continuous variables, comparisons were made using the Student's t-test to assess whether there were statistically significant differences between the groups. Chi-square ( $\chi^2$ ) test was used for qualitative or categorical variables to determine if there were significant differences in proportions between the groups. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered significant.

## Results

318 patients with severe asthma were included in the REDES study. Of these, 85 (27%) patients were aged  $\geq 65$  years, with a mean (SD) of 70.8 (4.6) years, and 233 (73%) patients were  $< 65$  years, with a mean age of 51.3 (10.2) years.

Elderly patients were characterized by a higher female presence, 76% vs 67%, than patients  $< 65$  years old. They also had their diagnosis of asthma at a posterior time (46.1 (17.7) vs 29.5 (15.8) years old) and were less likely to have comorbid nasal polyps, 38% vs 49% than the younger group. Atopic sensitization was more common in the younger group with 45% compared to 31% of elderly patients and

comorbid bronchiectasis was more prevalent in the older group, with 28%, compared with 15% in the younger group (Table 1).

No differences were found between subgroups at baseline in terms of eosinophil counts (mean (SD) of 660.4 cells/ $\mu$ L (1096) and 728.1 cells/ $\mu$ L (723.1) in elderly and younger patients, respectively), ACT scores (14.1 (4.82) and 14.1 (5.1) points) or in the proportion of patients with an ACT  $\geq 20$  (13% vs 16%) but, some differences ( $p < 0.05$ ) were found in the baseline annual rate of exacerbations, with a smaller rate of 3.8 (2.7) exacerbations/year in elderly patients than younger patients, with 4.7 (3.8) exacerbations/year.

Significant differences were also found ( $p < 0.0001$ ) in baseline lung function absolute values, with an FEV<sub>1</sub> of 1.5 L (0.6) and 2.0 L (0.8), however, this corresponded with similar predicted values of 71.4% and 69.7% respectively (Figure 1).

After 12 months of treatment with mepolizumab, the changes in ACT (6.5 and 7.3 points), exacerbation rates (75% and 78.4% reductions), and lung function parameters (Table 1) were overall similar between the two groups (Table 1). A greater reduction of OCS daily dose was observed in elder patients (71% vs 56%) with a final dose of 2.93 mg/day and 5.8 mg/day after 12 months of mepolizumab therapy in the elderly and younger patients, respectively ( $p < 0.05$ ) (Figure 2).

There was just one elderly patient that reported adverse events, compared with 8 younger patients (1% vs 3%). No particular safety signals were observed in the elderly population of the REDES study.

## Discussion

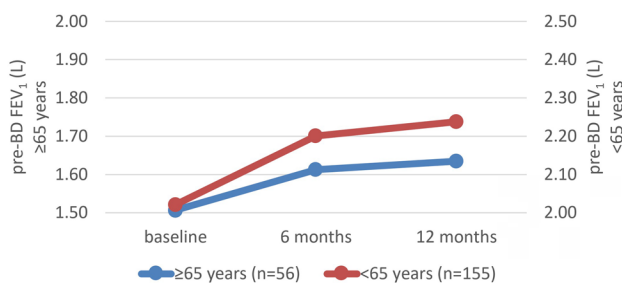
In this study, we report the results of 12 months of treatment with mepolizumab in an elderly population, defined as those patients aged  $\geq 65$  years. We chose 65 years of age, as most age stratifications in asthma use 6, 18, and 65 years as thresholds when patient populations are divided by age groups (3,6,7).

The proportion of elderly patients was 27%, which represents more than one quarter of severe asthma patients in the REDES real-world study. These results are descriptive, but they show that the use of mepolizumab in elderly patients was overall well tolerated and similarly effective than in younger patients. The main limitations of the study were the retrospective nature of the REDES study, subject to missing data specially in older patients, as clinical records of these patients are likely to have a longer trajectory and less frequent follow-up, the fact that atopic sensitization and nasal polyps are reported without the number of

**Table 1.** Stratification of clinical results according to age subgroup.

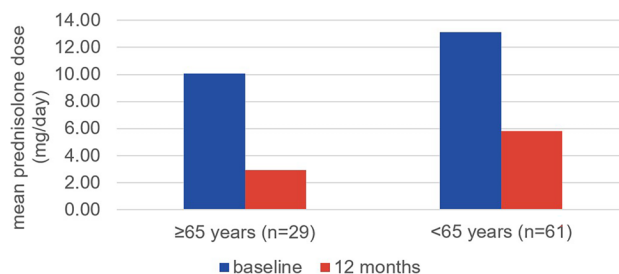
	≥65 years old (n=85)			<65 years old (n=233)			Inter-group p
Age, mean (SD), years	70.84 (4.58)			51.34 (10.19)			<0.0001
Asthma duration, mean (SD), years	25.8 (18.18)			21.67 (14.56)			0.06
Sex, female, n (%)	65 (76%)			155 (67%)			0.09
Comorbid nasal polyps, n (%)	32 (38%)			115 (49%)			0.06
Comorbid bronchiectasis, n (%)	24 (28%)			45 (15%)			0.09
Never smokers, n (%)	57 (67%)			141 (61%)			0.18
Ex-smokers, n (%)	24 (28%)			82 (35%)			0.29
Current smokers n (%)	0 (0%)			4 (2%)			0.23
Age of asthma diagnosis, mean (SD)	46.12 (17.67)			29.48 (15.75)			<0.0001
Atopic sensitization, n (%)	26 (31%)			105 (45%)			0.02
	Baseline	12 months	Intra-group p	Baseline	12 months	Intra-group p	
Blood eosinophil counts, mean (SD)	660.37 (1095.95)	93.89 (202.45)	0.0001	728.12 (723.11)	99.97 (248.19)	<0.0001	
ACT score, mean (SD)	14.10 (4.82)	21.40 (3.34)	<0.0001	14.05 (5.14)	20.58 (4.05)	<0.0001	
Patients with ACT score ≥20, n (%)	10 (13%)	61 (79%)	<0.0001	32 (16%)	128 (70%)	<0.0001	
Annual exacerbations, mean (SD)	3.84 (2.69)	0.96 (1.18)	<0.0001	4.70 (3.75)	1.02 (1.52)	<0.0001	
Prednisolone dose, mean (SD), mg/day	10.09 (8.48)	2.93 (4.11)	0.0002	13.13 (10.54)	5.80 (7.73)	<0.0001	
Patients that interrupted OCS, n/N (%)		14/29			29/61		
Pre-bronchodilator FVC, mean (SD), L	<b>2.47 (0.83)</b>	<b>2.61 (0.80)</b>	0.07	<b>3.14 (0.97)</b>	<b>3.30 (0.94)</b>	<0.0001	
Pre-bronchodilator FEV <sub>1</sub> , mean (SD), L	<b>1.51 (0.55)</b>	<b>1.63 (0.51)</b>	0.03	<b>2.02 (0.78)</b>	<b>2.24 (0.77)</b>	<0.0001	
Pre-bronchodilator FEV <sub>1</sub> , mean (SD), %	71.43 (21.45)	78.35 (21.42)	0.0152	69.65 (22.57)	81.34 (21.76)	<0.0001	
Ratio pre-bronchodilator FEV <sub>1</sub> /FVC, mean (SD)	61.52 (11.10)	<b>63.61 (11.85)</b>	0.35	64.11 (13.26)	<b>67.60 (11.73)</b>	<0.0001	
Post-bronchodilator FVC, mean (SD), L	<b>2.48 (0.77)</b>	<b>2.60 (0.72)</b>	0.02	<b>3.24(0.91)</b>	<b>3.38 (0.88)</b>	0.0016	
Post-bronchodilator FEV <sub>1</sub> , mean (SD), L	<b>1.64 (0.56)</b>	<b>1.69 (0.54)</b>	0.04	<b>2.17 (0.74)</b>	<b>2.31 (0.68)</b>	<0.0001	
Post-bronchodilator FEV <sub>1</sub> , mean (SD), %	77.22 (25.41)	78.87 (23.96)	0.11	75.94 (22.22)	83.96 (23.18)	<0.0001	
Ratio post-bronchodilator FEV <sub>1</sub> /FVC, mean (SD)	66.11 (13.04)	64.55 (13.07)	0.83	66.89 (11.91)	67.82 (11.90)	0.0036	
Patients with adverse events related to treatment, n (%)	1 (1%)			8 (3%)			

Bold: intergroup  $p < 0.05$  at baseline or at 12 months.

**Figure 1.** Change in pre-bronchodilator FEV<sub>1</sub> according to age subgroup.

patients with the specific tests for these comorbidities represents another significant limitation. On the other hand, the strengths of the REDES study data are the fact that it was developed originally in specialized asthma units (which would imply a higher completeness and accuracy of data collection in severe asthma patients), and the sample size was big enough to conduct several post-hoc analyses.

The safety and efficacy of mepolizumab has been documented previously (8–12). In pivotal trials, additional treatment with mepolizumab reduced exacerbations in 50–58%, improved FEV<sub>1</sub> by 120 ml (10), and had an acceptable safety profile, compared to placebo. In our study, we show >75% reduction of exacerbations, albeit without placebo arm in real-world patients, and a 120 ml and 220 ml improvement in

**Figure 2.** Reduction of OCS according to age subgroup.

FEV<sub>1</sub> in elderly and younger patients, respectively, with comparably acceptable safety profile. Overall our results are in line with previous real-world evidence studies and add some specific data on elderly patients that has not been extensively explored in patients with severe asthma (7,13,14).

Lung function decreases with age, due to the stiffening of the chest wall, reduced respiratory muscle function, and an increase in the residual volume due to a loss of elasticity. Bronchiectasis is also a more common comorbidity in these patients. Overall, elderly patients show a reduced response to bronchodilators and inhaled glucocorticoids because of these physiological changes (15). At the same time, aging-related immunosenescence encompasses changes in adaptive and innate immune pathways, that could entail increased susceptibility to foreign and self-antigens,

infections, autoimmune disease, and other chronic processes (16,17). Besides, elderly patients struggle to adhere to inhaled treatments, because they have more difficulties to competently operate their inhalers (18).

Overall, elderly patient population has been shown to represent a clinically different, more frail, phenotype of patients with asthma, with higher disease severity and higher frequency of relevant comorbidities, thus, requiring a multidimensional management (16).

Our study supports the use of mepolizumab for severe asthma in this difficult to treat population, without remarkable differences in effectiveness or safety with younger patients. Exacerbations and asthma control were reduced similarly in both groups of patients. A numerical greater reduction of oral corticoids was observed in elderly patients, which could be related to an excess of OCS use in this population due to the long trajectory of their disease an/or other comorbidities. On this, it should be noted that cumulative doses of oral glucocorticoids are associated with weight gain, sleep apnea-hypopnea syndrome, osteoporosis, and other adverse events, and that sparing strategies should be used to avoid and reduce such consequences (16,19).

The only adverse event reported to be related with mepolizumab in the elderly population was an acneiform dermatitis which didn't lead to treatment withdrawal.

The most evident difference between these population was the lower lung function in elderly patients at baseline, and although the percent predicted lung function was somewhat similar and increased similarly after treatment, only the younger group was able to normalize the mean pre-bronchodilator FEV<sub>1</sub> (FEV<sub>1</sub>>80%). In general, lower absolute improvements were seen in elderly patients, compared with younger patients, supporting the notion that these patients have suffered a greater or longer irreversible lung function decline. Our results are aligned with the thesis that an earlier intervention could imply better outcomes for asthma patients, to normalize as best as possible their lung function trajectories during the duration of disease.

## Conclusion

Elderly patients with severe asthma are a difficult to treat phenotype of patients that struggle to normalize the lung function, possibly due to a longer impact of airway inflammation on their age-related lung function decline. These results further support the use of mepolizumab in these patients as an effective and well tolerated therapy.

## Author contributions

EMM and DBC contributed to the study design. EMM, CP, LPM, MME, AGB, JR, MDP, TH, SQ enrolled patients. DBC performed the analyses. All authors critically reviewed and approved the manuscript.

## Declaration of interest

EMM reports consulting fees from AstraZeneca, GSK, Sanofi, and Teva, and Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from AstraZeneca, Chiesi, Gebro, GSK, Novartis, Sanofi, and Teva. CP reports consulting fees from AstraZeneca, GSK, and Sanofi, and honoraria for lectures or presentations from GSK, AstraZeneca, Sanofi, and Gebro. LPM reports: Educational an investigation grants for my Institution from GSK, AZ, and Chiesi. Consulting fees from MSD, honoraria for lectures from AZ and Chiesi. MME reports consulting fees, and payment or honoraria for lectures or presentations from AstraZeneca, Chiesi, GSK, Sanofi, Novartis, and Teva. AGB reports consulting fees from AstraZeneca, GSK, and Sanofi, and honoraria for lectures or presentations from AstraZeneca, Gebro, GSK, Menarini, and Sanofi. JR reports consulting fees from AstraZeneca and Sanofi, and honoraria for lectures or presentations from GSK, AstraZeneca, Sanofi and Gebro, Novartis, and Menarini. MDP reports consulting fees and honoraria for presentations from AstraZeneca and GSK. TH reports consulting fees from AstraZeneca, GSK, and Sanofi, and honoraria for lectures or presentations from GSK, AstraZeneca, Sanofi, and Gebro. SQ reports consulting fees and honoraria for lectures from ALK, Allergy Therapeutics, AstraZeneca, Chiesi, GSK, Mundipharma, Novartis, Sanofi, and Teva. DBC is employee of GSK and hold stocks/shares in GSK.

## Data sharing statement

For requests for access to anonymised subject level data, please contact corresponding author.

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