

Therapeutic Switch From Omalizumab to Mepolizumab in Patients With Uncontrolled Severe Eosinophilic Asthma: Treatment Effect by ACQ and SGRQ Quartiles

Poster No. 083

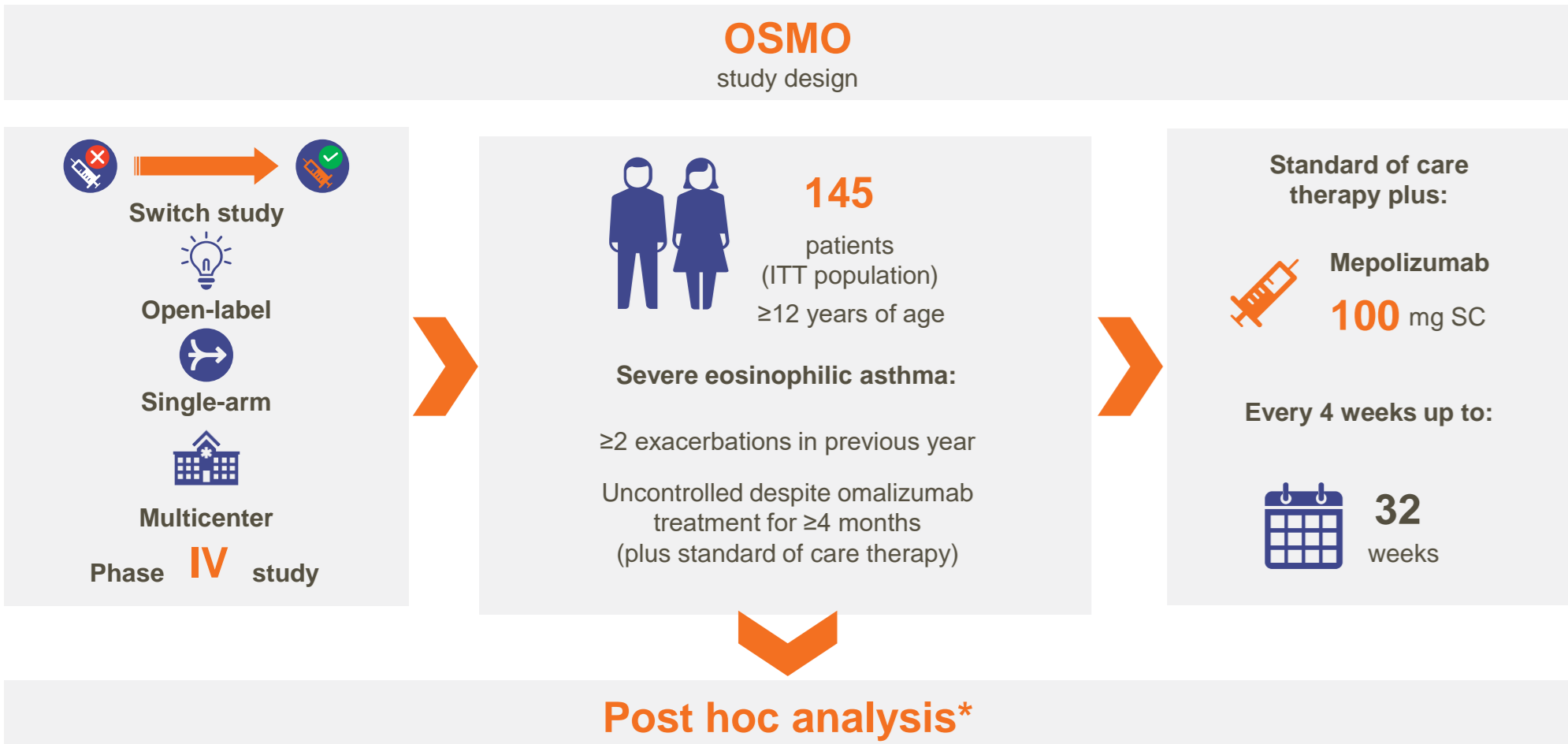
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Aims

- Mepolizumab is approved as an add-on maintenance treatment for patients with severe eosinophilic asthma.¹ Data from the OSMO study demonstrated that patients with uncontrolled severe eosinophilic asthma despite treatment with omalizumab experienced significant and clinically relevant improvements in asthma control, health-related quality of life, lung function, and asthma exacerbations following a switch from omalizumab to mepolizumab treatment.²
- However, it has not yet been determined whether clinical outcomes differ according to asthma control and health-related quality of life at baseline.
- The aim of this post hoc analysis of the OSMO study was to evaluate the relationship between baseline asthma control and health-related quality of life and changes in clinical outcomes after switching from omalizumab to mepolizumab in patients with uncontrolled severe eosinophilic asthma.

Methods



Endpoints

- Mean changes from baseline in **ACQ-5 score***
- Mean change from baseline in **SGRQ total score***
- Mean change from baseline in **pre-bronchodilator FEV₁***
- Annualized rate of clinically significant **exacerbations***

Subgroup analysis

By baseline ACQ-5 and SGRQ total score quartiles

4 categories in each

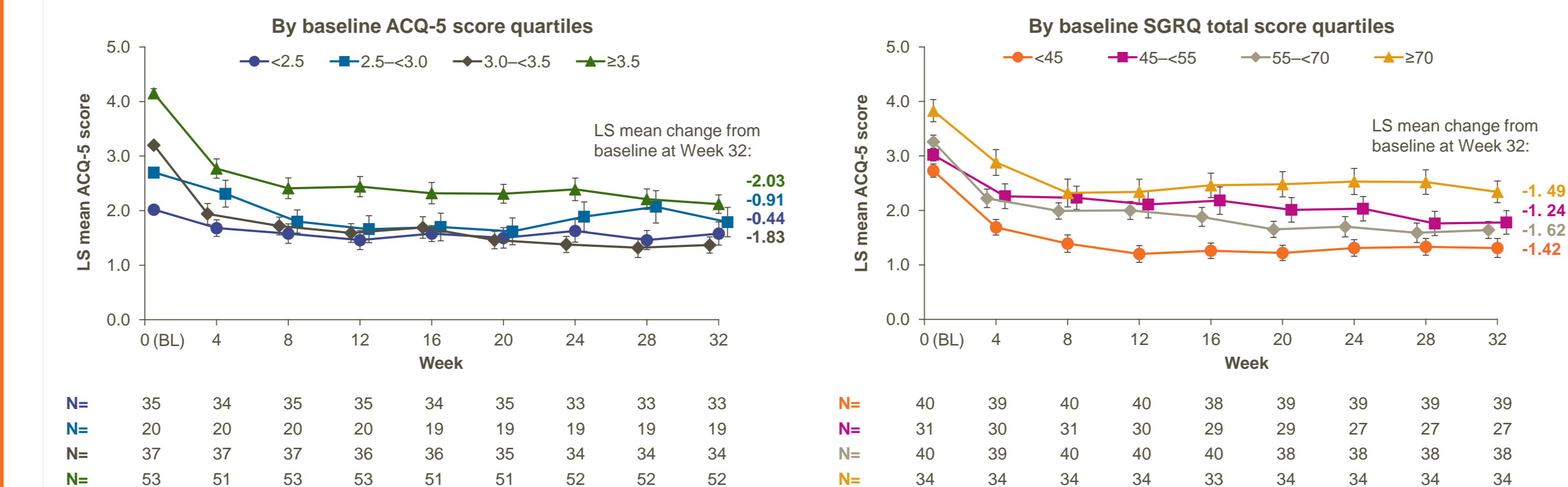
Baseline ACQ-5 score quartiles:	Baseline SGRQ total score quartiles:
<2.5	<45
2.5–<3.0	45–<55
3.0–<3.5	55–<70
≥3.5	≥70

Results

Baseline demographics and disease characteristics	Baseline ACQ-5 score quartiles (N=145)				Baseline SGRQ score quartiles (N=145)			
	<2.5 (n=35)	2.5–<3.0 (n=20)	3.0–<3.5 (n=37)	≥3.5 (n=53)	<45 (n=40)	45–<55 (n=31)	55–<70 (n=40)	≥70 (n=34)
Age, years	51.9 (14.3)	56.9 (11.2)	54.7 (14.3)	52.7 (14.2)	49.3 (16.5)	54.2 (14.0)	56.5 (12.0)	54.7 (11.4)
Female, (%)	60	55	65	57	58	45	70	62
Asthma duration, years	23.5 (12.7)	28.0 (18.7)	25.8 (15.8)	25.9 (19.3)	26.4 (14.8)	20.9 (13.5)	32.2 (18.8)	21.0 (17.1)
Prior duration of omalizumab treatment, months, median (range)	29.7 (5–92)	34.3 (6–161)	24.7 (4–110)	31.1 (5–129) [†]	32.0 (5–161)	29.3 (4–110)	26.3 (6–129)	32.7 (5–104) [†]
On maintenance OCS at baseline, n (%)	3 (9)	6 (30)	7 (19)	19 (36)	3 (8)	8 (26)	13 (33)	11 (32)
ACQ-5 score	2.0 (0.39)	2.7 (0.10)	3.2 (0.15)	4.2 (0.61)	2.7 (0.76)	3.0 (0.68)	3.3 (0.79)	3.8 (1.13)
SGRQ total score	46.6 (16.2)	52.2 (14.6)	55.2 (12.6)	65.8 (17.7)	35.6 (7.0)	50.8 (2.8)	62.0 (4.4)	80.2 (7.2)
Pre-bronchodilator FEV ₁ , mL	2080 (760)	1710 (570)	1580 (610)	1690 (660)	2010 (820)	1930 (670)	1510 (590)	1600 (460)
Exacerbations in previous year	3.2 (1.6)	2.6 (1.4)	2.9 (1.3)	3.8 (3.9)	2.5 (0.9)	3.1 (1.7)	3.9 (4.2)	3.6 (2.3)
Exacerbations requiring hospitalization and/or ER visits in previous year, n (%)	12 (34)	4 (20)	7 (19)	20 (38)	7 (18)	6 (19)	12 (30)	18 (53)
Blood eosinophil count, cells/μL*	290 (1.0)	420 (0.9)	210 (1.2)	320 (1.2)	330 (0.7)	240 (1.0)	230 (1.4)	390 (1.2)

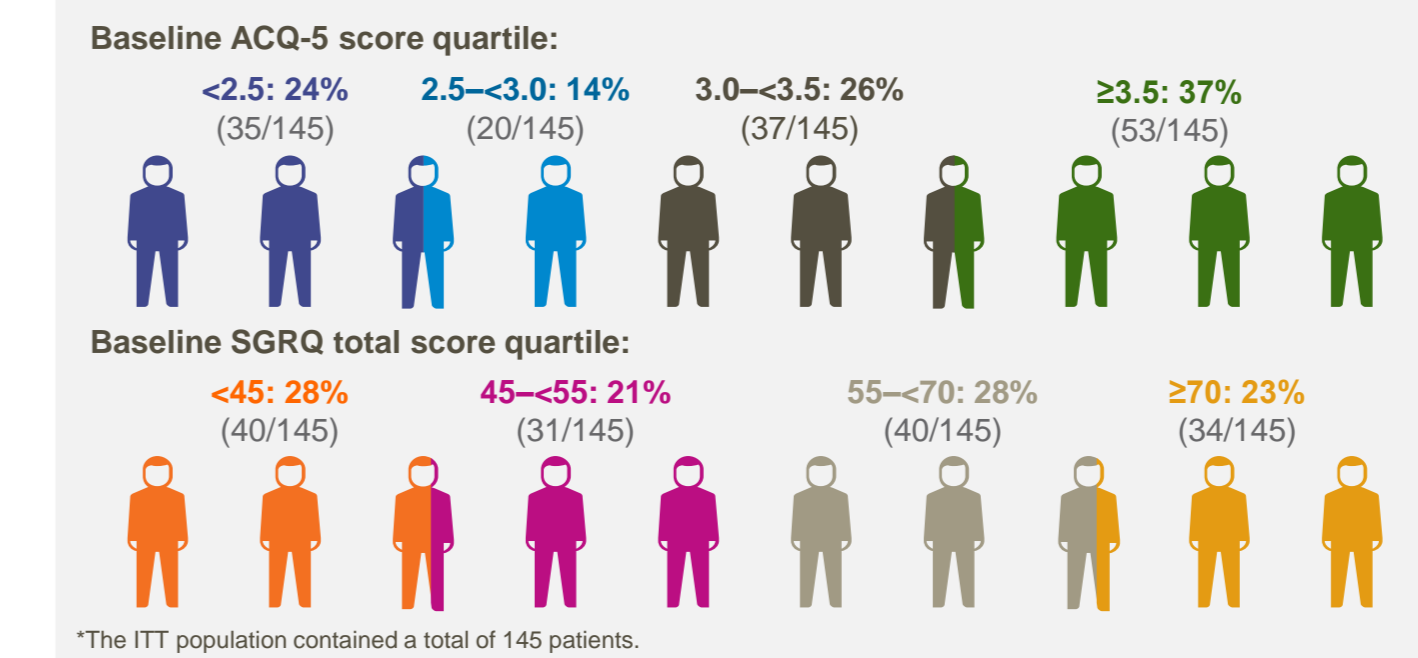
Values are presented as mean (SD) unless otherwise stated. *Data are presented as geometric mean on a log scale. SD of log-transformed eosinophil count; [†]n=52; [†]n=33. ER, emergency room; SD, standard deviation

Patients experienced improvements in ACQ-5 scores regardless of their baseline ACQ-5 or SGRQ total score

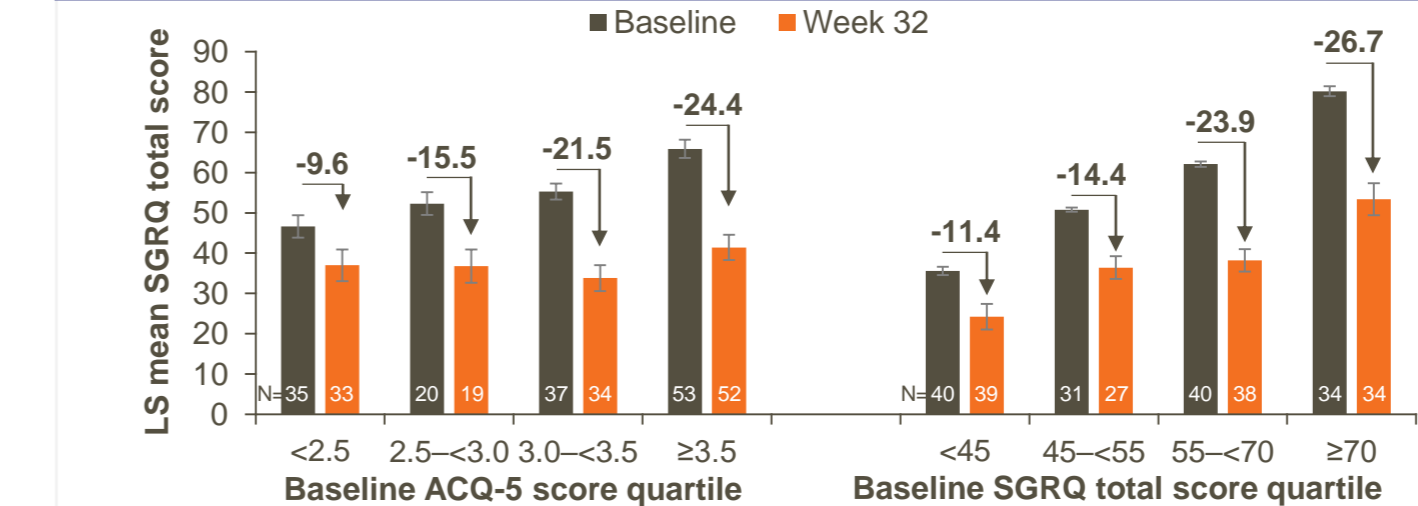


The MCID for ACQ-5 is 0.5, with higher scores indicating worse asthma control. Numbers of patients are shown at the bottom of each graph. Error bars are shown as SE. BL, baseline; LS, least squares; MCID, minimal clinically important difference; SE, standard error

Proportion of patients in each subgroup*

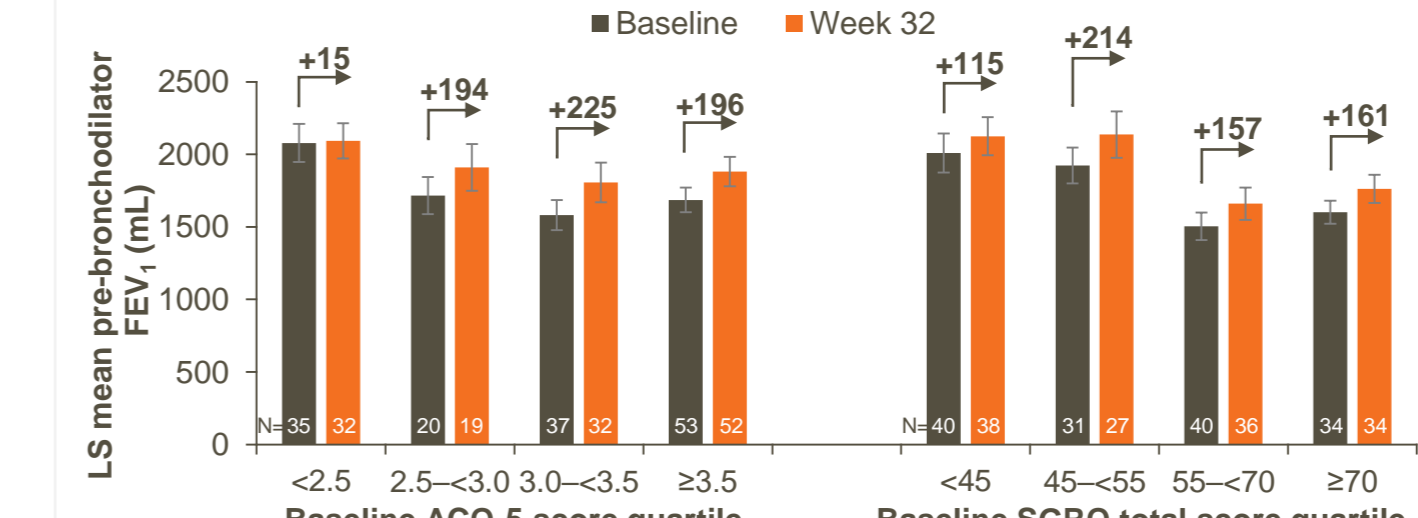


Improvements in SGRQ total scores from baseline to Week 32 were observed irrespective of baseline ACQ-5 or SGRQ total score, with numerically larger improvements seen in those with worse scores at baseline



The MCID for SGRQ is 4.0, with higher scores indicating worse health status. LS mean change from baseline is shown in bold font. Numbers of patients are at the bottom of the bars. Error bars are shown as SE.

Pre-bronchodilator FEV₁ increased from baseline to Week 32 regardless of baseline ACQ-5 or SGRQ total score

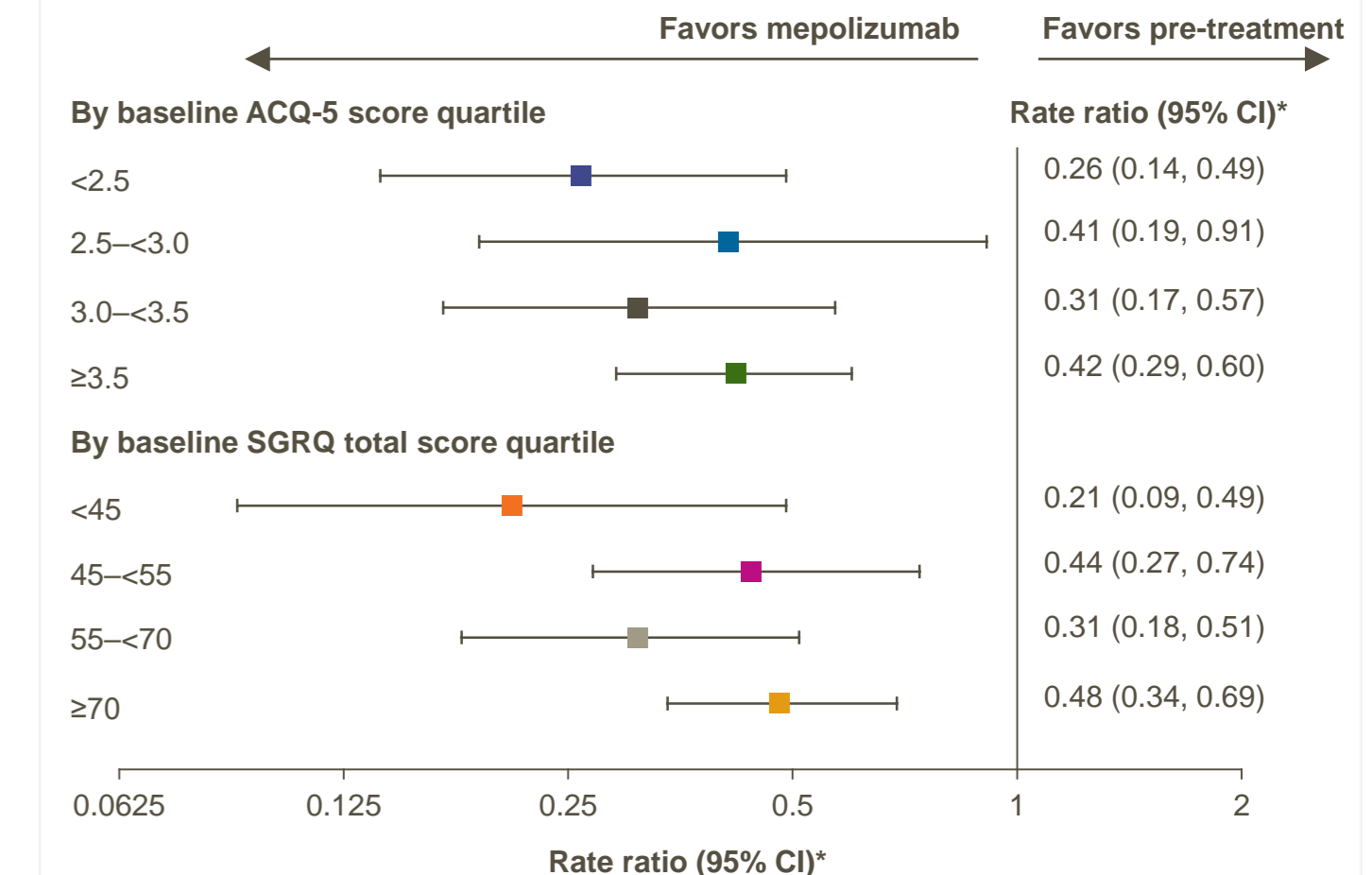


The MCID for FEV₁ is 100 mL, with higher values indicating greater lung function. LS mean change from baseline is shown in bold font. Numbers of patients are at the bottom of the bars. Error bars are shown as SE.

Conclusions

- A direct switch to mepolizumab in patients with severe eosinophilic asthma uncontrolled by omalizumab resulted in improved clinical outcomes.
- Mean improvements in ACQ-5 and SGRQ total scores exceeded the MCID regardless of baseline ACQ-5 or SGRQ total score, with the exception of asthma control in the <2.5 baseline ACQ-5 category.
- Consistent improvements in FEV₁, and reductions in exacerbations, were observed regardless of baseline ACQ-5 score or SGRQ total score with the exception of FEV₁ in the <2.5 baseline ACQ-5 category.
- Baseline ACQ-5 and SGRQ total scores did not alter clinical efficacy in terms of asthma control, health status, lung function, and exacerbation rates.
- However, these data should be interpreted with caution given that this was a non-planned post hoc analysis.

Patients experienced improvements in exacerbation rate compared with the pre-treatment period regardless of baseline ACQ-5 or SGRQ total score



*Rate ratio (mepolizumab/pre-treatment). CI, confidence interval

References

- GSK. Mepolizumab (NUCALA) US prescribing information. September 2019. Available from: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL.PDF [last accessed January 2020].
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Disclosures

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FCA was an employee of GSK at the time of the analysis and holds stocks/share options in GSK; he is now employed by Avillion. DVG was an employee of GSK at the time of the analysis and holds stocks/share options in GSK; he is now employed by Chiesi USA. MCL has received grants and personal fees from GSK, Boehringer Ingelheim, Mereo Biopharma, and MedImmune.
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