Title: Effectiveness of Mepolizumab in Patients with OCS-Dependent Severe Asthma: A Real-World Study

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Supplementary material

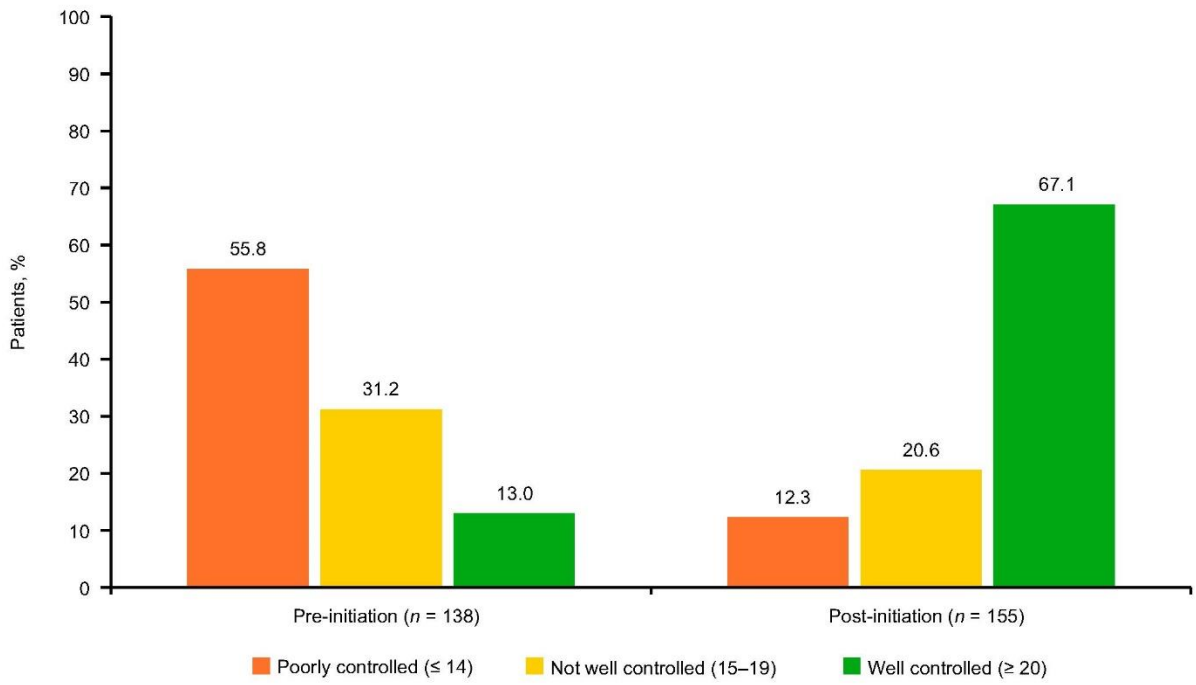
Outcomes for patients who were not OCS dependent

Of the 218 patients without OCS dependence, 10.1% (*n* = 22) had received OCS pre-initiation; post-initiation, only 3.7% (*n* = 8) of patients used OCS. The mean (SD) OCS dose pre-initiation was 24.4 (14.9) mg/day, compared with 9.6 (18.6) mg/day post-initiation. Among patients without OCS dependence, the majority (89.4% [*n* = 195]) never used OCS in either the pre- or post-initiation period; only 3.2% (*n* = 7) of patients continued OCS use post-initiation and 6.9% (*n* = 15) of patients stopped OCS use altogether. The most frequently used OCS treatment both pre- (54.5% [*n* = 12]) and post-initiation (57.1% [*n* = 4]) was prednisolone.

For patients without OCS dependence (*n* = 218; **Supplementary Table 1**), the mean (SD) number of CSEs per patient pre-initiation was 1.5 (1.2–1.9). Post-initiation, the mean (95% CI) number of CSEs per patient was 0.5 (0.4–0.7), reflecting an absolute difference of –1.0. The IRR (95% CI) was 0.3 (0.2–0.4), reflecting a significant relative reduction in CSEs of 70% (*P* < 0.001). Amongst patients with no OCS dependence and available asthma exacerbation data (*n* = 108), 73.1% (*n* = 79) experienced a reduction in asthma exacerbations of ≥ 50–100% and 25.0% (*n* = 27) of patients experienced no change or an increase in asthma exacerbations.

In patients without OCS dependence, the mean ACT score pre-initiation was 13.3 (5.2), in comparison to 19.9 (4.7) post-initiation (**Supplementary Table 2)**. The proportion of patients who had a score of ≥ 20 increased from 13.0% (n = 18) pre-initiation to 67.1% (*n* = 104) post-initiation; 77.8% (*n* = 91) of patients had an increase in ACT scores of ≥ 3 points post-initiation.

Supplementary Fig. 1 Change in ACT scores from pre- to post-initiation in patients without OCS dependence



ACT Asthma Control Test; *OCS* oral corticosteroid.

Supplementary Table 1 Change in OCS use and dose pre- versus post-initiation

Variable	**Patients without OCS-dependence (*n* = 218)**			
	n	Pre-initiation	*n*	Post-initiation
OCS use, *n* (%)	218		218	
OCS use		22 (10.1)		8 (3.7)
No OCS use		196 (89.9)		210 (96.3)
Change in OCS use pre- versus post-initiation, *n* (%)			218	
Stopped OCS use				15 (6.9)
Continued OCS use				7 (3.2)
Never used OCS				195 (89.4)

Unknown				0
Started OCS use				1 (0.5)
Change in OCS use post-initiation among patients using OCS pre-initiation, *n* (%)			22	
Stopped OCS use				15 (68.2)
Continued OCS use				7 (31.8)
OCS dose, mg/day[a]	22			
Mean (SD)		24.4 (14.9)		9.6 (18.6)
Median (IQR)		25.0 (10.0–40.0)		0.0 (0.0–5.0)
Change in OCS dose, mg/day[a]			22	
Mean (SD)				14.8 (18.6)
Median (IQR)				18.0 (5.0–30.0)
Category, *n* (%)				
Decrease				17 (77.3)
No change				4 (18.2)
Increase				1 (4.5)
OCS treatment, *n* (%)	22		7	
Methylprednisolone		1 (4.5)		1 (14.3)
Prednisolone		12 (54.5)		4 (57.1)
Prednisone		7 (31.8)		2 (28.6)
Deflazacort		2 (9.1)		0
Dexamethasone		0		0

[a]Prednisone equivalent.

IQR interquartile range; *OCS* oral corticosteroid; *SD* standard deviation.

Supplementary Table 2 Change in CSEs and asthma control pre- versus post-initiation

Variable	Patients without OCS dependence (*n* = 218)			
	n	Pre-initiation	*n*	Post-initiation
CSEs, mean (95% CI)[a]	218	1.5 (1.2–1.9)	218	0.5 (0.4–0.7)
Absolute difference				–1.0
Relative difference, %				–67.7
IRR (95% CI)			218	0.29 (0.21–0.42)
P-value				< .001
Reduction in asthma exacerbation, *n* (%)			108	
No change/increase				27 (25.0)
> 0–50% decrease				2 (1.9)
≥ 50–100% decrease				79 (73.1)
ACT score[b]	138		155	
Mean (SD)		13.3 (5.2)		19.9 (4.7)
Median (IQR)		13.0 (9.0–18.0)		21.0 (17.0–23.0)
Improvement in ACT post-initiation, *n* (%)[c]			117	
Improvement				91 (77.8)
No improvement				26 (22.2)

[a]Estimated via generalized estimating equation models assuming a negative binomial distribution (of CSEs) and a log link function. A covariate for treatment period (i.e. pre- or post-initiation) was included and the logarithm of time was used as an offset variable. An autoregressive correlation structure of order 1 was used to correct for within-participant correlation.

[b]Only patients with ACT scores (at the relevant time points) were included in ACT score analyses.

[c]Improvement measured by an increase of three points.

ACT Asthma Control Test; *CI* confidence interval; *CSE* clinically significant exacerbation; *IQR* interquartile range; *IRR* incident rate ratio; *OCS* oral corticosteroids; *SD* standard deviation.