

Does asthma control change when patients transition to home administration of mepolizumab?

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Introduction

Mepolizumab is licensed as add-on therapy for severe eosinophilic asthma. It was initially administered in the hospital out-patient setting but with the option of home administration introduced in 2019, the 4-weekly subcutaneous injections could be self-administered by suitably trained patients. We investigated whether this transition to home administration brought about a change in asthma control, and specifically investigated if there was a differential effect between those patients who transitioned before the onset of the COVID-19 pandemic shielding restrictions and those who transitioned after it.

Methods

Patients receiving mepolizumab via home care were stratified according to those who had a "planned" transition prior to 1st Feb 2020 versus those who had an "unplanned" transition after this date (that is necessitated by the COVID-19 pandemic). The last maintenance corticosteroid (mOCS) dose, Asthma Control Questionnaire-6 (ACQ6), and peak expiratory flow rate (PEFR) measured in clinic (*baseline*) was compared with that collected by telephone consultation 8-12 weeks and 8-12 months after transition. Patients were excluded if all values were not available.

Results

87 mepolizumab patients were identified, but several were subsequently excluded due to missing data. Of 46 "planned" patients, 3 was uncontactable at 8-12 months; while of 41 "unplanned", 1 could not be contacted and 1 switched from mepolizumab during the study.

The impact of transition on the remote mOCS wean was not investigated because there were too few patients receiving mOCS (2 planned patients, 1 was not for asthma; 11 unplanned patients, 7 were not for asthma). However, at 8-12 months, the mean annualised exacerbation rate of the planned group was significantly lower (0.16) than the 0.51 of the unplanned patients ($p=0.04$)

Results (cont)

Table 1. Baseline Characteristics

	Duration of mepolizumab at transition (months)	Age (years)	BMI	FeNO (ppb)	ACQ-6	PEFR (L/min)
Planned (n=43, 14 male)						
Mean	25.8	52.1	29.6	51	1.24	411
SD	5.5	14.1	6.6	63	1.11	138
Unplanned (n=39, 18 male)						
Mean	20.4	55.2	28.1	47	1.80	332
SD	12.4	16.7	5.3	44	1.11	165
					$p=0.015$	$p=0.0127$

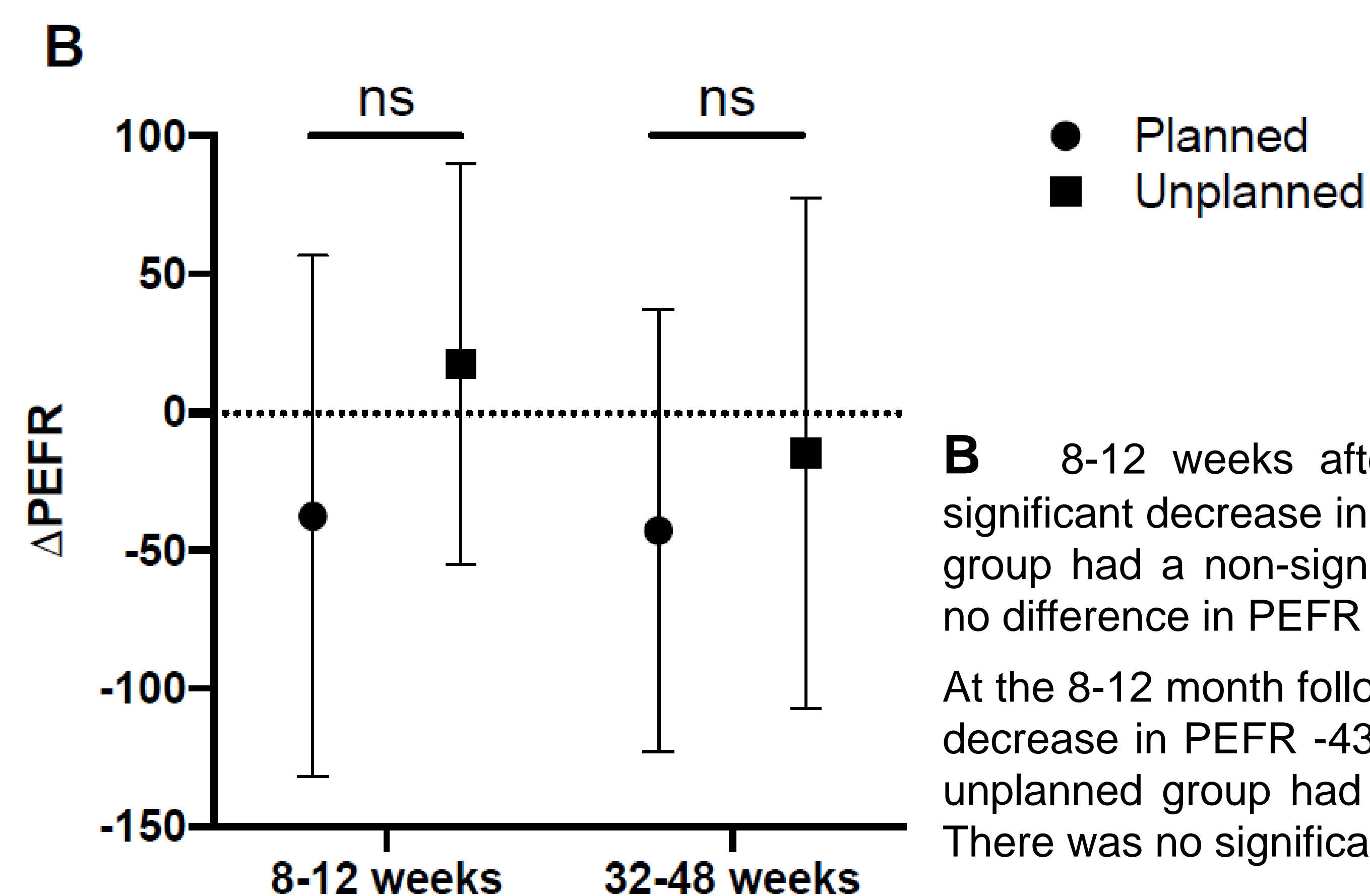
At baseline, the planned group had been receiving mepolizumab longer, were slightly younger, and had a female predominance. The mean BMI and FeNO were similar.

There was a statistically significant difference between groups with the planned group having better asthma control ($p=0.015$) and higher PEFR ($p=0.0127$).

Figure 1A. and 1B. Change in ACQ-6 and Peak Flow from baseline to 8-12 weeks and 8-12 months after transition

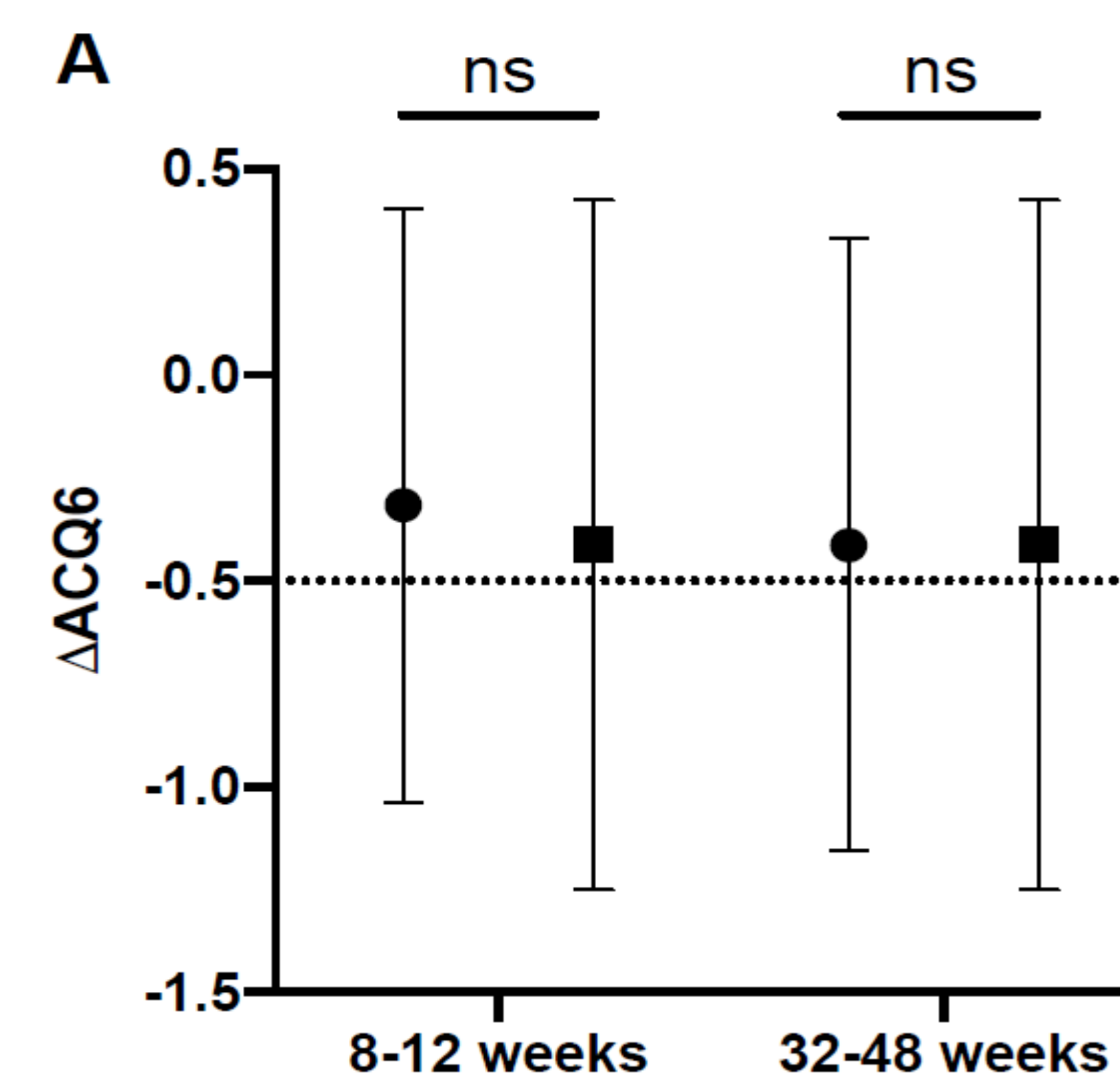
A There was a statistically significant decrease in ACQ-6 for both planned and unplanned patients 8-12 weeks following their transition to home administration of mepolizumab (-0.32; $p=0.0054$ and -0.41; $p=0.0030$ respectively), but no difference between groups ($p=0.4744$).

At 8-12 months, the statistically significant improvement from baseline was maintained in both groups (-0.41, $p=0.0004$ and -0.35, $p=0.0002$ respectively), but again, there was no difference between groups



B 8-12 weeks after transition, the planned group had a statistically significant decrease in PEFR (-38mL/min; $p=0.0047$). The unplanned patient group had a non-significant increase (+17mL/min; $p=0.05251$). There was no difference in PEFR between groups ($p=0.0893$).

At the 8-12 month follow up, the planned cohort saw a statistically significant decrease in PEFR -43mL/min ($p=0.0013$) from baseline, whilst those in the unplanned group had a non-significant decrease of 15mL/min ($p=0.5572$). There was no significant difference in PEFR between groups ($p=0.1328$).



Discussion and Conclusions

We believe these data provide considerable reassurance as to the utility of home administration of mepolizumab. Patients had begun to transfer to home administration prior to the COVID-19 pandemic, with preferential transition offered to the most stable patients first. However, when shielding restrictions were announced, it was felt that the risks of continuing clinic administration were outweighed by the benefits of transitioning patients earlier than had been originally planned.

Not only did symptoms not deteriorate after transition, there was a significant improvement in ACQ-6. While this was not clinically significant (MCID ≥ 0.5), it is notable that patients had been receiving mepolizumab for ~2 years, so any further improvement is surprising.

Caution is advised in interpreting the clinical significance of the variation in PEFR as the baseline clinic values were from a spirometer and home PEFR measurements provided from a manual peak flow device.

While the exacerbation rate in the unplanned group was statistically higher, re-assurance can be taken from the actual rates being so low across both groups and that detection of deterioration was sufficient enough to see that a patient was switched from mepolizumab to an alternative biologic. This also suggests that the initial stratification method to prioritise home care suitable patients was highly effective.

There are limitations to this work. Unfortunately several patients could not be contacted for the second follow up telephone call and commonly measured biomarkers (FeNO, eosinophil count) and spirometry data could not be gathered during the telephone consultation. However, as remote monitoring technology and increased access to biomarker measurement in primary care progresses, the capacity to safely monitor biologic patients will progress similarly.

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