Does asthma control change following transition to home benralizumab administration in severe asthma?

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Introduction

The COVID-19 pandemic and resultant shielding requirements for patients deemed extremely clinically vulnerable (including asthma biologic recipients), necessitated the rapid transition of large numbers of patients onto home administration. Patients also continued to need to be initiated on biologic therapy. As the optimal time to transition to home care and the impact of administering biologic therapy at home are largely unknown, we investigated whether patients deteriorated following their transition, and if there was a differential response between patients who were established on treatment versus those who transitioned soon after initiation.

Methods

Patients with severe eosinophilic asthma receiving home benralizumab were stratified according to those who had received ≥3 doses prior to transfer to home care ("**established**" patients) versus those who were transferred having had less than 3 doses in clinic ("**new**" patients).

We compared the Asthma Control Questionnaire-6 (ACQ6), PEFR, and maintenance oral corticosteroid (mOCS) dose last measured in clinic, with that collected by telephone 8-12 weeks and 8-12 months following transition to home administration. Patients were excluded if pre-transition and both follow up values were not available.

Results

246 benralizumab patients were identified, but between the first and second home data collection points, 12 patients were excluded (1 new patient could not be contacted; 7 established patients were uncontactable and 4 were switched to another biologic agent). A full data set was available for 186 established and 48 new benralizumab patients.

Results (continued)

Table 1. Baseline Characteristics

	Duration of benralizumab at transition (months)	**Age** (years)	**BMI**	**FeNO** (ppb)	**ACQ-6**	**PEFR** (L/min)
Established (n=186, 72 male)						
Mean	12.3	54.7	31.1	58	1.97	384
SD	6.5	13.5	7.2	66	1.4	144
New (n=48, 16 male)						
Mean	1.2	52.1	28.5	63	2.12	382
SD	0.4	13.8	4.9	67	1.5	157
					p=0.5297	p=0.9042

New patients had 2 doses of benralizumab 4-weeks apart then moved to home administration. Established patients had at least 3 doses in clinic 4 weeks apart, then further doses 8 weekly.
There was no significant difference between groups pre-transition (baseline) for age, BMI, FeNO, ACQ-6 or PEFR.

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 in new and established patients at 8-12 weeks (-0.79 and -0.73 respectively; p<0.0001). This improvement was sustained at 8-12 months (-0.65, p=0.0004 and -0.49, p<0.0001 respectively).

B] At 8-12 weeks, there was a decrease in PEFR. It was statistically significant in the established group (p=0.0066), but not new patient group (p=0.3417). At 8-12 months, the PEFR had recovered to above baseline value. It had increased significant for the established patients only (p<0.0001).

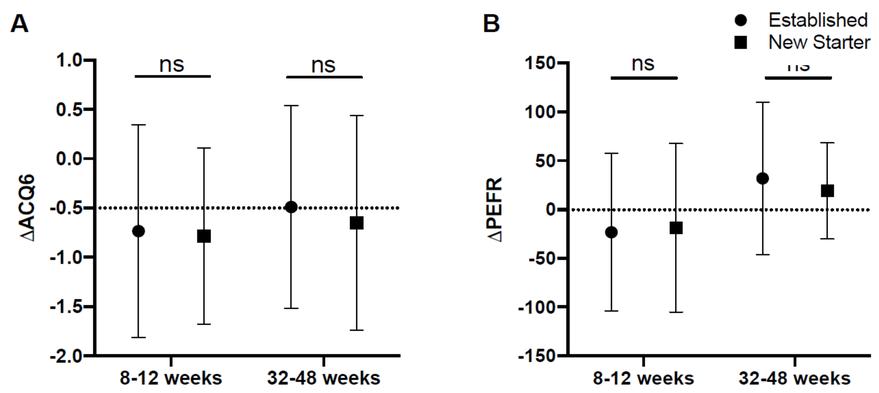

Table 2. Change in maintenance corticosteroid dose from baseline to 8-12 weeks and 8-12 months after transition

mOCS dose (prednisolone equivalent mg)	**Established** n=57	**New** n=17	**Between group p-value**
Baseline	5 (4-7.5)	5 (5-10)	0.1069
At 8-12 weeks	5 (3-6)	5 (3-7.5)	0.3656
At 8-12 months	4 (2-5)	3 (0.5 – 5)	0.3571
Percent reduction at 8-12 weeks	0 (0– 40)	25 (0-61)	0.1989
Percent reduction at 8-12 months	25 (0 – 50)	50 (29-90)	**0.0070**
Within group p-value			
Δ 8-12 weeks	**P=0.0251**	P=0.1665	
Δ 8-12 months	**P=0.0001**	**P=0.0003**	

64 established and 20 new patients were taking mOCS at transition, however 10 patients were excluded from the analysis due to their OCS wean being hampered by a non-respiratory indication (adrenal insufficiency or rheumatological disease).

Established patients had a statistically significant decrease in mOCS at 8-12 weeks (p=0.0251), but this was not seen in new patients (p=0.1665). In contrast, at 8-12 months, there was a significant decrease in prednisolone dose for both established and new patients (p=0.0001 and p=0.0003 respectively).

Discussion and Conclusions

This work provides much needed reassurance that the transition to home administration of benralizumab is not associated, in the short or longer term, with a deterioration in clinical outcomes as assessed by ACQ-6, peak flow or the ability to wean mOCS. Crucially, it also demonstrates that this is valid option for those patients who have had just 2 doses in clinic (in our service, the first dose is administered by the specialist nurse, the second self-administered under the supervision of the nurse), as well as those established on therapy.

The improvement in ACQ-6 was statistically and clinically significant (an increase of ≥0.5). While this may be expected in new patients its presence in both groups in interesting. It should be borne in mind that this could be a home care effect, but may also reflect a shielding and lockdown effect.

The preservation of peak flow seen in both newly initiated and established patients following transition and at 8-12 months is very encouraging. So too is that in spite of having few face-to-face consultations in this period, that it was still possible to safely wean patient's mOCS dose remotely. This was possible in part by blood monitoring (e.g. cortisol) support from primary care.

There are several limitations to this work and administration of benralizumab outside clinic. Unfortunately, though <3% of the total, some patients could not be easily contacted. It also meant that outcome measures were limited to those achievable remotely. However, innovations like access to home spirometry and primary care FeNO are planned, so the on-going utility of home administration can be monitored after all COVID-19 restrictions have been lifted.

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