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Title: The APEX study: A retrospective review of outcomes in patients with severe allergic asthma who were or were not hospitalised in the year prior to omalizumab initiation in UK clinical practice

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Body: The link between increasingly severe asthma and increased hospitalisation risk is well established. We retrospectively reviewed medical records 12 months pre- and post-omalizumab initiation in patients (≥12 years) with severe persistent allergic asthma who were (n=81) or were not (n=55) hospitalised for asthma in the year before omalizumab initiation. Baseline characteristics in hospitalised and non-hospitalised patients were similar: mean age 39.7 and 43.6 years; 27.2% and 38.2% male; mean IgE 278 and 309 IU/mL, respectively. Post-omalizumab initiation there were significant improvements in oral corticosteroid (OCS) burden (primary endpoint), % patients stopping OCS, exacerbation rates and Asthma Quality of Life Questionnaire (AQLQ) scores.

	Hospitalised (n=81)	Non hospitalised (n=55)
Responders†, n (%)	67 (82.7)	45 (81.8)
Patients stopping OCS, n (%)	40 (49.4)	26 (47.3)
Total OCS burden (g)		
Mean change	-1.81*	-1.96*
12 months pre-→12 months post-omalizumab	5.77 -> 3.96 (-31.4%)	5.08 -> 3.12 (-38.6%)
Exacerbations		
Mean change	-1.56*	-2.51*
12 months pre-→12 months post-omalizumab	3.4->1.84 (-45.9%)	4.07→1.56 (-61.7%)
AQLQ scores at 16 weeks		
Mean change	+2.03*	+1.87*

Baseline→Week 16	3.11→5.13 (+65.3%) ^a	2.91→4.78 (+64.3%)b

*p<0.001 vs pre-omalizumab; †significant improvement on physician's assessment at 16 weeks; an=49; bn=34

Overall, similar benefits were seen regardless of hospitalisation in the previous year. This suggests that prior hospitalisation is not a good predictive discriminator of response to omalizumab in patients with severe allergic asthma.