1.08 A randomised trial of a T2-composite-biomarker strategy adjusting corticosteroid-treatment in severe asthma, a post- hoc analysis by sex

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5–10% of patients with asthma have severe disease with a consistent female preponderance. Asthma guidelines recommend stepwise, symptom-driven disease control with no differential treatment considerations for either sex. This post-hoc analysis of a 48-week, multicentre, randomised controlled clinical trial, compared a T2 biomarker-defined treatment algorithm with standard-care, stratifying patient outcomes by sex. The primary outcome was the proportion of patients with a reduction in corticosteroid treatment (log-regression models). Secondary outcomes included exacerbation rates, hospital admissions and lung function (linear/Poisson/logistic/cox regression models).301 patients were randomised: 194 (64.5%) females and 107 (35.5%) males. The biomarker algorithm led to more females being on a lower corticosteroid dose vs standard-care, compared to males (effects estimate females: 3.57, 95% CI: 1.14, 11.18 vs. males 0.54, 95% CI: 0.16, 1.80). In T2-biomarker low females, reducing the corticosteroid dose was not associated with increased exacerbations. Females scored higher in all ACQ-7 domains, but with no difference when adjusted for BMI/depression/anxiety. Dissociation between symptoms and T2-biomarkers were noted in both sexes, with more females being symptom high/T2-biomarker low (22.8% vs. 15.5%; p=0.0002), whereas males were symptom low/T2-biomarker high (11.5% vs. 22.3%; p<0.0001).We identified females achieved a greater benefit from biomarker-directed corticosteroid optimisation versus symptom-directed treatment.

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