

MEETING ABSTRACT

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Tiotropium respimat® add-on therapy reduces airflow obstruction in patients with symptomatic moderate asthma, independent of T_H2 inflammatory status

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Rationale

In patients with symptomatic asthma receiving ICS or ICS +LABA, Phase III studies have demonstrated improved lung function with tiotropium Respimat*, a once-daily long-acting anticholinergic bronchodilator. The efficacy of some treatments (eg ICS and omalizumab), appears higher in T_H2 -high phenotypes, but no specific treatments are available that work equally well in both T_H2 -high and T_H2 -low phenotypes. We explored whether T_H2 biomarker status influenced responses to tiotropium in patients with moderate symptomatic asthma.

Methods

In two replicate Phase III, randomized, double-blind, placebo-controlled, parallel-group trials (NCT01172808/NCT01172821), patients with moderate symptomatic asthma, using medium-dose ICS (400-800 μ g budesonide equivalent), were administered once-daily tiotropium Respimat® 5 μ g or 2.5 μ g, placebo, or salmeterol (active comparator without inferential analysis). Co-primary endpoints included peak and trough FEV₁ response (difference from baseline) at 24 weeks. Pre-planned analyses (pooled population) were performed in T_H2 -high and T_H2 -low subgroups defined at baseline as total serum IgE \leq or >430 μ g/L) or blood eosinophils \leq or >0.6×10 9 /L.

Results

Of 1545 patients in the full analysis set who received tiotropium or placebo, 915/1455 were reported with IgE >430 μ g/L and 300/1461 with an eosinophil count of >0.6×10⁹/L. Peak FEV₁ improved with tiotropium versus placebo, independent of IgE (p<0.0001 both doses) and eosinophil count (p<0.0001 both doses). Trough FEV₁ also improved with tiotropium versus placebo, irrespective of IgE (p<0.0001 both doses) and eosinophil count (p<0.005 both doses).

Conclusions

Once-daily tiotropium Respimat[®] as add-on to ICS reduces airflow obstruction in patients with moderate symptomatic asthma, independent of T_H2 phenotype, and thus may potentially provide an important therapeutic option.

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