

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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From Canadian Society of Allergy and Clinical Immunology Annual Scientific Meeting 2014 Ottawa, ON, Canada. 23-26 October 2014

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 $T_{\rm H}2$ -high and $T_{\rm H}2$ -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.

Funding source

Study supported by Boehringer Ingelheim. Previously presented at AAAAI 2014 in San Diego, CA, USA.

Acknowledgements

We thank Dr W.H. Yang for presenting this study on behalf of the authors.

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Published: 18 December 2014

doi:10.1186/1710-1492-10-S2-A52

Cite this article as: Yang et al.: Tiotropium respimat® add-on therapy reduces airflow obstruction in patients with symptomatic moderate asthma, independent of T_H2 inflammatory status. Allergy, Asthma and Clinical Immunology 2014 10(Suppl 2):A52.

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