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Title: Tiotropium as add-on to inhaled corticosteroids significantly improves asthma control as reflected by the ACQ responder rate

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Body: Background: Despite current medications, there remains an unmet need for asthma control in patients with moderate asthma receiving at least ICS. We analysed ACQ data in patients treated with once-daily long-acting anticholinergic bronchodilator tiotropium who had symptomatic asthma despite treatment with medium-dose ICS (400-800 µg budesonide equivalent). Methods: 2103 patients were randomised in 2 identical Phase III, double-blind, double-dummy, parallel-group studies (NCT01172808 and NCT01172821). Patients received tiotropium 2.5 µg or 5 µg or placebo (all doses via Respimat® Soft Mist™ Inhaler). A salmeterol arm (active comparator) was included with no inferential analysis. Key inclusion criteria included a pre-bronchodilator FEV_1 60-90% of predicted and ACQ score ≥1.5. A pre-planned pooled analysis was performed for ACQ responder rate, a co-primary end point; responders were defined as ACQ improvement ≥0.5 at 24 weeks. Results: Baseline characteristics in patients were similar across both trials and all treatment groups. Mean baseline ACQ total score was 2.18 (SD 0.49). Both doses of tiotropium significantly improved the ACQ responder rate at 24 weeks compared with placebo (299/518 responders; 57.7%): tiotropium 2.5 µg, 332/515 (64.5%; p=0.03); tiotropium 5 µg, 330/513 (64.3%; p=0.03); salmeterol

356/535 (66.5%; p=0.004). Conclusion: In patients with symptomatic asthma despite ICS therapy, the addition of once-daily tiotropium provided a statistically significant and clinically relevant improvement in asthma control. A similar ACQ responder rate was observed with tiotropium (2.5 µg and 5 µg) and the active comparator salmeterol.