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Title: Poor generalisability of uplift findings to clinical practice

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Body: Background Initial concerns that the inhaled anticholinergics agents ipratropium bromide and tiotropium may increase the risk of serious cardiovascular events and mortality were allayed with the publication of the Understanding Potential Long-term Impacts on Function with Tiotropium (UPLIFT) study which reported no increased risk of mortality or myocardial infarction with tiotropium delivered by the Spiriva HandiHaler.[1] However, the UPLIFT findings may be poorly generalisable to COPD patients, due to the exclusion of potential study participants with co-existing illnesses “that might interfere with the study results", including cardiac and renal co-morbidities. Aims This audit aims to determine the proportion of admitted patients who were prescribed tiotropium that would have been ineligible for the UPLIFT study. Methods Admissions to Wellington Regional Hospital were examined in chronological order, from 1 January 2011 until 100 patients prescribed tiotropium on discharge were included. Data was collected to determine whether each patient would have been eligible for UPLIFT based on cardiovascular (recent unstable arrhythmias, myocardial infarction or heart failure) and renal (moderate to severe impairment) co-morbidities. Results Of the patients prescribed tiotropium 38/100, 38% (95% CI 28.5 to 48.3) would have been excluded from the UPLIFT trial based on recent cardiovascular or renal comorbidities. Conclusion Our findings have shown that in New Zealand practice, the favourable risk/benefit profile established in UPLIFT is not generalisable to at least one third of patients treated with tiotropium. 1.Tashkin DP et al. A 4-year trial of tiotropium in chronic obstructive pulmonary disease. N Engl J Med 2008; 359: 1543-54.