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Title: Increased risk of mortality in COPD patients using tiotropium respimat vs. tiotropium Handihaler

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Body: Background: Tiotropium is a long-acting, once daily anticholinergic drug that is delivered via Handihaler (dry powder inhaler) or via Respimat (soft mist inhaler). Data from RCTs suggest that use of tiotropium Respimat is associated with an increased risk of mortality. Objectives: To explore the risk of mortality in users of either tiotropium Handihaler or tiotropium Respimat. Methods: Within the IPCI database, a Dutch GP database, we defined a source population of patients > 40 years with at least 1 year of follow-up. The study ran from 2008 to 2011. Patients were followed from start of the study until the patient died or end of follow-up. Date and cause of death were verified for all patients. From the source population, we defined a cohort of tiotropium users (Handihaler and/or Respimat) and created episodes of use. To assess the risk of dying, we considered a 30-day carry-over effect. The risk of mortality was calculated using a Cox proportional hazard regression analysis. Crude and adjusted HRs were calculated with corresponding 95% CI. Results: From the source population, we defined a tiotropium cohort of 11,287 users providing 24,540 episodes of use. 496 patients died while being exposed to either Handihaler or Respimat. Use of Respimat was associated with an increased risk of dying (HR_{crude} 1.52, 95% CI 1.24-1.87) and this association remained upon adjustment (HR_{adj} 1.33, 95% 1.07-1.65). The association was strongest for incident users and cardiovascular or cerebrovascular death, but due to low numbers not longer statistically significant (HR_{adj} 1.87, 95% CI 0.74-4.73). Conclusions: Use of tiotropium Respimat vs tiotropium Handihaler is associated with a 30% increase of mortality.