European Respiratory Society
Annual Congress 2013

Abstract Number: 7120

Publication Number: P1860

Abstract Group: 1.1. Clinical Problems

Keyword 1: Comorbidities **Keyword 2:** Extrapulmonary impact **Keyword 3:** No keyword

Title: Clinical profile, outcomes, and ivabradine effects in patients with chronic obstructive pulmonary disease and chronic heart failure: The SHIFT trial analysis

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Body: Introduction. Concomitant chronic obstructive pulmonary disease (COPD) and chronic heart failure (CHF) is frequent, but prognostic and therapeutic implications remain poorly defined. This analysis of the SHIFT trial investigated: 1) the clinical profile and outcomes, and 2) the safety and efficacy of ivabradine. Methods. Patients with stable systolic CHF in sinus rhythm of ≥70 bpm (N=6505) were randomized to placebo or ivabradine (2.5 to 7.5 mg bid). We report hazard ratios (HR) with 95% confidence intervals (CI) from multivariate Cox model analyses comparing the COPD (N=730) and non-COPD patients, and treatment effects of ivabradine vs placebo in both subgroups. Results. COPD patients were older (65 vs 60y), more often men (82% vs 76%), and had more comorbidities. Beta-blockers were prescribed to 69% and 92% of COPD and non-COPD patients, respectively, with lower daily doses in COPD cohort ($p<0.001$). Composite primary endpoint (PE), (cardiovascular [CV] death and hospitalisation for worsening heart failure [HFH]), as well as HPH were more frequent in COPD patients (PE: 1.22, 1.06–1.40; HFH: 1.34, 1.14–1.57), while CV death was not. All were reduced similarly by ivabradine in both COPD (14%; 17%, 24%); and non-COPD (18%;27%, 7%) patients. Adverse events (AE) were more common in COPD patients (83% vs 73% in placebo arms), but AE rate was similar in the ivabradine and placebo arms of both subgroups. Conclusions. COPD reduced the beta-blocker therapy implementation and worsened the prognosis in CHF. Ivabradine efficacy and safety were similar in COPD and non-COPD patients, and combination with

beta-blockers was safe.