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Title: Cardiac events among patients with CV comorbidities: Pooled analysis of COPD trials comparing tiotropium with salmeterol

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Body: Background: Subgroup analyses of patients with concomitant cardiovascular (CV) diseases may help characterise safety profiles of COPD maintenance therapies. Aims and objectives: To compare the serious cardiac adverse event (SCAE) profiles, including fatalities, of patients with baseline CV conditions in a pooled analysis of 4 double-blind, randomized, parallel-group clinical trials of tiotropium HandiHaler® (HH) vs salmeterol metered dose inhaler (MDI). Methods: Incidence rates (IR): number of patients with event divided by 100 patient-years at risk. Rate ratios (RR) and 95% confidence intervals (CI): derived from Cochran-Mantel-Haenszel test stratified by study. Results: In total, 8836 patients were included. The IRs of SCAEs, and fatalities from cardiac diseases, during treatment by CV conditions at baseline are in the table.

	SCAEs*			Fatalities		
Condition at baseline (No. patients)	Tiotropium (IR)	Salmeterol (IR)	RR (95% CI)	Tiotropium (IR)	Salmeterol (IR)	RR (95% CI)
CV medication (4741)	3.58	3.45	1.03 (0.74, 1.43)	0.71	0.74	0.96 (0.47, 1.95)
Cardiac, total (2239)	6.04	5.47	1.11 (0.76, 1.61)	1.58	1.03	1.53 (0.69, 3.36)
	6.54	5.59		1.54	1.20	

- Coronary artery disease (1664)			1.17 (0.78, 1.77)			1.29 (0.54, 3.05)
- Cardiac arrhythmia (324)	10.70	10.71	1.04 (0.46, 2.33)	2.82	2.37	1.17 (0.24, 5.78)
Hypertension (3979)	3.75	3.38	1.11 (0.78, 1.57)	0.78	0.84	0.94 (0.45, 1.95)
IR expressed in 100 patient-years. *MedDRA Version 14.1.						

Conclusion: Tiotropium once daily via HH showed a comparable cardiac safety profile to salmeterol MDI in subgroups with CV conditions at baseline.