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Title: Comparison of cardiovascular safety in a pooled analysis of COPD trials comparing tiotropium with salmeterol

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Body: Background: Guidelines recommend long-acting bronchodilators as preferred options for maintenance treatment of COPD. Cardiovascular (CV) safety of these treatments is of interest. Aims and objectives: To compare the CV safety of tiotropium vs the long-acting β2-agonist salmeterol in a large number of patients (pts) with COPD. Methods: Pooled analysis of 4 double-blind, randomized, parallel-group clinical trials comparing the CV adverse event profile of tiotropium HandiHaler® (HH) vs salmeterol metered dose inhaler (MDI). Incidence rates (IR): number of pts with event divided by pt-years at risk. Rate ratios (RR) and 95%CI: derived from Cochran-Mantel-Haenszel test stratified by study. Results: In total, 8836 pts were included; 25.3% had a cardiac disorder and 53.7% used CV medication at baseline. IRs (per 100 pt-yrs) for tiotropium vs salmeterol were: all-cause mortality, 1.74 vs 2.08 (RR: 0.84, 95% CI: 0.61, 1.16); fatal major adverse cardiac events (MACE), including death unknown, 0.72 vs 0.92 (RR: 0.78, 95% CI: 0.47, 1.28). IRs of serious adverse CV events during treatment for selected major CV diagnoses are in the table.

	Tiotropium (IR) n=4437	Salmeterol (IR) n=4399	RR (95%CI)
All cardiac events	2.65	2.57	1.03 (0.78, 1.36)
- Cardiac arrhythmia	0.54	0.63	0.85 (0.47, 1.53)

- Myocardial infarction	0.67	0.50	1.33 (0.74, 2.41)
- Other ischaemic heart diseases	0.74	0.63	1.18 (0.68, 2.02)
Stroke	0.38	0.42	0.91 (0.45, 1.85)
IR expressed in 100 pt-yrs. MedDRA v14.1.			

Conclusion: Tiotropium HH once daily showed a comparable CV safety profile to salmeterol MDI treatment in a pooled analysis of double-blind, randomized, parallel group studies.