

# European Respiratory Society Annual Congress 2012

**Abstract Number:** 432

**Publication Number:** P2101

**Abstract Group:** 5.1. Airway Pharmacology and Treatment

**Keyword 1:** COPD - management **Keyword 2:** Bronchodilators **Keyword 3:** No keyword

**Title:** Effectiveness of indacaterol and tiotropium in patients with severe dyspnoea

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**Body:** Introduction. Dyspnoea is a common, troublesome symptom of COPD. It is useful to know how patients (pts) with varying degrees of breathlessness respond to treatment. Aim. We explored the effectiveness of the once-daily(od) long-acting inhaled bronchodilators indacaterol(IND) and tiotropium(TIO) in COPD pts according to baseline dyspnoea severity(median modified Medical Research Council[mMRC] score <2.0 or ≥2.0[ie less or more dyspnoea]). Methods. Data were pooled from three randomized studies of double-blind IND 150µg od(n=745), IND 300µg od(n=849) and placebo(PBO; n=1171) and open-label(o/l) TIO 18µg od(n=411) in pts with moderate-to-severe COPD. Trough FEV<sub>1</sub>, transition dyspnoea index(TDI), St George's Respiratory Questionnaire(SGRQ) and odds ratios(OR) for clinically relevant response in TDI(≥1 point) and SGRQ(≥ -4 units) were evaluated at 6 months. Results. In pts with mMRC <2/≥2 respectively(n=1425/1752), mean age was 63.1/63.9 years, FEV<sub>1</sub> 57.6/51.8% predicted, FEV<sub>1</sub>/FVC 53.9/51.6%. Differences vs PBO for outcomes in each subgroup are shown in table(p<0.05 vs \*PBO, †TIO or ‡IND 150).

	mMRC <2			mMRC ≥2		
	IND150	IND300	TIO	IND150	IND300	TIO
n	341	373	173	404	476	238
Trough FEV <sub>1</sub> , mL	180*	180*	150*	140*	170*†	130*
TDI total score	1.21*	1.33*	1.26*	0.83*	1.24*†	0.63*
TDI responder OR	2.09*	2.44*	1.79*	1.77*	2.91*†‡	1.34
SGRQ total score	-4.7*	-3.9*	-2.3	-4.0*†	-3.0*	-1.6
SGRQ responder OR	2.03*	1.56*	1.40	1.90*†	1.74*	1.29

Conclusions. In pts with less severe dyspnoea (mMRC <2), IND 150, IND 300 and o/l TIO were similarly effective. In pts with more severe dyspnoea (mMRC ≥2), IND 300 was more effective than IND 150 and o/l TIO in improving dyspnoea. Increasing the IND dose to 300µg may be useful for pts with more severe dyspnoea.