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Background The novel LABA olodaterol has 24-h bronchodilator activity.
Objective To evaluate the symptomatic benefit of olodaterol QD in patients with GOLD 2–4 COPD.
Methods In replicate, randomised, double-blind, placebo-controlled, parallel-group studies, patients with post-bronchodilator FEV_1 <80% predicted normal and FEV_1/FVC <70% received olodaterol (5 or 10 g) QD via Respimat®, formoterol (12 µg) BID via Aerolizer® or placebo for 48 weeks (Study A: NCT00793624; Study B: NCT00796653). Patients continued to receive usual care background COPD maintenance therapy, including SAMA, LAMA, ICS and xanthines. In addition to FEV_1-based primary end points, TDI and SGRQ after 24 weeks were identified as co-primary and key secondary symptomatic end points, respectively.
Results 904 (Study A) and 934 (Study B) patients were treated. In the primary analysis using a mixed model for repeated measures (MMRM; combined dataset), there was no significant difference in TDI focal score after 24 weeks for olodaterol or formoterol vs placebo. A post hoc analysis using pattern mixture modelling (PMM) to account for discontinued patients demonstrated statistical significance for olodaterol vs placebo. There were significant improvements in SGRQ total score with olodaterol, but not formoterol, vs placebo after 24 weeks using MMRM and PMM.
Conclusions Lung function improvements with olodaterol QD translated into symptomatic benefit in COPD patients receiving usual care background therapy.

Abstract P230 Table 1.

Adjusted mean difference vs placebo after 24 weeks (combined dataset)

	TDI focal score		SGRQ total score	
	MMRM	PMM	MMRM	PMM
Olodaterol 5µg	0.3*	0.5†	-2.8†	-2.3†
Olodaterol 10µg	0.2*	0.5†	-3.4†	-3.1†
Formoterol 12µg	0.2*	0.4*	-1.2*	-1.2*

*p=ns; †p<0.05

P231 THE IMPACT OF INDACATEROL (ONBREZ®) ON THE DAILY LIVES AND HEALTH STATUS OF PATIENTS WITH COPD: INTERIM RESULTS

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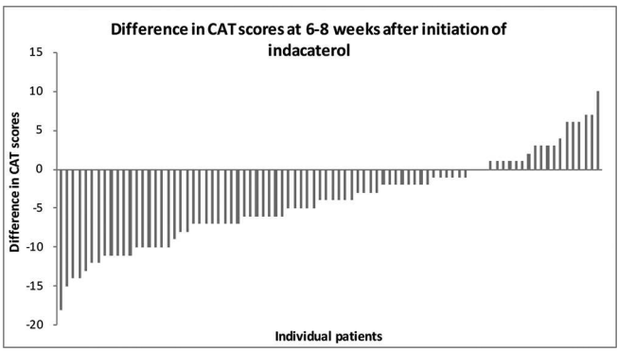
Introduction The GOLD guidelines recommend that the COPD Assessment Test (CAT)[1] can be used in guiding and optimising therapy, however there is little evidence on its use in monitoring treatment. Aim We have conducted a 6-month prospective observational study describing the impact of COPD on daily life, following the initiation of maintenance indacaterol, a once-daily long-acting beta-agonist.
Method Subjects from 39 UK GP practices (April 2012 to May 2013) with a diagnosis of COPD and were newly-prescribed indacaterol for routine COPD management, either as maintenance mono-therapy or add-on therapy to long-acting muscarinic antagonists (LAMA) were recruited. Here we present interim results of completed CAT and a descriptive Daily Life Impact Questionnaire (DLIQ), developed for specifically for the study, at treatment initiation and 6–8 weeks. Further assessments will be made at 6 months, when treatment changes in addition to indacaterol will be recorded.
Results One hundred and three subjects (61 males, 42 females), with a mean age of 67 years (range 44–86) and a median baseline FEV1% predicted of 61% (n = 100; IQR 51–70%) were recruited. Median time from diagnosis to indacaterol initiation was 6 months (IQR 0–37). Of the 86 (83.5%) subjects evaluated for change in CAT score, 65 (76%) had a reduction (i.e. improved health status), 18 (21%) increased and 3 (3%) remained the same (Figure 1); with a mean overall change of -4.1 (SD ± 5.6; $p < 0.001$). Fifty-nine (69%) subjects had a ≥2 point (clinically significant) reduction in CAT score. Ninety-two patients completed the DLIQ; 42 (46%) patients reported an improved ability to perform activities important to them, which had previously been rated as being challenging (e.g. walking, gardening, housework).
Conclusion The CAT appears responsive to treatment for COPD with indacaterol when assessed in routine practice and the average size of improvement was large. Alongside this mean improvement, nearly half of patients reported the ability to do more activities that previously they had found difficult. These initial results require further confirmation when full results are available at 6 months.

REFERENCES

1. Jones PW, Harding G, Berry P, Wiklund I, Chen WH, Kline Leidy N. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–54



Abstract P231 Figure 1. The impact of indacaterol (Onbrez) on the daily lives and health status of patients with COPD: interim results.

P232 ONCE-DAILY CO-ADMINISTRATION OF GLYCOPYRRONIUM AND INDACATEROL VIA BREEZHALER® DEVICE IMPROVES LUNG FUNCTION AND SYMPTOMS IN PATIENTS WITH COPD VERSUS INDACATEROL ALONE: THE GLOW6 STUDY

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