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Title: Short-acting bronchodilator reversibility does not predict the response to long-term treatment by indacaterol 150 μg in COPD: REVERBREZ study

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Body: Despite not being stated in treatment guidelines, bronchodilator reversibility testing is commonly used in COPD patients to guide treatment decisions. This phase IV study evaluated the correlation between immediate reversibility to salbutamol, a short acting bronchodilator, and the response (clinical & functional) at 5 months to treatment with indacaterol (Onbrez® Breezhaler®, an inhaled long acting β2-agonist bronchodilator). Methods: At Visit (V)1, patients with stable moderate-to-severe COPD took a FEV1 reversibility test using salbutamol 400 μg according to which results they were split in 2 groups: Group R (reversible) with change from pre/post salbutamol in FEV1 \geq 12% and \geq 200 ml; Group NR (not reversible) with change in FEV1 < 12% or < 200 ml. From V2 (Day 0) to V5 (Day 148), all patients received indacaterol 150 μg once daily via the Breezhaler® single dose dry powder inhaler. Efficacy parameters included trough FEV1, health-related quality of life (HRQoL: VQ11 & CCQ) and dyspnea (mMRC). Results: A total of 537 patients had interpretable spirometry at screening with 106 in the R group, and 431 in the NR group. Indacaterol improved lung function, dyspnea and HRQoL in both groups. There were no statistically significant differences between the groups.

	Treatment duration				
	1 mo			5 mo	
change vs. baseline in	R	NR	R	NR	
FEV1 (ml)	130	100	120	90	
mMRC	-0.3	-0.2	-0.2	-0.2	
CCQ	-0.4	-0.3	-0.2	-0.3	
VQ11	-2.7	-1.9	-1.9	-2.1	

Common adverse events were COPD worsening (13.4%), acute bronchitis (9.2%), dyspnea (4.6%) and cough (4.6%). Conclusion: Immediate salbutamol reversibility testing didn't predict the efficacy of a longer term treatment with indacaterol.