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Title: Real-life study on the appropriateness of treatment in moderate COPD patients (OPTIMO)

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Body: Background Long-acting bronchodilators should be prescribed for symptomatic COPD patients with FEV1<80%pr. Inhaled corticosteroids (ICS) may be added in patients with FEV1<50%pr and frequent exacerbations (>2/yr). Real life shows a disconnection between Guidelines and clinical practice, with overprescription of ICS in COPD patients with moderate airflow obstruction and without frequent exacerbations (<2/yr). Objective To investigate whether ICS can be withdrawn safely if mild-moderate COPD patients are left on maintenance treatment with long-acting bronchodilators. Methods 914 consecutive patients (72.5±9.3yrs), with mild-moderate COPD and without frequent exacerbations, on maintenance treatment with fixed dose combination (FDC) of ICS and LABA were enrolled in 43 pulmonary units in Italy. At the first visit (T0) the clinicians decided, following her/his clinical judgment, if to maintain the FDC therapy or to withdraw ICS on maintenance treatment with long-acting bronchodilators (LABA or/and LAMA). FEV1, exacerbation rate and CAT (COPD Assessment Test) were evaluated after 6 months (T6). 817 patients concluded the study. Results

Table 1: Data comparison (mean±SD) T0 and T6

GROUP	FEV1%pr		CAT		N. Exac.	
	T0	T6	T0	T6	T0	T6
Total (817)	71.6±11	72.4±14.1	16±8	14±9	0.6±0.5	0.4±0.6
No change (467)	71.4±11.3	72.3±14.7	15±8	14±8	0.6±0.5	0.4±0.6
Change (350)	71.7±10.6	72.5±13.2	16±9	15±9	0.6±0.5	0.3±0.7
Tio (81)	76.4±11.8	77.7±13.5	14±7	12±7	0.6±0.5	0.3±0.5
Indacaterol (95)	72.4±10.5	73.7±13.8	15±8	14±8	0.6±0.5	0.3±0.6
Tio+Indacaterol (65)	67.2±6.9	67.3±11	24±8	22±9	0.5±0.5	0.4±0.9

Conclusions In non-exacerbators, mild-moderate COPD patients, ICS can be withdrawn safely if regular treatment with long-acting bronchodilators is maintained.