Abstract P121 Table 1 Characteristics of COPD patients with or without maintenance treatment at baseline, by GOLD stage

	Patients with maintenance treatment[a] (n = 3037)		Patients without maintenance treatment[a] (n = 2121)	
	GOLD 2[b]	GOLD 3/4[b]	GOLD 2[b]	GOLD 3/4[b]
Patients[c]	1440 (47.4)	1597 (52.6)	1148 (54.1)	973 (45.9)
Male	995 (69.1)	1202 (75.3)	796 (69.3)	768 (78.9)
Mean age, years (SD)	65.1 (8.6)	64.3 (7.8)	63.3 (8.6)	62.7 (8.1)
Age group, years				
<65	659 (45.8)	793 (49.7)	627 (54.6)	572 (58.8)
65– <75	580 (40.3)	648 (40.6)	409 (35.6)	330 (33.9)
75– <85	194 (13.5)	154 (9.6)	110 (9.6)	70 (7.2)
≥85	7 (0.5)	2 (0.1)	2 (0.2)	1 (0.1)
Smoking history				
Smoker	492 (34.2)	506 (31.7)	534 (46.5)	374 (38.4)
Ex-smoker	948 (65.8)	1091 (68.3)	614 (53.5)	599 (61.6)
Post-BD pulmonary function[d]				
Mean FEV_1 (SD), L	1.689 (0.418)	1.022 (0.288)	1.762 (0.463)	1.026 (0.293)
Mean% predicted FEV_1 (SD)	62.26 (7.94)	37.20 (8.18)	63.41 (8.37)	36.73 (8.64)
Pulmonary medication at baseline				
Yes	1440 (100)	1597 (100)	518 (45.1)	551 (56.6)
Anti-cholinergic (long acting/ inhaled)	860 (59.7)	979 (61.3)	-	-
Anti- cholinergic (short acting/ inhaled)	156 (10.8)	241 (15.1)	132 (11.5)	135 (13.9)
β adrenergics (long acting/ inhaled)	1070 (74.3)	1322 (82.8)	-	-
β adrenergics (oral)	4 (0.3)	14 (0.9)	8 (0.7)	8 (0.8)
β adrenergics (short acting/ inhaled)	580 (40.3)	792 (49.6)	348 (30.3)	358 (36.8)
Leukotriene receptor antagonists	22 (1.5)	22 (1.4)	11 (1.0)	12 (1.2)
Mucolytics	109 (7.6)	128 (8.0)	46 (4.0)	34 (3.5)
Oxygen	15 (1.0)	54 (3.4)	9 (0.8)	16 (1.6)
Steroids (inhaled)	903 (62.7)	1213 (76.0)	149 (13.0)	180 (18.5)
Steroids (oral)	19 (1.3)	37 (2.3)	6 (0.5)	14 (1.4)
Xanthines	132 (9.2)	218 (13.7)	57 (5.0)	109 (11.2)

Values are n (%) except for age and post-BD pulmonary function.
[a]No prior LABA or LAMA, or both treatments at baseline; [b]post-bronchodilator GOLD stage: GOLD 2 (FEV_1 50– <80% of predicted normal), GOLD 3 (FEV_1 30– <50% of predicted normal), GOLD 4 (FEV_1 <30% of predicted normal); [c]percentage of the total number of patients (3037 and 2121 for patients with and without maintenance treatment, respectively). All other percentages calculated from the number of patients in each row; [d]pulmonary function data measurements 10−45 min after inhalation of 4 puffs of 100 μg salbutamol at screening.
BD, bronchodilator; FEV_1, forced expiratory volume in 1 s; SD, standard deviation.

Conclusions A high proportion of GOLD 3/4 patients not receiving maintenance treatment were not receiving any other pulmonary medication. One could hypothesise that these patients had either been diagnosed recently or that they were not treated according to current COPD guidelines.

P122 COMBINATION THERAPY WITH INHALED SALMETEROL PLUS FLUTICASONE PROPIONATE IS MORE EFFECTIVE THAN SALMETEROL ALONE IN REDUCING THE RISK OF CLINICALLY IMPORTANT DETERIORATION IN COPD: A POST-HOC ANALYSIS OF THE TORCH TRIAL

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Background Most COPD patients will deteriorate over time, so a key aim of COPD management is to minimise this risk. We developed a composite endpoint of three aspects of worsening: COPD exacerbations, clinically important deteriorations (CID) in lung function and health status. This method was applied in a *post hoc* analysis of TORCH, a 3-year, double-blind, placebo-controlled trial in moderate/severe COPD that compared salmeterol 50 mcg/fluticasone proprionate 500 mcg combination (SFC) with placebo (PBO), salmeterol 50 mcg (SAL) alone and fluticasone 500 mcg alone. In this analysis, SFC was compared with SAL to test whether the addition of inhaled corticosteroids (ICS) reduced the risk of a CID beyond their known effect on exacerbations.

Method The overall analysis was performed in 6112 patients, 3054 treated with SFC and SAL. A CID was defined as a decrease ≥100 mL in post-bronchodilator FEV_1, an increase (worsening) in St George's Respiratory Questionnaire (SGRQ) total score of ≥4 units, or an on-treatment moderate/severe exacerbation. The time to the first deterioration of each component and the composite endpoint was analysed using a Cox's proportional hazards model with covariates of: treatment, smoking status and geographical region; baseline values for FEV_1 and SGRQ score were included for those individual component endpoints. The analysis was performed on the intention-to-treat (ITT) population and in patient categorised into GOLD grades I/II and III/IV.

Abstract P122 Table 1 Time to first CID with SFC compared with SAL

Deterioration criteria	SFC (N = 1533)	SAL (N = 1521)	Hazard ratio (95% CI) vs. SAL
≥100 mL decrease in post-bronchodilator FEV_1 from baseline, n (%)	754 (49%)	842 (55%)	0.80 (0.73, 0.88) **
SGRQ total score ≥4 unit deterioration from baseline, n (%)	531 (35%)	569 (37%)	0.85 (0.75, 0.96)*
≥1 Moderate/severe exacerbation, n (%)	1039 (68%)	1065 (70%)	0.93 (0.85, 1.01)
Composite (≥1 event above) ITT pop., n (%)	1279 (83%)	1325 (87%)	0.84 (0.77, 0.92) **
Composite in GOLD I/II subgroup, n (%)	445 (79%)	446 (86%)	0.81 (0.69, 0.94)*
Composite in GOLD III/IV subgroup, n (%)	834 (86%)	879 (87%)	0.86 (0.77; 0.96)*

**p < 0.001; *p < 0.01.

Results A similar percentage of patients in both treatment groups eventually experienced ≥1 category of deterioration during the 3-year trial. The Hazard Ratios (HR) show that compared to SAL, SFC significantly reduced the time to first worsening of

FEV_1 and SGRQ (Table 1). The benefit of SFC over SAL was seen with the composite endpoint in the ITT population and both GOLD subgroups.

Conclusion This *post hoc* analysis showed that, although most patients eventually experienced one of the three measures of deterioration, SFC significantly reduced the risk of a first composite CID compared to SAL. This added benefit of ICS was equally present in patients with mild/moderate or severe/very severe COPD.

P123 INHALED CORTICOSTEROID PLUS LONG-ACTING β2-AGONIST THERAPY IS OVERUSED IN THE TREATMENT OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: POST HOC ANALYSES OF TWO 1-YEAR STUDIES

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Rationale Inhaled corticosteroid (ICS) plus long-acting β_2-agonist (LABA) therapy is indicated for different patient groups with chronic obstructive pulmonary disease (COPD) in the USA and Europe. In the previous version of the Global initiative for chronic Obstructive Lung Disease (GOLD) recommendations, the use of ICS plus LABA therapy was restricted to patients with severe and very severe lung-function impairment and frequent exacerbations, with overtreatment in milder patient populations well documented. The current GOLD document recommends the use of ICS plus LABA maintenance therapy for patients in categories C and D.

Methods We present *post hoc* analyses from the two pivotal 1-year TONADO studies to assess the use of ICS plus LABA maintenance therapy in patients classified as GOLD A/B and C/D. As these studies were initiated before the update of the GOLD recommendations, no modified Medical Research Council Dyspnoea scale or COPD Assessment Test data were available to further classify these patients into categories A or B and C or D. Based on the reported COPD exacerbation history and lung-function measurements, 2259 patients were classified as GOLD A/B and 2903 as GOLD C/D. Baseline characteristics and concomitant medications at baseline are presented in Table 1.

Results In the GOLD A/B subgroup, 7.3% of patients were receiving treatment with ICS alone and 31.3% were receiving treatment with ICS plus LABA at study baseline. In the GOLD C/D subgroup, the incidences of patients receiving treatment with ICS alone and ICS plus LABA at study baseline were 8.8% and 45.5%, respectively.

Conclusions Almost 40% of patients classified as GOLD A/B are receiving treatment with ICS maintenance therapy, either alone, in free combination or as a fixed-dose combination therapy, despite GOLD recommendations for use only in patients with more severe lung-function impairment and frequent exacerbations. Our analyses confirm previous reports, highlighting that treatment regimens containing ICS therapy are being used early in the management of patients with COPD, which may not be appropriate based on current GOLD recommendations.

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Abstract P123 Table 1

	GOLD A/B	GOLD C/D
n	2259	2903
Age (years), mean ± SD	64.3 ± 8.6	63.8 ± 8.0
Male, n (%)	1576 (69.8)	2186 (75.3)
Ex-smoker, n (%)	1348 (59.7)	1906 (65.7)
Post-bronchodilator FEV_1 (L), mean ± SD	1.73 ± 0.44	1.1 ± 0.37
Post-bronchodilator FEV_1 (% predicted), mean ± SD	62.9 ± 8.2	39.9 ± 11.6
Reversibility (mL), mean ± SD	193 ± 158	154 ± 131
Baseline maintenance medication, n (%)		
ICS	871 (38.6)	1575 (54.3)
ICS without LABA	165 (7.3)	255 (8.8)
ICS plus LABA	706 (31.3)	1320 (45.5)
LABA	904 (40.0)	1489 (51.3)
LAMA	768 (34.0)	1072 (36.9)
Xanthines	153 (6.8)	363 (12.5)

SD, standard deviation; FEV_1, forced expiratory volume in 1 s; LAMA, long-acting muscarinic antagonist.

P124 A RANDOMISED, PARALLEL-GROUP STUDY TO EVALUATE THE EFFECT OF UMECLIDINIUM ADDED TO INHALED CORTICOSTEROID/LONG-ACTING BETA-AGONIST COMBINATION THERAPY IN SUBJECTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Rationale To evaluate efficacy and safety of adding umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), to inhaled corticosteroid (ICS)/long-acting β-agonist (LABA) in patients with moderate-to-very severe chronic obstructive pulmonary disease (COPD) for 12-weeks.

Methods Multicentre, randomised, double-blind, parallel-group study. Inclusion criteria included diagnosis of COPD, modified Medical Research Council Dyspnoea Scale score $\geq$2 (i.e. patients symptomatic on ICS/LABA), post-salbutamol forced expiratory volume in one second (FEV_1) ≤70% predicted and FEV_1/forced vital capacity ratio of 1 at Day 85; other endpoints included 0–6 h weighted mean FEV_1, rescue medication use, COPD assessment test (CAT) score, and transition dyspnoea index (TDI) score. Adverse events (AEs) were also investigated.

Results In the UMEC+ICS/LABA and PBO+ICS/LABA groups, 119 and 117 patients were randomised, respectively, receiving fluticasone/salmeterol (40%), budesonide/formoterol (43%), and other ICS/LABA, including generics (17%). Compared with PBO +ICS/LABA, UMEC+ICS/LABA resulted in statistically significant improvements in change from baseline trough FEV_1 at Day 85 and 0–6 h weighted mean FEV_1 at Day 84 (Table 1). UMEC +ICS/LABA resulted in a statistically significant reduction in change from baseline mean puffs/day of rescue salbutamol over Weeks 1–12 versus PBO+ICS/LABA, but not for percentage of rescue-free days. Change from baseline in CAT score at Day 84 was statistically significantly different for UMEC+ICS/LABA versus PBO+ICS/LABA, but TDI score was not significantly different for UMEC+ICS/LABA versus PBO+ICS/LABA; the study was not powered for these endpoints. Incidence of AEs was similar with UMEC+ICS/LABA and PBO+ICS/LABA; n = 45 (38%) and n = 49 (42%), respectively. The most common AEs were nasopharyngitis (13–15%) and headache (3–7%).