Conclusions Non-eosinophilic COPD subjects have more exacerbations, with more co-morbidities and bacterial burden (see Figure 1). Further work is required to understand the pathogenesis of this phenotype.

P120 REAL LIFE DISTRIBUTION OF COPD SEVERITY IN THE GERMAN DACCORD REGISTRY: LUNG FUNCTION IS THE MAIN DRIVER OF CLASSIFICATION IN GOLD GROUP C AND D

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Introduction Currently there is limited real-life data available regarding the distribution of COPD patients using the GOLD 2011 criteria. The German DACCORD registry that collects data from a large 'real life' population sample was used to categorise COPD patients according to GOLD 2011.

Methods To be eligible for entry into DACCORD, all patients had to have a diagnosis of COPD (consistent with the German Disease Management Programme definition), and, prior to entry, had to have either newly initiated bronchodilator maintenance medication, or to have a bronchodilator added to their maintenance regimen. No other inclusion criteria were applied, and the only exclusion criterion was a diagnosis of asthma. In primary and secondary care, data were collected from 4,123 COPD outpatients, including spirometry, exacerbations, CAT and mMRC.

Results The mean age of patients was 65.7 years with 40.3% of patients still working and 73.3% patients with duration of disease $\geq$1 year.

Based on mMRC 0–1, 37.2% of patients had few symptoms (A and C); using CAT <10, only 9.0% were categorised into these two groups. 32.5% of the patients were assigned to C and D groups solely due to FEV1 <50%.

After 12 months, 41.4% patients in GOLD A were categorised in a higher GOLD category, while 42.7% of GOLD D patients were categorised in a lower GOLD category (GOLD categorization based on CAT). 67.6% of patients categorised as D at baseline due to exacerbation history alone were categorised as GOLD B after 1 year follow-up.

Almost 80% of GOLD B patients were still categorised as GOLD B after the observation period of 12 months and were therefore the most stable subgroup with regards to COPD severity according to GOLD 2011 (Figure 1).

		GOLD 2011 at 12 months					
		A	B	C	D1*	D2*	D3*
	N (% of total)	**370** (9.4%)	**2144** (54.3%)	**139** (3.5%)	**936** (23.7%)	**169** (4.3%)	**169** (4.3%)
GOLD 2011 at baseline	A **232** (5.9%)	**136** (3.4%)	68 (1.7%)	16 (<1 %)	7 (<1%)	2 (<1%)	2 (<1%)
	B **1774** (44.9%)	142 (3.6%)	**1419** (35,9%%)	15 (<1%)	114 (2.9%)	68 (1.7%)	17 (<1%)
	C **124** (3.1%)	30 (<1%)	14 (<1%)	**39** (<1%)	32 (<1%)	7 (<1%)	2 (1%)
	D1* **865** (21.9%)	23 (<1%)	176 (4.5%)	42 (1.0%)	**553** (14.0%)	5 (<1%)	59 (1.5%)
	D2* **599** (15.2%)	32 (<1%)	405 (10.3%)	12 (<1%)	50 (1.3%)	**76** (1.9%)	22 (<1%)
	D3 * **355** (9.0%)	7 (<1%)	65 (1.6%)	15 (<1%)	181 (4.5%)	11 (<1%)	**67** (1.7%)

Abstract P120 Figure 1

Conclusion A significant proportion of patients in the DACCORD registry are classified in GOLD C and D groups based solely on airflow limitation, in accordance with previous studies. Patients categorised as GOLD B were the most stable over the observational period of 12 months according to GOLD 2011. With the prospective collection of exacerbations over the second year of follow-up, a clearer picture of progression of GOLD 2011 categorisation might be drawn.

P121 CHARACTERISTICS OF COPD PATIENTS WITH AND WITHOUT MAINTENANCE TREATMENT AT BASELINE, BY GOLD STAGE: TONADO

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Rationale The efficacy and safety of the once-daily combination of tiotropium (T), a long-acting muscarinic antagonist (LAMA), and olodaterol (O), a long-acting β_2-agonist (LABA), for the treatment of chronic obstructive pulmonary disease (COPD) has been established. We investigated whether there was a difference in the characteristics of COPD patients with and without baseline maintenance treatment.

Methods Two replicate, randomised, 52-week, double-blind, parallel-group, Phase III trials (NCT01431274; NCT01431287; n = 5162) assessed the efficacy and safety of once-daily treatment with T+O (2.5/5 µg; 5/5 µg; Respimat® inhaler) compared to the individual components. Baseline characteristics of COPD patients within Global initiative for chronic Obstructive Lung Disease (GOLD) subgroups 2 and 3/4, with/without maintenance treatment (prior LABA, LAMA or both at baseline), are presented, based on data from the pooled set.

Results Most patients received baseline maintenance treatment (3037 vs 2121) and of those, there was a greater proportion of GOLD 3/4 compared to GOLD 2 patients (52.58% vs 47.42%, respectively). An opposite trend was observed in patients not receiving maintenance treatment (GOLD 3/4, 45.87% vs GOLD 2, 54.13%). The proportion of current smokers was lower in GOLD 3/4 than GOLD 2 patients, as expected (Table); nevertheless, irrespective of GOLD stage, there was a greater proportion of smokers without maintenance treatment than with maintenance treatment (42.81% vs 32.86%, respectively). As expected, pulmonary function was reduced in GOLD 3/4 compared to GOLD 2 patients, although it appeared comparable between patients with and without maintenance treatment. Of the patients with maintenance treatment, a considerably greater proportion received inhaled steroids compared to those without prior LAMA/LABA treatment (69.67% vs 15.51%, respectively). Furthermore, a smaller proportion of patients without prior LAMA/LABA treatment received short-acting β-adrenergics compared to those with maintenance treatment (Table 1). Of the GOLD 3/4 patients without baseline maintenance treatment, 43.4% were not receiving any other pulmonary medication.

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