P129 WHAT IS THE PATIENT'S PREFERENCE: TIOTROPIUM MONOTHERAPY OR FIXED-DOSE INDACATEROL/GLYCOPYRRONIUM COMBINATION THERAPY? - THE FAVOUR STUDY

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10.1136/thoraxjnl-2015-207770.266

Introduction and objectives Shared decision-making for drug and inhaler-device use improves adherence and outcomes in COPD. Physicians are encouraged to involve patient's opinion in choosing drugs and inhalers. It remains unclear, however, whether the superior effect on FEV1 shown for the fixed-dose combination of indacaterol/glycopyrronium (IND/GLY) compared to tiotropium (TIO) translates into medication preference by patients.

The present study was conducted to evaluate the overall preference for IND/GLY and TIO respectively, in patients who are still symptomatic under a TIO treatment.

Method This multicenter, cross-over, open-label study randomised COPD patients with moderate to severe airflow limitation and a CAT score of $\geq$10 to either receive 4 weeks o.d. IND/GLY (110/50 µg) followed by 4 weeks o.d. TIO (18 µg) or *vice versa* in a 1:1 ratio. To determine patient's treatment preference and satisfaction as secondary and explorative objectives, respectively, several validated and new questionnaires were used. As primary endpoint, FEV1 1 h post-inhalation after 4 weeks was investigated.

Results Of 88 patients (mean age, 65 years; post-bronchodilator FEV1, 57.7% predicted; mean CAT score, 17.6) randomised, 87 patients completed the study. After 4 weeks treatment, 1 h post-inhalation FEV1 was significantly higher with IND/GLY compared to TIO (LSM difference, 81 ml; p = 0.0017). Importantly, a higher proportion of patients preferred IND/GLY (69.4%) over TIO (30.6%) at the end of the study. Reduction of dyspnea was mentioned as an important or very important reason for favouring IND/GLY by 91.5% of the patients.

Conclusion This study indicated that beyond FEV1, patients reported outcomes improve with the dual bronchodilator IND/GLY compared to TIO monotherapy. Further studies are needed to investigate how the favoured treatment option translates into improved adherence and long term treatment outcomes.

P130 EFFECTIVENESS AND SAFETY OF INITIATING TREATMENT WITH FLUTICASONE/SALMETEROL VIA MDI VERSUS DPI IN COPD

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10.1136/thoraxjnl-2015-207770.267

Introduction and objectives Fluticasone propionate/salmeterol (FP/SAL), can be delivered by metered-dose inhaler (MDI) or dry powder inhaler (DPI). The choice of device may affect adherence to and effectiveness of treatment. Although only 1000 mcg/day DPI is licensed for the treatment of COPD in the UK, the MDI and lower doses are regularly used in real-world practice. The aim of this study was to compare the effectiveness and safety of FP/SAL MDI or DPI at two doses (500 and 1000 mcg/day) in COPD patients.

Methods Historical, matched cohort study using the Optimum Patient Care Research Database in patients with COPD, aged $\geq$35 years and initiating with FP/SAL via either MDI or DPI. Conditional Poisson regression and conditional logistic regression were used respectively to compare the rate of moderate/severe COPD exacerbations and the odds of diagnosis of pneumonia and diabetes mellitus (including anti-diabetic drug prescriptions) between MDI and DPI during one year outcome period. Models were adjusted for the respective baseline values of the outcome variable of interest where possible. Addition of LAMA therapy during the outcome period was compared using conditional logistic regression.

Results 472 and 1172 patients initiated on FP/SAL at 500 mcg/day and 1000 mcg/day, respectively. The rate of moderate/severe COPD exacerbations was significantly lower for patients prescribed

Abstract P130 Table 1 Moderate/severe exacerbations, pneumonia and diabetes mellitus during the outcome period for patients initiating on FP/SAL at 500 mcg/day andmcg/day via MDI versus DPI

		Initiating at 500 mcg/day FP/SAL N = 472 (100%)		Initiating at 1000 mcg/day FP/SAL N = 1172 (100%)	
		MDI N = 236 (100%)	DPI N = 236 (100%)	MDI N = 586 (100%)	DPI N = 586 (100%)
Number of all moderate/severe COPD exacerbations	**0**, n (%)	137 (58.1)	121 (51.3)	299 (51)	317 (54.1)
	1, n (%)	56 (23.7)	59 (25.0)	152 (25.9)	149 (25.4)
	2–3, n (%)	35 (14.8)	35 (14.8)	100 (17.1)	87 (14.8)
	4+, n (%)	8 (3.4)	21 (8.9)	35 (6.0)	33 (5.6)
	Rate ratio (95% CI)	0.72 (0.55, 0.95)	1	1.10 (0.93, 1.30)	1
	Adjusted rate ratio (95% CI)	0.71 (0.54, 0.93)	1	1.11 (0.94, 1.30)	1
Pneumonia	**No**, n (%)	231 (97.9)	232 (98.3)	582 (99.3)	583 (99.5)
	Yes, n (%)	5 (2.1)	4 (1.7)	4 (0.7)	3 (0.5)
	Odds ratio (95% CI)	1.25 (0.33, 4.76)	1	1.33 (0.30, 5.88)	1
Diabetes mellitus	**No**, n (%)	214 (90.7)	211 (89.4)	493 (84.1)	497 (84.8)
	Yes, n (%)	22 (9.3)	25 (10.6)	93 (15.9)	89 (15.2)
	Odds ratio (95% CI)	0.87 (0.59, 1.43)	1	1.05 (0.80, 1.39)	1
	Adjusted odds ratio (95% CI)	0.88 (0.40, 1.92)	1	1.10 (0.71, 1.69)	1

MDI versus DPI initiating with 500 mcg/day of FP/SAL; no significant difference was observed between MDI and DPI for those initiating at 1000 mcg/day. There were no significant differences in the odds of diagnosis of diabetes mellitus or pneumonia between MDI and DPI, irrespective of the initiation dose of FP/SAL (Table 1). LAMA prescription during the outcome period was significantly lower for patients prescribed MDI versus DPI initiating at 1000 mcg/day; no significant difference was observed between MDI and DPI for those initiating at 500 mcg/day.

Conclusions This study showed greater reduction in exacerbations for patients using MDI than those using DPI when initiating with FP/SAL 500 mcg/day; no differences in exacerbation reduction and safety were seen for FP/SAL at 1000 mcg/day. Fewer patients using MDIs than DPIs at 1000 mcg/day were prescribed LAMAs, suggesting less need for treatment intensification.

P131 EFFICACY OF TIOTROPIUM AND OLODATEROL COMBINATION IN PATIENTS WITH COPD ON β-BLOCKERS

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10.1136/thoraxjnl-2015-207770.268

Rationale The efficacy and safety of a new once-daily combination with tiotropium (T), a long-acting muscarinic antagonist, and olodaterol (O), a long-acting β_2-agonist, was established for the treatment of chronic obstructive pulmonary disease (COPD) in the TONADO studies (NCT01431274; NCT01431287). This analysis evaluates the efficacy of the combination in a subpopulation of patients receiving β-blockers in these studies.

Methods Two replicate, randomised, double-blind, parallel-group, 52-week, Phase III trials assessed the efficacy and safety of T+O (2.5/5 μg; 5/5 μg; via Respimat® inhaler) once daily compared to the monocomponents. Key primary end-point data for the combined analysis of the replicate trials in patients with COPD receiving β-blockers during treatment are presented.

Results 5136 patients were evaluable; 556 (10.8%) received β-blockers. At 24 weeks, similar improvements in mean forced expiratory volume in 1 s (FEV_1) area under the curve from 0–3 h (AUC_{0-3}) responses for T+O compared to monocomponents were seen across β-blocker subgroups (Table 1), with no significant treatment interaction effect observed. A similar trend was observed with trough FEV_1 and quality of life scores.

Abstract P131 Table 1 Efficacy of T+O versus monocomponents by β-blocker use

	Treatment difference	
	Adjusted mean FEV_1 AUC_{0-3}, L [95% confidence interval]	
Treatment comparison, μg	β-blockers (n = 556)	No β-blockers (n = 4580)
T+O 5/5 – O 5	0.114 [0.06, 0.169]	0.129 [0.111, 0.147]
T+O 5/5 – T 5	0.078 [0.025, 0.131]	0.114 [0.097, 0.132]
T+O 2.5/5 – O 5	0.122 [0.069, 0.174]	0.114 [0.096, 0.132]
T+O 2.5/5 – T 2.5	0.108 [0.058, 0.158]	0.113 [0.095, 0.130]
T+O 2.5/5 – T 5	0.085 [0.034, 0.136]	0.099 [0.081, 0.117]

Conclusions While the β-blocker patient group analysed was small, these data demonstrated similar sustained improvements in lung function, irrespective of β-blocker use. These data support the efficacy of T+O in this patient group.

Funding Boehringer Ingelheim.

P132 HEALTH CARE UTILISATION AND COSTS AMONG COPD PATIENTS NEWLY PRESCRIBED MAINTENANCE THERAPY IN THE UNITED KINGDOM (UK)

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10.1136/thoraxjnl-2015-207770.269

Aim To characterise disease burden, health care resource utilisation (HCRU), and costs among a cohort of COPD patients newly prescribed maintenance therapy in UK general practice.

Method A retrospective cohort of COPD patients aged ≥40 yrs and newly prescribed COPD monotherapy (long acting beta-agonists [LABA] or long acting muscarinic antagonist [LAMA]), dual therapy (LABA+LAMA; LABA+inhaled corticosteroid (ICS); LAMA+ICS) or open triple therapy (LAMA+LABA+ICS) between 1/1/2009 and 30/11/2012 was identified from UK Clinical Practice Research Datalink (CPRD).

Health care resource utilisation assessed in the 12 months prior to maintenance therapy initiation included moderate (community treated) and severe (hospital or A&E treated) COPD exacerbations (rate per 100 person years [PY]), general practice (GP) interactions, other COPD treatments, and non-COPD related hospitalisations. The costs associated with HCRU were calculated using National Health Services reference costs for 2013–14 and PSSRU costs for 2014.

Results A total of 39,639 COPD patients were included (54% male, mean age 68 yrs (SD: 11)). LABA+ICS (39%) and LAMA (34%) were the most commonly initiated LABD; 13% were first exposed to LABD as part of an open triple regimen (Table 1). Patients initiating an ICS-containing regimen had a higher exacerbation rate (moderate or severe) in the 12 months prior to maintenance therapy initiation (LABA+ICS: 0.74 per PY [95% CI:0.72–0.75]; LAMA+ICS: 0.86 per PY [0.82–0.90] and LAMA+LABA +ICS: 0.83 per PY [0.80–0.85]) compared to patients on bronchodilators alone (LAMA: 0.55 per PY [0.54–0.57]; LABA: 0.56 per PY [0.54–0.59]; LAMA+LABA: 0.50 per PY [0.44–0.56]). Patients on open triple therapy demonstrated the highest rates of non-COPD related hospitalisations. The annual per patient cost ranged from £2,139 (LABA) to £2,876 (LAMA+LABA+ICS); approximately half were due to GP visits and a third resulted from non-COPD related hospitalisations (Table 1).

Abstract P132 Table 1 Annual per patient health care utilisation costs 12 months prior to LABD initiation

	LABA (N = 2899)	LAMA (N = 13511)	LABA +LAMA (N = 525)	LABA +ICS (N = 15374)	LAMA +ICS (N = 2370)	LAMA +LABA+ICS (N = 4960)
Total costs	£2,139	£2,223	£2,240	£2,334	£2,410	£2,876
GP visits	£1,230	£1,249	£1,237	£1,224	£1,313	£1,272
All exacerbations	£173	£192	£179	£247	£287	£400
Non-COPD hospitalisations	£709	£759	£795	£811	£703	£1,159
Treatment	£27	£23	£29	£51	£106	£46