Abstract P226 Table 1.

	CA (n=23)	AA (n=27)	ADULT (n=50)	COPD (n=50)	HA (n=50)
Spiromax: Before enhanced training					
PIF, L/min	69.5 (17.2)	67.9 (15.10)	74.4 (18.1)	57.5 (21.0)	85.0 (13.6)
ΔP, kPa	5.0 (2.5)	4.7 (2.2)	5.7 (2.6)	3.7 (2.7)	7.3 (2.3)
ACC, kPa/s	13.6 (11.8)	12.1 (8.8)	15.6 (15.7)	11.0 (12.8)	15.9 (13.5)
Turbuhaler: Before enhanced training					
PIF, L/min	58.5 (14.7)	57.8 (13.4)	65.4 (17.5)	50.1 (16.2)	78.0 (11.8)
ΔP, kPa	3.9 (2.0)	3.9 (1.8)	5.1 (2.6)	3.1 (2.0)	7.0 (2.1)
ACC, kPa/s	11.3 (8.5)	11.4 (7.2)	13.0 (12.1)	8.4 (9.5)	12.8 (9.6)
Spiromax: % improvement after enhanced training					
Improvement in ΔP, % (SD)	53.46 (60.32)		49.30 (74.81)	35.94 (81.15)	46.36 (58.85)
Improvement in ACC, % (SD)	165.71 (231.22)		247.72 (482.94)	152.83 (233.91)	212.09 (284.44)
Turbuhaler: % improvement after enhanced training					
Improvement in ΔP, % (SD)	67.44 (68.36)		57.12 (89.53)	60.30 (73.15)	44.96 (55.92)
Improvement in ACC, % (SD)	221.64 (335.34)		188.77 (271.47)	254.32 (426.12)	275.05 (389.83)

All values are mean, standard deviation (SD) unless otherwise indicated. ACC = inspiratory acceleration; FEV₁, forced expiratory volume in 1 second; PIF, peak inspiratory flow; ΔP, maximum pressure change

training with a focus on maximising inspiratory effort produced significant improvement in inhalation parameters with both devices, and significantly greater improvements in these parameters with Spiromax versus Turbuhaler in adult patients.

REFERENCES

1. Laube BL, et al. *Eur Respir J* 2011;37:1308–31.

P227 EFFECT OF A NEW TRAINING DEVICE ON PMDI TECHNIQUE

¹MJ Sanders, ¹R Bruin, ²R Featherstone; ¹Clement Clarke International Ltd., Harlow, UK; ²Medical Device Usability Limited, Cambridge, UK

10.1136/thoraxjnl-2013-204457.379

Introduction A simple training device (In-Check Flo-Tone®) has been developed to teach pMDI users when and how to actuate their inhaler via the sounding of an inspiratory flow whistle. Samples of the device plus instructions were made available to UK healthcare professionals who were invited, from April 2013, to take part in a short questionnaire survey. The objective was to assess the effect of the Flo-Tone device on pMDI technique.

Method Patient details (age, sex, asthma/COPD diagnosis and spacer use) were recorded. Four assessments were made by the healthcare professionals concerning the patients' ability to: Q1 - generate an appropriate flow rate; Q2 - press the can during the early part of the inspiration; Q3 - maintain adequate inspiratory flow after pressing the can; and Q4 - an overall assessment of pMDI technique. Ability was graded Poor, Average or Good on each occasion. Assessments were made before and after Flo-Tone training, and changes in technique were determined from the

responses. A sign-test for improvement was carried out on those not already assessed as Good.

Results To date, 27 assessments of pMDI users have been received: 15 male and 12 female, age range 11–90 years (mean 51 years) with recorded diagnoses of asthma (n = 17) and COPD (n = 7). Four were spacer-users. The shift table (Table 1) shows the categorical changes before and after training. Following training, 19 users had improved their overall technique and 7 remained at the pre-training level (Q4); 20 had improved their ability to maintain an adequate flow and 6 remained at the pre-training level (Q3). Data for Q1 and Q2 were 15 and 12, and 8 and 18 users, respectively. The single loss of technique was an 83 year-old combined asthma/COPD patient. Analysis of those users not already rated as Good showed statistically significant improvements ($P < 0.05$) for Questions 1, 3 and 4.

Conclusion The data indicate that the Flo-Tone device may be a positive addition to the training tools available for pMDI users, and may be particularly useful for improving overall technique and the ability to generate and to maintain an adequate inspiratory flow.

Abstract P227 Table 1.

			AFTER TRAINING		
			Poor	Average	Good
Q1	BEFORE	Poor	2	3	6
		Average	0	3	6
		Good	0	0	7
Q2	BEFORE	Poor	2	3	0
		Average	1	3	5
		Good	0	0	13
Q3	BEFORE	Poor	2	3	4
		Average	1	1	13
		Good	0	0	3
Q4	BEFORE	Poor	2	3	5
		Average	1	2	11
		Good	0	0	3

P228 IMPACT OF LONG-ACTING BRONCHODILATOR THERAPY ON MORTALITY IN COPD: A REAL-LIFE RETROSPECTIVE COHORT STUDY

A Manoharan, PM Short, WJ Anderson, BJ Lipworth; *University of Dundee, Dundee, United Kingdom*

10.1136/thoraxjnl-2013-204457.380

Introduction and Objectives Long-acting muscarinic antagonists (LAMA) and long-acting beta-agonists (LABA) are first-line treatments for COPD. The addition of inhaled corticosteroids (ICS) is recommended for patients with frequent exacerbations who are not adequately controlled with long-acting bronchodilators. These medications have been largely evaluated independently in placebo controlled randomised trials. In this 'real-life' study we investigated the impact of these medications used independently and in combination on mortality.

Methods We conducted a retrospective cohort study using data from patients with a diagnosis of COPD in NHS Tayside between 2001 and 2010. All-cause and cardiovascular mortality was assessed using Cox proportional hazard regression after

adjustment for FEV₁, age, sex, smoking pack-years, oxygen saturation, cardiovascular and respiratory admissions; cardiovascular medications and diabetes. Patients on short-acting bronchodilators only were used as the controls.

Results A total of 5048 patients were included in the study with mean age at diagnosis of 69.4 years and mean follow-up of 4.0 years. 623 were on long-acting bronchodilators only, 3510 on long-acting bronchodilator and ICS; and 915 controls. Crude hazard ratios are shown in Table 1. Adjusted HR (95%CI) for all-cause mortality for LABA only, LAMA only; and LABA + LAMA were 0.70 (0.45–1.09), 0.52 (0.37–0.73) and 0.53 (0.34–0.84) respectively. Adjusted HR for all-cause mortality for LABA + ICS, LAMA + ICS; LABA + LAMA + ICS were 0.56 (0.45 – 0.70), 0.34 (0.25 – 0.47) and 0.29 (0.24 – 0.36) respectively. Adjusted HR for cardiovascular mortality for LABA only, LAMA only; and LABA + LAMA were 0.63 (0.28–1.44), 0.41 (0.21 – 0.79) and 0.39 (0.17 – 0.90) respectively, and for LABA + ICS, LAMA + ICS; LABA + LAMA + ICS were 0.50 (0.33 – 0.75), 0.23 (0.12 – 0.45) and 0.22 (0.15 – 0.33) respectively.

Conclusions LABA monotherapy does not confer any mortality benefit but when used in combination with ICS reduces both all-cause and cardiovascular mortality. In contrast, LAMA whether given alone or in combination with a LABA and /or ICS reduces both all-cause and cardiovascular mortality. This ‘real-life’ study suggests that LABA should perhaps not be given as monotherapy but only in conjunction with a LAMA or ICS.

Abstract P228 Table 1.

Treatment Group	Crude hazard ratio (95% CI)*	
	All-cause mortality	Cardiovascular mortality
LABA only	1.06 (0.79-1.43)	1.06 (0.60-1.85)
LAMA only	0.71 (0.57-0.88)	0.59 (0.38-0.92)
LABA + LAMA	0.71 (0.52-0.97)	0.51 (0.26-1.00)
LABA + ICS	0.72 (0.62-0.84)	0.66 (0.50-0.89)
LAMA + ICS	0.61 (0.49-0.76)	0.48 (0.30-0.75)
LABA + LAMA + ICS	0.61 (0.53-0.69)	0.40 (0.31-0.53)

*Patients on short-acting bronchodilator only were used as the controls

Table 1: Crude hazard ratio for all-cause and cardiovascular mortality by treatment groups

P229 ADJUNCTIVE TREATMENT WITH ORAL AKL1, A BOTANICAL NUTRACEUTICAL, IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

¹C Brockwell, ²S Ampikaipakan, ³D Sexton, ³D Price, ⁴D Freeman, ⁵M Thomas, ³M Ali, ²AM Wilson; ¹Norfolk and Norwich University Hospital NHS Foundation Trust, Norwich, UK; ²University of East Anglia, Norwich, UK; ³Research in Real Life, Cambridge, UK; ⁴Mundesley Medical Centre, Mundesley, UK; ⁵University of Southampton, Southampton, UK

10.1136/thoraxjnl-2013-204457.381

Background Treatment for chronic obstructive pulmonary disease (COPD) includes both bronchodilating and anti-inflammatory therapies. However majority of patients with COPD show corticosteroid resistance and alternative therapies are need. AKL1 is a patented botanical formulation containing extracts of *Picrorhiza kurroa*, *Ginkgo biloba*, and *Zingiber officinale* which has shown anti-inflammatory effects *in vitro*.

Methods We undertook a randomised double-blind, placebo-controlled trial to determine the safety and efficacy of AKL1 in patients with a clinical labelled diagnosis of COPD and Leicester

Cough Questionnaire (LCQ) score of <17. The 10-week study period comprised a 2-week single-blind placebo run-in period followed by add-on treatment with AKL1 or placebo twice daily for 8 weeks. The primary study end-point was the change from week 0 to week 8 in cough-related health status, as assessed by the LCQ. Secondary endpoints were St. George's Respiratory Questionnaire, MRC dyspnea score, forced expiratory volume in 1 second (FEV1) and 6 minute walk test.

Abstract P229 Figure 1.

Results Of 33 (19 male) patients mean (SD) age of 67 (9.4) years 57.9 (17.2) FEV1% predicted enrolled into the study, 15 (45%) patients were smokers and 16 (49%) were ex-smokers. Twenty patients were randomised to AKL1 and 13 to placebo. The mean (SD) change from baseline in LCQ score at 8 weeks was 2.3 (4.9) in the AKL1 group and 0.6 (3.7) in the placebo group (p = 0.43). The St. George's Respiratory Questionnaire score improved significantly more in the AKL1 treatment group (mean [SD], -7.7 [11.7]) than in the placebo group (+ 1.5 [9.3]; p = 0.042). There were no significant differences between treatment groups in change from baseline to week 8 in other patient-reported measures, lung function, or the 6-minute walk distance. Five patients reported adverse events. Chest infections were diagnosed in one patient in each treatment allocation group. In the AKL1 group, one patient reported nightmares and one patient had right shoulder pain at the baseline visit; and one patient had influenza at the final visit.

Conclusion Further study is needed with a larger patient population and over a longer duration to better assess the effects of add-on therapy with AKL1 in COPD

P230 SYMPTOMATIC BENEFIT OF OLODATEROL QD DELIVERED VIA RESPIMAT® VS PLACEBO AND FORMOTEROL BID IN PATIENTS WITH COPD: COMBINED ANALYSIS FROM TWO 48-WEEK STUDIES

¹A Koch, ²P Paggiaro, ³A Hamilton, ³L Hart, ⁴L Korducki, ⁵Mc De Salvo, ⁶E Pizzichini; ¹Medizinische Klinik III for Pneumology, Allergy and Sleep-Medicine, University Hospital Bochum-Bergmannsheil, Bochum, Germany; ²Dipartimento Cardio-Toracico e Vascolare, Università di Pisa, Pisa, Italy; ³Boehringer Ingelheim, Burlington, Ontario, Canada; ⁴Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, Connecticut, USA; ⁵Centro Médico Dra. De Salvo/Fundación Respirar, Buenos Aires, Argentina; ⁶NUPAIVA