

adjustment for FEV<sub>1</sub>, 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

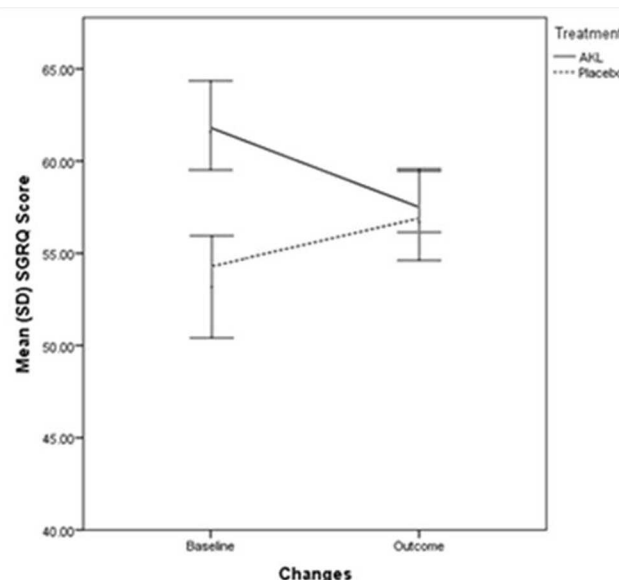
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**Background** Treatment for chronic obstructive pulmonary disease (COPD) includes both bronchodilating and anti-inflammatory therapies. However majority of patients with COPD show corticosteroid resistance and alternative therapies are need. AKL1 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

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