and, with pressurised metered-dose inhalers (pMDIs), the failure to inhale “slowly”. We present an easy to remember ‘2–3–4’ training paradigm, designed to address these errors, that was used in an open-label, cross-over study comparing patient handling of fluticasone propionate/formoterol (FP/FORM; *flutiform*[®]) breath-actuated inhaler (BAI) and pMDI devices. Here we present the pMDI data.

Methods The study was carried out in 311 patients (≥ 12 years) with persistent asthma (64%), COPD (28%), or both asthma and COPD (8% of patients). Patients were randomised to one of two sequences (BAI/pMDI or pMDI/BAI). Patients were trained to correctly use each device prior to an assessment of correct handling according to prespecified criteria. Eight steps were assessed including, but not limited to: exhale ≥ 2 s; inhale ≥ 3 s; hold breath ≥ 4 s: the 2–3–4 technique. Patients were assessed on a single device (BAI or pMDI) at each visit, with 7–21 days between the two visits.

Results Overall, 77.2% of patients demonstrated correct performance of all steps of FP/FORM pMDI use at their first attempt post-training (N = 307); a further 14.0% required 2 attempts. 99.3% of patients were successfully trained within 15 min. Step 2 (Removes cap) and steps 4–6 (Places upright in mouth; starts inhaling and actuates; inhales for at least 3 s) were considered critical steps, and 82.4% of patients demonstrated correct performance of all 4 critical steps at their first attempt post-training. 96.1%, 87.6% and 95.8% of patients correctly followed each component of the ‘2–3–4’ training paradigm with the pMDI at the first attempt post-training (exhale ≥ 2 s, inhale ≥ 3 s; hold breath ≥ 4 s, respectively).

Conclusions Almost all patients can be rapidly taught to use a pMDI (within 15 min) using a simple training method suitable for all clinical settings. An easy to remember, sequential “2–3–4” paradigm is effective in encouraging patients to exhale to residual volume, to inhale slowly, and to breath hold satisfactorily: manoeuvres that are frequently performed incorrectly without such instruction.

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EVALUATION OF INHALER TECHNIQUE MASTERY FOR BUDESONIDE FORMOTEROL SPIROMAX[®] COMPARED WITH SYMBICORT TURBOHALER[®] IN ADULT PATIENTS WITH ASTHMA: PRIMARY RESULTS FROM THE EASY LOW INSTRUCTION OVER TIME (ELIOT) STUDY

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Introduction and objectives Technical errors in the use of inhalers are associated with poor asthma control. This study evaluated achievement of mastery in a training environment using a randomised cross-over design (stage 1), followed by randomization into a prospective 12-week trial to assess maintenance of mastery in patients receiving inhaled corticosteroids (ICS)/long-acting β_2 -agonists (LABA) via SPIROMAX versus ICS/LABA received via TURBOHALER (stage 2).

Methods Patients with asthma were randomised to a 6-step training protocol using empty Spiromax and empty Turbohaler devices. The proportion of patients achieving and maintaining inhaler mastery, respectively defined as the absence of health care professional (HCP)-observed errors by training step 3 (instructional video) in stage 1, and the absence of HCP-observed errors after 12 weeks of inhaler use in stage 2, were analysed using logistic regression. The maintenance of independent expert video-observed inhaler mastery was analysed using logistic regression. Total observed errors (HCP and technology) were analysed using a negative binomial regression model. Vitalograph Pneumatic Spirometry results were compared using a Mann Whitney U test.

Results A total of 493 (89.1%) patients (stage 1) and 305 (61.9%) (stage 2) were eligible for the full analysis set. The odds of maintaining inhaler mastery were not significantly different

Abstract P154 Table 1

Inhaler technique variables		Spiromax	Turbohaler	p-value [‡]	Odds ratios (95% CI) [§]	Rate ratios (95% CI)	Treatment difference (95% CI) [*]
Inhaler mastery achievement, stage 1, n (%) [*]	Yes	454 (94)	418 (87)	<0.001	3.77	—	—
	No	27 (6)	63 (13)		(2.05–6.95)		
Inhaler mastery maintenance, stage 2, n (%) [†]	Yes	89 (59)	82 (53)	0.316	1.26	—	—
	No	62 (41)	72 (47)		(0.80–1.98)		
Total HCP-observed errors, mean (SD)	—	0.50 (0.67)	0.81 (1.10)	—	—	0.61 (0.44–0.84)	—
HCP-observed mastery assessed by independent video review, n (%)	Yes	122 (81)	92 (60)	0.001	2.84	—	—
	No	29 (19)	62 (40)		(1.69–4.76)		
Change in 6-item Asthma Control Questionnaire, week 12, mean (SD)	—	-0.22 (0.95)	-0.36 (1.05)	—	—	—	0.13 (-0.10–0.37)

^{*}In stage 1, 493 patients were randomly assigned to either empty Spiromax followed by empty Turbohaler or empty Turbohaler followed by empty Spiromax. Achieving inhaler mastery was defined as the absence of HCP-observed errors by the end of step 3 of a 6-step standardised inhaler training protocol for empty Spiromax compared to empty Turbohaler inhalers; [†]In stage 2, 305 out of 395 patients (61.9%) patients were eligible for the full analysis set. Maintaining inhaler mastery was defined as the absence of HCP-observed errors after 12 weeks of inhaler use;

[‡]The p-value for the treatment comparison is based on chi-square. p < 0.05 considered statistically significant; [§]Logistic regression; ^{||}Negative binomial regression; ^{*}Analysis of variance; CI: confidence interval; HCP: Health care professional; SD, standard deviation.

for patients using either inhaler, although achieving inhaler mastery was significantly greater in patients using Spiromax compared with Turbohaler at baseline. A higher, non-significant percentage of patients using Spiromax maintained inhaler mastery (assessed by HCPs). This result was supported by significantly higher odds of maintaining mastery when HCP errors were calibrated using independent video assessment in patients using Spiromax (consented videos available for 243/305 patients [79%]). Maintaining inhaler mastery improved asthma control in both treatment groups and was not significantly different (Table 1).

Conclusions The proportion of patients achieving inhaler mastery at baseline was significantly greater for Spiromax compared with Turbohaler; no significant difference was found in inhaler mastery at 12 weeks. Patients using Spiromax made significantly fewer errors overall (HCP-observed and HCP- and technology-observed) than patients using Turbohaler. Maintaining inhaler mastery improved asthma control in both treatment groups. Independent video assessment can assist HCPs in evaluating device mastery, and is proposed as the gold standard in such studies.

P155 FLUTICASONE FUROATE (FF)/VILANTEROL (VI) ONCE DAILY REDUCES RESCUE MEDICATION USE BOTH DAY AND NIGHT

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Introduction and objectives FF/VI is the first once daily inhaled corticosteroid/long-acting β_2 -agonist combination available for the treatment of asthma. Data from five phase III studies that have previously been presented have generally demonstrated a sustained 24 h improvement in lung function and improvement in rescue-free 24 h periods compared with placebo (P), FF alone or fluticasone propionate (FP). Due to differences in study comparators, duration of study and primary endpoints, integration of the study results has not been possible therefore each study is considered separately.

Methods Post-hoc analyses of diary card data from the 5 studies were performed to examine whether there was any difference in the contribution of the day and night time rescue medication use to the 24 h rescue-free period. Patients recorded in an electronic diary card the number of inhalations of rescue salbutamol/albuterol inhalation aerosol used during the day and night.

To be counted as rescue-free during the day or night the patient needed to record a no use of rescue medication during that period.

Results The post-hoc analyses demonstrated that the improvements in day and night time rescue-free periods were similar to the 24 h rescue free periods. See Figure 1 below.

Conclusions In general the benefit of FF/VI on rescue free 24 h periods is reflected in the improvements seen in day and night time rescue use.

Abstract P155 Figure 1