

prednisolone. Procedures were performed by 2 physicians or by 1 physician and a nurse, using conscious sedation with alfentanil and midazolam. One patient required deeper sedation [remifentanyl and propofol] due to a complicated medical history. Bronchial thermoplasty was administered in three sessions, treating the right lower lobe, the left lower lobe and both upper lobes respectively. Follow up is at 3 monthly intervals for both safety and efficacy outcomes.

Results Between 2nd June 2011 and 30th April 2012, ten patients underwent bronchial thermoplasty in Glasgow [7 males, 3 females] (Table 1). Six patients were at Step 5 and four at Step 4 of the British Guideline on the Management of Asthma scale. 4/10 were taking oral prednisolone daily and 2/10 were receiving omalizumab treatment [for 4th year and 3rd year respectively]. Treatment sessions were largely uneventful and adverse effects were similar to those reported in clinical trials. To date, there has been a reduction in some asthma medications: two patients receiving omalizumab have successfully discontinued treatment; those taking oral steroids are being weaned off prednisolone.

Conclusion Bronchial thermoplasty can be safely delivered in a clinical setting to patients with severe asthma.

References

1. Thomson NC, Bicknell S, Chaudhuri R Bronchial thermoplasty for severe asthma. *Curr Opin Allergy Clin Immunol* 2012; 12:241–248.

Abstract P5 Table 1 Baseline demography of 10 patients with severe asthma treated with bronchial thermoplasty

	Mean [SD]	Min–Max
Age (years)	48 [10]	35–65
Beclometasone equivalent ICS dose (µg)	2580 [1425]	1000–6000
ACT Score	11.3 [4.27]	6–20
AQLQ Score	3.94 [0.83]	2.7–5.1
HADS Total	11.6 [8.7]	2–27
FEV ₁ (L)	2.55 [0.6]	1.6–3.46
FEV ₁ (% predicted)	71.4 [16.8]	43–96
Exhaled nitric oxide (ppb)	43 [40]	2.7–126
Exacerbations in past 12 months	2.9 [3.1]	0–8
Hospital admissions/A&E in past 12 months	1 [1.9]	0–5

Abbreviations ACT=asthma control test; AQLQ=asthma quality of life questionnaire; HADS=hospital anxiety and depression scale, FEV₁=forced expired volume in one second.

P6 FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY HAS AN EFFICACY PROFILE SIMILAR TO THAT OF ITS INDIVIDUAL COMPONENTS ADMINISTERED CONCURRENTLY

doi:10.1136/thoraxjnl-2012-202678.147

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Background A new asthma therapy containing a combination of the inhaled steroid fluticasone propionate (FLUT) and the long-acting β_2 agonist (LABA) formoterol fumarate (FORM) in a metered-dose inhaler has been developed (FLUT/FORM; *flutiform*®). In a double-blind, double-dummy, randomised, multicentre, four arm parallel group study, the efficacy and safety of FLUT/FORM vs. FLUT and FORM administered concurrently (FLUT+FORM) was assessed. Here we present efficacy results of a post-hoc subgroup analysis comparing FLUT/FORM 500/20 µg vs. FLUT+FORM 500 µg + 24 µg (both twice-daily) by baseline asthma severity.

Methods In total, 620 patients were randomised 1:1:1:1 to receive FLUT/FORM 500/20 µg, FLUT/FORM 100/10 µg, FLUT+FORM

500 µg + 24 µg or FLUT 500 µg. Randomisation was stratified by percentage predicted FEV₁ at baseline [≥ 40 – ≤ 60 % ('severe asthma'; 52% of patients) vs. > 60 % – ≤ 80 % ('moderate asthma'; 48% of patients)], allowing a post-hoc dichotomised analysis by baseline FEV₁ severity of spirometric and symptom-based endpoints.

Results Similar improvements in lung function (change in pre-dose FEV₁ and change in 2-hour post-dose FEV₁) were seen in the FLUT/FORM 500/20 µg treatment group and the FLUT+FORM 500 µg + 24 µg treatment group overall [treatment difference 0.079 (95% CI: –0.032, 0.190) $P=0.164$ and treatment difference 0.040 (95% CI –0.069, 0.149) $P=0.471$, respectively]. Both severe and moderate asthmatic subgroups demonstrated mean changes from baseline approximating or exceeding a minimally important improvement (200 mL)¹ with similar efficacy in the FLUT/FORM 500/20 µg and the FLUT+FORM 500 µg + 24 µg moderate and severe subgroups (Table 1).

There were no statistically significant or clinically relevant differences overall or in either of the subgroups between FLUT/FORM 500/20 µg and FLUT+FORM 500 µg + 24 µg for any symptom-based endpoints. These included asthma symptom scores, sleep disturbance scores, rescue medication use and asthma control days.

Conclusion FLUT/FORM and FLUT+FORM demonstrated similar improvements in lung function (pre-dose and 2-hour post dose FEV₁) and symptom-based endpoints in the overall population, and in both subgroups.

Abstract P6 Table 1 Summary of LS mean changes from baseline for spirometric endpoints, overall and stratified by FEV₁ % predicted – ITT population

Endpoint	FLUT/FORM 500/20 µg n=154	FLUT + FORM 500 µg + 24 µg n=156
Change in pre-dose FEV ₁ from Day 1 to Day 56		
All patients	0.346	0.267
Treatment difference (95% CI)		0.079 (–0.032, 0.190)
P-value		$P = 0.164$
FEV ₁ ≤ 60 % subgroup	0.414	0.353
Treatment difference (95% CI)		0.061 (–0.108, 0.231)
P-value		$P = 0.477$
FEV ₁ > 60 % subgroup	0.260	0.173
Treatment difference (95% CI)		0.087 (–0.053, 0.227)
P-value		$P = 0.222$
Change in pre-dose FEV ₁ from pre-dose Day 1 to 2-hours post-dose Day 56		
All patients	0.517	0.477
Treatment difference (95% CI)		0.040 (–0.069, 0.149)
P-value		$P = 0.471$
FEV ₁ ≤ 60 % subgroup	0.569	0.577
Treatment difference (95% CI)		0.007 (–0.172, 0.157)
P-value		$P = 0.930$
FEV ₁ > 60 % subgroup	0.449	0.367
Treatment difference (95% CI)		0.082 (–0.056, 0.221)
P-value		$P = 0.244$

P7 ASSESSING THE INTUITIVE EASE OF USE OF A NOVEL DRY POWDER INHALER, THE FORSPIRO™ DEVICE, FOR ASTHMA AND COPD

doi:10.1136/thoraxjnl-2012-202678.148

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Poor inhaler technique has been recognised as a significant contributor to poor control.⁽¹⁾ A number of authors have attempted