

with exacerbations defined as asthma related hospital, accident and emergency or out-of-hours attendance, GP consultations for lower respiratory tract infection and/or use of acute oral steroids (where asthma related includes all events with a lower respiratory Read code). All patients had 2 years of data: 1 year before and 1 year post therapy switch.

Results Out of a total of 365 patients, 334 had complete data for the analysis. 80 of these received a lower dose of BDP/FOR while 254 received an equivalent dose. In the year immediately before their therapy review, 69.5% (n=232) of patients had no exacerbations, compared to 76.9% (n=257) of patients following the review ($p=0.075$ Wilcoxon signed ranks). Prior to review, 20.4% of patients had 1 exacerbation compared with 12.0% of patients after the change, while 10.2% of patients had >1 exacerbation compared with 11.1% of patients following the review.

Conclusion These data suggest an increase in the number of patients not suffering from exacerbations and no deterioration in the number of exacerbations following the alteration in therapy. This indicates that BDP/FOR can be a valid therapy change in real-world patients on existing FDC ICS/LABA therapy.

P3 OXIDATIVE DISTRESS AND ANTIOXIDANTS IN SEVERE ASTHMA

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Background The role played by oxidative stress (OS) burden and antioxidant (AO) defences in severe asthma (SA) have been inconsistent.

Aims To compare levels of OS markers and AO between subtypes of SA, mild asthma (MA) and control (N).

Methods A longitudinal case control study (2009–2010) included 15 N, 15 corticosteroid naive MA, 10 SA not dependent on oral corticosteroids (OCS), 10 SA dependent on OCS (NOCS) and 10 type-1 brittle asthma (BA). Subjects taking vitamin supplementation were excluded. Serum AO – vitamin A (vit-A) and E (vit-E), copper(Cu), selenium(s) and zinc (Zn) were measured at first visit. Exhaled breath condensate (EBC) nitrate and 8-isoprostane(iSo), Fractional exhaled Nitric Oxide (FeNO) were measured on 3 visits 3 weeks apart as markers of OS. OS and AO markers were correlated with asthma-severity.

Results Sixty subjects were recruited (16 males, age 19–57 yrs). 8-iSo was not detectable in all of our samples. Significant correlations ($p<0.05$) between AO and OS markers are given in the table below

Abstract P3 Table 1

	Vit A	Vit E	Cu	Se	Zn
FEV1	-0.268	-0.436	-0.367	NS	NS
FeNO	0.286	NS	NS	NS	NS
EBC nitrate	0.369	NS	NS	NS	NS

NS- not significant.

Between group analyses revealed correlation of FeNO with increasing asthma-severity, but EBC nitrate did not differ significantly amongst the 5 groups. Vit-A was significantly higher in OCS group, and vit-E was significantly higher in the OCS, NOCS and BA groups as compared to N. There was no significant difference between the 5 groups in Cu, Zn or Se levels. Regression analysis identified age, height, and vit-E as best predictors of FEV1.

Conclusion This study indicates paradoxically increased levels of some of the AO in severe asthmatics. We hypothesise that the mechanics by which AO counteracts the OS in severe asthmatics

could be impaired rather than AO deficiency. This needs to be researched further in larger studies.

P4 OMALIZUMAB: A NATIONAL REVIEW OF PRACTISE ACROSS THE UNITED KINGDOM

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A varied approach to the initiation, assessment and delivery of Omalizumab across the United Kingdom has been observed. To analyse the disparity in practise a questionnaire was disseminated to centres administering Omalizumab. Completed questionnaires n=43 (32.5% paediatric/67.5% adult). Questions asked were specific to the initiation, assessment and delivery of Omalizumab, the results identified a wide disparity in practise.

Adherence assessment prior to Omalizumab initiation was completed by all centres; however there was a varied approach of each centre in their assessment. 90.6% assessed prescription records, 74.4% questioned patients regarding medication adherence, 32.5% measured prednisolone levels and 4.6% utilised a validated questionnaire (4.6%) Longitudinally 48.8% continue to monitor adherence every 0–6 months, 27.9% every 6–12 months whilst 11.6% do not cheque adherence long term. Centres were diverse in their period of recommended observation post first dose. 4.6% advocate a 0–60 minute observation, 25.5% 1–2hrs, 39.5%, 2–3 hrs and 23.3% >4hrs, subsequent dose administration also varied across centre 37.2% advocated a 0–30min observation, 25.5% a 30–60min period and 11.6% 2–3hrs (11.6%). Paediatric centres advocated a longer observation period post injection. Across centres there is a huge inconsistency in weight observation 46.5% of centres weigh patients each visit, 27.9% 1–3 monthly and 16.2% 3–6 monthly. Dose of Omalizumab is only altered specific to weight fluctuation by 60.4% of which a higher percentage is practised in paediatric compared to adult centres (71.4%/55.1%). Out of dosing range prescribing is undertaken by 57.1% (paediatric) 29% (adult). Use of adrenaline auto injectors were not advocated by 60.4% of the centres, of the remaining 39.5% who advocate adrenaline auto injectors only 47% of this population have specific guidance relating to length of time to keep the injector available.

Results of this audit provide evidence for the requirement for national evidence based guidelines, to procure a standardised collaborative approach regarding the use of Omalizumab for patients with severe persistent allergic asthma, with this in situ best practise can be delivered throughout the United Kingdom.

P5 INTRODUCING BRONCHIAL THERMOPLASTY TREATMENT INTO A SEVERE ASTHMA CLINICAL SERVICE

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Introduction and Objectives Bronchial thermoplasty involves the delivery of radio frequency energy to the airways during flexible bronchoscopy, and possibly exerts its effect by reduction of airway smooth muscle mass (1). Clinical trials of bronchial thermoplasty have shown benefits in the treatment of patients with moderate or severe asthma. We describe our experience of introducing bronchial thermoplasty into a severe asthma clinical service.

Methods Funding was obtained from the Greater Glasgow and Clyde NHS Health Board to evaluate bronchial thermoplasty in the treatment of ten patients with moderate to severe asthma. Patients were assessed at the Difficult Asthma Clinic and selected for the procedure using criteria similar to those employed in clinical trials of bronchial thermoplasty. Patients on all forms of asthma medication were eligible for treatment including omalizumab and oral

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

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Background A new asthma therapy containing a combination of the inhaled steroid fluticasone propionate (FLUT) and the long-acting β₂ 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)
<i>P</i> -value		<i>P</i> = 0.164
FEV ₁ ≤60% subgroup	0.414	0.353
Treatment difference (95% CI)		0.061 (-0.108, 0.231)
<i>P</i> -value		<i>P</i> = 0.477
FEV ₁ >60% subgroup	0.260	0.173
Treatment difference (95% CI)		0.087 (-0.053, 0.227)
<i>P</i> -value		<i>P</i> = 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)
<i>P</i> -value		<i>P</i> = 0.471
FEV ₁ ≤60% subgroup	0.569	0.577
Treatment difference (95% CI)		0.007 (-0.172, 0.157)
<i>P</i> -value		<i>P</i> = 0.930
FEV ₁ >60% subgroup	0.449	0.367
Treatment difference (95% CI)		0.082 (-0.056, 0.221)
<i>P</i> -value		<i>P</i> = 0.244

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

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