S9 EQUIVALENCE OF FLUTICASONE PROPIONATE/ SALMETEROL DELIVERED VIA AIRFLUSAL® FORSPIRO® AND SERETIDE® ACCUHALER® IN ADOLESCENT AND ADULT ASTHMA

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Introduction and objectives Guideline-defined asthma control may be achieved and maintained in the majority of patients by treatment with a combination of a corticosteroid and a long-acting ß$_2$-agonist. AirFluSal® Forspiro®, a multi-dose dry powder inhaler (mDPI), provides this proven combination of inhaled corticosteroid fluticasone propionate (FP) and a long-acting inhaled ß$_2$-agonist salmeterol (Sal). This study compared the efficacy of AirFluSal® Forspiro® with Seretide® Accuhaler® in adolescent and adult patients with moderate-to-severe persistent asthma.

Methods This study, conducted in 279 patients (12–65 years) with GINA guideline-defined moderate-to-severe persistent asthma, was undertaken as a double-blind, double-dummy, parallel-group, multicentre trial. Patients were randomised to 12 weeks treatment with AirFluSal® Forspiro® 500 µg/50 µg, or Seretide® Accuhaler® 500 µg/50 µg. Primary efficacy measures were the change from baseline of the forced expiratory volume in 1 s (FEV_1) to show non-inferiority of AirFluSal® Forspiro® to Seretide® Accuhaler® (non-inferiority margin Δ = -0.200 L) and the area under the FEV_1 curve at study termination ($AUC_{0–12}$). Secondary endpoints included mean changes in FEV_1, FEV_1% predicted, morning peak expiratory flow (PEF) and global evaluation of efficacy. Safety was assessed and patient preference for each device was rated using a visual analogue scale (VAS).

Results Assessment of the effect of treatment on the absolute change in FEV_1 from baseline to study termination demonstrated non-inferiority between AirFluSal® Forspiro® and Seretide® Accuhaler® (difference in least squares mean [95% CI] = -0.032 L [-0.121;0.057]). Assessment of $AUC_{0–12}$ at study termination demonstrated equivalence between devices. All secondary efficacy measures demonstrated comparable results for both inhalers, with no significant differences observed. The use of rescue medication and the average asthma symptom scores decreased from baseline in a similar manner for both devices. Overall safety profiles were equivalent. Patient ratings for each device were 81.97 ± 13.89 mm VAS for AirFluSal® Forspiro® and 79.67 ± 16.48 mm VAS for Seretide® Accuhaler® (data includes 276 patients randomised at baseline to use the devices at a dose of 100 µg/50 µg).

Conclusions AirFluSal® Forspiro® shows therapeutic equivalence to Seretide® Accuhaler®, providing a proven combination treatment in an intuitive, easy-to-use device.

S10 THE IMPACT OF OMALIZUMAB ON LUNG FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH SEVERE ALLERGIC ASTHMA IN UK CLINICAL PRACTICE: A MULTI-CENTRE PROSPECTIVE OBSERVATIONAL STUDY – APEX II

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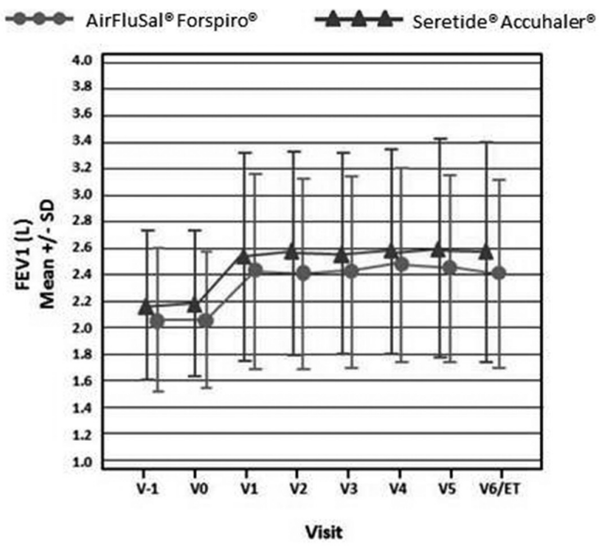
Background A previous retrospective UK study (APEX I) demonstrated omalizumab significantly reduced oral corticosteroid (OCS) use, exacerbations, lung function and quality of life (QoL in severe allergic asthmatic (SAA) patients.

Aim This multi-centre observational study was conducted to confirm the observed retrospective findings prospectively.

Methods Retrospective data were collected 12 months prior to and prospective data were collected 12 months following omalizumab initiation in SAA patients ≥16 years. The primary endpoint was the change in mean daily oral corticosteroid (OCS) dosage. Secondary endpoints included changes in lung function, ACT and AQLQ scores and missed days in education/work and



Abstract S9 Figure 1 Effect of treatment on baseline* FEV_1 by inhalation with AirFluSal® Forpiro® 500 µg/50 µg or Seretide® 500 Accuhaler®

employment in the 12 months pre and post omalizumab initiation.

Results 258 patients were enrolled from 22 UK centres (January 2012–February 2015); mean age 44.7 years (±SD 14.2), 65% females, mean asthma duration 25.1 years (±SD 15.1) For the ITT population (n = 235), 82.4% of patients were classified as responders. At 12 months, mean daily OCS dose significantly decreased by 16% from 10.3 mg/day (±7.1) to 8.7 mg/day (±8.6) (n = 211, p < 0.001) and 61.6% of patients stopped OCS or reduced OCS dose by ≥20%. The mean (±SD) FEV_1 significantly increased from 66.9% (±19.35%) to 71.3% (±20.9%) in the 12 months post compared to pre- omalizumab initiation (p < 0.001 n = 118). Comparing the 12 months periods prior to and following initiation of omalizumab, the mean ACT score improved from 9.8 (±4.3) to 14.4 (±5.7) (n = 162, p < 0.001) and the mean AQLQ score improved from 3.2 (±1.3) to 4.4 (±1.5) (n = 161, p < 0.001). There was a significant decrease in missed days from work/education following omalizumab initiation (12 months pre-omalizumab: 14.65 days; 12 months post-omalizumab 6.22 days with p < 0.01; n = 63). For 93 patients unemployed/not in education at the study start, 72 were unemployed/not in education at study end.

Conclusions The data prospectively confirm that omalizumab is associated with significant reduction in OCS use, lung function, ACT, AQLQ and days missed from work/education.

S11 AUDIT OF THE SAFETY OF BRONCHIAL THERMOPLASTY USING A NATIONAL REGISTER AND HOSPITAL EPISODE STATISTICS

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Introduction and objectives NICE Guidance for bronchial thermoplasty (BT) recommends the collection of long term safety evidence. In this study we assess patient characteristics and safety outcomes using the British Thoracic Society (BTS) UK Difficult Asthma Registry (DAR) and the Hospital Episodes Statistics (HES) database.

Methods BT patient records were extracted from DAR. HES was searched for episodes from 1st April 2011 to 31st January 2015 with OPCS-4 code combinations known to be used for BT; for these patients, inpatient and A&E episodes were extracted in a second search from 1st April 2010 to 31st January 2015.

DAR and HES were reviewed for complications, post-procedure stay, 30-day readmissions and A&E attendances. Using anonymised matching, records from both sources were used to calculate combined safety outcomes. As BT is usually delivered in three treatments, first, second and third BT procedures were analysed separately.

Results Details of 215 BT procedures (83 patients) were extracted from DAR and 203 procedure episodes (85 patients) were extracted from HES, of which 152 procedures (59 patients) matched. In comparison with three clinical trials (AIR, AIR2 and RISA), patients receiving BT in routine clinical practice were on average older, had worse baseline FEV_1 (except for RISA trial) and had lower AQLQ scores (Table 1).

There were no significant differences in outcomes between first, second and third BT procedures; hence rates for all three procedures were combined for the matched cohort (Table 1). In the matched cohort, 27% (41/152) of procedures were associated with a complication, readmission or A&E attendance. This is higher than reported hospitalisation rates for the AIR2 8.4% (16/190) and AIR trials 7.3% (4/55), and comparable with the RISA trial, 26.7% (4/15).

Conclusion We present the safety of BT in routine clinical practice using combined information from a clinical register with good coverage and routine administrative data. It is likely that the clinical practice has been to treat patients with severity levels of asthma comparable to that seen in the RISA trial (high severity), compared to those used in the pivotal trial AIR2 or AIR studies, (moderate to severe), nevertheless these findings warrant further study.

Abstract S11 Table 1 Baseline characteristics and safety outcomes

(a) Baseline characteristics of BT patients and control (C) groups

	DAR	AIR2 trial	AIR trial	RISA trial
Mean age (years)	43.5 ± 12.0 (n = 83)	40.7 ± 11.9 (BT, n = 190)	39.4 ± 11.2 (BT, n = 55)	39.1 ± 13.0 (BT, n = 15)
	Range 21–69	40.6 ± 11.9 (C, n = 98)	41.7 ± 11.4 (C, n = 54)	42.1 ± 12.6 (C, n = 17)
% female	71	57 (BT), 61 (C)	56 (BT), 57 (C)	60 (BT), 41(C)
Pre-bronchodilator FEV_1	70.2 ± 21.8 (n = 65)	77.8 ± 15.7 (BT)	72.7 ± 10.4 (BT)	62.9 ± 12.2 (BT)
(% of predicted)	Range: 18–109	79.7 ± 15.1 (C)	76.1 ± 9.3 (C)	66.4 ± 17.8 (C)
AQLQ score	3.74 ± 1.13 (n = 48)	4.30 ± 1.17 (BT)	5.6 ± 1.1 (BT)	3.96 ± 1.34 (BT)
	Range 1.0–6.31	4.32 ± 1.21 (C)	5.7 ± 0.9 (C)	4.72 ± 1.06 (C)

(b) Safety outcomes in matched DAR-HES cohort

	n	% (95% CI)
Procedures with complications	17/152	11.2 (6.7 – 17.3)
Procedures followed by readmission within 30 days due to respiratory events	27/152	17.8 (12.0 – 24.8)
Procedures followed by A&E attendance within 30 days due to any cause	13/152	8.6 (4.6 – 14.2)
Procedures followed by overnight stay	70/152	46.1 (37.9 – 54.3)