benefits. Direct prescription of LTOT from primary care by comparison carries a risk of inadequate initial assessment and follow-up.

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Managing asthma: inhaled therapy and beyond

P107 EFFECTIVENESS OF OMALIZUMAB ON ASTHMA CONTROL AND LUNG FUNCTION IN SEVERE ALLERGIC ASTHMA PATIENTS IN THE CZECH REPUBLIC

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Introduction Anti-IgE therapy (omalizumab) is indicated for severe persistent allergic asthma, which is uncontrolled despite appropriate therapy according to current GINA guidelines.

Aim of this study Aim of this study was to describe changes of selected parameters (FEV₁, life quality and FeNO₅₀) in all patients treated with omalizumab in the Czech Republic for more than 12 months in a real life clinical setting.

Methods Data of 127 patients treated 12 months by omalizumab in eight Czech centres were prospectively observed in Czech Anti-IgE Registry and analysed. Respiratory specialist and allergist together decided indication of anti-IgE therapy after extensive evaluation process in each patient.

Results Median IgE level was 223 IU/ml, all patients experienced during previous year at least two exacerbation treated by oral steroid burst. 69 patients were dependent on oral steroids, mean dose 5 mg prednisolone/day. After 12 months of omalizumab therapy FEV₁ improved from 65% to 72% ($p < 0.001$), asthma control test changed from 13 to 18 points score ($p < 0.001$) and FeNO₅₀ decreased from 48 to 32 ppb ($p = 0.001$). Emergency visits, steroid bursts for asthma exacerbation and mean oral steroid dose were lower after the 12 months of therapy as well (all $p < 0.001$). Observed side effects were mild (headache, weight gain) in 21.3% patients. Overall response to anti-IgE therapy measured by clinical evaluation of treatment benefit was 80.8%.

Conclusion Rigorous selection of candidates for anti-IgE therapy based on consensus of allergology and respiratory specialists leads to

very good therapeutic response, we have observed significant improvement in lung functions.

P108 OMALIZUMAB FOR SEVERE ALLERGIC ASTHMA: COST-EFFECTIVE OR PRICELESS?

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Background Omalizumab is licensed for the treatment of severe allergic asthma to help reduce severe exacerbations. However the decision as to whether to consider Omalizumab therapy is based on a 16 week assessment period with no reference to the licensed indication at all! We were therefore keen to examine omalizumab efficacy in terms of exacerbation reduction in our severe asthma clinic.

Methods 40 patients had received omalizumab treatment for at least 12 months, on the basis of a successful 16 week assessment period. Hospital and GP records were scrutinised to assess exacerbation frequency and unscheduled hospital attendance before and after treatment. Costs for asthma admissions, attendance for clinic and price per omalizumab vial were analysed. In addition a repeat patient survey was undertaken to assess satisfaction with therapy and our service using a previously validated tool.¹

Results Complete data was available for 20 patients. A sequential education in unscheduled hospital; contacts was seen throughout the first year following commencement of omalizumab. Average cost savings on unscheduled hospital attendances were £2500 per annum. Average costs of attendance for injections were £2080 per annum. Treatment costs varied between £3250 and £26 000 per patient per annum. We did not have data on the absenteeism rates from those patients currently in full or part time employment. Patient satisfaction with both Omalizumab and the clinic set up remained high as in keeping with our previous assessment.

Conclusions

1. Omalizumab does reduce exacerbation frequency in patients with severe allergic asthma.
2. Patients are extremely satisfied with the efficacy of therapy.
3. The costs of reduced unscheduled care offset the costs of extra planned attendances for injections.
4. Although an expensive treatment, there may be many potentially hidden physical, social and economic benefits of omalizumab therapy.
5. Sophisticated health economic analysis is required to pursue this hypothesis.

FEV1 at the onset and after 12 months

Abstract P107 Figure 1 Spirometry after 12 months of omalizumab therapy.

Abstract P108 Figure 1 Total hospital contacts by intervals: first year before and first year after the start of treatment.

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P109 INTRAVENOUS AMINOPHYLLINE IN THE TREATMENT OF SEVERE ASTHMA: DO WE NEED ECG MONITORING?

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Introduction Intravenous (IV) aminophylline has an established role in the management of acute severe asthma, with beneficial bronchodilatory, anti-inflammatory and immunomodulatory effects. However, concern is often raised regarding its potential to prolong the QT interval and precipitate cardiac arrhythmias, given its catecholamine enhancing effect.¹ Despite this, the influence of IV aminophylline on electrocardiographic (ECG) parameters in patients with acute severe asthma is not fully known. We routinely perform 12-lead electrocardiography on all patients before and 24 h after commencing IV aminophylline.

Objective To evaluate the effect of intravenous aminophylline on ECG parameters in patients with acute severe asthma.

Method We assessed electrocardiographic parameters in 26 (21 female) consecutive patients, with a mean (SD) age of 48 (11) years, admitted with severe asthma. We measured serum electrolytes, aminophylline levels and ECG parameters at baseline and within 48 h of commencing IV aminophylline. ECGs were independently assessed by a cardiologist blinded to patient identity and ECG timings.

Results No significant difference in mean QTc, PR or QRS interval was found following treatment (Abstract P109 table 1). Furthermore, there was no difference in number of atrial or ventricular ectopics, T-wave amplitude or frequency of arrhythmias. However, in four patients the QTc was prolonged above the upper limit of normal (447 ms to 519 ms, 450 ms to 516 ms, 516 ms to 568 ms and 471 ms to 548 ms).

Abstract P109 Table 1

	Baseline	IV Aminophylline	p Value
QTc (ms)	460 (36.2)	466 (46.7)	0.49
QRS duration (ms)	84 (7.0)	84 (9.1)	1.00
PR (ms)	145 (20.6)	142 (16.3)	0.13
Aminophylline level (mg/l)	4.6 (4.4)	10.6 (2.2)	<0.001
Serum K ⁺ (mmol/l)	4.1 (0.4)	4.0 (0.3)	0.19

Data as mean (SD).

Conclusions These findings are largely reassuring with regard to the safety of IV aminophylline in severe asthma, in terms of its effects on standard electrocardiographic variables and the incidence of arrhythmias. There was, however, evidence of QTc prolongation in four subjects indicating a need for caution and ECG checks, especially with concomitant use of QT prolonging drugs.

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P110 FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY IS MORE EFFICACIOUS IN IMPROVING LUNG FUNCTION THAN ITS INDIVIDUAL COMPONENTS IN PATIENTS WITH ASTHMA

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Italy; ³SkyePharma, Muttenz, Switzerland; ⁴Mundipharma Research Limited, Cambridge, UK

Introduction and Objectives Combination therapy with an inhaled corticosteroid (ICS) and a long-acting β_2 -agonist (LABA) is the most effective treatment option for patients with asthma uncontrolled with ICS monotherapy.¹ In practice, asthma symptoms remain uncontrolled or only partly controlled in many patients. A new therapy option for asthma combining the ICS fluticasone propionate (FLUT) and the LABA formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; *flutiform*®), has been developed at doses of 100/10, 250/10 and 500/20 µg for twice-daily administration. In this analysis, data were pooled from up to five randomised, double-blind, parallel-group studies in order to assess the efficacy of FLUT/FORM in terms of improvement in lung function (as indicated by change in FEV₁).

Methods The analysis included adults and adolescents with a range of asthma severities who were treated for 8 or 12 weeks with FLUT/FORM (100/10, 250/10 or 500/20 µg twice daily) or the equivalent nominal dose of FLUT monotherapy (100, 250 or 500 µg twice daily; five studies) or FORM monotherapy (10 µg twice daily; three studies).

Results FLUT/FORM was associated with a significantly greater improvement in lung function, as indicated by change in FEV₁, compared with its individual components (Abstract P110 table 1). FLUT/FORM was superior to FORM with regard to change in pre-dose FEV₁ from baseline to study end; the least-squares (LS) mean difference for FLUT/FORM vs FORM was 0.13 l (95% CI 0.07 to 0.19; p<0.001). Similarly, FLUT/FORM was superior to FLUT with regard to change in FEV₁ from pre-dose at baseline to 2 h post-dose at study end (LS mean difference FLUT/FORM vs FLUT 0.15 l [95% CI 0.10 to 0.19; p<0.001]).

Conclusions The combination of fluticasone/formoterol in a single aerosol inhaler is more effective than fluticasone or formoterol given alone in improving lung function for patients with a range of asthma severities.

Abstract P110 Table 1

FLUT/FORM vs FORM*		
	FLUT/FORM (N = 341)	FORM (N = 345)
Mean FEV ₁ at baseline, L (SD)	2.33 (0.60)	2.34 (0.62)
Pre-dose at study end		
N	341	345
Mean FEV ₁ , L (SD)	2.53 (0.71)	2.4 (0.76)
LS mean change, L (95% CI)†	0.19 (0.15 to 0.24)	0.06 (0.02 to 0.10)

FLUT/FORM vs FLUT‡		
	FLUT/FORM (N = 641)	FLUT (N = 643)
Mean FEV ₁ at baseline, L (SD)	2.11 (0.62)	2.11 (0.65)
2 h post-dose at study end		
N	629	613
Mean FEV ₁ , L (SD)	2.52 (0.78)	2.38 (0.75)
LS mean change, L (95% CI)†	0.41 (0.38 to 0.44)	0.27 (0.23 to 0.30)

Study end was at week 8 or 12.

Analysis of covariance was calculated with treatment and baseline pre-dose forced expiratory volume at 1 s as covariates, and centre as a random effect.

*Pooled analysis from three studies to include only studies with treatment arms of equivalent nominal doses to FLUT/FORM.

†Least-squares mean change from baseline.

‡Pooled analysis from five studies to include only studies with treatment arms of equivalent nominal doses to FLUT/FORM.

FLUT, fluticasone propionate; FORM, formoterol fumarate.

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