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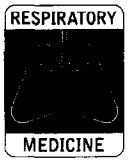

Fluticasone propionate: an audit of outcomes and cost-effectiveness in primary care

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Introduction

The inhaled corticosteroid fluticasone propionate (FP) was introduced into the Thorpewood General Practice, Norwich, U.K. in 1993 — initially in treating relatively severe asthmatics. Observed beneficial effects led to expanded use — particularly for poorly controlled asthma not responsive to increased inhaled anti-inflammatories. However, an early review suggested little advantage over existing agents (1), and FP was marketed at a price premium. The aims of this study were to investigate whether continued and expanding use of FP was justified in terms of improved clinical outcomes, and if such improvements were associated with reduced NHS costs (offsetting more expensive prescriptions). A controlled, retrospective, non-randomized primary care audit compared clinical outcomes and asthma management costs 1 year prior to and 1 year into FP therapy.

Patients and Methods

Patients studied were diagnosed asthmatics registered at the practice and monitored regularly. The treatment group comprised those patients ($n=21$) first prescribed FP during 1993. Their final year of treatment prior to FP therapy (Year 1) was compared with their first full year on FP (Year 2) (4/92–11/94). Changes in practice staff or clinical procedures can affect clinical outcomes and/or costs, and a second group of patients was included as a control for such non-drug effects. These patients ($n=24$) were first prescribed FP in 1994 subsequent to the period of study, and were followed over the 2-year period immediately preceding (1/92–7/94). The rationale for studying patients subsequently given FP was that their asthma was likely to be similar to the treatment group. Demographic and baseline comparisons were made and reasons for prescribing FP (and at what dosage) noted. The following asthma management data were collected and Year 1: Year 2 comparisons were made:

- Peak expiratory flow (PEF) measurements
- Number/type prescriptions — short-acting β_2-agonist inhalers, courses of oral prednisolone
- Number/type general practice consultations — surgery (GP/nurse) and home visits (day/night)
- Hospital attendance — outpatient/admissions

Where numbers justified formal statistical analysis and Year 1:Year 2 changes were normally distributed, paired *t*-tests were employed. Otherwise, the Wilcoxon signed-rank test was used (exact methods as appropriate). All tests were two-sided and used a significance level of 5%.

Healthcare and prescriptions were costed, and total management costs per patient were calculated. Sources for unit costs varied according to category but were generally based on practice/local authority estimates for 1994.

Results

BASELINE COMPARISONS

Demography (gender, smoking, asthma duration) was broadly similar. Median dosage of inhaled corticosteroid (beclomethasone dipropionate or budesonide) was the same for both groups (800 μg day^{-1}). Median FP dosage was 500 μg day^{-1}. The two main reasons for prescribing FP were persistent symptoms (around 50% patients in both groups) and frequent exacerbations (~20%).

CLINICAL OUTCOMES — YEAR 1: YEAR 2 COMPARISONS

- Percentage predicted mean PEF increased by a mean difference of 9·1% ($P=0·001$) in the FP group with little change in the controls.
- The median number of short-acting bronchodilator prescriptions was halved from 8 to 4 ($P=<0·001$) with no corresponding fall in the control group. There was a reduction from 39 to 19% in the proportion of FP patients prescribed 10 or more items.
- Among FP patients, the median number of prescriptions of oral prednisolone fell from 1 to zero ($P=0·037$), with the proportion having zero courses increasing from 29 to 71% [Fig. 1(a)].

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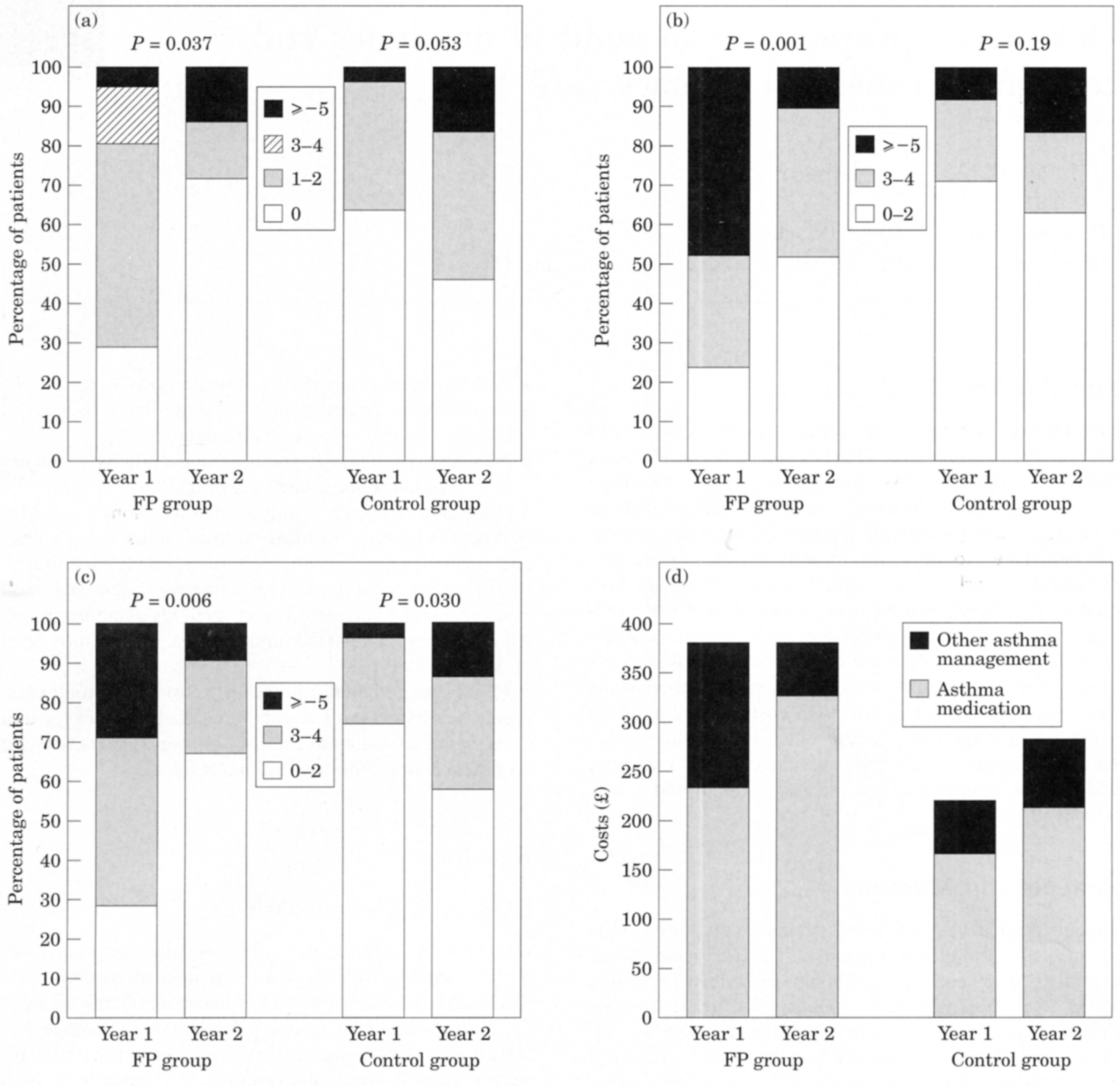

FIG. 1. (a) Number of oral prednisolone courses prescribed during each year. (b) Frequency of GP clinic visits during each year. (c) Frequency of nurse clinic visits during each year. (d) Change in mean patient asthma medication and other asthma management costs during each year.

- Surgery visits decreased significantly during FP treatment. The median frequency of GP consultations fell from 4 to 2 per year (P=0·001) [Fig. 1(b)], and for asthma nurse attendances from 4 to 1 (P=0·006) [Fig. 1(c)]. By contrast, control group GP consultations remained steady (median number 2) and nurse attendance increased (mean difference +0·9, P=0·03). Two notable reductions in the treatment group were (i) a 48 to 10% drop in the proportion of patients making five or more GP visits; and (ii) a 72 to 34% drop in the proportion seeing the asthma nurse three or more times.
- The small number of GP home visits and hospital attendances precluded statistical comparison, although there were recorded reductions in the FP group for Year 2.
- One patient (FP group) was admitted to hospital in Year 1.

COST COMPARISONS — YEAR 1: YEAR 2

The average percentage change in total costs per patient for the FP group was +0·5%(£2) – a 39%(£91) increase in medication costs almost completely offset by a 64%(£90) reduction in other management costs [Fig. 1(d)]. The control group was cheaper to manage throughout, but average total costs rose by 28%(£61) [drug +27%(£46), consultations +31%(£15)].

Discussion

Changes in all primary outcome criteria investigated — percentage predicted peak expiratory flow (PEF) as a measure of lung function, short-acting bronchodilator prescriptions as a marker for symptoms; oral prednisolone prescriptions for exacerbations and surgery attendance as an overall measure of asthma control — indicated that switching inhaled anti-inflammatory therapy to FP was associated with significant patient benefits.

- The increased percentage predicted peak flow observed during FP treatment is likely to be clinically significant, as studies with smaller changes in lung function have been associated with improved asthma symptom scores (2).
- The fall in the number of FP patients collecting 10 or more short-acting bronchodilator prescriptions (from 8 to 4) is of particular interest. 'Weaning off' reliever medication in a high-use group is often regarded as either medically or behaviourally difficult, with some studies finding *increased* bronchodilator prescribing associated with improving care or higher inhaled steroid prescribing (3,4).
- The decrease in GP and nurse consultations is hard to explain as a non-drug effect, since no reduction occurred in the control group. Moreover, the decrease is set against a trend of increased consulting generally and for asthma in particular (5).

Average asthma medication costs increased substantially more for FP patients than for the controls [39%(£91) *vs* 27%(£46)]. However, when other healthcare costs were taken into account, the increase in costs for FP treatment was very small — on average, 0·5%(£2) per patient. Moreover, this minimal increase was associated with a marked improved in 'healthiness' as measured by all the primary outcome markers, whereas increased costs for the control group brought no such improvement.

Apparent improvements seen in the FP treatment group might be due to increased patient adherence to the prescribed treatment regimes of a new drug, with attendant potential benefits. There was, however, no increase in repeat prescriptions to suggest significantly improved compliance, and any such effect is likely to be transient. Any benefit could also be due to an increase in effective inhaled corticosteroid dose, rather than the change to a new drug. However, the median dose of inhaled corticosteroids fell from 800 μg (BDP and budesonide) to 500 μg (FP). Changes in delivery device may also be cited, but there was little change in devices from Year 1 to Year 2.

The design limitations of this study — chiefly that it was retrospective and non-randomized — restrict the degree of data analysis that is justifiable and the extent to which observed effects may be interpreted as irrefutable fact. Selection of patients for the control group was not ideal but was, again, dictated by the retrospective nature of the study. However, and despite these limitations, the data collected strongly indicate that for asthmatics with persistent symptoms and frequent exacerbations, switching to FP therapy can bring an improvement in clinical outcomes and be cost-effective in terms of total NHS costs. In order to verify these initial findings, a prospective, clinically-controlled, double-blind study is currently being undertaken.

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