

Efficacy of fexofenadine in the prophylactic control of cat allergen–induced allergic rhinitis

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Background: To date, it is unknown whether fexofenadine mitigates the worsening of symptoms induced by the cat allergen *Felis domesticus* allergen 1.

Objective: To determine the effects of a single dose of fexofenadine hydrochloride, 180 mg, in preventing and controlling cat allergen–induced allergic rhinitis symptoms using the cat room challenge model.

Methods: This single-center, randomized, double-blind, placebo-controlled, 2-way crossover study consisted of a screening visit, 1 or 2 qualifying visits, and 2 treatment periods separated by a mean $\pm$ SD washout period of 14 ± 3 days. Patients were randomized to treatment sequence 1 (placebo followed by fexofenadine) or sequence 2 (fexofenadine followed by placebo). Baseline end points were obtained before study drug administration, and allergen challenges were initiated 1½ hours after dosing. The primary end point was the change from predose baseline in the total symptom score (sum of rhinorrhea, itchy nose/palate/throat, sneezing, and itchy/watery/red eyes) after 30 minutes of allergen exposure compared with placebo.

Results: Of 211 patients screened, 66 were randomized and 63 completed the study. Mean change in the total symptom score from predose baseline was significantly less with fexofenadine compared with placebo 30 minutes after initiation of the cat allergen challenge (2 hours after dosing) ($P = .03$). The overall incidence of treatment-emergent adverse events was low and comparable for both groups.

Conclusion: Prophylactic treatment with a single dose of fexofenadine hydrochloride, 180 mg, significantly mitigated the worsening of allergic rhinitis symptoms induced by exposure to cat allergen compared with placebo use.

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INTRODUCTION

In the United States, allergy to cat dander is a common complaint, yet its prevalence in patients with allergic rhinitis (AR) is not well known. Data from a population study of 6- to 24-year-old white male and female patients ($N = 4,295$) estimated that the frequency of allergy to the domestic cat was 2.8% in the overall sample population but approximately 25% in patients with AR.¹ As expected, the level of *Felis domesticus* allergen 1 (Fel d 1), the major cat allergen found in cat dander, is typically high in homes with cats.² It has been reported that cat dander is present in nearly all homes in the United States, regardless of whether a cat is present, suggesting that its presence may be sufficient to induce allergic symptoms.³ If left untreated, AR symptoms can possibly decrease a patient's quality of life (QoL).^{4,5}

It is difficult to remove cat allergen from the environment because it can remain airborne in undisturbed conditions for extended periods as a result of its adherence to walls, carpets, mattresses, and furniture.^{6,7} Because Fel d 1 is ubiquitous, avoidance of this allergen is difficult and unlikely, in partic-

ular for cat owners. Many individuals who experience cat allergies, therefore, require pharmacologic interventions (such as antihistamines or corticosteroids) to help control their allergen-induced AR symptoms.

Fexofenadine is a potent, selective, nonsedating, H_1 -receptor antagonist with proven efficacy in clinical symptom relief and in improving QoL in patients with seasonal AR (SAR) and chronic idiopathic urticaria.^{8–10} Because the symptoms of SAR and cat allergy are similar, antihistamine treatment would be expected to effectively alleviate the AR symptoms associated with cat allergies. The purpose of this exploratory study was to evaluate the effects of a single dose of fexofenadine hydrochloride, 180 mg, in preventing and controlling AR symptoms in individuals with known cat allergies using the well-characterized cat challenge model.^{11–14}

METHODS

Study Design

This was a single-center, randomized, double-blind, placebo-controlled, 2-way crossover study conducted at the Good Mews Cat Shelter in Marietta, GA, between November 2003 and February 2004. Figure 1 illustrates the study design, and Table 1 indicates the assessments performed at each visit. Patients who failed to meet the prechallenge criterion for forced expiratory volume in 1 second (FEV₁) at the initial qualifying or treatment visit were eligible to return for a

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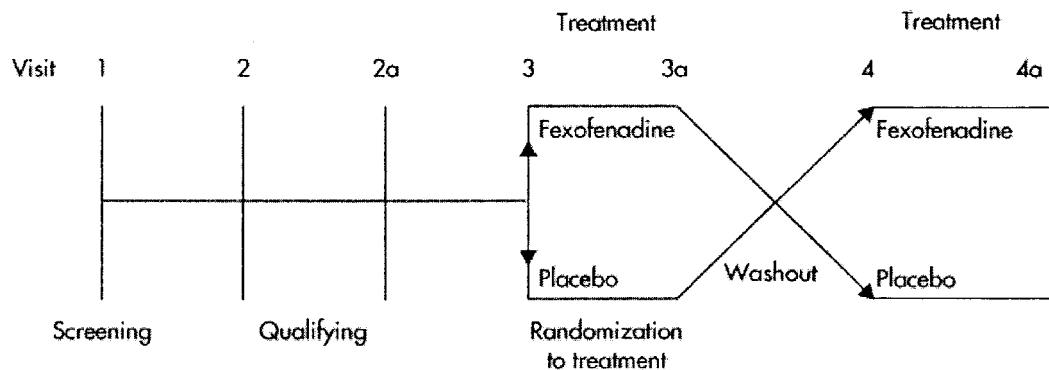


Figure 1. Study design. Patients failing to qualify during the qualifying challenge or during the treatment visit were allowed to have 1 repeated qualifying (2a) or treatment (3a or 4a) visit. The 2 treatment periods were separated by a mean $\pm$ SD washout period of 14 ± 3 days.

follow-up qualifying or treatment visit 3 to 5 days later (visit 2a, visit 3a, or visit 4a).

The study was performed in accordance with the principles of Good Clinical Practice as set out in the Declaration of Helsinki and its amendments. Ethical approval was obtained from the Sterling Institutional Review Board (Atlanta, GA). All the study participants provided written informed consent and Health Insurance Portability and Accountability Act compliance. If patients were younger than 18 years, the parent or legal guardian was required to provide written informed consent.

Patients

Eligible patients included male or female individuals 12 years or older with at least a 2-year history of cat-induced AR that required the use of allergy medication or that had resulted in the avoidance of cats. All the patients were required to have a positive skin prick test result to cat allergen (containing Fel d 1) at screening, defined as a wheal size greater than half of

the diameter of the histamine control and at least 3 mm larger than the diameter of the glycerin-saline solution control. Patients were required to have mild-to-moderate allergic symptoms, defined as a total symptom score (TSS) (sum of rhinorrhea, itchy nose/palate/throat, sneezing, and itchy/watery/red eyes) of 8 or less at screening and minimal allergic symptoms at the qualifying baseline evaluation ($TSS \leq 4$). Study participants were evaluated at screening for reversibility of their FEV_1 through the process of bronchodilation; patients demonstrating reversibility of more than 12% were excluded. Furthermore, patients were required to have an FEV_1 of 80% or more of the predicted value before the cat challenge and at the qualifying and treatment visits. Patients were evaluated for changes in postchallenge FEV_1 , and those exhibiting a 12% or greater decline in FEV_1 were further evaluated by medical personnel.

Patients were excluded from the study if they had asthma that required treatment with medications other than inhaled

Table 1. Assessments Performed at Each Visit

Assessment	Screening (visit 1)	Qualifying (visit 2/2a)	Treatment period 1 (visit 3/3a)	Treatment period 2 (visit 4/4a)
Symptom screening	Yes	Yes*	No	No
FEV_1 (with bronchodilation)†	Yes	No	No	No
FEV_1 and PEFR‡	No	Yes	Yes	Yes
<i>Felis domesticus</i> allergen 1 sample collection	No	Yes	Yes	Yes
Symptom assessment§	No	Yes	Yes	Yes
PNIF¶	No	Yes	Yes	Yes

Abbreviations: FEV_1 , forced expiratory volume in 1 second; PEFR, peak expiratory flow rate; PNIF, peak nasal inspiratory flow.

* Patients were required to have a qualifying baseline total symptom score of 4 or less.

† Initial FEV_1 was required to be at least 80% of the predicted value. Assessment of FEV_1 was repeated after bronchodilation, and patients who demonstrated reversibility of more than 12% were considered ineligible.

‡ The FEV_1 and PEFR were measured within 10 to 40 minutes before and after each cat challenge and at each treatment visit. During the qualifying and treatment visits, PEFR was also measured at 15-minute intervals.

§ Symptom assessments were completed 5 minutes before each cat challenge, at 5-minute intervals during each challenge, and 5 minutes before treatment with study medication.

¶ The PNIF assessment was completed 10 minutes before cat challenge, at 10-minute intervals during each cat challenge, at the completion of each cat challenge, and 10 minutes before treatment with study medication.

short-acting β -agonists or asthma known to be exacerbated by exposure to cats. The use of short-acting β -agonists was permitted if they were not taken within 6 hours before the qualifying or treatment visits. Other exclusion criteria included any medication for rhinitis that could not be withheld, a cat in the home, upper respiratory tract infection within 4 weeks of study entry, a history of severe reactions to cat exposure by self-report, acute or chronic sinusitis or other nasal conditions that resulted in irreversible nasal obstruction within 4 weeks of study entry, known hypersensitivity to fexofenadine or to drugs with similar chemical structures, clinically significant electrocardiographic values, clinically significant medical conditions (cardiovascular, hepatic, neurologic, hematologic, renal, gastrointestinal, endocrine, or other major systemic disease), and pregnancy or breastfeeding. Individuals were excluded if they were undergoing treatment with corticosteroids, antihistamines, antileukotrienes, amphetamines, anticholinergic agents, ipratropium bromide, atropine, or monoamine oxidase inhibitors. If excluded medications were used by the patient, washout periods were required before entering the study.

Eligible patients were randomly assigned in a 1:1 ratio to a treatment sequence of fexofenadine hydrochloride, 180 mg, and placebo. Patients were included in either sequence 1 (placebo followed by fexofenadine) or sequence 2 (fexofenadine followed by placebo). The 2 treatment periods were separated by a mean $\pm$ SD washout period of 14 ± 3 days.

Cat Allergen Challenge

A live cat challenge model was used for exposing patients to Fel d 1.¹¹⁻¹⁴ Cat allergen challenge took place in a 26×8 -ft room in the Good Mews Cat Shelter that housed up to 80 cats. The cat challenge room shared the same ventilation system as the cat shelter. Immediately before the challenge, all the cats were removed from the challenge room and placed in the general shelter, where they remained during testing. Challenges during treatment visits were initiated 1½ hours after study drug administration. Patients remained in the room until they could no longer tolerate their symptoms: up to 30 minutes at qualifying and 60 minutes at the treatment visits. Cat bedding (towels) was shaken vigorously before patient entry and once every 15 minutes while the patients were in the cat challenge room. Up to 12 patients were challenged during a single session.

During the qualifying and treatment sessions, the TSS and nasal congestion were scored by each patient on diary cards 5 minutes before dosing (treatment sessions only), 5 minutes before the cat challenge, and every 5 minutes during the cat challenge. Peak nasal inspiratory flow (PNIF) was evaluated 10 minutes before dosing (treatment sessions only), 10 minutes before the cat challenge, every 10 minutes during the cat challenge, and on termination of the cat challenge. Peak expiratory flow rate (PEFR) measurements were performed within 10 to 40 minutes before either the cat challenge in qualifying sessions or dosing in treatment sessions and every 15 minutes during the cat challenge. The FEV₁ was evaluated

within 10 to 40 minutes before either the cat challenge in the qualifying session or dosing in the treatment sessions and on termination of the cat challenge. The Fel d 1 levels were measured throughout the cat challenge.

Symptom Evaluation

The severity of signs and symptoms of rhinorrhea, itchy nose/palate/throat, and itchy/watery/red eyes were evaluated using a 5-point scale from 0 (absence of symptoms) to 4 (severe symptoms that were very bothersome, disabling sleep or daily activities). For sneezing, symptom severity was based on the number of sneezes that occurred in the previous 5 minutes, from 0 (no sneezes) to 4 (≥ 4 sneezes). The TSS was defined as the sum of the following symptoms: rhinorrhea (nasal discharge/runny nose or postnasal drip), itchy nose/palate/throat, sneezing, and itchy/watery/red eyes. Nasal congestion was also measured by the patients' evaluation of their symptoms and based on a 5-point scale of nasal stuffiness from 0 (clear, fully open, with no obstruction of the air passage) to 4 (blocked, with no air movement through the nostrils).

PNIF and Lung Function

The PNIF was measured using an Incheck PNIF meter (Clement-Clark Ltd, Harlow, England) with an inflatable face mask (KingSystems, Noblesville, IN). The FEV₁ was measured using the KoKo spirometer (Pulmonary Data Services Inc, Louisville, CO) after β -agonists and caffeinated beverages were withheld for 6 and 8 hours, respectively. The PEFR was measured by means of a Mini Wright peak flow meter (Clement-Clark Ltd, Columbus, OH). All the PNIF, FEV₁, and PEFR measurements were performed as 3 consecutive attempts at each time, and the highest reading was recorded.

Fel d 1 Counts

Air samples were collected using the GilAir-5 Air Sampling System (Sensidyne Inc, Clearwater, FL), with an air flow rate of 4 L/min, and was worn by each patient while seated during the cat challenge in the challenge room. Levels of airborne Fel d 1 were quantified using an enzyme-linked immunosorbent assay test performed by INDOOR Biotechnologies Inc (Charlottesville, VA).

Primary and Secondary Efficacy Evaluations

The primary efficacy end point was the change from baseline (predose) in the TSS 30 minutes (or earlier in cases of premature termination) after initiation of the cat allergen challenge (2 hours after dosing). Secondary efficacy end points included the total time spent in the cat challenge room and the percentage changes in the TSS and individual symptom scores from predose baseline at each 5-minute interval. In addition, mean and percentage changes in the TSS and individual symptom scores from predose baseline for the duration of exposure were evaluated. Changes in the TSS and individual symptom scores using prechallenge (1½ hours after dosing but before entering the cat challenge room) as baseline were also evaluated. Mean changes in PNIF measurements from predose baseline at each 10-minute interval

and the mean change during the duration of exposure were also evaluated.

Safety Assessments

Safety and tolerability were evaluated by means of the spontaneous reporting of adverse events (AEs) by the patient and the investigator and by the evaluation of FEV₁ and PEFR throughout the study.

Statistical Analysis

All the efficacy analyses were performed on the completer population, which comprised patients who presented to both treatment periods, had no major protocol violations, and had at least 1 valid primary efficacy evaluation 5 minutes after each of the 2 cat exposure challenges. Analysis of TSS was based on an analysis of variance (ANOVA) model. An ANOVA model with fixed-effects terms of sequence (confounded with carryover effect), period, and treatment and a random-effects term of patient nested within sequence was used to determine whether any carryover or sequence effect existed before the final model was selected for data analysis. After confirmation of no significant sequence or carryover effects, an ANOVA model with fixed-effects terms of period and treatment and a random-effects term of patient nested within sequence was performed. Least squares means of treatments, treatment least squares mean difference, and its 95% confidence interval were evaluated.

Analyses of the total time spent in the cat challenge room were performed using Kaplan-Meier survival curves, and a Wilcoxon matched-pairs signed rank test was used to evaluate the differences between the treatment groups. Mean changes in PNIF measurements from baseline at each 10-minute interval were calculated. All the statistical tests were 2-sided, at a $P = .05$ significance level. Levels of Fel d 1 collected during the treatment visits were summarized using descriptive statistics by treatment and period combination. In addition, the Fel d 1 level was added as a covariate to the final ANOVA model for the primary efficacy analysis, and its effect on TSS was analyzed.

Safety analyses were performed on the safety population, which included all the patients who received at least 1 dose of the study medication. Change in FEV₁ was summarized by sequence and visit, and mean changes in PEFR were evaluated. Demographic and baseline characteristics were summarized by treatment sequence using descriptive statistics. Comparability among treatment groups was evaluated using a 1-way ANOVA method for continuous measures and Fisher exact tests for categorical measures. It was estimated that a sample size of 63 patients would provide 80% power, with a 2-tailed $\alpha = .05$, to detect a difference of 1.2 points in the TSS between treatment groups, assuming a within-patient SD of 2.34 points.

RESULTS

Study Participants

Of 211 patients screened, 66 met the entry criteria and were randomized to receive study treatment. Sixty-three partici-

pants completed the study: 32 in sequence 1 and 31 in sequence 2. Of the 3 patients who discontinued, 2 in sequence 1 withdrew owing to AEs and 1 in sequence 2 was lost to follow-up.

The baseline characteristics of the completer population are given in Table 2. Most patients were female (81%) and black (64%). A significant difference in mean age was observed between the sequence 1 (39.9 years) and sequence 2 (32.3 years) treatment groups ($P = .02$), and this was reflected in their history of AR, which was of longer duration in the sequence 1 group (22.6 years) compared with the sequence 2 group (16.0 years) ($P = .04$). Baseline TSS and PNIF, predose and prechallenge, and baseline PEFR predose did not differ between sequence groups. Forty patients were receiving concomitant medications, and the most commonly used medications included immunotherapy, multivitamins, and acetaminophen (11, 9, and 5 patients, respectively).

Primary Efficacy Evaluation

Baseline symptoms were evaluated before drug administration (predose baseline) and after treatment before entering the cat challenge room (prechallenge baseline). There was no treatment sequence carryover effect on the TSS 30 minutes after initiation of the cat challenge when symptoms were compared with predose ($P = .87$) or prechallenge ($P = .99$) baseline. Analysis of the primary efficacy variable revealed that the mean change in the TSS from predose baseline was significantly less with fexofenadine compared with placebo 30 minutes after initiation of the cat allergen challenge, corresponding to 2 hours after dosing ($P = .03$) (Fig 2). Analysis including Fel d 1 as a covariate revealed no significant effect of Fel d 1 levels on the TSS.

Secondary Efficacy Evaluation

Change in TSS. The mean change in the TSS from prechallenge baseline was significantly less with fexofenadine compared with placebo ($P = .01$). The percentage change in the TSS from predose baseline at 5-minute intervals was significantly lower with fexofenadine hydrochloride, 180 mg, compared with placebo at 15, 25, 30, 35, 40, 45, and 60 minutes ($P < .05$). For those points where statistical significance was not achieved, there was a trend in favor of fexofenadine. Similarly, the percentage change in the TSS from prechallenge baseline at 5-minute intervals revealed that fexofenadine produced significantly lower changes at all times, except 10 minutes, compared with placebo ($P < .05$).

Change in individual symptom scores. All individual symptom scores showed a trend in improvement from predose baseline after fexofenadine treatment compared with placebo, with fexofenadine-treated patients exhibiting significantly fewer sneezes compared with placebo users ($P = .004$). In addition, analysis of the percentage change from predose baseline showed statistically significant differences compared with placebo for sneezing ($P = .004$) and nasal congestion ($P = .046$) 30 minutes after challenge.

Table 2. Patient Characteristics and Baseline Scores (Completer Population)*

Characteristic	Sequence 1 (n = 32)	Sequence 2 (n = 31)	Total (N = 63)	P value†
Age, y	39.9 ± 13.0	32.3 ± 11.7	36.2 ± 12.9	.02
Sex, No. (%)				
M	6 (19)	6 (19)	12 (19)	>.99
F	26 (81)	25 (81)	51 (81)	
Race, No. (%)				
White	12 (38)	10 (32)	22 (35)	.79
Black	20 (63)	20 (65)	40 (64)	
Other	0	1 (3)	1 (2)	
Weight, lb	162.8 ± 31.0	175.5 ± 41.6	169.0 ± 36.9	.17
Height, inches	65.8 ± 3.3	65.5 ± 3.5	65.6 ± 3.4	.70
History of allergic rhinitis, y	22.6 ± 14.3	16.0 ± 9.5	19.4 ± 12.5	.04
Predose baseline TSS				
Tx period 1	1.2 ± 1.75	1.1 ± 1.36	NA	.82
Tx period 2	1.0 ± 1.06	1.2 ± 1.27		
Prechallenge baseline TSS				
Tx period 1	1.0 ± 1.81	1.1 ± 1.43	NA	.94
Tx period 2	0.9 ± 1.23	1.1 ± 1.46		
Predose baseline PNIF				
Tx period 1	148.6 ± 38.96	148.1 ± 37.87	NA	.59
Tx period 2	149.8 ± 52.15	139.7 ± 33.32		
Prechallenge baseline PNIF				
Tx period 1	151.3 ± 39.90	147.9 ± 38.12	NA	.88
Tx period 2	150.5 ± 46.11	144.5 ± 27.55		
Predose baseline PEFR				
Tx period 1	428.0 ± 73.11	413.2 ± 76.35	NA	.80
Tx period 2	423.8 ± 80.47	412.1 ± 82.05		

Abbreviations: NA, not available; PEFR, peak expiratory flow rate; PNIF, peak nasal inspiratory flow; TSS, total symptom score (sum of rhinorrhea [nasal discharge/runny nose or postnasal drip], itchy nose/palate/throat, sneezing, and itchy/watery/red eyes); Tx, treatment.

* Data are given as mean ± SD except where indicated otherwise. Sequence 1 indicates placebo followed by fexofenadine; sequence 2, fexofenadine followed by placebo.

† Two-sided P values were reported via 1-way analysis of variance for continuous variables, and the Fisher exact test was used for categorical measures.

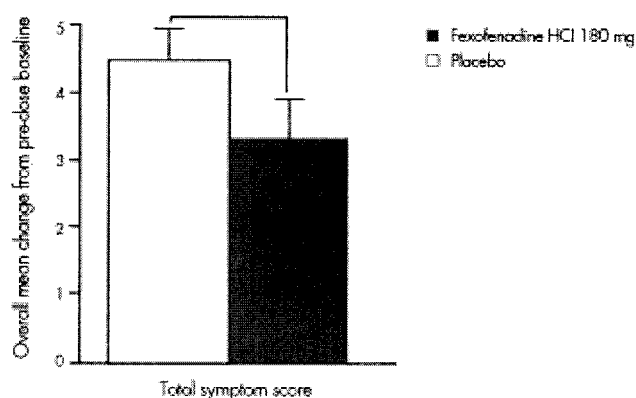


Figure 2. Least squares mean change from predose baseline in the total symptom score 30 minutes after initiation of the cat allergen challenge. Patients given fexofenadine showed significant improvement in total symptom scores compared with placebo users ($P = .03$). Error bars represent SE.

Total time spent in cat challenge room. There was no difference between treatment groups in the total time spent in

the cat challenge room. All the patients completed the 60-minute exposure for both treatment periods, except for 1 participant in the placebo group who was removed after 50 minutes owing to chest discomfort and a decrease in pulmonary function.

PNIF measurements. No differences were observed between treatment groups in PNIF measurements during the study.

Allergen Levels

Levels of Fel d 1 varied widely between patients; however, allergen levels were balanced and not significantly different between treatment groups ($P = .89$). Mean ± SD levels of Fel d 1 in the placebo- and fexofenadine-treated groups were $2,700.7 \pm 2,044.9$ ng/m³ and $2,646.1 \pm 2,271.7$ ng/m³, respectively (Table 3).

Safety

All the treatment-emergent AEs were considered to be mild or moderate, with no serious AEs reported. Overall, 8 treatment-emergent AEs were reported in 6 patients (9.1%): 3 and 5 in the fexofenadine and placebo groups, respectively. These

Table 3. Summary of *Felis domesticus* Allergen 1 Levels (Completer Population)*

Patients, No.		<i>Felis domesticus</i> allergen 1 level, mean $\pm$ SD (range), ng/m ³	
		Placebo	Fexofenadine
Sequence 1	32	2,530.8 $\pm$ 2,188.79 (98.0–7,048.0)	2,559.8 $\pm$ 1,799.82 (164.0–6,833.0)
Sequence 2	31	2,876.2 $\pm$ 1,904.88 (528.0–6,840.0)	2,735.2 $\pm$ 2,702.18 (94.0–9,101.0)
Total	63	2,700.7 $\pm$ 2,044.86 (98.0–7,048.0)	2,646.1 $\pm$ 2,271.69 (94.0–9,101.0)

* Sequence 1 indicates placebo followed by fexofenadine; sequence 2, fexofenadine followed by placebo.

cases included somnolence with fexofenadine treatment and toothache, chest discomfort, sinusitis, wheezing, and a greater FEV₁ and PEFr parameter pulmonary function test reduction with placebo treatment. Two placebo-treated patients discontinued owing to AEs: 1 experienced moderate wheezing and the second developed a sinus infection. One participant experienced a concussion and skin lacerations due to events unrelated to study medication.

Overall, patients treated with fexofenadine showed smaller mean $\pm$ SD decreases in PEFr (-12.9 ± 5.26 L/min, $-2.7\% \pm 1.29\%$) compared with placebo users (-27.6 ± 5.26 L/min; $-6.0\% \pm 1.29\%$), with a statistically significant difference observed 30 minutes after allergen challenge between treatment groups ($P = .03$). In addition, patients treated with fexofenadine showed smaller decreases in FEV₁ compared with placebo users; although these differences were not statistically significant. After the 60-minute cat challenge, only the placebo group showed a significant mean $\pm$ SD decrease in FEV₁ of -0.041 ± 0.015 L/s ($P = .007$), with a percentage change of $-1.327\% \pm 0.508\%$ ($P = .01$), compared with prechallenge baseline.

DISCUSSION

The findings presented herein suggest that a single dose of fexofenadine hydrochloride, 180 mg, is effective as a prophylactic agent in alleviating the AR symptoms induced by Fel d 1. A single dose of fexofenadine hydrochloride, 180 mg, significantly alleviated the worsening of AR symptoms compared with placebo.

Perennial AR (PAR) occurs throughout the year and is usually triggered by indoor allergens, such as house dust mite and cat and dog allergens. The clinical symptoms of PAR, of which nasal congestion is considered the most troublesome, are often debilitating. If left untreated, individuals with cat allergies can experience decreased QoL, such as impaired functioning and disturbed sleep.^{4,5} Although allergen avoidance is often advocated as a first step in the management of PAR, complete avoidance is often not practical in the case of cat or dog allergens. In terms of pharmacologic intervention, the newer-generation prescription antihistamines have been widely used to treat the symptoms of AR.¹⁵

We report herein the first off-label exploratory study evaluating the efficacy and safety of the newer-generation antihistamine fexofenadine in the prophylactic control of AR symptoms after exposure to the cat allergen Fel d 1 in individuals with a known cat allergy using a live cat challenge

model. Previous studies^{13,14,16–18} have examined the effects of intranasal corticosteroids in patients who have cat allergy and the effects of oral leukotriene receptor antagonists in patients with a history of cat-induced asthma or comorbid asthma and AR, demonstrating the sensitivity of this model.

In the present study, the mean change in the TSS from predose baseline was significantly less with fexofenadine compared with placebo 30 minutes after initiation of the cat challenge, corresponding to 2 hours after dosing. Significantly less sneezing was also reported in the fexofenadine treatment group 30 minutes after cat challenge. In addition, fexofenadine was well tolerated during the cat challenge study.

Although fexofenadine treatment did not result in any significant effect on PNIF, the subjective measurement of nasal congestion was found to be significantly lower in patients administered fexofenadine. This finding is consistent with other researchers¹⁹ who reported nasal congestion relief in patients with PAR treated with fexofenadine hydrochloride, 120 mg ($P = .03$) or 180 mg ($P = .01$) once daily. Furthermore, previous research²⁰ in 49 patients with SAR has shown that fexofenadine hydrochloride, 180 mg once daily, improved subjective and objective measures of nasal congestion during a 2-week period.

Although based on limited data, the fexofenadine treatment group demonstrated smaller decreases in lung function as measured by FEV₁ and PEFr compared with placebo. This observation would suggest that fexofenadine pretreatment may have a protective effect on pulmonary function; however, the patients enrolled in this study did not have documented asthma. Further research is needed to prove a therapeutic benefit of fexofenadine on cat allergen-induced bronchospasm in asthmatic individuals with cat allergy.

Levels of Fel d 1 in the cat challenge room varied widely during the study (placebo group: $2,700.7 \pm 2,044.9$ ng/m³; fexofenadine group: $2,646.1 \pm 2,271.7$ ng/m³) and were higher than levels typically found in homes with cats ($1.8–578$ ng/m³).² Nevertheless, all the patients, except for 1 in the placebo group, completed the entire 1-hour cat allergen exposure. Two previous clinical studies^{14,16} using the cat challenge model reported airborne Fel d 1 levels ranging from 878 to 26,226 ng/m³ and 1,073 to 89,537 ng/m³. In these studies,^{14,16} many of the participants could not tolerate the allergen challenges for more than 15 minutes; however, these patients had documented asthma, which likely played a role in how well they tolerated the challenge. Similarly, variability

in airborne Fel d 1 concentrations was reported by Perry et al¹³ (placebo group: 51–13,201 ng/m³; montelukast group: 94–5,709 ng/m³) and Corren et al¹⁷ (approximately 30–3,000 ng/m³). It is unclear how the wide range of Fel d 1 concentrations across patients reported in these studies was attributed to the room layout and ventilation system and how such variability could affect study outcomes.

CONCLUSION

Prophylactic treatment with a single dose of fexofenadine hydrochloride, 180 mg, significantly mitigated the worsening of AR symptoms induced by exposure to cat allergen compared with placebo. Additional clinical studies would be valuable to confirm the benefits of fexofenadine in relieving oculonasal symptoms and lung function in patients diagnosed as having cat allergy, with or without asthma.

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