

# Evaluation of Fluticasone (Flixonase) Nasal Spray Versus Beclomethasone (Beconase) Nasal Spray in the Treatment of Allergic Rhinitis

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## ABSTRACT

Although response to intranasal steroid therapy has been reported in patients with allergic rhinitis, efficacy of some nasal steroids is noteworthy.

This study was undertaken to evaluate the efficacy of a two-week course of Fluticasone (Flixonase) nasal spray vs. Beclomethasone (beconase) nasal spray in patients with symptoms of allergic rhinitis referred to our clinic. This study reviewed sixty randomized studies with symptoms of allergic rhinitis which supported common aeroallergens with skin prick test. Patients received a total daily dose of nasal spray of Fluticasone (Flixonase) 100 mcg bid (N=30) compared with patients with allergic rhinitis who received a total daily dose of Beclomethasone (Beconase) 50mcg 2 puffs bid (N=30). Patients were visited before and after therapy, and efficacy of Flixonase and Beconase was evaluated by the change in nasal symptoms including: nasal discharge, nasal obstruction, nasal itching, and sneezing. After two weeks of treatment nasal symptoms of blockage, discharge, sneezing and itching were significantly better in the group treated with Fluticasone nasal spray (65%, 82%, 67%, 79% respectively ( $p < 0.001$ ) but after treatment with beconase nasal spray lower benefits in the nasal symptoms includes: 50%, 71%, 51%, 57% respectively. After two weeks of treatment no deleterious changes consequent to therapy were observed in nasal symptoms.

100 mcg bid Flixonase (Fluticasone) intranasal spray is more effective than 50 mcg 2 puffs bid Beconase (Beclomethasone) intranasal spray. Like asthma, allergic rhinitis is an inflammatory disease and should be managed with anti-inflammatory medication.

**Key words:** Allergic Rhinitis, Nasal Spray, Treatment.

## INTRODUCTION

Allergic rhinitis symptoms include nasal congestion, rhinorrhea, nasal itching, sneezing and associated symptoms including ocular burning, ocular itching, sleep disruption, fatigue, headache, and restlessness which promote irritability and impairment in con-

centration.<sup>2,4,5</sup> Left untreated, allergic rhinitis may predispose patients to other respiratory conditions such as asthma and sinusitis.<sup>6</sup>

Allergic rhinitis is a high-cost, high-prevalence disease. A one-year prevalence is estimated at 7.5 to 8.2% (1) with lifetime prevalence at home more than 20% among the population of the USA. In a study in London, UK, the period prevalence of all forms of rhinitis was 24%. 63% of the cohorts were considered to have atopy with nasal obstruction as the most common prin-

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cial symptom.<sup>3</sup>

In the USA the cost of medication to manage rhinitis for twelve months was \$3.1 billion. Seventy-seven percent of this amount was spent on prescribing pharmaceuticals, for non-sedating antihistamines \$1.6 billion, and for nasal steroids \$0.8 billion (Scott-Levin [Plymouth Meeting, Pa] and IMS [Newtown, Pa] sales data, 1997).

Primary care<sup>9,18</sup> and allergy textbooks recommend antihistamines as first-line therapy. But symptoms are often difficult to control with traditional rhinitis pharmacotherapy (e.g. antihistamine, decongestant) perhaps because allergic rhinitis is an inflammatory disease like asthma and the triggering agents are difficult to avoid. Also, symptoms often persist without any identifiable trigger.<sup>7,8</sup>

If avoiding allergens does not result in improvement, antihistamine therapy is a reasonable next step in mild nasal symptoms.<sup>9</sup> If it does not result in improvement with antihistamine or with moderate/severe nasal symptoms, nasal corticosteroids are recommended. Malone et al estimated the cost of treating patients with allergic rhinitis at \$0.8 billion to \$1.48 billion per year for 1994.<sup>10</sup> Loss of productivity due to allergic rhinitis is high<sup>11</sup> and this loss can be decreased with effective nasal steroids. Topical intranasal glucocorticosteroids are very effective in the treatment of patients with allergic and perennial rhinitis. Recently, a new and potent corticosteroid, fluticasone propionate aqueous nasal spray, has become available for treatment of allergic rhinitis. Systemic bioavailability of fluticasone nasal spray is extremely low. This data demonstrates the importance of studying this illness because the efficacy of intranasal flixonase is recommended in expert guidelines as first-line therapy when congestion and other symptoms are major components.<sup>12,13</sup>

### MATERIALS AND METHODS

This study was designed for a single center, Dr. Farid's Allergic Clinic. Out of the patients referred to above center, sixty cases were chosen at random with allergic rhinitis symptoms and positive skin prick test of common aeroallergens. Criteria for allergic rhinitis

**Table 1.** Thirty cases of allergic rhinitis. Advise fluticasone.

Sex	Mean age	Duration of treatment
16 male	37.5 years	14 days
14 female	35 years	14 days

**Table 2.** Thirty cases of allergic rhinitis given beclomethasone dipropionate.

Sex	Mean age	Duration of treatment
15 male	35 years	14 days
15 female	33 years	14 days

symptoms include: (1) nasal blockage, (2) nasal discharge, (3) sneezing, and (4) nasal itching. After meeting the study criteria at the screening (visit 1, day 1), we studied enrolled subjects who were randomly assigned to one of two treatment groups: (1) 100 mcg bid Fluticasone nasal spray or (2) 50 mcg 2 puffs bid Beclomethasone nasal spray. Treatment was administered as one spray/nostril from each bottle twice daily in the morning and at night. From thirty cases with flixonase nasal spray 16 males (54%) had a mean age of 37.5 years, and 14 females (46%) had a mean age of 35 years (Table 1).

From the other group in which thirty cases were treated with beconase nasal spray there were 15 males (50%) with a mean age of 35 years and 15 females (50%) with a mean age of 33 years (Table 2). On follow-up evaluation visits after two-weeks of treatment for allergic rhinitis (AR), based on symptoms observed by the principal investigatory at the time of visit and review of the subjects, after two weeks, the subjects' overall conditions of allergic rhinitis were assessed. At each clinic visit nasal mucosa was inspected with regard to the grade of mucosal congestion, secretion, polyps, crusting, bleeding, and candidiasis. The potency of nasal spray was determined.

Duration of Flixonase and Beconase treatment was two weeks. After treatment the patients were given a questionnaire. Analysis showed that total symptoms including nasal blockage, nasal discharge, sneezing, and nasal itching were the main outcome parameters evaluated.

### RESULTS

A total of sixty subjects with allergic rhinitis were enrolled in the study, with two immediate dropouts. Thirty subjects received 100 mcg bid fluticasone, and thirty subjects received 50 mcg 2 puffs bid beclomethasone. In all 100% of patients completed the protocol-specified fourteen-day treatment. Analysis of the primary efficacy showed that both flixonase and beconase improved total nasal symptoms.

In Flixonase treated subjects there were 55% males (n=16) with a mean age of 37.5 years, and 45% females

(n=14) with a mean age of 35 years. In comparison Beconase treated subjects were 50% male (n=15) with a mean age of 35 years, and 50% female (n=15) with a mean age of 33 years (Tables 1,2).

All patients were given questionnaires after two weeks of treatment. Analysis of the primary efficacy for both groups showed that fluticasone and beclomethasone nasal sprays decreased total nasal symptoms of allergic rhinitis (Table 3, figure 3). Analysis of the secondary efficacy showed fluticasone nasal spray to be significantly more effective than beclomethasone nasal spray after two weeks' treatment ( $p<0.001$ ).

In fluticasone treated subjects, nasal blockage response was 65% (n=20) compared to 50% (n=15) in beconase treated subjects ( $p<0.001$ ).

In flixonase treated subjects nasal discharge improved 82% (n=25) compared with 71% (n=20) in beconase treated subjects ( $p<0.001$ ).

In flixonase treated subjects sneezing improved 67% (n=20) compared with 51% (n=15) in beconase treated ( $p<0.001$ ).

In flixonase treated subjects nasal itching improved 79% (n=24) compared with 57% (n=17) in beconase treated ( $p<0.001$ ).

For all four nasal symptoms both active treatments demonstrated efficacy, but the fluticasone nasal spray treatment group showed a greater numerical decrease in each individual for nasal symptoms as compared with the beclomethasone nasal spray treatment group.

### DISCUSSION

The primary aim of this study was to investigate the efficacy of flixonase nasal spray itself and compare it with beconase nasal spray when used for a period of two weeks in the treatment of allergic rhinitis. Intranasal cortico-steroids are considered safe regarding their effect on nasal mucosa after short- and long-term use.

This integrated analysis of data from a randomized study, demonstrates the superiority of fluticasone (FT) nasal spray in a group of patients with allergic rhinitis over beconase nasal spray in the treatment of patients with allergic rhinitis. There is a clinical impression that allergic rhinitis symptoms are less responsive to nasal spray beconase. The flixonase nasal spray recommended dose of 100 mcg bid for two weeks is as effective as beconase nasal spray 50 mcg 2 puffs bid for two weeks. The results of this integrated analysis showed that the allergic rhinitis treated with nasal spray flixonase at 100 mcg twice daily and nasal spray beconase 50 mcg 2 puffs twice daily noted reduction of nasal symptoms during two weeks of treatment, exhibiting statistically significant decreases in symp-

toms with flixonase compared with patients treated with beconase. The broad efficacy of fluticasone for a range of nasal symptoms in allergic rhinitis differentiates it from ipratropium bromide, which has been shown to improve rhinorrhea, but not other nasal symptoms.<sup>16</sup> In the current study, the approved 100 mcg bid dose seemed to confer efficacy in relieving nasal symptoms comparable with that of the 50mcg 2 puffs bid dose of beconase.

Fluticasone nasal spray is also an effective treatment for perennial non-allergic rhinitis with or without nasal eosinophilia (nares or non-nares).<sup>15</sup>

The lack of effect of flixonase nasal spray on growth in this study distinguishes it from more bioavailable intranasal cortico-steroids such as beconase budesonide.<sup>14</sup> Beconase, administered twice a day, causes a 0.9 cm reduction in height.<sup>17</sup> Specifically, flixonase with very low systemic bioavailability does not suppress growth in long-term study. It has been suggested that patients with severe symptoms use nasal Flixonase and non-sedating antihistamines in combination.

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