Mometasone Is Effective With or Without Oral Antihistamines

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Abstract

Background: Clinical trials have demonstrated the efficacy of monotherapy with intranasal corticosteroids (INSs) for symptoms of allergic rhinitis (AR). ARIA guidelines suggest adding oral antihistamines to INS monotherapy when severe symptoms do not improve. An open-label multicenter study assessed efficacy and safety of mometasone furoate nasal spray (MFNS) alone or combined with an oral antihistamine in subjects with AR.

Methods: Subjects received MFNS 200 mcg QD for 56 days, with an oral antihistamine added at Day 28 or later if baseline symptoms (sneezing, nasal discharge/obstruction, tiredness, irritability) had not improved. Subjects rated individual symptom scores, daily routine and sleep limitations, and product attributes on Days 1, 28, and 56 on a scale of 0 to 10, and completed a compliance questionnaire on Day 56.

Results: Mean scores for AR symptoms and limitations on sleep and daily routines significantly improved from baseline to Day 28 and from 28 to 56 (P<0.001 for all). At Days 28 and 56, 47/48 and 45/56 subjects, respectively, were receiving MFNS monotherapy, and 13 required a concomitant oral antihistamine at Day 28 or later. By Day 56, symptom severity improved in 92% of subjects receiving concomitant therapy. At study end, 88% of subjects reported compliance with QD MFNS. Average product attribute scores ranged from 7.2 to 8.4. No severe adverse events were reported.

Conclusions: MFNS 200 mcg QD, alone or combined with an oral antihistamine, was safe and effective against AR nasal symptoms and limitations of sleep and daily activities.

Background

• With a prevalence of approximately 10%–20% worldwide, allergic rhinitis (AR) is associated with considerable discomfort, decreased quality of life, and loss of productivity.1,4

• Intranasal corticosteroids (INSs) are effective for the treatment of all symptoms of AR, particularly congestion, and are considered first-line therapy for moderate-to-severe or persistent AR.1,4

• In clinical practice, an antihistamine is often added to INS therapy for the treatment of AR, based on the theory that combining agents that impact different mediators involved in the allergic reaction should improve clinical outcome.6,9

• The results of clinical studies to date do not support this hypothesis. They indicate, rather, that the addition of an antihistamine to an INS is not superior to INS monotherapy for improving AR symptoms.12

• Mometasone furoate nasal spray (MFNS) is a potent, topically active, synthetic 17-heterocyclic corticosteroid that has been shown to be well tolerated and effective for the control of AR symptoms.14-17

• Medications involved in the allergic reaction should improve clinical outcome.6,9

• The theory that combining agents that impact different mediators involved in the allergic reaction should improve clinical outcome.6,9

Objective

• To assess the efficacy of regular use of MFNS alone or in combination with an oral antihistamine in relieving nasal symptoms in subjects with AR.

• Secondary objectives were to investigate factors that may influence control of symptoms, including:

  – Patient satisfaction with INS monotherapy

  – Potential benefit of an oral antihistamine in combination with an INS

Methods

• A noncomparative, open-label, multicenter study in Portugal in which subjects with AR received MFNS 200 mcg QD for 56 days.

  – At Day 28 (Visit 2), an oral antihistamine could be added at the physician’s discretion if subject’s scores for signs/symptoms of AR (sneezing, nasal discharge, nasal obstruction, tiredness, irritability) had not improved from baseline (Day 1) scores.

End Points Assessed

• On Days 1, 28, and 56, subjects recorded scores for:

  – Individual signs and symptoms (listed above)

  – Limitations of use, and packaging

• All scores were recorded on a 0 (none/no interference/disatisfaction) to 10 (very severe/very affected/very satisfied).

• An overall symptom score was calculated by adding the scores of the five symptoms being evaluated.

• On Day 56, a compliance questionnaire was also completed.

Inclusion/Exclusion Criteria

• Subjects between 18 and 65 years of age who had been diagnosed by a physician with moderate-to-severe AR in accordance with guidelines from the Allergic Rhinitis and its Impact on Asthma Workshop could participate.

• Subjects were excluded if they had a significant comorbidity, respiratory tract infection, or any contraindication listed in the MFNS product monograph, or if they had received antihistamine treatment within 5 days, or corticosteroid treatment within 30 days of the start of the study.

Statistical Analysis

• Mean changes in total nasal symptom scores and in secondary variables from baseline to final visit were analyzed using ANOVA and 95% confidence intervals determined.

• The statistical significance of the difference between visits in the overall symptom score and in the scores for each symptom/limitation was assessed with the paired Student t test.

• The Mann-Whitney test was used to compare results between subjects treated with both MFNS and antihistamine and those treated with MFNS monotherapy.

Results

• A total of 72 subjects participated in the study; of these, 56 subjects completed the Day 56 visit.

• Mean scores for signs/symptoms of AR and limitations on sleep and daily routine significantly improved from baseline (=11) to Day 28 (n=60) and from Day 28 to Day 56 (n=56) (P<0.001 for all; Figures 1, 2, and 3).

• On Days 28 and 56, 47/48 and 45/56 subjects (80%), respectively, were receiving MFNS monotherapy.

• Only 13 subjects (23%) needed concomitant oral antihistamine, beginning at Day 28 or later, because signs/symptoms did not improve from the baseline score.

• By Day 56, 92% of subjects who took concomitant antihistamine reported improvement in symptom severity.

• Degree of improvement, assessed by symptom scores, was similar between subjects who received MFNS monotherapy and those who received combination therapy (MFNS plus antihistamine; P=ns) (Figure 4).

Figure 1. Mean scores for allergic rhinitis (AR) signs/symptoms per visit.

Figure 2. Mean overall symptom score at each visit.

Figure 3. Mean scores for sleep and daily routine limitations per visit.

Figure 4. Comparison of overall symptom scores for subjects receiving mometasone furoate nasal spray (MFNS), monotherapy versus combination therapy with antihistamine.

Conclusions

• Mometasone furoate nasal spray 200 mcg QD monotherapy or in combination with an oral antihistamine was safe and efficacious in improving nasal symptoms of AR.

• Mometasone furoate nasal spray monotherapy or in combination with an oral antihistamine was safe and effective against AR nasal symptoms and limitations of sleep and daily activities.

References


