

Correspondence

MOMETASONE FUROATE NASAL SPRAY FOR THE TREATMENT OF ELDERLY PATIENTS WITH PERENNIAL ALLERGIC RHINITIS

The predicted doubling of the population older than 65 years by 2030 will likely lead to increased numbers of elderly patients with allergic rhinitis (AR).¹ Intranasal corticosteroids have proven safety and efficacy in adults with AR.^{2,3} In-class differences in frequency of administration and bioavailability are particularly relevant to elderly patients. A literature review found that clinical trials in adults with perennial AR (PAR) typically included those 65 years and older but did not report data specific to this population. One study was identified assessing fluticasone propionate in elderly patients with rhinitis, but it included those with allergic and nonallergic disease.⁴ We present the first data from a 12-week study of 334 patients 65 years and older with PAR who received either once-daily mometasone furoate nasal spray, 200 μ g, or placebo.

The study was conducted at 24 sites in Des Plaines, Illinois; Mission Viejo, California; Salt Lake City, Utah; North Dartmouth, Massachusetts; Lenexa, Kansas; Forked River, New Jersey; Tampa, Florida (2 sites); Tucson, Arizona; New Braunfels, Texas; Chapel Hill, North Carolina; San Diego, California; Houston, Texas; Princeton, New Jersey; San Antonio, Texas; Fairfax, Virginia; Easton, Pennsylvania; Los Angeles, California; Ocala, Florida; Rolla, Missouri; Englewood, Colorado; Sylvania, Ohio; and Sarasota, Florida. All study participants were clinically symptomatic at screening and baseline and free of unstable or clinically significant disease. Eligible patients had a positive skin prick test result (wheal size ≥ 3 mm greater than control) to perennial allergens at the investigator's office, if not performed within the past 2 years, or a positive (wheal size ≥ 7 mm greater than control) intradermal skin test result. Patients with rhinitis medicamentosa, recurrent sinusitis, or nasal structural abnormalities interfering with airflow were excluded. Rescue

medications were not permitted during the study. Study participants rated nasal symptoms on a 4-point scale (0 indicating none and 3 indicating severe) twice daily (in the morning before dosing and in the evening, based on how patients felt since the prior evaluation). The primary efficacy variable was the average change in total nasal symptom score (TNSS; sum of diary scores for congestion, rhinorrhea, nasal itching, and sneezing) from baseline during days 1 to 15 in the efficacy evaluable population. Change in TNSS during the subsequent 15-day intervals and at the end point (the last interval for which the patient had nonmissing data) was also assessed. Statistical analysis was based on least squares means from 2-way analysis of variance, with significance set at .05 (2-sided).

Although the primary efficacy end point for this study was the efficacy evaluable population (ie, randomized eligible patients who completed at least 1 valid postbaseline visit), the more robust data set is the intent-to-treat and safety population. Therefore, we report primary and secondary efficacy variables in the intent-to-treat and safety population.

A total of 170 patients were randomized to receive mometasone furoate nasal spray and 164 to receive placebo. Baseline demographic characteristics and disease severity were similar between groups, including mean age (71 years; range, 65-85 years; and 70 years; range, 65-87 years), mean duration of PAR (29 and 28 years), and mean baseline TNSS (5.7 and 5.7) (for the mometasone furoate nasal spray and placebo groups, respectively). More patients discontinued early in the placebo arm (32 [20%]) than in the mometasone furoate nasal spray arm (17 [10%]); discontinuation because of treatment failure was also more common with placebo (17 [10%]) than with mometasone furoate nasal spray (6 [4%]).

Mean change in TNSS during days 1 to 15 was -1.1 (17%) with mometasone furoate nasal spray vs -0.7 (11%) with placebo ($P = .03$). Mean change from baseline at study end was also significantly greater with mometasone furoate nasal spray vs placebo (-2.2 vs -1.6 ; $P = .03$). During each of the 5 secondary treatment intervals, mometasone furoate nasal spray was numerically superior to placebo (Figure).

The incidence of treatment-related adverse events was slightly higher in the mometasone furoate nasal spray group (31%) than the

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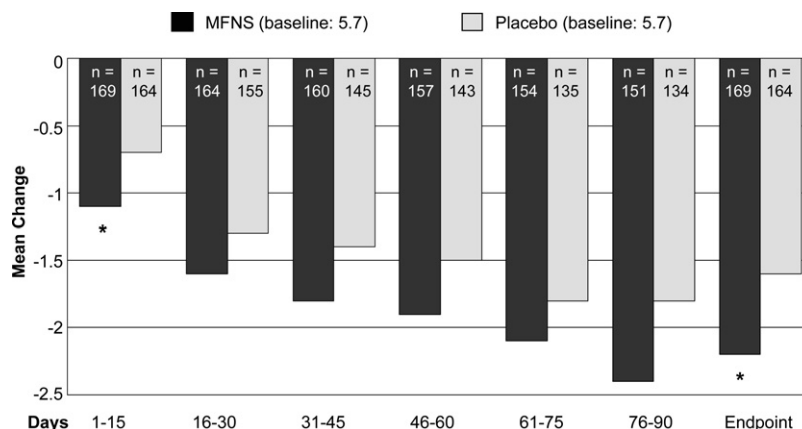


Figure. Mean change from baseline in total nasal symptom scores (TNSSs) in the mometasone furoate nasal spray (MFNS) and placebo groups. * $P \leq .05$.

placebo group (21%). The most common treatment-related adverse events in the mometasone furoate nasal spray and placebo groups, respectively, were epistaxis (13% vs 5%), headache (8% vs 5%), and pharyngitis (5% vs 2%). These results are consistent with previously published data in adults with PAR. No serious treatment-related adverse events or clinically meaningful changes in electrocardiograms, vital signs, or laboratory test results occurred.

This study demonstrates that mometasone furoate nasal spray, 200 µg once daily, was well tolerated and significantly improved nasal symptoms in elderly subjects with PAR. Because rescue medications were not permitted, patient dropouts in the placebo arm likely contributed to the reduced treatment effect in the mometasone furoate nasal spray arm during later secondary assessments conducted at 15-day intervals throughout the trial. These data are the first characterizing the benefits of intranasal corticosteroid treatment in elderly patients with AR; additional data are needed in this growing population.

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