



# Evaluation of Intranasal Corticosteroid Sensory Attributes and Patient Preference for Fluticasone Furoate for the Treatment of Allergic Rhinitis

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## ABSTRACT

**Purpose:** Allergic rhinitis (AR) is a highly prevalent disease, affecting the quality of life of millions of Americans. Intranasal corticosteroids (INCs) are widely recommended as first-line therapy for moderate to severe AR. Although these drugs exhibit similar safety and efficacy, a potentially differentiating factor within this class is the varying sensory attributes associated with each INC. The objective of this literature review was to evaluate product characteristics, sensory attributes, and patient preferences of fluticasone furoate intranasal spray (FFNS) compared with other INCs.

**Methods:** A narrative literature search for studies evaluating FFNS was performed in MEDLINE and Google Scholar. Key terms included “allergic rhinitis,” “anti-allergic agents,” “intranasal administration,” “fluticasone furoate,” and “patient preference.” Studies published from 2007 to present were included. Nine trials met the search criteria, each evaluating FFNS versus placebo or other INCs for efficacy, safety, and/or preference, and were included. Approximately 2400 patients with AR were enrolled across varying study protocols.

**Findings:** In 4 placebo-controlled trials, FFNS showed significant efficacy in relieving symptoms of AR and a tolerable safety profile. Three trials evaluating FFNS and fluticasone propionate nasal spray (FPNS) found that FFNS was significantly preferred over FPNS regarding scent, aftertaste, and leakage down the throat/nose. The results of 2 trials found that FFNS was preferred overall over mometasone furoate nasal spray (MFNS).

**Implications:** INCs are effective first-line treatments for AR and show significant reduction in nasal and ocular symptoms. Patients preferred the scent, aftertaste, and mist gentleness of FFNS ~2:1 over the

same sensory attributes of FPNS. Patients experienced less negative sensory characteristics with FFNS compared with MFNS, preferring FFNS to MFNS overall. Selecting an INC with favorable attributes in accordance with patient preferences could potentially improve adherence, therapeutic outcomes, and health care costs. (*Clin Ther.* 2019;41:1589–1596) © 2019 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**Keywords:** allergic rhinitis, antiallergic agents, corticosteroids, fluticasone furoate, intranasal administration, patient preference.

## INTRODUCTION

Allergic rhinitis (AR) is a chronic inflammatory disease affecting 10% to 30% of Americans and >1 billion people worldwide, with increasing prevalence.<sup>1,2</sup> AR can have a significant impact on patient quality of life and health care costs. AR can also cause serious complications and is a risk factor for the development of asthma.<sup>2</sup> AR is an antibody-mediated disorder involving inflammation of the nasal mucosa caused by interaction of allergens with immunoglobulin E antibodies bound to the surface of mast cells.<sup>3</sup> Activated mast cells release a host of inflammatory mediators, resulting in an immediate hypersensitivity reaction and allergic symptoms.<sup>3</sup> Classic presenting symptoms include nasal congestion, rhinorrhea, sneezing, and nasal itching.<sup>2</sup>

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Traditionally, AR is classified as seasonal or perennial. Seasonal allergic rhinitis (SAR), also known as hay fever, occurs during seasons with high counts of outdoor allergens such as pollen or mold.<sup>4</sup> Perennial allergic rhinitis (PAR) generally occurs throughout the year and is triggered by a variety of indoor allergens such as dust mites, animal dander, cockroaches, and mold.<sup>4</sup> Classification is based on symptom severity, categorized as mild or moderate/severe, and the extent of impairment of daily activities and quality of life, as well as the duration of symptoms.<sup>3</sup> Clinical trials and studies generally use SAR and PAR to differentiate types of AR and patients. Overall, guideline recommendations for treatment are made based on symptom frequency, duration, and severity.

Many medication classes are available, by prescription or over-the-counter (OTC). Intranasal corticosteroids (INCs) have become the mainstay of AR therapy and are recommended as first-line treatment for moderate or severe AR.<sup>2</sup> There are multiple INCs, including beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone furoate, fluticasone propionate, mometasone, and triamcinolone.<sup>2</sup> Their potent anti-inflammatory effects lead to a reduction in inflammation, edema, and vascular leakage, and thus improve rhinorrhea and congestion. INCs decrease the number of histamine-containing mast cells in the nasal mucosa, improving pruritus and sneezing.<sup>5</sup> INCs are preferred for persistent AR, defined as >4 days per week or >4 weeks per year,<sup>3</sup> as they are highly effective at preventing and relieving symptoms of both early- and late-phase reactions.

Although systemic steroids have significant side effects, INCs have limited systemic bioavailability, and when used at recommended doses and durations, they have very low rates of systemic adverse events (AEs) such as hypothalamic-pituitary-adrenal axis suppression or growth suppression sometimes reported with oral steroids.<sup>6</sup>

An updated practice parameter, established by the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma and Immunology, provides recommendations for clinicians, based on quality of evidence, to guide treatment decisions in management of their patients with AR. According to these guidelines, INCs are the most effective monotherapy for relieving and preventing symptoms associated with SAR and PAR, including nasal congestion.<sup>2</sup>

## **Adherence and Sensory Attributes**

Patient adherence is essential in the treatment of any disease because improved health and optimal outcomes are dependent on patients receiving their medication appropriately. Adherence is imperative in long-term management of AR with INCs, and lack of adherence can be an obstacle to effective treatment. In the setting of AR, most patients should be treated before being exposed to allergens to keep allergy symptoms under control.<sup>7</sup> Patient education is crucial in improving adherence to INC therapy because without education, patients may not understand the need to use their medication regularly for maintenance, instead of using it as needed in an attempt to treat acute symptoms. INCs should be used continually for 3 to 4 weeks to achieve maximum benefit and relief,<sup>8</sup> but if only used when symptomatic, interrupted therapy can lead to suboptimal relief. As a result, patients may believe their AR medication does not work or has fading effectiveness, which may be due to the lack of immediate relief of symptoms when using INCs. If patients do not find relief, the perceived lack of efficacy can lead to continued unresolved symptoms and future nonadherence.

The Allergies in America landmark study surveyed 2500 adults with AR and their health care providers.<sup>9</sup> Patients reported significantly less satisfaction than their providers claimed. Almost one half of patients reported that their medication does not provide 24-hour relief and lost effectiveness after a few months. In another survey, of 860 respondents who had asked a physician to change their allergy medication, 66% reported lack of effectiveness as the reason for the change.<sup>10</sup> Another common reason for nonadherence with nasal allergy medication is bothersome side effects.<sup>9</sup> Such side effects associated with INCs are mainly sensory, largely related to the device and spray attributes. INCs possess several sensory attributes that contribute to patients' acceptance of the medication and willingness to adhere to treatment. These attributes are characteristics of the medication, including the actual device and spray (eg, scent, taste, irritation, or leakage).

A cross-sectional study asked patients to choose between sensory attributes of INCs: smell, taste, throat rundown, nose runout, and feel of spray.<sup>11</sup> According to patients, the most important attribute is taste or

aftertaste. Unpleasant sensory attributes can lead to decreased patient adherence to treatment, leading to suboptimal outcomes in AR management.<sup>11</sup> If instructed to take the medicine daily for 90 days, 77% of patients stated that they would be willing to adhere to the regimen if given an INC containing the lowest level of each sensory attribute. However, willingness to adhere dropped to 4% if patients were given an INC with moderate sensory levels. Furthermore, studies show that patients would be willing to pay more to avoid these unwanted sensory attributes.<sup>12</sup> Being aware of a patient's health-related preferences allows for treatment to be optimized, increasing the likelihood of adherence to an efficacious regimen.<sup>13</sup> Advice can be provided by health care providers, and patient adherence may be improved, by establishing open communication between patients and their health care providers so that adherence barriers can be discussed.<sup>14</sup> Education in terms of disease and potential complications as well as a discussion about available and alternative treatment options are key to helping patients identify their expectations and preferences. Health care providers have the opportunity to improve patient satisfaction with their medication and outcomes of treatment.

## MATERIALS AND METHODS

A comprehensive literature search was conducted to evaluate patient preference for certain sensory characteristics attributed to INCs, specifically fluticasone furoate intranasal spray (FFNS). This review was performed in MEDLINE and Google Scholar, using the keywords “allergic rhinitis,” “anti-allergic agents,” “intranasal administration,” “fluticasone furoate,” and “patient preference.” Studies published from 2007 to May 2017 were included to account for first availability of drug. A total of 5 trials met the search criteria, each evaluating FFNS versus placebo or other INCs for efficacy, safety, and/or preference, and were included. Approximately 2400 patients with AR were enrolled across varying study protocols.

## RESULTS

### INC Efficacy

An integrated analysis of 5 randomized placebo-controlled trials evaluated the efficacy of FFNS 110 µg once daily for 2 weeks in adult and adolescent patients with SAR. Significant improvements were noted in all individual nasal and

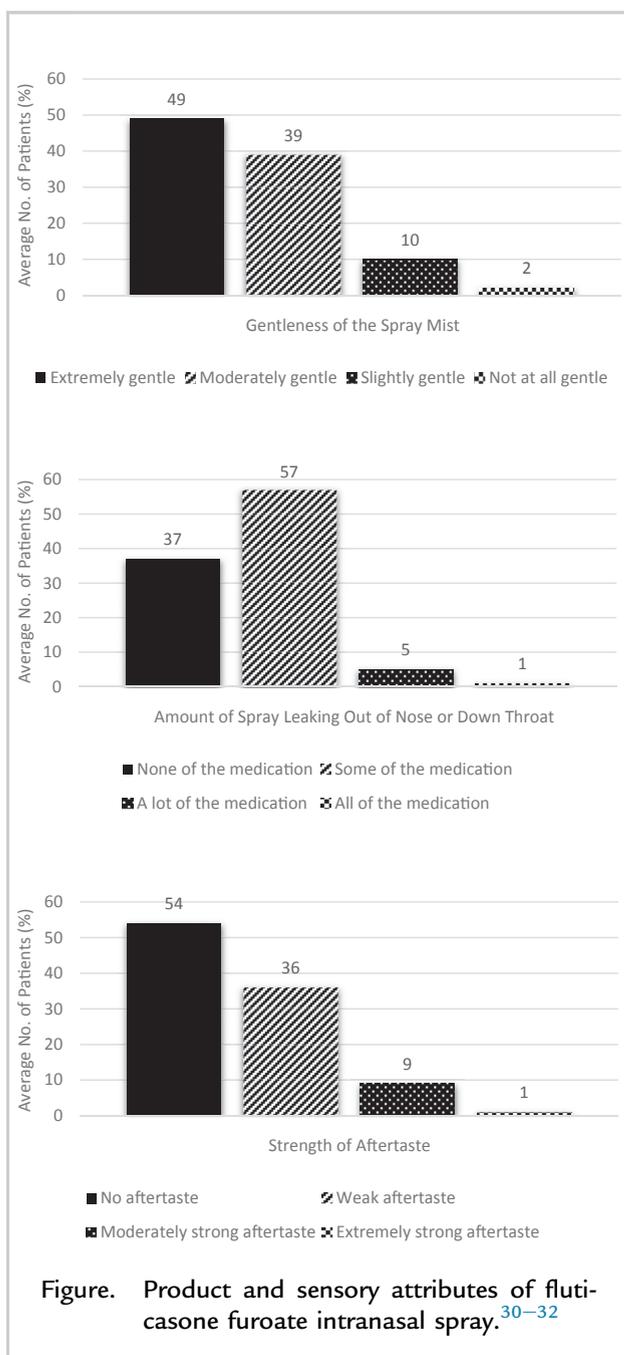
ocular symptoms in the FFNS group versus placebo, consistent across different pollen allergy seasons, geographical locations, and patient ethnicity.<sup>15</sup> Nasal symptoms evaluated included pruritus, sneezing, congestion, and rhinorrhea. Ocular symptoms included itching/burning, tearing/watering, and redness. Studies have shown that INCs are more effective than oral antihistamines for reduction of nasal symptoms and exhibit similar effectiveness for associated ocular symptoms.<sup>2,16</sup>

### Safety

Long-term use of corticosteroids with potentially significant systemic exposure can result in dose-related systemic AEs such as hypothalamic-pituitary-adrenal axis suppression, bone metabolism dysfunction, and growth suppression in children. Recognized AEs of corticosteroids include weight gain, osteoporosis, and hyperglycemia. Incidence of psychiatric and cognitive disturbances is rarer.<sup>17</sup> Topical corticosteroids administered intranasally, when used at recommended doses, are generally preferred over oral forms because they can achieve sufficient drug concentrations directly into the nasal mucosa, reducing the risk of AEs while providing effective allergy relief.<sup>18</sup> The most common local side effects include nasal dryness, burning, stinging, and sneezing. Nasal irritation and bleeding can occur, and nasal septal perforation is rare.<sup>2</sup> Temporarily stopping the medication, switching to another device, or counseling the patient on proper administration technique could alleviate these issues.<sup>2</sup> Due to similar efficacy and safety profiles within the INC class, differentiating factors are patient preference, dosing regimen, and delivery device.<sup>19</sup>

### Preference

Many clinical trials that evaluate efficacy and safety of newer formulations of INCs also include evaluations of patient preference of certain sensory attributes. Nine studies compared FFNS with placebo or other INCs for efficacy, safety, and preference.<sup>8,20–26</sup> In 4 placebo-controlled trials, FFNS exhibited significant efficacy in relieving symptoms of AR and a tolerable safety profile. These trials also assessed product and sensory attributes of FFNS, including administration ease, spray tip comfort, mist gentleness, spray leakage, and aftertaste (Figure). The placebo control used during the registrational trials allowed for the evaluation of



product efficacy and safety in a blinded fashion. Because both placebo and active drug recipients used the same delivery device, sensory attribute data were collected from all study participants. Overall, patients found the FFNS device easy to use and comfortable, and the mist to be gentle with little leakage or aftertaste. Of the studies comparing FFNS with an active comparator, 3 studies compared FFNS with

fluticasone propionate nasal spray,<sup>20,24,25</sup> and 2 with mometasone furoate nasal spray.<sup>26,27</sup> Overall, FFNS was significantly preferred over the other 2 INCs for a majority of sensory attributes (Table). Regardless of the presence or absence of active ingredient, the device performance in delivering on its design intent, improving upon the sensory attributes, was positively demonstrated. To increase patient compliance and show the efficacy of the product, the nasal spray sensory experience needs to be positive.

## DISCUSSION AND CONCLUSIONS

AR is a significant health problem with economic burdens that impairs patients' quality of life. In 2005, ~22 million Americans reported experiencing AR-related symptoms, visiting a physician, or receiving a prescription medication for AR.<sup>28</sup> A total of \$6.1 billion, adjusted for inflation, was spent on health care and treatment of AR in 2000 (excluding OTC medications). By 2005, total expenditures to treat AR almost doubled to \$11.2 billion.<sup>28</sup> AR is commonly treated with OTC allergy medications, a direct cost that was as high as \$1.5 billion in 2008.<sup>29</sup>

AR is also associated with a large amount of indirect costs, primarily money lost due to decreased productivity and days off work or school. AR symptoms can significantly affect patients' quality of life and are often associated with fatigue, headache, cognitive impairment, and sleep disturbance.<sup>2</sup>

Medication cost should be balanced with effective treatment, resolution of symptoms, and patients' quality of life. Studies have shown that patients are willing to adhere to an effective treatment without adverse sensory attributes. Patient adherence and patient preferences related to medication selection can lead to better treatment outcomes and potentially have a positive effect on total costs to treat AR.

INC's have a well-established role in the treatment of AR. Many of these agents are available OTC. When comparing the sensory attributes of FFNS with those of other INCs, patients preferred FFNS overall. Patients significantly preferred the scent or odor, aftertaste, and gentleness of the mist of FFNS over the same sensory attributes of fluticasone propionate nasal spray. Patients also experienced less unfavorable effects, significantly preferring FFNS to mometasone furoate nasal spray overall. Combined, these factors suggest that FFNS may be associated with improved adherence and decreased health care

Table. Patient preference for specific sensory attributes of fluticasone furoate intranasal spray (FFNS) compared with those of fluticasone propionate nasal spray (FPNS) or mometasone furoate nasal spray (MFNS).

Study	Design	Patient Population		Sensory Attributes			
				FFNS Preferred	FPNS Preferred	P	
Meltzer et al, <sup>24</sup> 2008	Randomized, double-blind, single-dose, crossover (N = 127)	PAR and/or SAR Mean age, 39.7 y 80% white 65% women	Odor	64%	29%	<0.001	No significant differences for soothing, nasal irritation, or sneezing
			Taste	47%	21%	<0.001	
			Less aftertaste	44%	22%	0.002	
			Drip down the throat	43%	27%	0.004	
			Nose runoff	49%	19%	<0.001	
Mohar et al, <sup>20</sup> 2009	Randomized, double-blind, crossover, 2-week (N = 377)	SAR Mean age, 39.9 y 89% white 69% women	Overall preference	60%	33%	0.003	No significant differences for delivery of consistent amount and comfort of nose tip
			Scent/odor	55%	25%	<0.001	
			Less aftertaste	68%	13%	<0.001	
			Leaking out of nose/down throat	58%	21%	<0.001	
			Gentleness of mist	56%	20%	<0.001	
Meltzer et al, <sup>25</sup> 2010	Randomized, double-blind, multidose, crossover, 2-week (N = 360)	SAR Mean age, 38.3 y 72% white 59% women	Ease of use	31%	51%	0.003	No significant differences for ease of use, delivery of consistent amount, delivery method, and device comfort
			Spray delivery method	32%	50%	0.014	
			Scent/odor	58%	27%	<0.001	
			Less aftertaste	60%	18%	<0.001	
			Leaking out of nose/down throat	59%	21%	<0.001	
Yonezaki et al, <sup>26</sup> 2016	Randomized, crossover, prospective, 4-week (N = 40)	SAR Mean age, 51.7 y 100% Japanese 58% men	Bitter taste*	0.98	2.06	0.01	*Patients were asked to score product attributes on a scale from 0–10, with lower scores
			Run down the throat*	1.2	2.27	0.033	
			Run out of the nose*	1.31	2.92	0.002	
			Nasal irritation*	1.22	2.43	0.012	

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Table. (Continued)

Yanez et al, <sup>27</sup> 2016 Randomized, double-blind, single-dose, crossover (N = 300)	Median age, 40.4 y	0.78	1.69	0.017	indicating favorable
	Scent/odor	29%	19%	0.065	No significant difference
	Less drip through throat	37%	18%	<0.001	for taste/aftertaste or
	Less run out of nose	34%	21%	0.017	urge to sneeze
	More soothing	44%	30%	0.046	
	Less irritating	38%	16%	<0.001	
	Overall preference	56%	32%	<0.001	
	Urge to sneeze*	0.78	1.69	0.017	indicating favorable
	Rhinorrhea*	1.18	2.53	0.007	sensory attributes or
	Overall preference	53%	23%	<0.001	characteristics

No significant differences for discomfort from the nozzle, ease to operate, and ease to press trigger

No significant difference for taste/aftertaste or urge to sneeze

PAR = perennial allergic rhinitis; SAR = seasonal allergic rhinitis.

costs, although this factor was not measured directly in these studies. In addition, more studies are needed to compare all of the agents and in nonallergic rhinitis.

These sensory characteristics have been shown to influence patient preference when comparing INCs for prevention and treatment of AR symptoms. Health care providers can be a useful resource, advising patients so that they recognize the importance of sensory attributes. Furthermore, the patient having a clear understanding of how these agents work is essential to their correct usage and should lead to more successful pharmacotherapy. In addition, an understanding of the sensory attributes and potential patient preferences that contribute to adherence will allow health care providers to provide informed treatment recommendations for patients with AR. Discussing the balance of efficacy, tolerance, and cost with the patient should lead to better outcomes that are associated with better compliance.

**CONFLICTS OF INTEREST**

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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### FURTHER READING

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