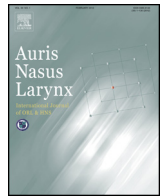




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Preference evaluation and perceived sensory comparison of fluticasone furoate and mometasone furoate intranasal sprays in allergic rhinitis

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ABSTRACT

Objective: Intranasal corticosteroid sprays (INCSs) are commonly used for therapy of allergic rhinitis (AR). Adherence to regular use of INCSs is influenced by patient perception and preferences of products. The study objective was to compare perceived sensory attributes of fluticasone furoate nasal spray (FFNS) and mometasone furoate nasal spray (MFNS) in AR patients.

Methods: In a multicenter, randomized, crossover, prospective study, 40 seasonal AR patients were administered both FFNS and MFNS for 2 weeks each in a crossover fashion, for a total of 4 weeks.

Patients completed questionnaires for each product regarding perceived sensory attributes at the end of each two-week period of product administration.

Results: FFNS was significantly preferred over MFNS. Significantly, fewer subjects perceived a bitter taste ($p = 0.01$), medication running down their throat ($p = 0.033$), and medication running out of their nose ($p = 0.002$) with FFNS. MFNS was more frequently reported to induce nasal irritation ($p = 0.012$), sneezing ($p = 0.017$), and rhinorrhea ($p = 0.007$) compared to FFNS. Interestingly, these findings were markedly observed in females. Medicine dripping out of the nose and nasal shooting were the most common problems reported for MFNS with a higher proportion of subjects who felt moderate-to-severe discomfort. Overall, 52.5% of patients expressed a preference for FFNS compared with 22.5% for MFNS. **Conclusion:** Several perceived sensory attributes of FFNS were rated significantly superior to MFNS. FFNS may contribute to enhanced treatment outcomes in AR patients due to improved treatment adherence.

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1. Introduction

Allergic rhinitis (AR) is one of the major chronic symptomatic diseases, which occur as an IgE-mediated immune reaction following exposure of the nasal mucosa to one or more allergens [1]. AR is a global health problem with prevalence increasing worldwide, and it is estimated that 10–30% of the global

population is affected [2]. In Japan, AR has also recently been increasing in prevalence, affecting up to 40% of the population [3]. AR is associated with various unpleasant nasal or ocular symptoms [4], and often affects social well-being, quality of life (QOL), and daily performance, in addition to its physical symptoms. Effective management of AR for individuals is essential; uncontrolled AR may cause tiredness, frustration, reduced concentration, sleep disturbance, etc.

Intranasal corticosteroid sprays (INCS) can inhibit the onset of local inflammatory responses, which involve certain types of inflammatory cells migrating to the nasal mucosa and releasing

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several mediators [5], and may also be effective for alleviation of both the early and late phase symptoms of AR [6]. INCSs are recommended by the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines [2], as well as the Japanese guideline for allergic rhinitis [3], as a first-line therapy for the treatment of moderate to severe AR, particularly if nasal congestion is the major symptom. Although INCSs are thought to be the most effective therapeutic drug available for AR treatment, several factors may limit a patient's willingness to adhere to regular use of INCSs [7]. Disagreeable perceived sensory attributes, such as scent, taste, and nasal irritation, may underlie decreased patient adherence, and are key contributors to the patient's perception of INCS products [8]. Fluticasone furoate nasal spray (FFNS) and mometasone furoate nasal spray (MFNS) are once-a-day, scent-free, aqueous-type sprays, and are a novel intranasal corticosteroid preparation with proven clinical efficacy in the treatment of AR. These INCSs have been available since 2009, and 2008, respectively, and control the largest market share in Japan.

The objective of the present study was to evaluate and compare seasonal AR patients' perceptions and preferences for specific perceived sensory attributes of an FFNS (Allermist[®]; GlaxoSmithKline K.K, Tokyo, Japan) and MFNS (Nasonex[®]; MSD K.K, Tokyo, Japan), and comparing the usability of each device.

2. Patients and methods

2.1. Patients

A multicenter, randomized, crossover, prospective study was conducted from February 2013 to March 2015 with seasonal AR patients. Eligible subjects were 48 adult patients who had been diagnosed with seasonal allergic rhinitis as defined by a clinical history of nasal allergic symptoms (e.g., nasal congestion, rhinorrhea, sneezing, nasal irritation, and ocular symptoms) for a minimum of 2 years with scores of 2 or more on the CAP radio-allergosorbent test corresponding to individuals. Specific IgE against house dust mites, Japanese cedar pollen, grass pollen (sweet vernal and orchard), and fall weed pollens (ragweed and wormwood) were measured in the present study. The exclusion criteria were as follows: patients with only perennial, and not seasonal, AR; history of treatment with oral, inhalation, or topical steroid therapy within 2 months of study enrollment; pregnant or breast feeding women; or presence of severe systemic diseases such as severe diabetes, uncontrolled asthma, and immunodeficiency.

2.2. Study design

Documents provided to subjects and study design were approved by the Institutional Review Board, Faculty of Medicine, Kagawa University (approval No. Heisei 26-019). Subjects were provided informative documents, and written informed consent was obtained after the subjects sufficiently understood the explanation of the study by an investigator. Subjects were then assigned randomly to one of two product usage sequences using a random number table. Subjects received one of the two study products for the first 2 weeks (days 1–14) at typical dosages for treatment of patients with AR: either FFNS (2 actuations in each nostril, 110 µg/100 µl total dose), or MFNS (2 actuations in each nostril, 100 µg/200 µl total dose). The second study product was then administered the following 2 weeks (days 15–28); subjects were first administered FFNS followed with MFNS (Group 1), and those first administered MFNS were followed with FFNS (Group 2).

Nose/eye symptoms and QOL for each subject were assessed using the Japanese Rhinoconjunctivitis Quality of Life Questionnaire (JRQLQ) on a scale of 0–4 (0: none; 1: mild; 2: moderate; 3: severe; 4: very severe). JRQLQ is considered to be an appropriate

questionnaire to evaluate the state of Japanese seasonal and perennial allergic rhinitis, and is widely used throughout Japan [9]. The questionnaire consists of three evaluations: I (nasal/eye symptoms), II (items concerning QOL), and III (overall facial scale). Preference and perceived sensory attributes for each product were evaluated using a product attributes questionnaire (10 items in total, Table 1), recorded by subjects on a visual analog scale (VAS) when subjects visited the outpatient clinic on days 14 and 28. Presence of adverse events was also checked for by the questionnaire, and simultaneously confirmed by interview with the subject. Some subjects were administered oral anti-histamine drugs on demand as a rescue drug.

2.3. Statistical analysis

Differences between the two groups of subject characteristics at baseline were tested using Student's *t*-test (mean age and JRQLQ score) and χ^2 test (sex ratio, severity of AR, and AR type). After 2 or 4 weeks of INCS administration, the mean change of individual JRQLQ scores from baseline was calculated in each treatment group, and *p*-values were obtained by paired *t*-test. Efficacy analysis between each group and overall were carried out using one-way ANOVA. At the end of the study, mean values for perceived product sensory attributes were calculated, and *p*-values were obtained by Student's *t*-test. Significant differences between the two groups in the proportion of subjects who provided a high score (higher than 5) for each perceived sensory attribute question were tested by χ^2 test. Significance was assumed when *p* < 0.05.

3. Results

3.1. Subjects

A total of 48 subjects were randomized to receive treatment. Eight subjects refused to attend the clinical visit and were eliminated from the study. Of these, 40 subjects were included in the intent-to-treat population. Thirty-four subjects (85%) started INCS treatment from early February to late March for relief against Japanese cedar pollen, including six subjects as prophylactic treatment. Six subjects (15%) joined the study with grass pollinosis from early April to early June. Five subjects affected by both seasonal and perennial AR were included. The mean subject age was 51.7 years (range: 28–77 years) and the ratio of males to females was 23:17. Baseline characteristics for the population are shown in Table 2. Approximately, equal number of subjects were assigned to each of the treatment groups (21 subjects in group 1, and 19 subjects in group 2, respectively), and subject characteristics were comparable between the two groups.

Table 1
Items assessed in the individual product attribute questionnaire.

Question	Response
1. Did this medicine have a bitter taste?	0 (none)–10 (very strong)
2. Did this medicine run down your throat?	0 (none)–10 (every time)
3. Did this medicine run out of your nose?	0 (none)–10 (every time)
4. Did you have discomfort when the nozzle was inserted into your nose?	0 (none)–10 (very discomfort)
5. Did this product cause nasal irritation?	0 (none)–10 (marked)
6. Did this product make you want to sneeze?	0 (none)–10 (every time)
7. Did this product cause rhinorrhea?	0 (none)–10 (every time)
8. How satisfied were you with this product?	0 (very satisfied)–10 (very dissatisfied)
9. How easy was it to operate this product?	0 (very easy)–10 (very complicated)
10. How easy was it to press the trigger?	0 (very easy)–10 (very difficult)

Table 2
Subjects' baseline characteristics ($n = 40$).

Age (mean $\pm$ SD)	51.7 $\pm$ 13.5
Sex, male/female	23/17
Therapeutic target antigen	
Japanese cedar pollen n (%)	34 (85.0)
Grass pollen n (%)	6 (15.0)
JRQLQ score	
I; nose/eye TSS (mean $\pm$ SD)	9.5 $\pm$ 3.9
6 items (max 24)	
severity 0–6 n (%)	9 (22.5)
7–12 n (%)	23 (57.5)
13–18 n (%)	7 (17.5)
19–24 n (%)	1 (2.5)
II; QOL total score (mean $\pm$ SD)	15.2 $\pm$ 10.3
17 items (max 68)	
III; facial scale (mean $\pm$ SD)	2.3 $\pm$ 0.9

AR, Allergic rhinitis; JRQLQ, Japanese Rhinoconjunctivitis Quality of Life Questionnaire; TSS, total symptom score; QOL, quality of life.

3.2. Assessments

The mean baseline scores of JRQLQ were as follows: nasal/eye total symptoms score was 9.5 ± 3.9 (TSS, includes 6 items, range 0–24), QOL total score was 15.2 ± 10.3 (includes 17 items, range 0–68), and general facial scale score was 2.3 ± 0.9 (range 0–4). The

subjects' baseline symptom grades according to nose/eye TSS were as follows: no to mild symptoms (score 0–6), 9 subjects; mild to moderate (score 7–12), 23 subjects; moderate to severe (score 13–18), 7 subjects; and severe to very severe (score 19–24), 1 subject (Table 2). There were no significant differences between Groups 1 and 2 in these baseline scores and severity. The mean change of JRQLQ scores from baseline after 2 or 4 weeks treatment of FFNS and MFNS is shown in Table 3. Overall, significant improvements from baseline were observed in all three JRQLQ categories at 2 weeks (-4.1 , -6.0 , and -1.0 , respectively) and at 4 weeks (-5.3 , -9.0 , and -1.2 , respectively). Subjects' symptoms in Groups 1 and 2 were reduced by approximately 40% and 55%, respectively. QOL scores of both treatment groups were also reduced after 2 or 4 weeks by approximately 40% and 60%, respectively. Similar changes were observed between Groups 1 and 2, and equivalent treatment efficacy was confirmed for FFNS and MFNS due to the lack of any statistically significant differences among Group 1, Group 2, and overall.

Mean subject ratings of individual perceived sensory attributes following crossover administration of both study products are illustrated in Fig. 1. FFNS was significantly preferred over MFNS for most of the questionnaire items, except for Q4 (discomfort when nozzle is inserted into nose), Q9 (ease of procedure), and Q10 (ease to push the trigger). Significantly fewer subjects perceived a bitter taste (0.98 vs 2.06 ; $p = 0.01$), medicine running down the throat (1.2 vs 2.27 ; $p = 0.033$), and medicine running out of the nose

Table 3
Mean change from baseline after 2 or 4 weeks of treatment in each group, and overall results.

JRQLQ category	Group 1 (FFNS/MFNS) $n = 21$		Group 2 (MFNS $\rightarrow$ FFNS) $n = 19$		Overall $n = 40$	
	2 weeks Mean change (%), SD	4 weeks Mean change (%), SD	2 weeks Mean change (%), SD	4 weeks Mean change (%), SD	2 weeks Mean change (%), SD	4 weeks Mean change (%), SD
I: nose/eye TSS	-4.2 (42%), 5.8	-5.5 (55%), 5.4	-4.0 (43%), 1.9	-5.1 (56%), 2.4	-4.1 (43%), 4.4	-5.3 (56%), 4.2
II: QOL total score	-6.2 (37%), 18.0	-10.2 (62%), 13.9	-5.7 (42%), 7.1	-7.7 (56%), 8.2	-6.0 (39%), 13.8	-9.0 (59%), 11.6
III: facial scale	-1.2 (46%), 1.4	-1.3 (49%), 1.2	-0.7 (37%), 0.7	-1.0 (56%), 0.8	-1.0 (42%), 1.1	-1.2 (50%), 1.0

All mean changes in score were statistically significant compared to baseline ($p < 0.001$). FFNS, fluticasone furoate nasal spray; MFNS, mometasone furoate nasal spray; JRQLQ, Japanese Rhinoconjunctivitis Quality of Life Questionnaire; TSS, total symptom score; QOL, quality of life.

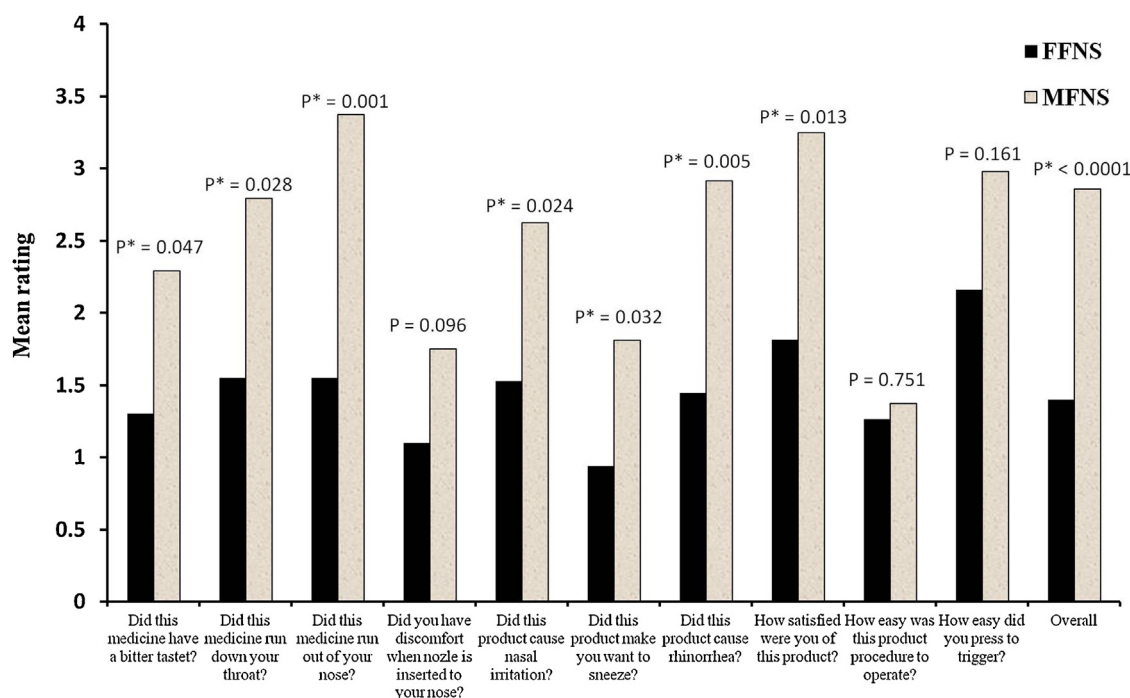


Fig. 1. Mean patient scoring for individual perceived sensory attributes of fluticasone furoate nasal spray (FFNS) and mometasone furoate nasal spray (MFNS). Each score ranged from 0 (very satisfied) to 10 (very dissatisfied). * Statistically significant ($p < 0.05$).

Table 4Mean gender-specific patient sensory attribute scores for each INCS ($n = 40$ (23 males and 17 females)).

Question	FFNS			MFNS		
	Male	Female	<i>p</i> value	Male	Female	<i>p</i> value
	Mean score (SD)			Mean score (SD)		
1. Did this medicine have a bitter taste?	1.0 (1.8)	1.2 (1.7)	0.7	1.8 (2.1)	3.2 (3.1)	0.09
2. Did this medicine run down your throat?	0.9 (2.1)	1.9 (3.0)	0.19	2.0 (2.0)	3.5 (3.6)	0.11
3. Did this medicine run out of your nose?	1.4 (2.0)	1.4 (2.5)	0.91	3.1 (3.0)	3.8 (3.8)	0.49
4. Did you have discomfort when the nozzle was inserted into your nose?	1.0 (1.9)	0.9 (1.3)	0.98	1.8 (2.2)	1.8 (2.5)	1
5. Did this product cause nasal irritation?	1.6 (1.8)	1.2 (1.6)	0.53	2.4 (2.8)	3.4 (2.8)	0.29
6. Did this product make you want to sneeze?	0.8 (1.5)	1.0 (1.5)	0.72	1.4 (2.0)	2.8 (2.8)	0.07
7. Did this product cause rhinorrhea?	1.2 (1.7)	1.6 (2.4)	0.52	1.9 (2.2)	4.4 (3.3)	<0.01*
8. How satisfied were you with this product?	1.8 (2.2)	1.2 (2.2)	0.36	2.6 (2.4)	4.9 (3.6)	0.02*
9. How easy was it to operate this product?	1.2 (1.4)	1.3 (1.8)	0.81	1.2 (1.7)	1.5 (2.0)	0.67
10. How easy was it to press the trigger?	2.2 (2.8)	2.2 (2.1)	0.98	2.6 (3.0)	3.0 (3.3)	0.76
Overall	1.3 (1.3)	1.4 (1.5)	0.49	2.1 (1.6)	3.2 (1.9)	0.04*

Each score ranged from 0 (very satisfied) to 10 (very dissatisfied). FFNS, fluticasone furoate nasal spray; MFNS, mometasone furoate nasal spray.

* Statistically significant ($p < 0.05$).

(1.31 vs 2.92; $p = 0.002$) with FFNS compared to MFNS, respectively. Furthermore, FFNS induced less nasal irritation (1.22 vs 2.43; $p = 0.012$), sneezing (0.78 vs 1.69; $p = 0.017$), and rhinorrhea (1.18 vs 2.53; $p = 0.007$). The mean overall score of FFNS was significantly lower than that of MFNS (1.17 vs 2.19; $p < 0.0003$). Additionally, we evaluated whether there were any gender-specific differences in perceived sensory attributes, by separately analyzing scores from males and females. Table 4 shows the overall scores comparing FFNS with MFNS [males, 1.31 vs 2.08 ($p = 0.02$); females, 1.4 vs 3.23 ($p = 0.004$)], demonstrating similar preference as the pooled results. While no significant difference was observed between genders in FFNS scores, females tended to report more discomfort than males for some of the sensory attributes when MFNS was administered (Table 4). Furthermore, there were no significant differences in baseline data between the two gender groups; nasal/eye total symptoms score was 9.2 ± 4.3 vs 9.5 ± 3.4 ($p = 0.815$), QOL total score was 14.9 ± 11.0 vs 15.4 ± 9.7 ($p = 0.896$), and general facial scale score was 2.3 ± 0.8 vs 2.2 ± 1.0 ($p = 0.896$).

The proportion of subjects in each group who provided a score over 5 points for each perceived sensory attribute question was calculated (Table 5). FFNS had significantly lower proportion of subjects providing a high score on Q3 (running out of nose, 7.5% vs 33.0%; $p = 0.01$), Q5 (induction of nasal irritation, 10.0% vs 30.0%; $p = 0.04$), Q7 (induction of rhinorrhea, 10.0% vs 30.0%; $p = 0.04$), and Q8 (overall satisfaction with the medication, 15.0% vs 37.5%; $p = 0.04$) compared with MFNS.

At the end of the study, the subjects were asked to select which INCS they wished to continue using. FFNS was preferred over MFNS

in 21 subjects (52.5%). Nine subjects (22.5%) selected MFNS, and 10 subjects had either no preference or preferred neither.

3.3. Safety

No severe safety issues were identified during the study. Adverse events occurred in 3 and 2 cases when using FFNS and MFNS, respectively. Two subjects experienced minor epistaxis when receiving FFNS and 1 subject when receiving MFNS. Complaints of a dull feeling of the pharynx were reported by 1 subject for both FFNS and MFNS, respectively, and only 1 subject complained of drowsiness when FFNS was administered. These occurrence rates were consistent with previous report [10,11].

4. Discussion

INCSs are effective for all major nasal and ocular symptoms associated with AR [12]. Previous reports have suggested that INCSs are more effective than oral anti-histamines [12], oral anti-leukotriene [13], and combinations of these two [14] if INCSs are administered daily; thus, INCSs are thought to be the most effective drug available for AR treatment. Two aqueous, alcohol-free, once-a-day type sprays (FFNS and MFNS) were used in this study, and showed a general improvement in nasal/eye symptoms as well as subject QOL evaluated using the JRQLQ. After a 4-week crossover treatment of two INCSs, TSS and QOL scores were reduced 56% and 59%, respectively. No significant differences between the two treatment groups were observed in this study, suggesting FFNS and MFNS may have comparable effects for short-term seasonal AR treatment.

On the other hand, continuing use of INCSs is often challenging in AR patients due to several factors limiting a patient's willingness to adhere to regular usage. The most common reason patients discontinue the use of INCSs was reported to be due to negative perceived sensory attributes of the INCS formulation, followed by device issues [14]. Therefore, patient perception of INCSs are influenced not only by effectiveness, but also by ease of use, comfort during administration, and perceived sensory attributes. Some comparison studies have shown that several INCSs vary in their perceived sensory attributes. Khanna et al. reported patient acceptance of INCSs based on sensory perception, comparing beclomethasone, budesonide, fluticasone propionate, and MFNS. They reported that MFNS was the most preferred INCS, due to less irritation, odor, and aftertaste, as well as superior moistness [8]. Kaiser et al. noted, while comparing FFNS and fluticasone propionate, that FFNS was significantly preferred based on

Table 5Ratio of patients who scored over 5 points for each product attributes ($n = 40$).

Question	FFNS (%)	MFNS (%)	<i>p</i> value
1. Did this medicine have a bitter taste?	12.5	25.0	0.25
2. Did this medicine run down your throat?	10.0	20.0	0.35
3. Did this medicine run out of your nose?	7.5	33.0	0.01*
4. Did you have discomfort when the nozzle was inserted into your nose?	5.0	20.0	0.09
5. Did this product cause nasal irritation?	10.0	30.0	0.04*
6. Did this product make you want to sneeze?	7.5	20.0	0.19
7. Did this product cause rhinorrhea?	10.0	30.0	0.04*
8. How satisfied were you with this product?	15.0	37.5	0.04*
9. How easy was it to operate this product?	7.5	10.0	1
10. How easy was it to press the trigger?	17.5	35.0	0.13

FFNS, fluticasone furoate nasal spray; MFNS, mometasone furoate nasal spray.

* Statistically significant ($p < 0.05$).

attributes of scent or odor, aftertaste, leakage out of the nose and down the throat, and mist gentleness [12]. Availability of nasal sprays and formulations varies from country to country. FFNS and MFNS are both available in Japan and occupy a large market share. Although many clinicians prefer to use either product for the treatment of AR, little attention may be paid to the patient's perception and satisfaction with INCSSs. Because there has not been any comparative study between FFNS with MFNS focusing on perceived sensory attributes or ease of use, we performed this study using a prospective, crossover design to assess the differences between these two INCSSs.

Although the perceived sensory attribute scores of either INCSS were not as high as reported in previous studies, FFNS was superior to MFNS for a number of individual perceived sensory attributes based on mean subject ratings in the present study. Additionally, we evaluated the proportion of subjects who provided a score over 5 points for each individual product attribute, which represents the proportion of subjects that feel moderate to severe sensory discomfort. A high proportion suggests possible decrease in patient adherence to regular use over a long-term period. From the results of the present study, medicine dripping out of the nose and nasal shooting are the most common problems with MFNS, indicating that FFNS should be selected if patients feel significant discomfort with these matters due to significantly fewer patients reporting strong discomfort with FFNS. The average dose of FFNS is 100 μ l per nostril when using the daily recommended two sprays per nostril, which is less than that of MFNS (200 μ l per nostril). Responses to Q3 (Did this medicine run out of your nose?) suggest that higher patient satisfaction may be obtained by use of FFNS compared to MFNS due to the smaller volume of drug, which is less likely to run out of the nose. In addition, the pH of the FFNS formulation is adjusted at 5.0–7.0, which is higher than MFNS formulation (pH 4.3–4.9), which may influence the difference in nasal shooting between the two INCSSs.

Furthermore, we investigated possible gender differences in perceived sensory attributes with INCSSs. Females tended to score some questionnaire items higher than males when MFNS was administered, and overall dissatisfaction was significantly greater in the female group. On the other hand, such gender differences were not observed with FFNS. Previous studies have suggested that females may have higher nasal sensitivity than males [15,16], and while the underlying reasons remain to be clarified, Shusterman et al. speculated that estrogen may play a role in this gender-specific difference [16]. Furthermore, Ishigaki et al. suggested that there was a significantly lower sensory threshold of the trigeminal nerve area in females than in males [17]. Thus, these factors may have influenced the differences observed in the present study between the genders in the perceived sensory attributes of MFNS. Our results suggested that females may experience more discomfort when using INCSSs, and more care may be needed when selecting which INCSS to use.

The drug delivery device also influences patient adherence to regular use. It was previously reported that 20% of patients stopped using INCSSs due to device issues alone [18]. FFNS was designed to have a side actuation trigger and a shorter delivery nozzle [18,19], in hopes to allow easier and less invasive usage. Contrary to expectations, subjects reported no significant differences in device attributes between FFNS and MFNS in the present study.

Overall, 52.5% of subjects expressed a preference for FFNS compared with 22.5% for MFNS. Although FFNS was favored for a number of perceived sensory attributes, some complaints were also noted (e.g. subjects were uncertain whether an accurate dose was applied due to variability in shooting, or the need for significant pressure to press the trigger due to its hardness). Emphasis should be placed on detailed interview with patients for their preferences and complaints to determine which INCSS is

suitable for the individual. Appropriate drug selection may contribute to maximizing effectiveness and promoting adherence to regular use of the treatment.

5. Conclusion

INCSSs are an important treatment for AR, and perceived product sensory attributes contribute to patient preference and good adherence of treatment. This study demonstrated that FFNS was superior to MFNS for a number of individual perceived sensory attributes due to less treatment running out of the nose, and less induction of nasal irritation or rhinorrhea, and was markedly preferred by females. On the other hand, patient satisfaction with either drug delivery device was comparable. Such findings suggest that FFNS may contribute to enhanced AR treatment outcomes due to improved treatment adherence.

Conflicts of interest

The authors report no conflict of interest in financial support and funding.

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