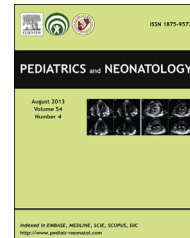




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ORIGINAL ARTICLE

# Comparison of Mometasone Furoate Monohydrate (Nasonex) and Fluticasone Propionate (Flixonase) Nasal Sprays in the Treatment of Dust Mite-sensitive Children with Perennial Allergic Rhinitis

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## Key Words

allergic rhinitis;  
eosinophil;  
fluticasone  
propionate;  
mometasone furoate  
monohydrate;  
nasal peak expiratory  
flow rate;  
Pediatric  
Rhinoconjunctivitis  
Quality of Life  
Questionnaire;  
total symptom score

**Background:** Various studies have investigated the efficacies of mometasone furoate monohydrate (MFM) and fluticasone propionate (FP) nasal sprays for adults. However, research on their effectiveness for children is limited. This study compares the efficacies of MFM and FP nasal sprays in pediatric patients with perennial-allergic rhinitis.

**Materials and methods:** For this study, 94 perennial allergic rhinitis patients aged 6–12 years were randomly assigned to two treatment groups: an MFM group and an FP group. Treatment was provided for 4 weeks. The effects of the two agents were compared using the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire and total symptom scores (TSSs). Nasal-peak expiratory flow rates and eosinophil percentage in nasal smears were also compared between the two groups.

**Results:** Patients in the MFM group exhibited significant improvement in their TSS ( $t = -2.65$ ,  $p < 0.05$ ). A detailed TSS analysis showed MFM to be more effective for relieving nasal symptoms, whereas FP was more effective for relieving non-nasal symptoms. Patient questionnaire scores suggested a significant reduction in symptoms for both the MFM ( $t = -7.23$ ,  $p < 0.01$ ) and FP ( $t = -5.43$ ,  $p < 0.01$ ) groups. The flow rate test results indicated significant improvements in the MFM group ( $t = 2.27$ ,  $p < 0.05$ ).

**Conclusion:** Following the 4-week therapy, MFM provided greater improvement compared to FP for symptoms of childhood perennial-allergic rhinitis. Based on their TSSs, the MFM group

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experienced more effective relief of nasal symptoms, whereas the FP group experienced more effective relief of non-nasal symptoms.

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## 1. Introduction

Allergic rhinitis (AR) is a common chronic condition among children that is typically diagnosed by age 6 years. In western countries, an estimated 10–25% of the population has AR, with 30–60 million people affected annually in the USA.<sup>1</sup> Rhinitis is characterized by recurrent chronic nasal symptoms such as congestion, rhinorrhea (often including postnasal drip), nasal itching, sneezing, and conjunctiva irritation. AR causes sleep disturbance, impairs psychosocial functioning, and reduces life quality.<sup>2</sup>

AR treatment presents a significant medical challenge. The Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines recommend intranasal corticosteroids as the first-line treatment for patients with moderate to severe or persistent rhinitis.<sup>3</sup> For adults, several intranasal corticosteroid treatment options exist. However, for children (age >4 years) the treatment options are limited. Mometasone furoate monohydrate (MFM; Nasonex) and fluticasone propionate (FP; Flixonase) nasal sprays have been approved by the Food and Drug Administration (FDA) in Taiwan for treating childhood AR. A multicenter study with patients aged 12–77 years found that both MFM and FP adequately controlled symptoms of perennial rhinitis and were well tolerated.<sup>4</sup> However, clinical physicians lack information on the effects of MFM compared to FP intranasal steroids for children with perennial AR. This study was a clinical trial comparing the efficacies of MFM and FP nasal sprays for treating perennial AR in children aged 6–12 years.

## 2. Materials and Methods

### 2.1. Participants

This study was conducted in the Division of Allergy, Asthma, and Rheumatology of the Department of Pediatrics at Chung Shan Medical University Hospital, Taichung, Taiwan, between December 2010 and June 2011. The study was approved by the Chung Shan Medical University Hospital Institutional Review Board, and written parental consent was obtained prior to commencement. The study did not receive the MFM and FP Corporate Support Grant. The inclusion criteria were: (1) moderate-to-severe perennial AR (defined in the ARIA classification as AR that occurs throughout the year) for at least 1 year; (2) a positive reaction to mite-specific IgE (Pharmacia, Uppsala, Sweden; entering this study >0.35 kUA/L); and (3) allergy to house dust mites confirmed by a skin-prick test response. Test-allergen extracts were prepared from dust mites (Alyostal; Stallergenes, Paris, France). All patients were required to undergo a control test (negative control with normal saline). In positive skin-prick test responses, the

skin becomes red and swollen with a wheal >3 mm in diameter.

The exclusion criteria were: (1) a positive response to other allergens; (2) deformities of the ear, nose, or throat, or infection in the 2 weeks preceding the initial visit; (3) medication consumption that may affect allergy symptoms (such as oral antihistamines, decongestants, steroids, or leukotriene antagonists) within 2 weeks prior to the study or during the study period; (4) upper and lower respiratory-tract infection within 2 weeks prior to the study; (5) intranasal corticosteroid use within 2 weeks prior to the study; and (6) nasal polyp disease. In total, 94 children with perennial AR aged 6–12 years met the inclusion criteria for this study.

### 2.2. Study design

In the initial-screening visit, comprehensive medical and allergy histories were obtained for all participants. Daily-activity diaries were provided to the participants, with instructions to record all symptoms once treatment began. Participant medication history was reviewed to ensure that they had not used an H1 antagonist, decongestant, oral steroid, or intranasal corticosteroid in the preceding 2 weeks. During the baseline visit, nasal-peak expiratory flow rate (nPEFR) tests and examinations of the eosinophil percentage in nasal smears were performed; patients were also instructed to complete the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ). The diaries of patient activity for the preceding 7 days were also reviewed.

The study design was randomized, prospective, and controlled. The participants were randomly divided into two groups. Of the 94 participants, 47 received a 100 µg dose of MFM nasal spray (1 spray/nostril) daily, and the remaining 47 participants received a 100 µg dose of FP nasal spray (1 spray/nostril) daily. Numerous envelopes were placed into a box, and the enrolled patients were instructed to randomly select one envelope. Patients were treated for 4 weeks and then transferred to our outpatient clinic. Physical examinations, nasal smears for eosinophil percent, and nPEFR tests were performed, and all daily diary cards were collected. Patients were then instructed to complete the PRQLQ again.

### 2.3. Total symptom score

Rhinitis symptoms were measured using a 4-point scale, with scores as follows: 0 denoted “none” (*no noticeable symptoms*); 1 denoted “mild” (*symptoms are noticeable but not bothersome*); 2 denoted “moderate” (*symptoms are noticeable and occasionally bothersome*); and 3 denoted “severe” (*symptoms are generally bothersome and occasionally extremely bothersome*). The patients recorded their daily scores for four nasal symptoms (rhinorrhea, nasal stuffiness, nasal itching, and sneezing) and four non-nasal symptoms

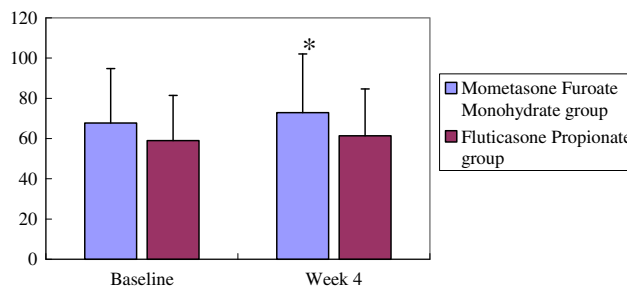
(throat itching, eye itching, tearing, and eye congestion). The symptom scores for younger children were recorded with parental assistance. Patients' total symptom score (TSS) was the sum of the eight recorded symptom scores. Baseline TSS and each symptom score were calculated as the mean of the daily scores during the baseline period of 7 days.<sup>5</sup>

### 2.4. PRQLQ

The PRQLQ contained 23 questions in five categories (nasal symptoms, eye symptoms, practical problems, activity limitations, and other symptoms).<sup>6</sup> The children recalled their experiences from previous weeks and responded to each question using a 7-point scale (ranging from 0 to 6).<sup>7</sup> The questionnaire was completed within 5 minutes, and the scores for younger children (age < 9 years) were recorded with parental assistance.

### 2.5. nPEFR

The nPEFR was measured using a Mini-Wright peak expiratory flow meter (HS clement Clarke international company). The flow meter was equipped with a purpose-built facemask that incorporated an effective facial seal, which was worn by the patients during tests. Each patient was instructed to blow forcefully through the nose after taking a deep breath, while keeping the mouth firmly closed. For



**Figure 1** Mean value of nasal peak expiratory flow rate in baseline and Week 4. By paired *t* test,  $\alpha = 0.05$ ,  $*p < 0.05$ . Baseline means the first day of treatment. Y axis is the average mean value of nasal peak expiratory flow rate. X axis is the therapy period. Mometasone furoate monohydrate group ( $t = 2.27$ ,  $p < 0.05$ ) significantly increased the nasal peak expiratory flow rate value.

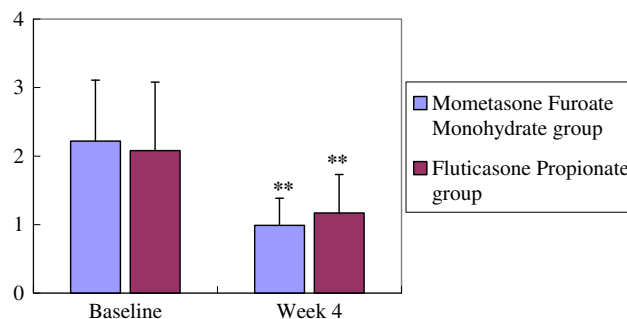
younger children, the nPEFR test was conducted with parental assistance. The test was performed three times, and the highest result was recorded.

### 2.6. Eosinophil percentage in nasal-smear examinations

The underside of the patients' inferior turbinate was swabbed with a cotton wool bud, and the obtained sample was smeared onto a glass slide. These slides were then stained with Leu stain and examined using a light microscope. An experienced cytologist, blind to the participants' clinical status, performed this assay. The patients' eosinophil percentage in nasal smears was determined by counting a minimum of 100 leukocytes, and the eosinophil count was expressed as a proportion of the total number of leukocytes.<sup>8</sup>

### 2.7. Statistical analysis

Statistical analysis was performed using SPSS/PC12.0 software (SPSS, Inc., Chicago, IL, USA). All data are expressed as mean  $\pm$  standard deviation. An independent-sample

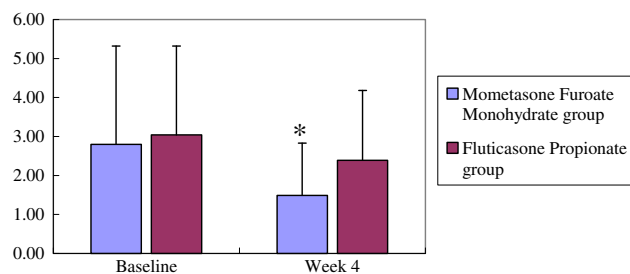


**Figure 2** Mean value of Pediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ) in baseline and Week 4. By paired *t* test,  $\alpha = 0.05$ ,  $*p < 0.01$ . Baseline means the first day of treatment. Y axis is the average mean value of PRQLQ. X axis is the therapy period. Both mometasone furoate monohydrate group ( $t = -7.23$ ,  $p < 0.01$ ) and fluticasone propionate group ( $t = -5.43$ ,  $p < 0.01$ ) significantly reduced the PRQLQ value.

**Table 1** Demography of characteristics and baseline data of the both mometasone furoate monohydrate (MFM) and fluticasone propionate (FP) groups.

Variables	MFM group	FP group
No.	40	43
Gender		
Male	23 (57.5%)	24 (55.8%)
Female	17 (42.5%)	19 (44.2%)
Height (cm)	125.92 $\pm$ 14.05	123.35 $\pm$ 13.43
Weight (kg)	28.79 $\pm$ 12.11	26.81 $\pm$ 10.01
Atopy history	32 (80.0%)	34 (79.1%)
Age (y)	9.96 $\pm$ 2.18	9.14 $\pm$ 2.41
Allergic rhinitis history		
Own	40 (100%)	43 (100%)
Mother	12 (30.0%)	19 (44.2%)
Father	19 (47.5%)	22 (51.2%)
Siblings	17 (42.5%)	16 (37.2%)
Asthma history		
Own	0 (0.0%)	3 (7.0%)
Mother	2 (5.0%)	1 (2.3%)
Father	0 (0.0%)	1 (2.3%)
Siblings	2 (5.0%)	1 (2.3%)
Atopic dermatitis history		
Own	0 (0.0%)	2 (4.7%)
Mother	0 (0.0%)	0 (0.0%)
Father	2 (5.0%)	0 (0.0%)
Siblings	4 (10.0%)	1 (2.3%)
Serum IgE (IU/mL)	482.80 $\pm$ 314.34	537.49 $\pm$ 519.83
Eosinophil % in nasal smear	54.68 $\pm$ 16.10	59.08 $\pm$ 16.38

Data are presented as *n* (%) or mean  $\pm$  standard deviation.



**Figure 3** Mean value of total symptom score (TSS) in baseline and Week 4. By paired *t* test,  $\alpha = 0.05$ , \* $p < 0.05$ . Baseline means the first week of treatment. Y axis is the average mean value of the TSS. X axis is the therapy period. Mometasone furoate monohydrate group ( $t = -2.65$ ,  $p < 0.05$ ) significantly reduced the TSS value.

*t* test was used to compare the improvement rates of the mean nasal PEFR, the mean PRQLQ score (for each question), and the mean TSS for the two groups. A *p* value  $< 0.05$  was considered statistically significant.

### 3. Results

A total of 94 patients were enrolled in this study, with 47 patients assigned to an MFM group and 47 patients assigned

to an FP group. However, 11 patients (7 from the MFM group and 4 from the FP group) with incomplete TSS recordings during the treatment period were subsequently excluded from this study. The mean age of the patients was 9 years (range, 6–12 years). No significant differences were observed between the two groups for baseline demographics or health characteristics (Table 1).

Regarding nPEFR, the MFM group improved significantly after 4 weeks of treatment (from  $67.71 \pm 23.24$  at the baseline to  $72.88 \pm 28.20$  at Week 4;  $p < 0.05$ ) (Figure 1). For PRQLQ scores, both the MFM group ( $2.22 \pm 0.92$  to  $0.99 \pm 0.69$ ;  $p < 0.01$ ) and the FP group ( $2.08 \pm 0.99$  to  $1.17 \pm 0.80$ ;  $p < 0.01$ ) improved significantly during treatment (Figure 2). The MFM group showed a greater decline in PRQLQ scores compared to that of the FP group; however, the difference was non-significant ( $t = -1.23$ ,  $p = 0.224$ ). The TSS for the MFM group also improved significantly following treatment (from  $2.80 \pm 2.55$  to  $1.49 \pm 1.30$ ;  $p < 0.05$ ; Figure 3).

The scores for each item in the PRQLQ were then analyzed. The MFM group exhibited a significant improvement for all symptom categories excluding eye symptoms, with swollen eyes ( $t = -1.50$ ,  $p = 0.148$ ) and sore eyes ( $t = -1.80$ ,  $p = 0.086$ ), showing limited or nonsignificant improvement. In other symptom categories, no significant improvement was noted for thirst ( $t = -2.01$ ,  $p = 0.056$ )

**Table 2** Change from baseline (first day of treatment) of individual symptom items Pediatric Rhinoconjunctivitis Quality of Life Questionnaire in the mometasone furoate monohydrate group ( $n = 40$ ).

Variables	Baseline	Week 4	Difference	<i>t</i>	<i>p</i>
<b>Nose symptoms domains</b>					
Sneezing	$2.67 \pm 1.40$	$1.21 \pm 1.10$	$-1.46 \pm 1.50$	-4.75	0.000***
Runny nose	$2.88 \pm 1.54$	$1.08 \pm 1.02$	$-1.79 \pm 1.64$	-5.35	0.000***
Stuffy	$3.79 \pm 1.84$	$1.00 \pm 1.06$	$-2.79 \pm 1.91$	-7.16	0.000***
Itchy nose	$3.08 \pm 1.41$	$1.29 \pm 0.86$	$-1.79 \pm 1.44$	-6.08	0.000***
<b>Eye symptoms domains</b>					
Itchy eyes	$2.29 \pm 1.55$	$1.42 \pm 1.25$	$-0.88 \pm 1.48$	-2.89	0.008**
Watery eyes	$1.08 \pm 1.06$	$0.54 \pm 0.83$	$-0.54 \pm 1.18$	-2.25	0.034*
Swollen	$0.67 \pm 0.70$	$0.38 \pm 0.71$	$-0.29 \pm 0.95$	-1.50	0.148
Sore eyes	$0.79 \pm 0.93$	$0.33 \pm 0.76$	$-0.46 \pm 1.25$	-1.80	0.086
<b>Practical problems domains</b>					
Rub nose and eyes	$2.92 \pm 1.44$	$1.54 \pm 1.28$	$-1.38 \pm 1.64$	-4.12	0.000***
Blow nose	$2.96 \pm 1.78$	$1.04 \pm 1.08$	$-1.92 \pm 1.86$	-5.04	0.000***
Carry Kleenex	$2.75 \pm 1.78$	$0.83 \pm 0.82$	$-1.92 \pm 1.91$	-4.92	0.000***
Take medications	$2.67 \pm 1.81$	$1.04 \pm 1.00$	$-1.63 \pm 2.02$	-3.95	0.001***
Feel embarrassed	$2.29 \pm 1.65$	$0.83 \pm 1.09$	$-1.46 \pm 1.25$	-5.71	0.000***
<b>Other symptoms domains</b>					
Thirst	$1.29 \pm 1.23$	$0.75 \pm 0.94$	$-0.54 \pm 1.32$	-2.01	0.056
Don't feel well all over	$2.00 \pm 1.44$	$1.17 \pm 0.92$	$-0.83 \pm 1.37$	-2.97	0.007**
Irritable	$2.29 \pm 1.73$	$1.04 \pm 1.08$	$-1.25 \pm 1.22$	-5.00	0.000***
Tired	$1.92 \pm 1.59$	$1.33 \pm 1.13$	$-0.58 \pm 1.61$	-1.77	0.090
Headache	$1.67 \pm 1.76$	$0.67 \pm 0.92$	$-1.00 \pm 1.59$	-3.09	0.005**
Itchy throat	$1.46 \pm 1.61$	$0.54 \pm 0.78$	$-0.92 \pm 1.32$	-3.41	0.002**
<b>Activities limitation domains</b>					
Playing outdoors	$1.33 \pm 1.86$	$0.46 \pm 0.78$	$-0.88 \pm 1.73$	-2.48	0.021*
Hard to get to sleep at night	$3.00 \pm 1.82$	$1.58 \pm 1.61$	$-1.42 \pm 1.53$	-4.54	0.000***
Hard to pay attention	$2.79 \pm 1.67$	$1.46 \pm 1.59$	$-1.33 \pm 1.40$	-4.65	0.000***
Wake up during the night	$2.50 \pm 1.72$	$1.21 \pm 1.47$	$-1.29 \pm 1.57$	-4.02	0.001**

By paired *t* test,  $\alpha = 0.05$ , \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . Data are presented as means  $\pm$  standard deviation.

and tiredness ( $t = -1.77$ ,  $p = 0.09$ ; Table 2). The FP group also showed improvement in all categories excluding eye symptoms, with limited or nonsignificant improvement for watery eyes ( $t = -1.99$ ,  $p = 0.054$ ) and sore eyes ( $t = -1.07$ ,  $p = 0.291$ ; Table 3).

For both the MFM and FP groups, we analyzed the change in TSS from baseline (Week 1) to Weeks 2, 3, and 4 of the treatment. The TSS was the sum of the eight symptom scores. No statistically significant differences were observed between the two groups for baseline (W1) TSS scores. The MFM group experienced improvement in AR nasal symptoms, with symptom improvements of rhinorrhea, nasal stuffiness, nasal itching, and sneezing achieving statistical significance. The FP group experienced improved non-nasal AR symptoms, with improved eye-itching symptoms, achieving statistical significance (Table 4).

An examination of eosinophil percentage in nasal smears showed statistically significant improvements for both the MFM (from  $54.68 \pm 16.10$  at baseline to  $39.30 \pm 15.09$  at Week 4;  $p < 0.01$ ) and FP (from  $59.08 \pm 16.38$  at baseline to  $40.92 \pm 14.84$  at Week 4;  $p < 0.01$ ) groups following treatment. No significant differences were observed between the two groups ( $t = -1.13$ ,  $p = 0.26$ ).

#### 4. Discussion

Previous clinical trials have found that intranasal corticosteroid sprays are effective for relieving adult AR.<sup>9–11</sup> However, clinical trials assessing the efficacy of such sprays for children with AR are scant.<sup>12–14</sup> Related literature does not report research comparing the use of MFM to FP in children. Our study results show that both intranasal corticosteroid sprays (MFM and FP) were effective for managing AR in children. MFM treatment was associated with a significant improvement in mean nPEFR values, mean PRQLQ scores, mean TSS, and eosinophil percentage in nasal smears. A further detailed analysis of TSS indicated that MFM was more effective than FP for relieving nasal symptoms, whereas FP was more effective than MFM for relieving non-nasal symptoms.

We also found that the nPEFR test results improved significantly for children with AR treated with MFM, but not for children treated with FP. Sharma and Baroody showed that MFM nasal sprays significantly reduced nasal-peak inspiratory flow in AR.<sup>15,16</sup> Their results were consistent with those of this study. By contrast, FP nasal sprays did not significantly reduce the expression of endothelial vascular cell adhesion molecule-1 or the

**Table 3** Change from baseline of individual symptom items Pediatric Rhinoconjunctivitis Quality of Life Questionnaire in the fluticasone propionate group ( $n = 43$ ).

Variables	Baseline	Week 4	Difference	<i>t</i>	<i>p</i>
Nose symptoms domains					
Sneezing	2.40 ± 1.43	1.56 ± 1.05	-0.84 ± 1.46	-3.75	0.001**
Runny nose	2.49 ± 1.44	1.53 ± 1.20	-0.95 ± 1.70	-3.67	0.001**
Stuffiness	3.65 ± 1.72	1.74 ± 1.18	-1.91 ± 1.84	-6.81	0.000***
Itchy nose	2.91 ± 1.80	1.47 ± 1.12	-1.44 ± 1.71	-5.53	0.000***
Eye symptoms domains					
Itchy eyes	2.21 ± 1.66	1.21 ± 1.10	-1.00 ± 1.60	-4.09	0.000***
Watery eyes	0.91 ± 1.06	0.56 ± 0.80	-0.35 ± 1.15	-1.99	0.054
Swollen	1.12 ± 1.47	0.63 ± 0.69	-0.49 ± 1.32	-2.43	0.019*
Sore eyes	0.74 ± 1.09	0.58 ± 0.76	-0.16 ± 1.00	-1.07	0.291
Practical problems domains					
Rub nose and eyes	2.91 ± 1.77	1.88 ± 1.31	-1.02 ± 1.82	-3.69	0.001**
Blow nose	2.74 ± 1.72	1.35 ± 1.25	-1.40 ± 2.05	-4.47	0.000***
Carry Kleenex	2.28 ± 1.83	1.12 ± 1.40	-1.16 ± 1.94	-3.93	0.000***
Take medications	2.65 ± 2.25	1.00 ± 1.30	-1.65 ± 2.45	-4.42	0.000***
Feel embarrassed	2.19 ± 1.48	1.23 ± 1.29	-0.95 ± 1.62	-3.87	0.000***
Other symptoms domains					
Thirst	1.05 ± 1.25	0.60 ± 0.88	-0.44 ± 1.16	-2.50	0.017*
Don't feel well all over	2.21 ± 1.41	1.44 ± 1.40	-0.77 ± 1.82	-2.76	0.009**
Irritable	2.09 ± 1.41	1.33 ± 1.27	-0.77 ± 1.56	-3.23	0.002**
Tired	2.23 ± 1.46	1.37 ± 1.16	-0.86 ± 1.63	-3.47	0.001**
Headache	1.16 ± 1.66	0.65 ± 1.00	-0.51 ± 1.61	-2.09	0.043*
Itchy throat	1.07 ± 1.44	0.56 ± 0.93	-0.51 ± 1.55	-2.17	0.036*
Activities limitation domains					
Playing outdoors	1.56 ± 1.79	0.72 ± 1.10	-0.84 ± 1.96	-2.80	0.008**
Hard to get to sleep at night	2.49 ± 1.62	1.33 ± 1.25	-1.16 ± 1.76	-4.34	0.000***
Hard to pay attention	2.86 ± 1.51	1.81 ± 1.58	-1.05 ± 1.72	-4.00	0.000***
Wake up during the night	1.93 ± 1.49	1.14 ± 1.32	-0.79 ± 1.83	-2.83	0.007**

By paired *t* test,  $\alpha = 0.05$ , \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . Data are presented as means ± standard deviation.

**Table 4** Changes in total symptom score from baseline (Week 1) of individual symptoms.

	Mometasone furoate monohydrate group (n = 40)	p	Fluticasone propionate group (n = 43)	p
<b>Nasal symptoms</b>				
<b>Rhinorrhea</b>				
W1–W2	−0.42 ± 3.27	0.539	0.12 ± 2.73	0.782
W1–W3	−1.54 ± 4.58	0.113	0.84 ± 3.86	0.163
W1–W4	−2.17 ± 4.74	0.035*	0.58 ± 4.33	0.384
<b>Nasal stuffiness</b>				
W1–W2	−1.13 ± 3.61	0.140	−0.87 ± 3.21	0.082
W1–W3	−1.83 ± 4.58	0.062	−0.35 ± 4.16	0.585
W1–W4	−2.04 ± 4.31	0.029*	−0.91 ± 4.36	0.180
<b>Nasal itching</b>				
W1–W2	−0.85 ± 2.76	0.143	−0.84 ± 2.76	0.053
W1–W3	−1.52 ± 3.28	0.033*	−0.91 ± 3.25	0.075
W1–W4	−1.54 ± 3.28	0.031*	−1.42 ± 3.27	0.007**
<b>Sneezing</b>				
W1–W2	−0.48 ± 2.53	0.364	−0.51 ± 2.25	0.144
W1–W3	−1.73 ± 2.80	0.006**	−0.38 ± 2.88	0.387
W1–W4	−1.73 ± 2.98	0.009**	−0.69 ± 3.23	0.170
<b>Non-nasal symptoms</b>				
<b>Throat itching</b>				
W1–W2	0.19 ± 1.88	0.630	0.02 ± 2.06	0.941
W1–W3	−0.50 ± 1.84	0.195	0.36 ± 2.65	0.377
W1–W4	−0.44 ± 2.97	0.478	−0.08 ± 2.57	0.837
<b>Eye itching</b>				
W1–W2	−0.27 ± 1.47	0.375	−1.14 ± 2.36	0.003**
W1–W3	−0.83 ± 2.66	0.139	−1.58 ± 3.28	0.003**
W1–W4	−0.63 ± 3.39	0.375	−1.37 ± 3.53	0.014*
<b>Tearing</b>				
W1–W2	−0.38 ± 0.95	0.065	−0.34 ± 1.55	0.160
W1–W3	−0.71 ± 1.69	0.052	−0.36 ± 1.96	0.234
W1–W4	−0.44 ± 2.05	0.307	−0.50 ± 1.75	0.068
<b>Eye congestion</b>				
W1–W2	−0.17 ± 0.72	0.267	−0.20 ± 1.20	0.285
W1–W3	−0.63 ± 1.61	0.070	−0.15 ± 1.71	0.565
W1–W4	−0.17 ± 1.61	0.618	−0.19 ± 1.89	0.521

By paired *t* test,  $\alpha = 0.05$ , \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . Data are presented as means ± standard deviation. W1 means the period from day 1 to day 7 of the first week. Scoring for each 1 week period was calculated as (daytime score + nighttime score)/2.

number of tumor necrosis factor- $\alpha$  or interleukin-1 $\beta$  mRNA+ cells.<sup>17</sup> This finding is reflected in clinical outcomes in which nasal sprays are ineffective for altering nasal or lower airway variables.<sup>17</sup>

In this study, both the MFM and FP groups showed limited improvement in PRQLQ scores for eye symptoms associated with childhood AR. Bielory et al<sup>18</sup> and Rodrigo et al<sup>19</sup> reported that the use of an FP nasal spray once daily effectively relieves ocular and nasal symptoms in adolescents and adults with AR. The patients included in the present study were all children. FP delivered through the intranasal route has an absolute bioavailability average of <2%, and MFM shows extremely low bioavailability (<1%) in plasma.<sup>20,21</sup> Thus, nasal sprays may fail to control ocular symptoms if they cannot induce any meaningful movement of allergens, their mediators, or antiallergy drugs from the nasal cavity to the ocular surface.<sup>22</sup>

We found MFM sprays to be significantly more effective than FP sprays for relieving nasal symptoms, as evidenced by the differences in TSS between the two groups. However, FP was significantly more effective than MFM for relieving non-nasal symptoms, which was also evidenced by the TSS differences. Keith and Scadding<sup>23</sup> indicated that not all intranasal corticosteroids are consistent for managing the ocular symptoms of seasonal AR. Meltzer et al<sup>24</sup> also reported that patients rated several sensory attributes of MFM nasal sprays as significantly superior to those of FP nasal sprays. One study found that FP nasal sprays were ineffective regarding mucociliary transport time.<sup>25</sup> Another reported that MFM nasal sprays (200  $\mu$ g twice daily) rapidly improved nasal polyposis symptoms and swelling.<sup>26</sup> These results may be due to patients objectively perceiving MFM nasal sprays to be superior in because in clinical settings.

This study was subject to several limitations. First, most of the younger participants required parental assistance to

record their responses to the PRQLQ and TSS, and may thus reflect the experiences of parents rather than their children. Recall bias also contributed to the inconsistent TSS and PRQLQ results. However, we employed various examinations, including nPEFR and the eosinophil percentage in nasal smears, to reduce questionnaire bias. Second, we did not classify the severity of patients' AR in this study; otherwise, the possible response differences to treatment for mild-persistent, severe-intermittent, or severe-persistent types of AR could have been analyzed. Finally, we lacked patient data on family-member smoking habits and household pets, which are factors that may affect AR symptoms.<sup>27</sup>

The results of our 4-week treatment program showed that MFM nasal sprays were more effective than FP nasal sprays for improving the symptoms of childhood perennial AR. Although the TSS for the FP group did not show significant improvement, the patients experienced more effective relief from non-nasal symptoms.

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