

A COMPARATIVE STUDY OF SENSORY ATTRIBUTES AND EFFICACY BETWEEN INTRANASAL CICLESONIDE AND FLUTICASONE PROPIONATE IN ALLERGIC RHINITIS

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ABSTRACT

Objectives: The objective of this study was to compare the clinical efficacy, sensory tolerability, and overall patient preference between fluticasone propionate (FLP) and ciclesonide (CIC) in patients with allergic rhinitis (AR).

Methods: An observational, crossover study was conducted at a tertiary ENT hospital in Hyderabad from December 2020 to November 2022. A total of 120 adult patients (n=120, 60 per sequence) with moderate-to-severe AR (total nasal symptom score [TNSS] ≥ 6) were enrolled. Participants received a single intranasal dose of FLP 200 mcg or CIC in a randomized sequence with a 30-min washout period before crossover. TNSS scores were recorded at baseline and 10 min post-dose. Sensory attributes were evaluated using a validated 7-point Likert scale, and overall treatment preference was recorded after both sprays. Data were analyzed using the Statistical Package for the Social Sciences v26, with $p < 0.05$ considered significant.

Results: Both sprays produced a significant reduction in TNSS within 10 min (median reduction: 5 points in both groups, $p < 0.001$). Between-group comparison showed no significant difference in total TNSS change ($p = 0.774$). Ocular itching improved significantly with FLP compared to CIC (19.2% vs. 12.5%, $p = 0.0442$), while other nasal symptoms (sneezing, congestion, nasal itch, and rhinorrhea) showed no significant differences. Sensory evaluation revealed that FLP was preferred for soothing feel (58.3% vs. 22.5%, $p < 0.0001$) and satisfying scent (55% vs. 8.3%, $p < 0.001$), whereas aftertaste and throat sensations were slightly better with CIC. Overall, 59.4% of patients preferred FLP, 28.3% CIC, and 12.3% had no preference.

Conclusion: FLP and CIC are both effective and well-tolerated for AR management. Fluticasone showed marginally superior ocular symptom relief and higher patient preference, while CIC offered slightly better throat tolerability. Tailoring intranasal corticosteroid selection to patient-reported sensory experience may enhance adherence and clinical outcomes.

Keywords: Allergic rhinitis, Fluticasone propionate, Ciclesonide, Sensory attributes, Total nasal symptom score.

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INTRODUCTION

Allergic rhinitis (AR) is a chronic, immunoglobulin E (IgE)-mediated inflammatory condition of the nasal mucosa triggered by exposure to environmental allergens. It is clinically characterized by four cardinal symptoms: Rhinorrhea, sneezing, nasal itching, and nasal congestion [1,2]. As a common and underdiagnosed condition, AR represents a substantial global public health burden, particularly in developing countries like India, where it affects a large segment of the population. Notably, up to 80% of asthmatic adults in India report concurrent symptoms of AR, underscoring the close association between upper and lower airway diseases [3].

The pathophysiology of AR is multifactorial and involves both early and late-phase hypersensitivity responses. On allergen exposure – such as pollen, house dust mites, mold spores, or animal dander – genetically predisposed individuals develop an exaggerated immune response [4]. The allergens cross-link IgE antibodies bound to receptors on mast cells and basophils, leading to degranulation and release of histamine, prostaglandins, leukotrienes, and cytokines. This cascade results in increased vascular permeability, mucosal edema, and stimulation of sensory nerves, producing symptoms such as sneezing, nasal discharge, and congestion [5-7].

With continued or repeated allergen exposure, chronic inflammation is perpetuated through the recruitment of eosinophils, T-helper cells, and additional mast cells, contributing to persistent symptoms and nasal hyperreactivity. The late-phase response, often peaking several hours

after initial allergen exposure, further exacerbates mucosal swelling and obstruction [6]. Glucocorticoids have been shown to suppress various inflammatory mediators involved in this phase, thereby reducing symptom severity and frequency.

Intranasal corticosteroids (INCs) are currently regarded as the most effective monotherapy for moderate to severe AR, offering superior control over nasal symptoms compared to antihistamines [8]. However, the clinical effectiveness and patient adherence to INC therapy are influenced not only by pharmacodynamics but also by the sensory attributes of the formulation – such as taste, smell, pH, osmolality, and the presence of preservatives. These factors can significantly affect patient tolerability and satisfaction [9,10].

Among the available INCs, ciclesonide (CIC) is a newer-generation corticosteroid with potent anti-inflammatory properties. It is an inactive prodrug that is enzymatically converted into its active metabolite, des-CIC, which exhibits a high affinity for glucocorticoid receptors. In addition to its anti-inflammatory effects, CIC has shown potential antiviral activity, including inhibition of human coronavirus replication [11]. While effective in reducing airway inflammation, its onset of action is delayed compared to some other corticosteroids.

Fluticasone propionate (FLP), another widely used intranasal steroid, is a synthetic glucocorticoid receptor agonist available as a furoate salt. It exhibits anti-inflammatory, antiallergic, and antipruritic properties.

By inducing lipocortin production, it inhibits phospholipase A2, thus reducing the synthesis of pro-inflammatory mediators such as prostaglandins and leukotrienes [12]. Its rapid onset of action and sustained effect make it a preferred choice in many clinical settings.

Given the range of available INCs, comparing their efficacy, tolerability, and patient-reported outcomes is essential for optimizing the management of AR. This study aims to evaluate and compare the therapeutic profiles of CIC and FLP in patients with AR, contributing to evidence-based selection of appropriate treatment.

METHODS

An observational study was conducted in the Department of Otorhinolaryngology at Government ENT Hospital, Koti, Hyderabad and Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India, between December 2020 and November 2022.

Inclusion criteria

- Adults aged between 18 and 65 years
- Clinical history of AR symptoms for at least 1 year
- Total nasal symptom score (TNSS) ≥ 6 , with at least one of the following:
 - Rhinorrhea score ≥ 2
 - Nasal congestion score ≥ 2 .
- Non-smokers.
- No use of corticosteroids, antihistamines, or other rhinitis medications in the 7 days before enrolment.
- Willingness to abstain from using allergy medications during the study period.
- Ability and willingness to provide written informed consent.
- Willingness to participate in both arms of the crossover study and complete follow-up assessments.

Exclusion criteria included

- Use of corticosteroids, antihistamines, or other rhinitis-related medications within the previous 7 days;
- Presence of structural nasal abnormalities (e.g., nasal polyps and deviated nasal septum), active upper respiratory tract infections, or other nasal pathologies (e.g., sinusitis and atrophic rhinitis);
- Recent nasal surgery or biopsy (within 30 days);
- Known hypersensitivity to any component of the study drugs;
- Pregnancy or lactation;
- Participation in another clinical trial within the previous 30 days;
- Any comorbid conditions that could interfere with nasal symptoms or their evaluation, such as asthma, chronic obstructive pulmonary disease, or autoimmune diseases.

Patients meeting the inclusion criteria were briefed about the study in their native language and underwent a structured assessment including detailed history (personal and family history of allergen exposure), completion of a standardized case history pro forma, general physical examination, and focused ENT evaluation. Vital signs were recorded before and after drug administration. Follow-up was conducted through telephone 24 h post-treatment to assess for any delayed adverse effects.

Participants were assigned to receive a single dose of either fluticasone propionate (two sprays per nostril; total dose 200 mcg) or CIC, in a crossover manner with a 30-min washout interval between treatments. The 30-min interval was chosen based on prior sensory evaluation studies of INCs [8]. However, CIC has a delayed onset of action because it is a prodrug converted to the active metabolite desisobutyl-CIC, which reaches peak local activity in approximately 60–90 min. This is acknowledged as a study limitation and may have introduced a minor risk of carryover effects (Fig. 1).

The sequence was computer generated. Both participants and outcome assessors were fully blinded. The nasal spray bottles were coded by an independent investigator who was not involved in data collection or analysis. Patients, the ENT specialists performing symptom scoring, and

the data analysts were unaware of the treatment sequence throughout the study period.

The TNSS was recorded at baseline and again 10 min following the first drug administration. After receiving both treatments, patients were asked to indicate their overall preference between the two.

A total of 120 patients (60 per sequence) were enrolled. The sample size was determined based on feasibility and reference to previous studies on sensory evaluation and efficacy of INCs [8], which typically included 74 participants to detect a clinically meaningful difference in TNSS or patient preference with 80% power at a 5% significance level. This ensured that our study could reliably detect small-to-moderate differences in sensory attributes and overall patient preference between the two sprays.

Symptom evaluation included nasal congestion, rhinorrhea, nasal itching, sneezing, and post-nasal drip. Patients rated their symptom severity on a 4-point scale:

- 0: No noticeable symptoms
- 1: Symptoms present but not bothersome
- 2: Symptoms are bothersome but manageable
- 3: Symptoms significantly interfere with daily activities

The TNSS was categorized as:

- Mild: <6
- Moderate: 6–9
- Severe: 9–12.

Sensory attributes of the nasal sprays were evaluated using a 7-point Likert scale, assessing aroma, taste, aftertaste, throat sensation, nasal sensation, calming effect, urge to sneeze, and nasal discomfort. These parameters were assessed immediately and 2 min after each treatment. Responses were scored from 0 to 6, where 0 represented the most positive or absent response, 6 represented the most negative response, and 3 indicated a neutral response. The questionnaire was adapted from validated tools used in prior research on the sensory properties of INCs (Fig. 2).

All data, including ENT specialist assessments, patient-reported outcomes, and pre- and post-treatment parameters, were collected and analyzed using the Statistical Package for the Social Sciences software (Version 26). Ethical approval for the study was obtained from the Institutional Ethics Committee of Osmania Medical College, Koti, Hyderabad (Approval Reference No: ECR/300/Inst/AP/2013/RR-16).

RESULTS

A total of 120 patients with AR were enrolled and divided equally into two treatment arms: FLP and CIC, each with 60 participants. No patients were lost to follow-up, and there were no missing data; hence, a complete case analysis was performed.

Both groups were comparable in age distribution, with no statistically significant difference among age categories ($\chi^2=2.2351$, $p=0.3270$). The gender distribution was also similar (male: 60% in FLP vs. 58% in CIC; $\chi^2=0.0344$, $p=0.8526$). Median symptom duration was 26 months in both groups, with overlapping interquartile ranges, and no significant difference ($t=1.750$, $p=0.0871$) (Table 1).

Both treatments resulted in improvement across key AR symptoms. Ocular itching showed statistically significant improvement in the FLP group compared to CIC (19.2% vs. 12.5%; $\chi^2=4.0473$, $p=0.0442$). For other symptoms – nasal itch ($\chi^2=0.1639$, $p=0.6855$), sneezing ($\chi^2=0.0666$, $p=0.7962$), nasal congestion ($\chi^2=0.8263$, $p=0.3633$), and rhinorrhea ($\chi^2=0$, $p=1.000$) – the differences were not statistically significant between the groups (Table 2).

Both groups demonstrated significant within-group reductions in TNSS scores. The FLP group showed a median reduction from 8 (interquartile

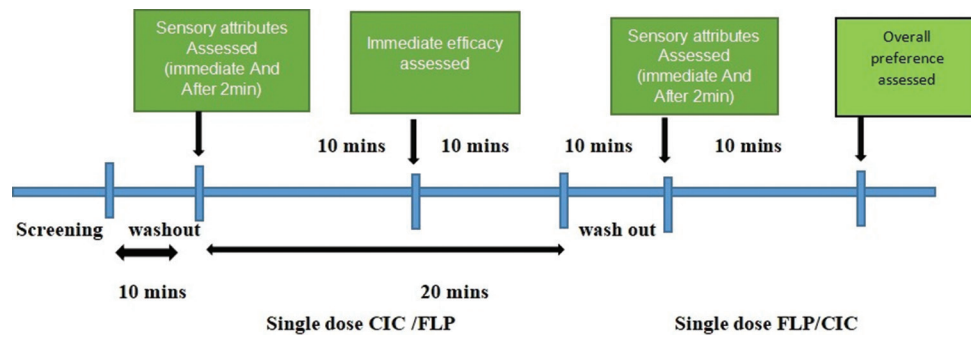


Fig. 1: Dosing schedule

1	Did this product have a scent?	0 None	1 Minimal	2 Mild	3 Moderate	4 Somewhat strong	5 Quite strong	6 Very strong
2	Are you satisfied with the scent?	0 Very satisfied	1 Quite satisfied	2 Somewhat satisfied	3 Neither satisfied nor dissatisfied	4 Somewhat dissatisfied	5 Quite dissatisfied	6 Very dissatisfied
3	Did this product have an immediate taste?	0 None	1 Minimal	2 Mild	3 Moderate	4 Somewhat strong	5 Quite strong	6 Very strong
4	Are you satisfied with the taste?	0 Very satisfied	1 Quite satisfied	2 Somewhat satisfied	3 Neither satisfied nor dissatisfied	4 Somewhat dissatisfied	5 Quite dissatisfied	6 Very dissatisfied
5	Did this product have an aftertaste?	0 None	1 Minimal	2 Mild	3 Moderate	4 Somewhat strong	5 Quite strong	6 Very strong
6	Are you satisfied with the aftertaste?	0 Very satisfied	1 Quite satisfied	2 Somewhat satisfied	3 Neither satisfied nor dissatisfied	4 Somewhat dissatisfied	5 Quite dissatisfied	6 Very dissatisfied
7	Did this product run down your throat?	0 Not at all	1 Minimally	2 Mildly	3 Moderately	4 Somewhat markedly	5 Quite markedly	6 Very markedly
8	Did this product run off your nose?	0 Not at all	1 Minimally	2 Mildly	3 Moderately	4 Somewhat markedly	5 Quite markedly	6 Very markedly
9	Did this product feel soothing?	0 Very markedly	1 Quite markedly	2 Somewhat markedly	3 Moderately	4 Mildly	5 Minimally	6 Not at all
10	Did this product make you want to sneeze?	0 None	1 Minimally	2 Mildly	3 Moderately	4 Somewhat markedly	5 Quite markedly	6 Very markedly
11	Did this product cause irritation of the nose?	0 Not at all	1 Minimally	2 Mildly	3 Moderately	4 Somewhat markedly	5 Quite markedly	6 Very markedly
12	How satisfied are you with this product?	0 Very satisfied	1 Quite satisfied	2 Somewhat satisfied	3 Neither satisfied nor dissatisfied	4 Somewhat dissatisfied	5 Quite dissatisfied	6 Very dissatisfied
	How likely are you to comply (use daily as directed) with this product if prescribed?	0 Very likely	1 Quite likely	2 Somewhat likely	3 Neither likely nor unlikely	4 Somewhat unlikely	5 Quite unlikely	6 Very unlikely

1-4, 7-10 were rated immediately following drug administration, while items 1, 2, 5-9, 11-13 were rated after 2 minutes

Fig. 2: Adapted from prior research comparing intranasal corticosteroid sensory properties [8]

Table 1: Demographic characteristics of study participants (n=120)

Variable	FLP Group (n=60) (%)	CIC Group (n=60) (%)	Total (n=120) (%)	Test statistic (t/ χ^2)	p-value
Age category (years)					
24-30	28 (47)	20 (33)	48 (40)	$\chi^2 = 2.2351$	0.3270
31-36	22 (37)	28 (47)	50 (41.7)		
37-41	10 (16)	12 (20)	22 (18.3)		
Gender					
Male	36 (60)	35 (58)	71 (59.2)	$\chi^2 = 0.0344$	0.8526
Female	24 (40)	25 (42)	49 (40.8)		
Symptom duration in months (median, IQR)	26 (12-72)	26 (12-60)	26 (12-78)	t=1.750	0.871

Data are presented as n (%) or median (IQR) for 120 participants. FLP: Fluticasone propionate, CIC: Ciclesonide, IQR: Interquartile range

Table 2: Symptom severity reduction compared to baseline

Symptom	FLP improved (n, %)	CIC improved (n, %)	Test statistic (χ^2)	p-value
Ocular itch	23 (19.2)	15 (12.5)	4.0473	0.0442
Nasal itch	44 (36.6)	41 (34.2)	0.1639	0.6855
Sneezing	60 (50)	58 (48.3)	0.0666	0.7962
Nasal congestion	50 (41.6)	57 (47.5)	0.8263	0.3633
Rhinorrhea	54 (45)	54 (45)	0	1.000

Data expressed as n (%); n=120. FLP: Fluticasone propionate, CIC: Ciclesonide

range [IQR]: 6-10) to 3 (IQR: 2-4) ($t=-6.712$, $p<0.001$), while CIC showed a reduction from 8 (IQR: 7-10) to 3 (IQR: 2-4) ($t=-6.648$, $p<0.001$). The between-group comparison did not yield a statistically significant difference in TNSS score change ($t=1.7325$, $p=0.774$). Similarly, the proportion of patients achieving $\geq 50\%$ reduction in TNSS was comparable between FLP and CIC groups (42.5% vs. 40%; $\chi^2=0.1547$, $p=0.6940$) (Table 3).

Significant differences in sensory perception were observed between the two groups. The FLP group reported substantially less nasal irritation (1.7% vs. 29.2%; $\chi^2=34.7969$, $p<0.0001$) and a lower urge to

Table 3: Comparison of TNSS scores before and after treatment

Group	Baseline TNSS (median, IQR)	Post-treatment TNSS (median, IQR)	Change in TNSS (median)	Test statistic (t/ χ^2)	p-value
FLP (n=120)	8 (6–10)	3 (2–4)	↓5	t=-6.712	<0.001
CIC (n=120)	8 (7–10)	3 (2–4)	↓5	t=-6.648	<0.001
Between Groups				t=1.7325	0.774
Proportion of patients with ≥50% TNSS reduction	51 (42.5%)	48 (40%)	—	$\chi^2=0.1547$	0.6940

Data are median (IQR) or n (%); n=120. IQR: Interquartile range, FLP: Fluticasone propionate, CIC: Ciclesonide, TNSS: Total nasal symptom score

sneeze (1.7% vs. 15.8%; $\chi^2=15.0815$, $p=0.0001$). FLP was rated as more soothing (58.3% vs. 22.5%; $\chi^2=31.9919$, $p<0.0001$) and had a more satisfying scent (55% vs. 8.3%; $\chi^2=60.3851$, $p<0.001$). Run-out from the nose and run-down to the throat were less common with FLP than CIC ($\chi^2=17.4222$, $p=0.00002$ and $\chi^2=7.3260$, $p=0.0067$, respectively). Aftertaste was more frequently noted with FLP ($\chi^2=4.4821$, $p=0.0342$), while immediate taste perception differences were not significant ($\chi^2=2.1430$, $p=0.1432$) (Table 4).

When asked about overall preference, a significantly higher proportion of patients favored FLP over CIC (59.4% vs. 28.3%), with 12.3% expressing no preference. This preference correlated with favorable sensory attributes in the FLP group (Table 5).

Both treatments were well tolerated. Headache was reported in 6.7% of patients receiving FLP and 10% in the CIC group, with no significant difference ($\chi^2=0.8727$, $p=0.3502$). Dizziness was reported only in the FLP group (1.7%; $\chi^2=2.0168$, $p=0.1555$). Nasal congestion as an adverse event occurred equally in both groups (1.7%; $\chi^2=0$, $p=1.000$), and no severe adverse events were recorded in either arm (Table 6).

DISCUSSION

Our study compared the efficacy, tolerability, and patient preference between FLP and CIC nasal sprays in patients with AR. The results showed that both INCS significantly reduced symptom burden as evidenced by comparable reductions in TNSS, consistent with the current consensus that INCS is the first-line therapy in AR management [13]. In line with our findings, Varshney *et al.* highlighted the utility of INCS as cornerstone treatment in AR, emphasizing symptom control and improved quality of life [8].

Our data showed that ocular itching was significantly better controlled in the FLP group compared to CIC ($p=0.0442$), whereas other nasal symptoms such as nasal itch, sneezing, congestion, and rhinorrhea showed no statistically significant differences. This superiority in ocular symptom relief with FLP may be attributed to its slightly higher anti-inflammatory potency and limited systemic absorption that can exert an effect on ocular conjunctiva. CIC, being a prodrug, requires conversion to desisobutryl-CIC in the nasal mucosa, which may delay its onset and limit immediate impact on ocular symptoms. This is similar to the findings by Buhl *et al.*, who found that both fluticasone and CIC demonstrated similar clinical efficacy in reducing nasal symptoms, although fluticasone showed marginal superiority in managing ocular symptoms, possibly due to its broader anti-inflammatory profile [14]. Similarly, Ratner *et al.* reported significant improvement in TNSS with both agents but did not note a consistent superiority of one over the other, echoing the comparable reduction seen in our study [15].

A unique aspect of our study was the detailed evaluation of sensory attributes and patient preference. The FLP group reported significantly fewer instances of nasal irritation, sneezing urge, and unfavorable sensations like run-out or run-down post-application. In addition, FLP was rated higher for scent and soothing feel, which may explain the higher overall preference in that group (59.4% vs. 28.3% for CIC; $p<0.0001$). Despite CIC's theoretical advantage of reduced irritation due to its prodrug design, fluticasone was more favorably perceived, likely due to differences in excipients, spray mechanics, and droplet size that enhance mucosal spread and patient comfort. This aligns with

Table 4: Sensory attributes comparison (n=120)

Attribute	FLP (n, %)	CIC (n, %)	Test statistic	p-value
Nasal irritation	2 (1.7)	35 (29.2)	$\chi^2=34.7969$	<0.0001
Sneezing urge	2 (1.7)	19 (15.8)	$\chi^2=15.0815$	0.0001
Soothing feel	70 (58.3)	27 (22.5)	$\chi^2=31.9919$	<0.0001
Run out from nose	44 (36.7)	16 (13.3)	$\chi^2=17.4222$	0.00002
Run down to throat	52 (43.3)	32 (26.7)	$\chi^2=7.3260$	0.0067
After taste	21 (17.5)	10 (8.3)	$\chi^2=4.4821$	0.0342
Immediate taste	28 (23.3)	19 (15.8)	$\chi^2=2.1430$	0.1432
Satisfying scent	66 (55)	10 (8.3)	$\chi^2=60.3851$	<0.001

Data expressed as n (%); n=120. FLP: Fluticasone propionate, CIC: Ciclesonide

Table 5: Patient treatment preference (n=120)

Treatment preference	n (%)
FLP	71 (59.4)
CIC	34 (28.3)
No preference	15 (12.3)

Data expressed as n (%); n=120. FLP: Fluticasone propionate, CIC: Ciclesonide

Table 6: Immediate adverse events

Adverse event	FLP (n=60) (%)	CIC (n=60) (%)	Test statistic	p-value
Headache	8 (6.7)	12 (10)	0.8727	0.3502
Dizziness	2 (1.7)	0 (0)	2.0168	0.1555
Nasal congestion	2 (1.7)	2 (1.7)	0	1

Data expressed as n (%); n=120. FLP: Fluticasone propionate, CIC: Ciclesonide

findings by Meltzer who noted that formulation and sensory experience strongly influence patient preference and adherence [16].

Our study also reinforces the tolerability of both treatments. The incidence of adverse effects was low and not statistically different between groups. These findings are corroborated by a study conducted by Buhl *et al.*, who observed that both fluticasone and CIC were well tolerated, with mild and self-limiting side effects being the norm [14]. No patients were lost to follow-up, and no missing data occurred, allowing a complete case analysis without the need for imputation or intention-to-treat adjustment.

Limitations of the study include the short follow-up period, which restricted the assessment of long-term efficacy, safety, and adherence. Objective measures such as nasal airflow, eosinophil counts, or serum IgE levels were not included, which could have provided additional mechanistic insights. Sensory evaluations were based on subjective patient-reported feedback, potentially introducing bias. In addition, the 30-min washout interval between crossover treatments was chosen based on prior sensory evaluation studies of INCS; however, CIC has a delayed onset of action because it is a prodrug converted to the active metabolite desisobutryl-CIC, which reaches peak local activity in approximately 60–90 min.

Overall, the findings suggest that while both agents are clinically effective and well tolerated, fluticasone's superior sensory profile and

modest advantage in ocular symptom control may enhance patient satisfaction and adherence in real-world practice.

CONCLUSION

Both FLP and CIC are effective in reducing AR symptoms, with no significant differences in their impact on overall TNSS or adverse events. However, FLP offers a more favorable sensory experience, including reduced nasal irritation and improved patient comfort, which may enhance compliance and preference. Given the similar clinical efficacy, these sensory advantages could guide clinicians when tailoring treatment based on patient satisfaction and adherence.

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AUTHORS' CONTRIBUTIONS

All the authors are equally contributed in designing, collecting the data and analysis of results, and writing the study.

CONFLICTS OF INTEREST

None declared.

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