ORIGINAL ARTICLE

Intranasal Mometasone Furate, Montelukast and Azithromycin: Three Modalities of Adenoid Hypertrophy Treatment; A Comparative Study

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Abstract

Background: ***While surgical intervention remains a common approach to adenoid hypertrophy (AH), medical therapies such as intranasal corticosteroids, leukotriene receptor antagonists, and macrolide antibiotics have shown promise.***

Aim: ***To compare the effectiveness of intranasal mometasone furoate (MF), oral montelukast (MO), and oral azithromycin in improving symptoms and reducing adenoid size in children.***

Methods: ***In this prospective comparative study, 60 children aged 2–14 years with grade 3 or 4 AH and an adenoid-to-nasopharynx (A/N) ratio >50% were randomized into three equal groups (n=20 each). Group 1 received MF nasal spray, Group 2 received oral MO, and Group 3 received oral azithromycin for six weeks.***

Results: ***All three treatment modalities led to significant reductions in nasal obstruction and snoring (p<0.001). Significant improvements were also observed in sleep apnea (MF: from 3.0±0.0 to 0.8±1.19; MO: from 2.65±0.67 to 1.1±1.07; azithromycin: from 2.0±0.65 to 1.1±1.21; p<0.001), and rhinorrhea in Groups 1 and 2 (MF: from 1.4±1.23 to 0.6±0.82; MO: from 1.05±1.15 to 0.3±0.73; both p<0.001), but not in Group 3 (p=0.068). Cough significantly improved in Groups 1 and 2 (MF: from 1.0±1.29 to 0.6±0.82, p<0.001; MO: from 0.35±0.49 to 0.0±0.0, p<0.001), while no significant change was observed in Group 3 (p=0.085). Adenoid grade significantly decreased only in Group 1 (p<0.001), with no significant reduction in Groups 2 and 3 (p=0.25 and 0.198, respectively).***

Conclusion: ***All three modalities demonstrated symptom improvement in children with AH; however, intranasal MF yielded the most consistent and significant reduction in both clinical symptoms and radiographic adenoid size.***

Keywords: Adenoid hypertrophy; MF; montelukast; azithromycin; conservative treatment

1. Introduction

In preschool children, symptoms such as nasal voice and recurrent otitis media, snoring, persistent rhinorrhoea, mouth breathing, recurrent upper respiratory tract infections, and nasal obstructions are all indicators of enlarged adenoids (nasopharyngeal tonsil), which leads paediatricians to be more likely to refer the patient to an ear, nose, and throat (ENT) specialist.[1]

It is estimated that 57.7% of young children brought to ENT outpatient clinics to treat nasal blockages have AH. After it has been determined that an enlarged adenoid is the cause of the symptoms, a conservative treatment consisting of saline irrigation and intranasal steroids should be administered.[2]

Researchers who looked at the number of eosinophils in children with allergic rhinitis found that a combination of steroids and saline was better than either treatment alone. Unfortunately, during the first two years following the initial diagnosis, close to 90 percent of children with adenoid symptoms and AH end up having surgery.[3]

Azithromycin, a widely used macrolide antibiotic, has demonstrated significant immunomodulatory and anti-inflammatory effects beyond its well-established antibacterial action. Azithromycin's prolonged tissue half-life, high intracellular concentration, and ability to modulate host immune responses make it particularly effective in reducing inflammation associated with chronic infections and persistent immune activation.[4]

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Intranasally administered Mometasone is a potent 17-heterocyclic corticosteroid that has a low systemic dosage (0.1%), an elevated affinity for corticosteroid receptors, and a substantial first-pass metabolism. Intranasal doses are not effective in suppressing the hypothalamic-pituitary axis.[5]

Leukotrienes are essential respiratory system inflammatory mediators. Typically, these mediators are implicated in the pathophysiology of paediatric illnesses like asthma. Additionally, the inflammation that occurs in AH is linked to them both locally and systemically. An elevated amount of the inflammatory pathway mediator cysteinyl leukotriene receptor-1 was found in the postoperative adenotonsillar tissues of young individuals with sleep obstruction apnoea.[6]

Allergic rhinitis and asthma can be avoided with oral MO, an antagonist of the cysteinyl leukotriene receptor. It is additionally being investigated for the management of AH in several clinical studies, based on the recent finding of increased expression of cysteinyl leukotriene receptors in the adenotonsillar tissues of children with sleep breathing difficulties.[7] The current study aimed to compare the effectiveness of intranasal MF, oral MO, and oral azithromycin in improving symptoms and reducing adenoid size in children.

2. Patients and methods

Study design

This study employs a prospective comparative design.

Study setting and duration

The current study was conducted on 60 children with AH symptoms presented in the outpatient clinic of Al-Azhar University Hospital (Cairo) for 6 months, from May 2023 to August 2024.

Study population

Sixty children presenting with symptoms of AH were assigned randomly to three equal groups, each comprising 20 patients. The first group received intranasal MF spray, the second group was treated with oral MO, and the third group was prescribed oral azithromycin.

Inclusion and exclusion criteria

Children between the ages of 2 and 14 were involved in the study with radiographically confirmed AH, showing an adenoid-to-nasopharynx ratio over 50% (grade 3 or 4), particularly in cases where surgery was contraindicated. Exclusion criteria included parental preference for surgery, prior adenoid-related surgeries, recent use of relevant medications, hypersensitivity to study drugs, AH with complications like otitis media, recent lower respiratory infections, and a history of certain medical conditions such as craniofacial anomalies, neuromuscular disorders, chronic epistaxis, immune diseases, asthma, or prior nasal surgery.

Initial examination

The initial examination included taking a general history and presenting symptoms. Each symptom was scored using a validated scale originally developed for the diagnosis of obstructive sleep apnea in children, with severity rated from 0 to 3 (0 = absent, 1 = mild, 2 = moderate, 3 = severe).[8] Additionally, all patients underwent a comprehensive physical examination, including general and full otorhinolaryngological (ORL) evaluation.

Radiological examination

The A/N ratio, or adenoidal/nasopharyngeal ratio, was assessed using the technique outlined by Fujioka et al.[9]. The choanal opening to adenoid tissue ratio was expressed as percentages (Grade 0: 0-25%, Grade 1: 25-50%, Grade 2: 50-75%, and Grade 3: 75-100% with total choanal obstruction).[10]

Lines of treatment, dosages, and duration

For six weeks, the first group got 100 micrograms of MF nasal spray, one puff in each nostril, once daily.

MO was given to the second group of 4 mg oral granules for kids ages 2-3, 4 mg chewable tablets for kids ages 3-4, 5 mg chewable tablets for kids ages 5-8, and 10 mg tablets for older kids. Once a day for six weeks at sleep time.

On days 1–5, the third group was given a daily prescription for 12 mg/kg of azithromycin suspension. For six weeks, this routine was repeated at 5-day intervals, that is, on days 11–15, 21–25, and 31–35.[11]

Calculation of Adenoid Nasopharyngeal Ratio (ANR)

To evaluate the extent of AH and guide the treatment plan, the Adenoid Nasopharyngeal Ratio (ANR) is often calculated using a lateral neck X-ray. ANR = A/N. A ratio above 0.7 is usually considered significant, indicating a high degree of airway obstruction.

Follow up

The second session (session 2) was scheduled six weeks after the intervention ended. The evaluation comprised a symptom assessment using the same 0–3 scale that was originally employed. Using the ANR categorisation and the radiological examination from the initial evaluation, all patients were referred for clinical examination.

Statistical analysis:

The data collected in this study were organized and analyzed using SPSS version 26. Comparative analyses between groups were conducted using the chi-square examination or, when applicable,

Fisher's exact test, and categorical data were displayed as percentages and counts. McNemar's test was employed to examine changes in paired categorical variables. Normality of continuous data was assessed using the Shapiro-Wilk test, with values above 0.05 indicating a normal distribution.[12] To compare repeated measures across three related variables, Friedman's test was used. At least a 0.05 p-value was deemed to indicate statistical significance.

3. Results

Features of the researched groups' demographics

Table 1. Features of the researched groups' demographics

VARIABLE	PARAMETER	GROUP 1	GROUP 2	GROUP 3	X2	P-VALUE
AGE (YEARS)	Mean ± SD	6.9 ± 2.02	6.4 ± 3.185	7.15 ± 2.907	2.003	0.367
	Min-max	4-10	3-11	4-12		
	≤5 years	4 (20%)	8 (40%)	7 (35%)		
	> 5 years	16 (80%)	12 (60%)	13 (65%)		
GENDER	Male	4 (20%)	10 (50%)	14 (70%)	10.17	0.006*
	Female	16 (80%)	10 (50%)	6 (30%)		
WEIGHT (KG)	Mean ± SD	21.2 ± 5.24	21.3 ± 7.66	24.2 ± 8.8	t-test=1.063	0.352
	Min-max	15-30	13-33	15-39		

Data expressed as Mean ± SD, number (percentage), SD: standard deviation, min: minimum, max: maximum, p-value: difference value among groups: *p significant if <0.05, x2: chi square test.

Enhancement of baseline and post-treatment symptom scores in the groups under investigation

Enhancement of baseline and post-treatment nasal obstruction scores in the groups under investigation

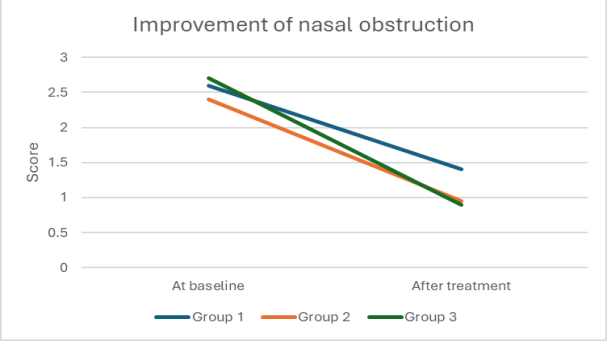

Figure 1. Enhancement of baseline and post-treatment nasal obstruction scores in the groups under investigation.

At baseline, the mean nasal obstruction scores were significantly different across the three groups (2.6 ± 0.503 in Group 1, 2.4 ± 0.821 in Group 2, and 2.7 ± 0.47 in Group 3). After treatment, significant improvements were observed in all three groups, with mean scores decreasing to 1.4 ± 0.503 in Group 1, 0.95 ± 0.99 in Group 2, and 0.9 ± 0.91 in Group 3 (p <0.001 for all groups). The p-values before and after treatment indicate a significant improvement (p <0.001) for all three groups (Figure 1).

Improvement of snoring at baseline and post-treatment among the studied groups

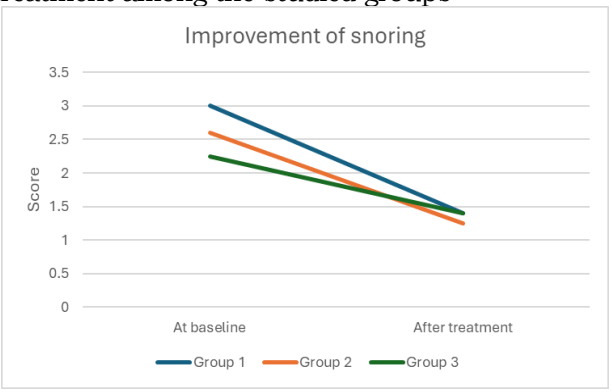

Figure 2. Improvement of snoring at baseline and post-treatment among the studied groups

Figure 2 presents that, at baseline, the three groups' mean snoring scores differed considerably (p <0.001), with Group 1 scoring the highest (3 ± 0.00) and Group 3 scoring the lowest (2.25 ± 1.07). After treatment, significant improvements were observed in all three groups, with mean scores decreasing to 1.4 ± 1.39 in Group 1, 1.25 ± 0.967 in Group 2, and 1.4 ± 0.754 in Group 3 (p <0.001 for all groups). The p-values before and after treatment indicate a significant improvement (p <0.001) for all three groups.

Improvement of sleep apneas at baseline and post-treatment among the studied groups

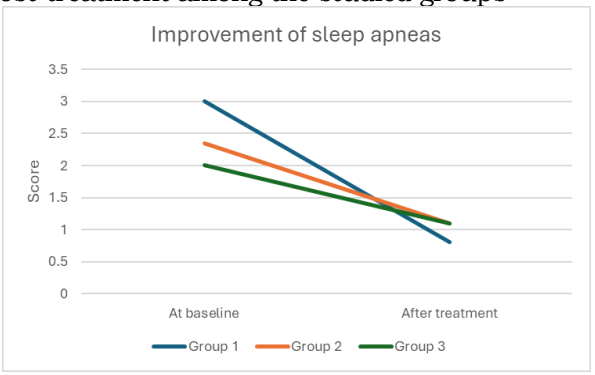

Figure 3. Improvement of sleep apneas at baseline and post-treatment among the studied groups.

Figure 3 presents that, at baseline, the three groups' mean sleep apnoea scores differed significantly (p <0.001), with Group 1 scoring the greatest score (3 ± 0.0) and Group 3 scoring the lowest score (2 ± 0.649). After treatment, significant improvements were observed in all three groups, with mean scores decreasing to 0.8 ± 1.196 in Group 1, 1.1 ± 1.07 in Group 2, and 1.1 ± 1.21 in Group 3 (p <0.001 for all groups). The p-values before and after treatment indicate a significant improvement (p <0.001) for all three groups.

Improvement of rhinorrhea at baseline and post-treatment among the studied groups

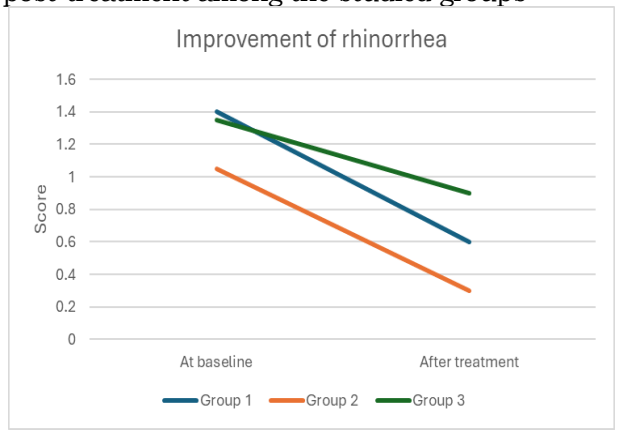

Figure 4. Improvement of rhinorrhea at baseline and post-treatment among the studied groups.

Figure 4 demonstrates a significant improvement in rhinorrhea scores among the three treatment groups from baseline to after treatment ($p < 0.001$), with Group 1 having the highest score (1.4 ± 1.23) and Group 2 having the lowest score (1.05 ± 1.146) at baseline. After treatment, significant improvements were observed in all group 1 and 2, with mean scores decreasing to 0.6 ± 0.821 in Group 1, 0.3 ± 0.73 in Group 2, and 0.9 ± 0.91 in Group 3 ($p < 0.001$, $p<0.001$, and $p=0.068$, respectively).

Improvement of cough at baseline and post-treatment among the studied groups

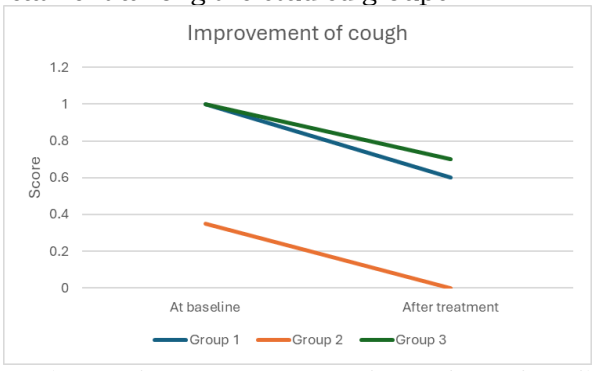

Figure 5. Improvement of cough at baseline and post-treatment among the studied groups

Figure 5 shows that the three groups' mean cough scores differed considerably ($p = 0.027^*$), with Group 1's mean score at baseline being 1 ± 1.29, Group 2's mean score being 0.35 ± 0.489, and Group 3's mean score being 1 ± 0.859. The mean scores of groups 1 and 2 showed substantial improvements after therapy, falling to 0.6 ± 0.821 in Group 1, 0.00 ± 0.00 in Group 2, and 0.7 ± 0.801 in Group 3 ($p < 0.001$, $p<0.001$, and $p=0.085$, respectively). Groups 1 and 2 showed significant improvements ($p < 0.001$), according to the p-values before and after therapy, however Group 3 showed no significant change ($p = 0.085$).

Improvement of AH grade at baseline and post-treatment among the studied groups

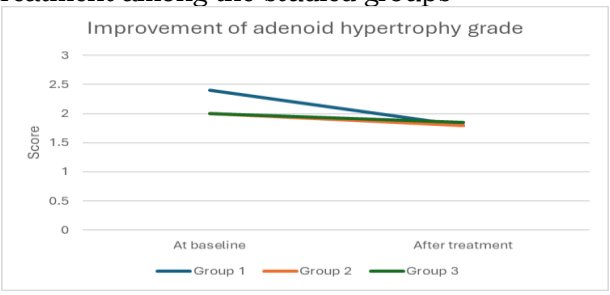

Figure 6. Improvement of AH grade at baseline and post-treatment among the studied groups.

Figure 6 presents that, group 1 had a substantially higher mean AH grade at baseline than Groups 2 and 3. Following therapy, the mean AH grade dropped in all three groups; group 1 showed a significant difference ($p<0.001$), while groups 2 and 3 showed no distinctions ($p=0.25$ and 0.198, respectively).

Cases

Group 1 (MF):

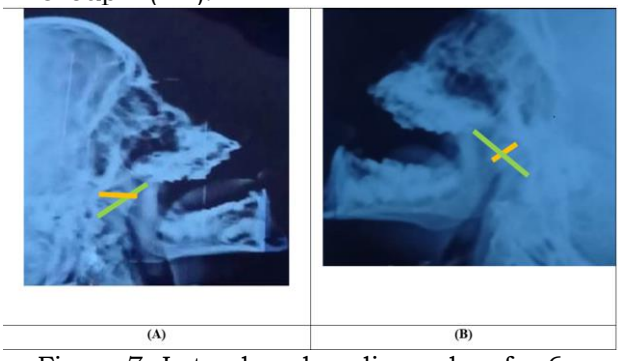

Figure 7. Lateral neck radiographs of a 6-year-old female for assessment of airway patency in mometasone furoate (MF) nasal spray group, the orange line represents the adenoid, and the green line represents the nasopharynx, ANR was reduced from 65% (grade2) to 42% (grade1). (A) before, and (B) after treatment.

Group 2 (Montelukast (MO)):

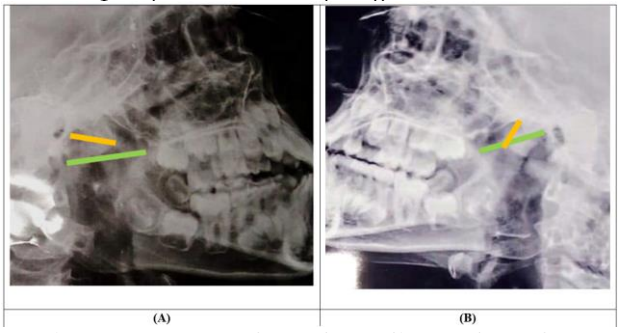

Figure 8. Lateral neck radiographs of a 10-year-old female for assessment of airway patency in Montelukast (MO) group, the orange line represents the adenoid, and the green line represents the nasopharynx, ANR was reduced from 58% (grade2) to 53% (grade2). (A) before, and (B) after treatment.

Group 3 (azithromycin group (AZM)):

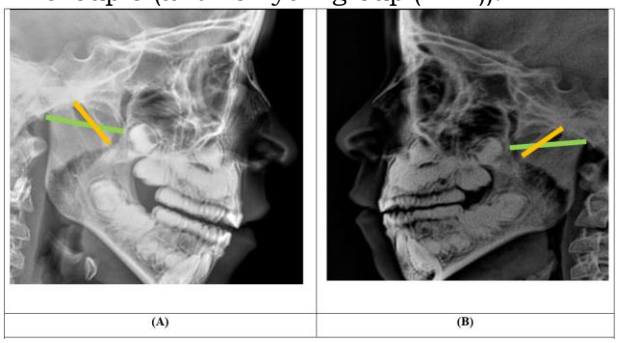

Figure 9. Lateral neck radiographs of a 6 year female for assessment of airway patency in in azithromycin group (AZM), the orange line represents the adenoid and the green line represents the nasopharynx, ANR was reduced from 64% (grade 2) to 62% (grade2). (A) before, and (B) after treatment.

4. Discussion

The most common therapy for AH worldwide is adenoidectomy; however, in addition to the hazards associated with general anaesthesia, this procedure has certain adverse effects, such as bleeding, infections, and palate malfunction. Adenoid tissue may increase following infections or long-term allergic reactions. 2 Further conservative therapies utilising anti-inflammatory and anti-allergy drugs are required due to the possibility of these side effects and the frequency of adenoid tissue recurrence. [13]

In the current study, all nasal symptoms (nasal obstruction, snoring, sleep apnea, rhinorrhea, cough, and AH grade) improved significantly after treatment in group 1, treated with MF ($p<0.001$).

In a prospective interventional study by Ghafar et al. to assess the effectiveness of MF intranasal spray in adolescents and children with AH, the scores for nose obstruction, rhinorrhea, cough, and snoring, as well as the overall score for nasal symptoms, significantly improved between weeks 0 and 12 ($p<0.001$). [14]

Ahmed et al. conducted research to investigate the adenoidal lymphoid tissue's light microscopic alterations following a month of topical steroid treatment. In comparison to the control group, the mometasone group's adenoidal tissue had fewer reactive germinal centres along with fewer spongiosis. [15]

The current results indicated that treatment with MO led to significant improvements in nasal obstruction, snoring, sleep apnea, rhinorrhea, and cough score, with p-values < 0.001. This suggests that the treatment was highly effective in alleviating these symptoms. However, the AH grade did not show any significant improvement after treatment ($p=0.25$).

Karaer and Cimen performed an investigation to determine whether or not MO therapy is a viable substitute for surgery. For a period of twelve weeks, MO was administered to all patients. The size of adenoid tissue was found to be unaffected by MO administration in both groups ($p=0.286$, 0.304, respectively). In contrast, MO therapy resulted in a statistically significant increase in sleep quality for patients in Group 1 ($p=0.006$). No such boost in sleep quality was found in participants in Group 2 ($p=0.91$). [16]

Naqi et al. carried out an investigation to evaluate the effects of MO sodium in children with enlarged adenoids. 76% of the trial group experienced a substantial decrease in adenoidal size after three months of medication, contrasted to only 3% of the control group receiving a placebo. MO sodium appears to be useful for improving clinical symptoms and shrinking adenoids. In children with adenoidal hypertrophy, it can be considered a feasible alternative to surgical therapy. [17]

In the current study, nasal obstruction, snoring, and sleep apnea significantly improved after treatment ($p<0.001$) in group 3, treated with azithromycin suspension; however, azithromycin suspension failed to improve the degree of rhinorrhea, cough, and AH grade after treatment ($p=0.068$, 0.085, and 0.198, respectively).

Jazi et al. partially agreed with the current study and found that azithromycin had a suitable impact on all AH-related parameters at one and eight weeks following therapy. Nevertheless, ratings of several symptoms, including sleep apnoea, hyponasal speech, snoring, and mouth breathing, were not decreased and, in fact, significantly elevated after 8 weeks as opposed to 1 week following the treatment. Consequently, the antibiotic's short-term effectiveness was significantly greater than its long-term effects, even if both post-treatment assessments indicated progress in symptoms as opposed to the starting condition. [18]

Results done by Don et al. partially agreed with the current study and suggested that, in light of adenotonsillar hypertrophy, an injection of broad-spectrum antibiotics could be useful in temporarily alleviating obstructive sleep apnea (OSA); however, it does not seem to eliminate the necessity for surgery. [11]

Recommendations: Physicians are advised to use intranasal corticosteroids as first-line therapy due to their strong local anti-inflammatory effects and favorable safety profile. MO should be used as an adjunct therapy, particularly in children with coexisting allergic rhinitis or asthma. Future studies should aim to include a larger sample size and recruit patients from multiple centers to increase the generalizability of the findings. Furthermore, future studies should assess the long-term effects of each treatment and

investigate the impact on quality of life and functional outcomes.

4. Conclusion

The results of this study suggest that MF nasal spray, MO, and azithromycin suspension are effective treatments for children with AH symptoms. The choice of treatment may depend on the severity of symptoms and the individual's response to each medication. Further studies are needed to compare the long-term effects of these treatments and to determine the optimal treatment duration.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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