Original Article

A Comparative Study of Fluticasone Propionate, Mometasone Furoate, and Saline Nasal Spray in the Treatment of Children with Adenoid Hypertrophy

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Abstract

Introduction: Adenoidectomy is currently considered the treatment of choice for relief of the nasal airway obstruction due to adenoid hypertrophy. Evidence suggests that topical nasal steroid sprays can cause a reduction in adenoid size. We aim to compare the effectiveness of fluticasone propionate, mometasone furoate (MF) and saline nasal sprays in relieving the signs and symptoms of adenoid hypertrophy and in reducing the size of the adenoids. **Materials and Methods:** We conducted a randomized comparative study on 60 patients divided into three groups A, B, C (20 each). Group A patients treated with fluticasone propionate nasal spray (400 μg/day), Group B patients treated with MF nasal spray (100 μg/day), and Group C patients treated with saline spray (0.65% w/v in purified water which is made isotonic and buffered). Treatment was given up to 12 weeks with follow-up at 4, 8, and 12 weeks and at each follow-up visit assessment was done. Final data were analyzed using SPSS software version 21 and numerical variables associated with different groups were analyzed and analysis of variance test was used. **Results:** Diagnostic nasal endoscopy and X-ray grades at day 1 among the study groups were not statistically significant, whereas, at 12 weeks results among fluticasone and mometasone groups were significantly better ($P < 0.001$) as compared to the saline group. There was a significant improvement in the symptoms under all the categories with the use of fluticasone and mometasone. **Conclusion:** In our study, both fluticasone propionate and MF were able to effectively reduce symptoms and signs of adenoid hypertrophy as well as help in reducing the size of the enlarged adenoid. Both these drugs were well tolerated by the patients.

Keywords: Adenoid hypertrophy, adenoidectomy, fluticasone propionate, mometasone furoate

Introduction

The nasopharyngeal tonsil commonly known as adenoids, are single, pyramidal in shape, situated at the junction of the roof and posterior wall of the nasopharynx.[1] Hypofunction of local and systemic immunity may cause hypertrophy of the adenoids. One of the unique features of the adenoids is that they are involved in local immunity as well as in the immune surveillance for the development of body's immunologic defense. Leukocytes in the surface secretion of the adenoids can secrete IgA, IgG and IgM, which are essential in antigen phagocytosis.[2,3] The surface secretion of adenoids also contains a large number of activated T cells, which participate in the cellular immunity.[4] Therefore, the removal of adenoids in early childhood may be considered as immunologically undesirable.[2,3]

The adenoids continue to grow rapidly during infancy and plateaus between 2 and 14 years of age. They regress rapidly after 15 years of age in most of the children.[5] An enlarged adenoid usually causes the obstruction of nasal airway. Symptoms due to airway obstruction such as mouth breathing, hyponasal speech, difficulty in feeding, drooling of saliva, and snoring in children are observed. The most common symptoms are habitual mouth breathing and snoring causing craniofacial anomalies such as the

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"adenoid facies."[6] In long-term unattended cases, may develop otitis media with effusion, sinusitis, and in the most serious cases, obstructive sleep apnea (OSA) and accompanying growth retardation and cor pulmonale can also occur.[7]

Although, adenoidectomy is currently considered the treatment of choice for relief of nasal airway obstruction, significant risks and problems are associated with it, such as bleeding, dental trauma, nasopharyngeal blood clot, infection, adverse anesthetic events and cervical spine injury and in long-term Eustachian tube block, velopharyngeal dysfunction, re-growth of adenoid may occur.[8] Hence, there was a need to explore alternate methods that led to the assumption that anti-inflammatory treatment can reduce adenotonsillar size and improve OSA symptoms. Thus, systemic or topical anti-inflammatory agents are suggested to have a potential role in reversing adenotonsillar enlargement.[9]

There is now a reasonable amount of evidence that topical nasal steroid sprays can cause a reduction in adenoid size with improvements in the presence of middle ear fluid, audiometric thresholds, nasal obstruction, rhinorrhea, cough, snoring, and sleep apnea.[10] Topical steroids have limited side effects. Fluticasone propionate and mometasone furoate (MF) were chosen as the drugs of discussion due to the advantages such as high potency, longer duration of action, and negligible oral bioavailability. Fluticasone is a synthetic trifluorinated glucocorticoid receptor agonist with antiallergic, anti-inflammatory, and antipruritic effects. MF is a potent 17-heterocyclic corticosteroid. On intranasal administration, it has a higher binding affinity to corticosteroid receptors, poor systemic concentration (0.1%), and extensive first-pass metabolism. Fluticasone propionate and MF are potent synthetic corticosteroids that are widely used as anti-inflammatory agents to treat respiratory diseases. MF is considerably less specific for the glucocorticoid receptors than fluticasone propionate, showing significant activity at other nuclear steroid receptors. Therefore, both the drugs were chosen and their effect on decreasing the size of adenoids and relieving the signs and symptoms was studied.

Saline sprays are typically nonmedicated and can improve symptoms like nasal congestion by helping to thin the mucous, reduce the amount of secretions and increasing the nasociliary activity. Recent studies showed that topical nasal corticosteroid spray reduced adenoid size and improved symptoms of nasal airway obstruction due to adenoids. In the present study, we compared the effectiveness of MF, fluticasone propionate, and saline nasal sprays in relieving the signs and symptoms of adenoid hypertrophy and in reducing the size of the adenoids.

Materials and Methods

This randomized comparative study was conducted in the Department of Otorhinolaryngology, GGS Medical College and Hospital, Faridkot for 18 months that is from January 2019 to June 2020. In this study, a sample size of 60 patients (20 in each group) of age group 4–12 years and of either sex with symptoms and signs consistent with adenoid hypertrophy were taken. Group A consisted of 20 patients, randomly selected for treatment with fluticasone propionate nasal spray (400 µg/day). Group B had 20 patients, randomly selected for treatment with MF nasal spray (100 µg/day), and Group C had 20 patients, for treatment with saline spray (0.65% w/v in purified water which is made isotonic and buffered) one puff in each nostril twice a day. This study was approved from the institutional Ethical Committee. (GGS/IEC/38).

Clinical examination was done after obtaining informed consent from the parent/legal guardian of each child enrolled. Initial assessment of each patient on entering the study included: History taking and physical examination (including body weight and height). The parent/guardian of the patient filled a questionnaire about their child's symptoms. The questionnaire included questions about age, sex, history, drug history, and obstructive symptoms such as hyponasal speech, snoring, daily somnolence, open-mouth breathing, night cough, nasal congestion, and nasal obstruction. All these parameters were calculated through OSA-18 score sheet. The following elements under this scoring system were evaluated (and scoring done as; 0 = Never; 1 = Almost never; 2 = Sometimes; 3 = Often; 4 = Very often; 5 = Could not be worse).

OSA-18 survey score as follows:

- Scores <60 suggest a small impact on health-related quality of life
- Scores between 61 and 80 suggest a moderate impact and
- Scores above 81 suggest a large impact.

The patients treated with fluticasone propionate or MF or saline nasal spray were evaluated by clinical examination, X-ray, and nasal endoscopy. Evaluation by clinical examination was done at 0 week (before starting of therapy), at 4 weeks, 8 weeks, and 12 weeks and symptom score was calculated at each visit.

Diagnostic nasal endoscopies and X-ray nasopharynx open mouth, lateral view was done at the beginning of the study and at the end of 12 weeks.

All nasal endoscopies were performed when the patient was performing quiet nasal breathing. The degree of adenoid obstruction was estimated as described in the grading for adenoid hypertrophy by the Clemens grading system as: Grade 1: Adenoid tissue filling 1/3rd of the vertical portion of choana; Grade 2: Adenoid tissue filling from 1/3rd to 2/3rd of choana [Figure 1]; Grade 3: Adenoid tissue filling from 2/3rd to nearly complete obstruction of choana; Grade 4: Complete choanal obstruction.[11]

Lateral neck radiography was interpreted by COHEN and KONAK method.[12] According to this method, the thickness of the soft palate in its superoanterior part (SP) and the airway column (AC) immediately posterior to it was measured and AC/SP ratio was calculated and graded as follows: Grade 0: AC/SP ≥1 suggest no obstruction; Grade 1: AC/SP = 0.5–0.99 suggest mild obstruction; Grade 2: AC/SP = 0.01–0.49 suggest severe obstruction; Grade 3: AC/SP = 0 indicates complete obstruction [Figure 2].

Final data were analyzed using Statistical package or social sciences (SPSS), IBM, New York,U.S.A and numerical variables associated with different groups were analyzed and analysis of variance (ANOVA) test was used.

Inclusion criteria

- Age between 4 and 12 years
- Symptoms consistent with adenoid hypertrophy lasting more than or for 12 months
- Adenoid hypertrophy was confirmed by X-ray findings and nasal endoscopy by an otorhinolaryngologist.

Exclusion criteria

- Patients receiving systemic or intranasal steroid therapy, antibiotics or antihistamines within 4 weeks before the study
- Immuno-compromised patients
- Symptoms of acute rhinitis, rhino-sinusitis, or respiratory infection
- Nasal structural disease (like polyp or septal deviation), craniofacial, neuromuscular, genetic disorder, cardiovascular disorder, or severe underlying disease
- Tonsillar hypertrophy of grade more than or equal to 3
- Prior tonsil or adenoid surgery.

Results

Age distribution

The descriptive statistics such as mean and standard deviation (SD) values of age among fluticasone propionate, MF and saline nasal spray groups did not show any statistical significance (P = 0.819), with the mean age in respective groups being 8.00, 7.75 and 8.20 respectively.

Physical discomfort

At the beginning of the study, the mean score of respective groups A, B, C was 16.5, 15.3, and 15.10, respectively. The mean score after intervention and follow-up at 12 weeks were 10.40, 10.40, and 14.3; showing significant results in Groups A and B.

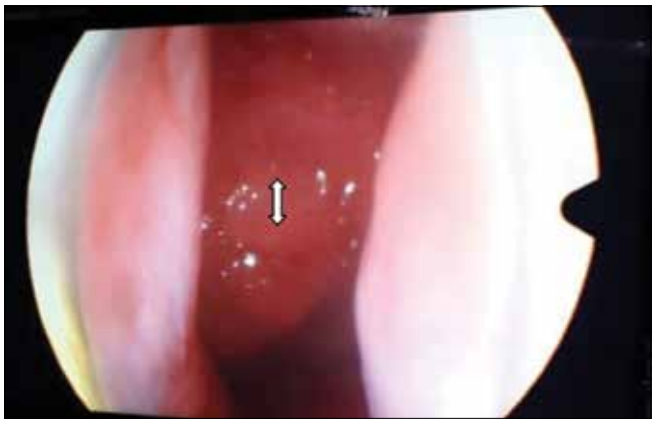


Figure 1: Endoscopic view of the adenoids suggesting of grade 2 hypertrophy

Sleep disturbances

At the beginning of the study, the mean score of respective groups A, B, C was 14.4, 13.9, and 14.15, respectively. The mean score after intervention and follow-up at 12 weeks were 9.30, 9.80, and 13.70; showing significant results in Group A and B.

Deglutition disorders

At 0 week, there was no statistical significance between the mean scores of the three groups. The mean was significantly lower among the fluticasone propionate and MF groups at 4 weeks (P = 0.015), 8 weeks (P = 0.002) and 12 weeks (P < 0.001), and improvement in the symptoms was reported.

Emotional discomfort

At 0 week and at the end of 12 weeks, the mean symptom score of the fluticasone group was 9.50 and 7.20 respectively and; the mometasone 9.70 and 6.40, respectively.

Restriction of activities

The mean score improved from 9.25 to 6.65 in the fluticasone group and from 9.90 to 6.80 in mometasone group.

The mean OSA-18 score sheet and pediatric sleep questionnaire were significantly lower among the fluticasone propionate and MF groups at 4 weeks, 8 weeks, and 12 weeks. The mean, SD, ANOVA P value of OSA-18 score sheet and pediatric sleep questionnaire at 0, 4, 8, 12 weeks among different groups were represented in the following Tables 1 and 2.

Impact on health-related quality of life between the groups

This was scored as an OSA-18 survey score and was

Table 1: Obstructive sleep apnoea-18 score sheet and pediatrics sleep questionnaire at 0, 4, 8, 12 weeks among groups

	Mean	SD	*P* using ANOVA
SS at 0 week			
Fluticasone propionate	60.05	8.617	0.778 (not significant)
Mometasone furoate	61.85	9.43	
Saline	59.85	11.23	
Total	60.21	9.73	
SS at 4 weeks			
Fluticason propionate	48.60	10.83	0.002 (significant)
Mometasone furoate	49.90	10.39	
Saline	59.65	9.06	
Total	50.22	10.06	
SS at 8 weeks			
Fluticasone propionate	43.40	12.43	<0.001 (significant)
Mometason furoate	45.60	11.68	
Saline	58.20	9.08	
Total	46.90	11.53	
SS at 12 weeks			
Fluticasone propionate	41.00	13.50	<0.001 (significant)
Mometasone furoate	41.85	13.32	
Saline	57.9	9.29	
Total	44.80	12.92	

ANOVA: Analysis of variance, SD: Standard deviation, SS: Symptom score

Table 2: Line diagram comparing the means of the obstructive sleep apnoea-18 score sheet and pediatric sleep questionnaire at 0, 4, 8, 12 weeks among three groups

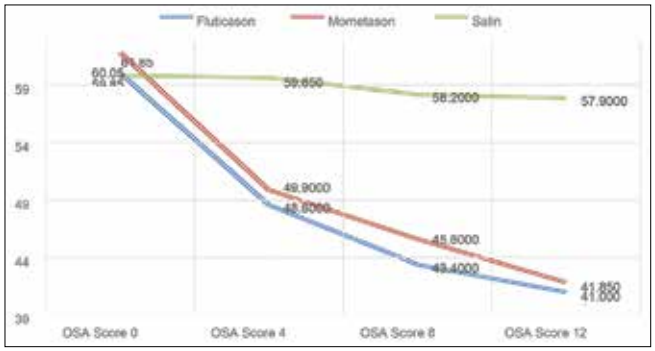
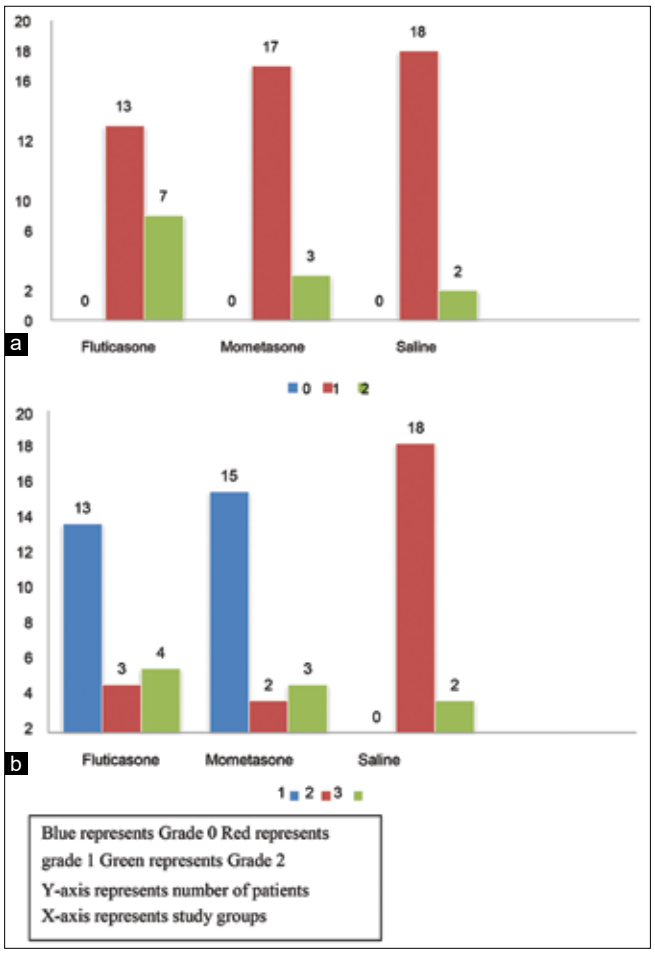


Table 3: (a and b) Bar chart for X-ray grades at 0 and 12 weeks among the study groups



categorized into mild or small impact (0–60), moderate (61–80) and severe (>80). In the fluticasone propionate group, at 0 week, 11 showed moderate and 9 showed small impact, and at the end of study 4 showed moderate impact and 16 had small impact showing major improvement in signs and

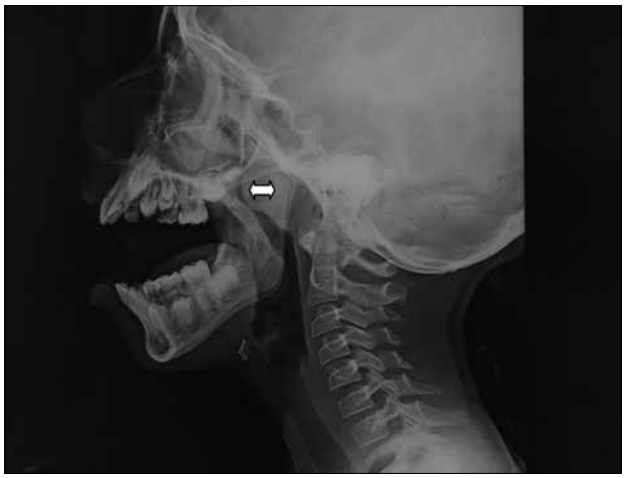


Figure 2: X-ray of patient suggesting of grade 3 adenoid hypertrophy

symptoms. On the other hand, in MF group 12 had a moderate impact whereas 9 had small impact at 0 week. At 12 weeks, 3 showed moderate and 17 showed small impact and was a considerable improvement. The saline group, however, did not suggest much of the significant results.

X-ray gradings among the study groups

X-ray grades on day 1 among fluticasone propionate, MF and saline groups were not statistically significant ($P = 0.112$). X-ray grades at 12 weeks among fluticasone propionate and MF groups were significantly better compared with the saline group ($P < 0.001$).

Nasal endoscopy gradings among the study groups

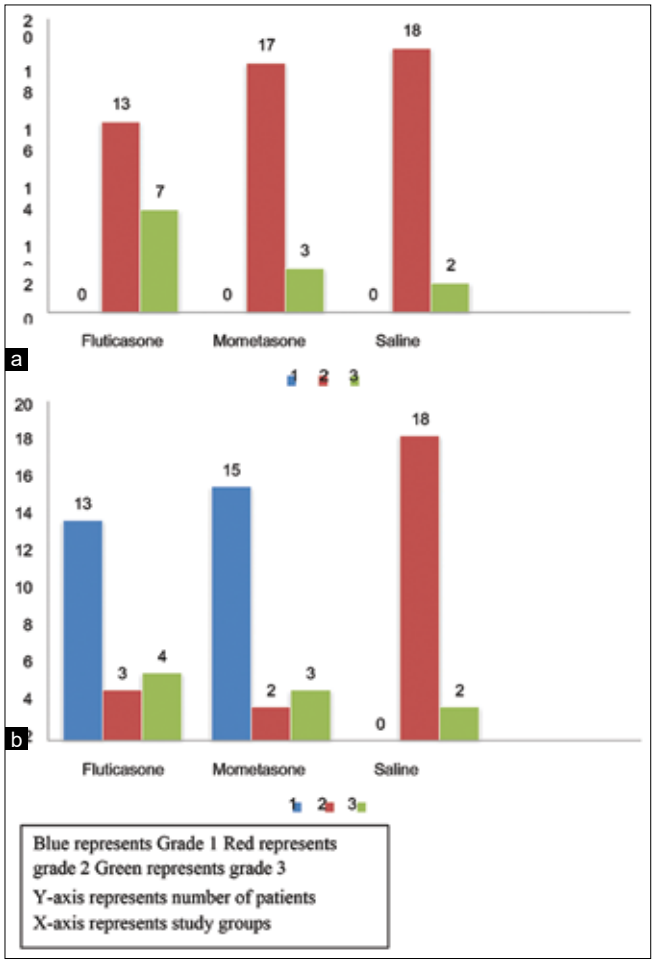
Nasal endoscopy grades at day 1 among the study groups were not statistically significant ($P = 0.112$) whereas at the end of 12 weeks, fluticasone and mometasone groups showed significantly better results in comparison to the saline groups ($P < 0.001$).

Discussion

Hypertrophied adenoids are responsible for various clinical manifestations depending upon their size, degree, and duration of obstruction. One of the most common complaints is bilateral nasal airway obstruction which may be responsible for sleep disorders, speech difficulties, deglutition problems, and even OSAs. They are even a cause of considerable morbidities including neurocognitive and behavioral disturbances in the children. Although adenoidectomy is the treatment of choice but due to various risks associated with the procedure as well as parents' apprehension for the surgery, alternate methods were developed. The administration of intranasal corticosteroids is the most popular choice due to their easy availability, well-tolerated by most of the patients, fast action, simple to use, and safe for long-term use.

Demain and Goetz in 1995 were first to introduce the successful use of intranasal steroid spray in children with adenoid hypertrophy. They used beclomethasone intranasal steroid treatment and showed its potency in reducing nasal airway

Table 4: (a and b) Bar chart for nasal endoscopy grades at day 1 and 12 weeks among the study groups



obstruction due to adenoids and after that many researchers followed their footsteps with encouraging results.[13] Allen *et al*. in a year-long study assessed that there was no growth suppression in children treated with the maximum recommended dose of fluticasone propionate aqueous nasal spray at maximum recommended dose of 200 µg/day.[14] A similar year-long study was conducted by Schenkel *et al*. and assessed that there was no growth suppression after treatment with MF aqueous nasal spray. Both studies suggested the safety of these drugs in the pediatric population and no drug showed hypothalamic-pituitary axis suppression at any point of time.[15]

The age of patients included in the study was 4–12 years. The *P* value for the mean difference of age came to be 0.819 and hence was not significant. Majority were male (40 male patients out of total of 60 patients), i.e., 65.0%, 75.0%, 60.0% males and 35.0%, 25.0%, 40.0% females in fluticasone propionate, MF and saline nasal spray groups respectively. However, this difference in gender in the study population was not statistically significant and was in accordance with the inclusion and exclusion criteria.

Commonly observed symptoms in adenoid hypertrophy include nasal obstruction, snoring, nasal discharge, hyponasal speech, nasal discharge, open mouth breathing. All these symptoms were assessed together under OSA-18 score sheet, as well as individually assessed under the following elements of OSA-18 score sheet, i.e., physical discomfort, sleep disorders, deglutition disorders, emotional discomfort, and restriction of activities. There was a significant improvement in the symptoms under all the categories with the use of fluticasone and mometasone. Various studies were found in the literatures which are in accordance with our study. A study done by Sahayam and Kulandaiammal[16] with MF, showed improvement at the end of 12 weeks of treatment with MF as compared with the nasal saline group. Similar studies were done by Islam *et al*.[17] with intranasal fluticasone furoate and Gupta *et al*.[18] with MF showed improvement in the mean physical symptom score, sleep disturbance score, deglutition disorders, emotional distress, and restriction of activities. In a similar study, histopathological evaluation of the adenoids after 4 weeks of topical MF administration suggested a decrease in reactive lymphoid follicles, spongiosis, and congested blood vessels compared with the control group.[19]

Diagnostic nasal endoscopy [Table 4] and X-ray grades [Table 3] at day 1 among the study groups were not statistically significant, whereas, at 12 weeks results among fluticasone and mometasone groups were significantly better as compared to the saline group. In a study done by Mohebbi S *et al*., effect of intranasal mometasone was seen on adenoid hypertrophy. Lateral neck radiography was done to evaluate the adenoid size in the treatment group and it showed statistically significant response at the end of the study and hence showed, direct and potent relation between adenoid size and symptoms ($P < 0.001$). This also explains that the decreasing adenoid size led to clinical sign and symptom improvement.[20]

Many studies are found in literature where a course of intranasal steroids is preferred over the surgery. In most of the developing nations, the burden of disease is more. Therefore, conservative method like use of intranasal steroids is beneficial as well as immunologically desirable than surgery. Therefore, it is evident from our study that mild to moderate cases of Adenoid hypertrophy (AH) can be successfully treated with intranasal Fluticcasone propionate (FP) or MF. Since our study is for limited period, long-term effects of these intranasal steroid sprays as well as relapse of the disease after discontinuation of the intranasal sprays cannot be assessed. The dose given to the study groups was fixed and hence effective maintenance dose could not be assessed. The saline nasal spray is not an effective drug to relieve symptoms and signs caused by AH.

Unfortunately, the present study had some limitations. First, data were collected according to parental reports on studied children with adenoid hypertrophy. Second, we did not perform polysomnography as a pre- and post-trial tool for evaluating the efficacy of the drugs for the obstructive symptoms which would have given our study more precise and relevant results.

Conclusion

Intranasal steroids are safe, cheap, and easy to use. Although adenoidectomy is considered the treatment of choice due to various complications, the use of intranasal steroids for grade 2 and 3 adenoid hypertrophy with mild to moderate symptoms is advisable. In our study both our aims were fulfilled and we can conclude that both fluticasone propionate and MF were able to effectively reduce symptoms (OSA scoring suggesting $P < 0.01$ in the follow-up period). Signs of adenoid hypertrophy were reduced as well and were observed in the follow-up weeks by X-ray grading ($P < 0.01$) and nasal endoscopy ($P < 0.01$). Both these drugs were well tolerated by the patients and helped in improving health-related quality of life in both groups using intranasal steroids. Results with intranasal saline administration were not significant.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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