

## Original Research Article

# Role of mometasone furoate nasal spray versus saline nasal spray in treatment of adenoid hypertrophy: a prospective, randomized study

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## ABSTRACT

**Background:** Adenoid hypertrophy is a common disorder in the paediatric population, presenting with multiple signs and symptoms ranging from nasal obstruction to obstructive sleep apnoea. Most common symptom is usually nasal airway obstruction. This prospective, randomized study aims to evaluate the efficacy of mometasone furoate spray in reducing size and clinical symptoms in patients with adenoid hypertrophy compared to saline spray.

**Methods:** 60 patients in the age group of 3-11 years were enrolled in the study. Five symptoms were included that were hypo nasal speech, snoring, night cough, open mouth breathing and nasal obstruction which were scored as never=0, mild (sometimes)=1, moderate (less than 50% of times)=2, and severe (constant)=3. Diagnosis of adenoid hypertrophy was made on basis of nasal endoscopy.

**Results:** Significant improvement was seen in individual as well as overall symptom score in group A as compared to group B after 8 weeks of treatment ( $p < 0.001$ ). There was significant improvement in mean adenoid grade as per nasal endoscopy at 8 weeks post therapy ( $p < 0.001$ ) which was not seen after 4 weeks of therapy.

**Conclusion:** Intranasal steroid sprays have good role in decreasing the symptoms of adenoid hypertrophy and has reduced number of adenoidectomies required. The long-term effects as well as optimal duration of therapy is still controversial and needs to be studied further.

**Keywords:** Adenoid hypertrophy, Mometasone nasal spray, Adenoidectomy, Nasal obstruction

## INTRODUCTION

Adenoid hypertrophy (AH) is a common disorder in the pediatric population, presenting with multiple signs and symptoms ranging from nasal obstruction to obstructive sleep apnea. Most common symptom, ordinarily, is nasal airway obstruction leading to mouth breathing, snoring, difficulty in eating, drooling of saliva and toneless voice. This progresses to development of true adenoid facies and eustachian tube obstruction often leading to otitis media with effusion and hearing impairment. In more severe

cases, cor pulmonale, pulmonary hypertension may also develop.<sup>1</sup>

Adenoidectomy is considered the treatment of choice for severe cases but is not free of complications. Bleeding, eustachian tube dysfunctions, velopharyngeal insufficiency, regrowth of adenoids among others are few of the commonest adverse effects of surgery. Medical management has traditionally been directed towards control of infections, which is considered to be the primary cause for adenoid hypertrophy. Systemic steroids temporarily decrease the adenoid size but have major side

effects especially in children. However, intranasal topical steroids have shown encouraging efficacy and safety of intranasal steroids for use in adenoid hypertrophy.<sup>2</sup>

Topical intranasal mometasone furoate therapy can be considered a good therapeutic option to decrease adenoidal hypertrophy. Daily use for 2 weeks per month after an initial 40-day daily treatment seems to be the ideal maintenance schedule. This prospective, randomized study aims to evaluate the efficacy of mometasone furoate spray in reducing size and clinical symptoms in patients with adenoid hypertrophy compared to intranasal saline spray.

**METHODS**

This case-control study was conducted from August 2014 to September 2016 at the Department of Ear, neck and throat (ENT), Government Medical College, Patiala. A total of 60 patients presenting in the outpatient department were enrolled in this study after approval from the institute ethics committee. Patients who fulfilled the following inclusion criteria were enrolled in the study: Age between 3 to 11 years; symptoms of adenoid hypertrophy lasting ≥12 months; grade 3 and 4 adenoid hypertrophy and no previous adenoidectomy.

The parents of enrolled patients gave informed consent and filled a questionnaire about their child’s symptoms. Questionnaire included questions about age, sex, allergy history, drug history and obstructive symptoms. Five symptoms were evaluated viz. hypo nasal speech, snoring, night cough, open mouth breathing and nasal obstruction which were scored as never=0, mild (sometimes)=1, moderate (less than 50% of times)=2, and severe (constant)=3. Diagnosis of adenoid hypertrophy was established on the basis of nasal endoscopy. Lateral neck radiographs were taken in patients not cooperative for nasal endoscopy.

Nasal endoscopy was performed using 2.7 mm endoscope to confirm the size of adenoid tissue which was graded as follows: grade 1, adenoid occupying less than 25% of the choanal area; grade 2, adenoid occupying 25-50% of the choanal area; grade 3, adenoid occupying 50-75% of the choanal area; grade 4, adenoid occupying 75-100% of the choanal area.

After confirming the diagnosis of adenoid hypertrophy, patients were divided randomly into two groups. Group A consisted of thirty patients who were treated with mometasone furoate nasal spray one puff in each nostril twice a day (100 mcg). Group B consisted of thirty patients who were treated with saline nasal spray one puff in each nostril twice a day. Patients were followed up at week 4 and 8 after initiation of therapy with clinical examination, nasal endoscopy and lateral nasopharynx radiographs wherever indicated. Statistical analysis of the data was performed by  $\chi^2$  test (chi-square test) and the Fisher exact

probability test (2-tailed); p values less than 0.05 were considered statistically significant.

**RESULTS**

Sixty children were enrolled in the study and during the first stage were assigned randomly to receive mometasone spray (group A; n=30, 22 male subjects and 8 female subjects; median age: 7 years) or saline spray (group B; n=30, 15 male subjects and 15 female subjects; median age: 6 years). More than half of the children were from low socioeconomic strata. Majority were in the age group of 6-8 years. No patient had personal or family history of allergy or atopy, had undergone previous surgery, had received any anti-histamines or steroids in the past 4 weeks, or had immunodeficiencies.

There was no significant difference in the mean symptom score between the two groups at the time of recruitment. Significant improvement was seen in individual as well as overall symptom score in group A as compared to group B after 8 weeks of treatment (p<0.001). There was significant improvement in mean adenoid grade as per nasal endoscopy at 8 weeks post therapy (p<0.001), however at 4 weeks the improvement was non-significant.

**Table 1: Age comparison in group A (steroid) and group B (saline).**

Age (in years)	Group A		Group B	
	Number of patients	Percentage	Number of patients	Percentage
3-5	6	20.0	10	33.33
6-8	15	50.0	15	50.0
9-11	9	30.0	5	16.67
<b>Total</b>	<b>30</b>	<b>100.0</b>	<b>30</b>	<b>100.0</b>

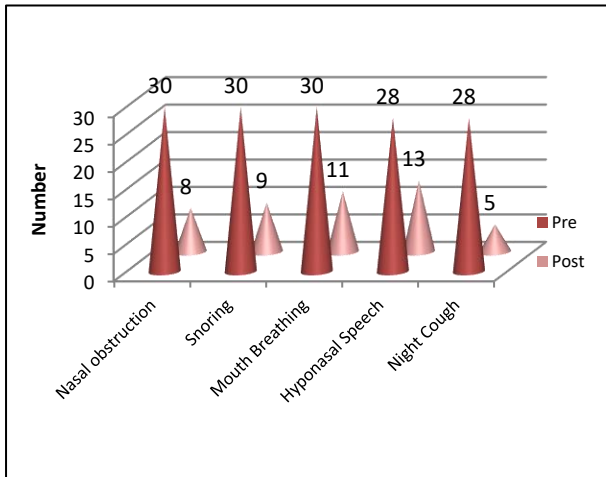
**Table 2: Comparison of mean adenoids grade by rigid nasal endoscopy at baseline (T0), at 4 weeks (T1) and at 8 weeks (T2) of groups i.e. A (steroid) and B (saline).**

Time of follow up	Groups	Mean	SD	p value
<b>T0</b>	A	3.5333	0.50742	0.018
	B	3.2333	0.43018	
<b>T1</b>	A	2.9000	0.60743	0.113
	B	3.1333	0.50742	
<b>T2</b>	A	2.4000	0.72397	0.001
	B	3.0000	0.52523	

**DISCUSSION**

Adenoid hypertrophy is one of the most frequent indications for surgery in childhood and adenoidectomy commonly, is considered definitive treatment for

nasopharyngeal obstruction.<sup>3</sup> Nevertheless, this surgical technique has been the subject of some criticism. Paulussen et al hypothesized that the removal of adenoid lymphatic tissue could have a negative impact on the systemic immunologic system.<sup>4</sup> Immediate postoperative or late bleeding is observed in 1% of children who undergo adenoidectomy. Furthermore, it is well demonstrated that adenoids may recur after surgery in 10% to 20% of cases.<sup>1</sup>



**Figure 1: Number of patients showing improvement in clinical symptoms after 8 weeks of nasal steroid treatment.**

Many studies have reported that treatment with intranasal corticosteroids, like beclomethasone, fluticasone, and mometasone can decrease the size of adenoids.<sup>1-3</sup> Mometasone furoate was selected in this study because of its favorable benefit-risk ratio. It has not been reported to cause any adverse effect on nasal mucosa on long term use and has no effect on growth and hypothalamic-pituitary-adrenal axis. Also, the systemic availability of the drug after topical administration is lower than that of other steroids.<sup>5</sup>

Sixty children in the age group of 3-11 years were divided into two groups with mean age of 7.2 and 6.5 years respectively (table 1). Similar age group observed in other studies in literature can be attributed to the fact that adenoids appears to be at its largest in the 7 year old age group and starts regressing afterwards.<sup>6</sup> The narrow size of nasopharynx and recurrent upper respiratory infections results in presentation in this age group. However, in some patients, adenoids can persist or even grow in size after 7 years leading to presentation in older age groups.<sup>7</sup> None of the studies in the literature including ours has shown any significant difference in gender distribution.

We observed that almost half of children with adenoid hypertrophy belong to lower socioeconomic strata in our study. Eziyi et al also noted similar findings in their study where close to half of the subjects belonged to low socioeconomic class.<sup>8</sup> Parents of low socioeconomic class live in overcrowded and highly dense environment with poor

sanitary conditions; this may predispose the children to repeated viral and allergic infections which can aggravate their state.<sup>7</sup> Our study was conducted in a government run tertiary hospital where most of the attending patients are from rural and lower social classes of the society which is a possible reason for this observation.

Symptoms and signs indicative of nasal airway obstruction caused by adenoid hypertrophy in children are mouth breathing, hyponasal speech and nocturnal snoring. We observed that the most common presenting complaints of patients with adenoid hypertrophy were nasal obstruction, snoring, mouth breathing, hyponasal speech and night cough in decreasing frequency. We evaluated these 5 clinical symptoms individually and scored as never=0, mild (sometimes)=1, moderate (less than 50% of times)=2, and severe (constant)=3(9) with total symptom score ranging from 0-15. (Figure 1)

Total clinical score was calculated by combining scores of all the 5 clinical symptoms studied at T0, T1 and T2 for both the groups. The mean total score at 8 weeks post treatment changed from 12 to 5.8 and 12.06 to 11.1 for group A and B respectively which was statistically significant ( $p > 0.001$ ) (table 2). Demirhan et al also observed that at the end of 8 weeks, the average total symptom score of fluticasone treated group dropped from 13.72 to 2.96 while the saline treated group's score changed from 14.85 to 14.65. After the treatment, a statistically significant ( $p > 0.05$ ) difference was observed between average total symptom scores of the two groups.<sup>10</sup> The mechanism of improvement in nasal symptoms with mometasone is not clear. It could be a direct effect of mometasone on nasal mucosa or through the decrease in the size of adenoid. Various other studies in literature have also observed decrease in adenoid size corresponding with improvement in nasal symptoms with mometasone.<sup>11</sup>

The overall AC/SP ratio of 24 patients (80%) showed regression to a lower grade. This improvement in the AC/SP ratio in the treatment group was statistically significant when compared with the control group ( $p < 0.001$ ). This observation was comparable to the study by Ciprandi et al who observed that the use of intranasal flunisolide was associated with a significant ( $p < 0.02$ ) reduction of adenoid size in 72.6% of the children as seen by fiberoptic endoscopy.<sup>2</sup> HB Yilmaz et al, however, failed to demonstrate any difference in the reduction of the adenoid size on nasal endoscopies between the steroid group and saline group. This deviation may have been seen because this study was conducted on 12-18-year-old subjects and persistent infection might be the cause of resistance to medical therapy in older age groups.<sup>12</sup>

Adenoid hypertrophy is still the most common indication for surgery in children. Despite medical treatment few of the patients need adenoidectomy for their symptoms. In the present study, adenoidectomy was needed in 7 patients out of 30 who received intranasal steroids, while in the saline group, all 30 patients needed adenoidectomy. Only

21 patients in group B, however, underwent the procedure while remaining 7 refused surgery. Similar results were observed by Demirhan et al where 76% of the patients were excluded from the waiting list of adenoidectomy after treatment with steroid nasal spray.<sup>11</sup> Usta et al reported that after mometasone furoate treatment only 2 of 39 patients who required adenoidectomy underwent the surgery.<sup>13</sup> It can therefore be concluded that the use of intranasal steroids can significantly reduce the number of adenoidectomies required in children with adenoid hypertrophy. Even when the surgery is indicated, topical steroids can help control the symptoms till the child is old enough to undergo the surgery.

Recurrence of symptoms and long-term side effects of therapy were not examined in this study because of shorter follow up and fixed duration and dosage of mometasone furoate. However, this was a prospective, randomized and comparative study so there was no bias in patients selection. Further studies are needed to evaluate the long-term results of intranasal steroid therapy and the recurrence of symptoms on stoppage of treatment.

## CONCLUSION

Adenoid hypertrophy is a common cause of nasal obstruction and recurrent ear problems in small children. Earlier, adenoidectomy was considered to be the only option. Use of intranasal steroids has reduced the need for adenoidectomy in majority of the cases. However, the optimal dosage and duration of therapy as well as the adverse effects of long-term therapy need to be studied further.

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