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Original Research Article

Mometasone Nasal Spray in Children with Adenoid Hypertrophy – A Longitudinal Study

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ABSTRACT

Background and Objectives
Adenoid hypertrophy is a condition associated with a high morbidity among children. We conducted a study to evaluate the effectiveness of the intranasal mometasone steroid spray on adenoid hypertrophy and to identify the age group of children who most benefitted.

Methods
It was a hospital based longitudinal study. 110 children with adenoid hypertrophy were enrolled with 71 in the 4-9 years and 39 in the 10-14 years of age group. Data was collected using a structured questionnaire to assess the related symptoms. Children were given mometasone furoate aqueous nasal spray once daily for two months. Assessment was done at the end of the first month, second month and 3 months after discontinuing the nasal spray.

Results
There was a significant improvement in nasal obstruction and hyponasality of speech with reduced frequency of upper respiratory infections and allergic symptoms (p value <0.001). Highest pretreatment score with a mean score of 5.5+/- 1.2 was noticed for nasal obstruction (98%). Improvement was not statistically significant in children with ear complaints (p value of 0.112) and in children of 10-14 years with sleep disturbances (p value of 0.194). 54.5% of cases had a good symptomatic outcome. 27 patients (24.65%) were advised adenoidectomy.

Conclusion
This study observed a statistically significant reduction for total symptom score and adenoid size after initiation of mometasone furoate nasal spray, especially in younger children, thus reducing the need for adenoidectomy.

Keywords: Adenoid Hypertrophy, Nasal Endoscopy, Intranasal Mometasone Furoate, Steroid Nasal Spray, Adenoidectomy.

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INTRODUCTION

Adenoids are a mass of lymphoid tissue in the junction of the roof and posterior wallof the nasopharynx. It was first described by Meyer as a mucosa-associated lymphoid tissue in the year 1868.[1] Around 2 to 3% of children worldwide may experience apnoea or hypopnoea due to obstructed airway by adenoid hypertrophy.[2] Adenoid hypertrophy is associated with chronic sinusitis, obstructive sleep apnoea and otitis media with effusion.[3] Medical management with antibiotics, antihistamines, decongestants and saline douchings are not found to be very effective in adenoid hypertrophy and adenoidectomy is the surgical management.[3,4]

Both adenoids and tonsil are involved in the regulation of secretory immunoglobulin production. But there is at least a transient fall in the immunoglobulin levels following adenoidectomy especially for serum IgA.[5,6] Adenoidectomy is also contraindicated in conditions causing velopharyngeal insufficiency.[7]

Therefore, the long-term consequences of adenoidectomy on immunity as well as its peri operative complications like respiratory distress and bleeding become a matter of concern while considering the surgical management of adenoid hypertrophy.[8]

Adeno tonsillar hypertrophy is associated with the presence of inflammatory mediators which responds well to anti-inflammatory agents like corticosteroids.[9] But the long-term side effects of oral steroid usage limit their role in treating adenoid hypertrophy.[10]

There are studies indicating the use of topical intranasal steroids to reduce the airway resistance at the nasal, adenoidal and tonsillar levels.[9] Researchers have reported the safety of nasal steroid sprays like mometasone furoate nasal spray, fluticasone propionate, ciclesonide, and fluticasone furoate.[11]

Bitar MA, Mahfoud et al. in their pilot study found that intra nasal mometasonenasal spray was effective against obstructive adenoids and no systemic side effects were observed with the use of the spray. Mometasone has a low aqueous solubility which allows only a small fraction of the drug to penetrate the nasal mucosa on intranasal administration and a low systemic availability of <1%. Mometasone is not seen to suppress the hypothalamus- pituitary- adrenal axis.[11,12,13] Demain (1995) suggested that intranasal steroids reduce the size of the adenoids by the lympholytic and the anti-inflammatory action of steroids.[14]

Ahmed MR, Abou-Halawa[15] noted histo pathologically, less reactive germinal centres and spongiosis indicating that mometasone could halt the proliferative changes of adenoid lymphatic tissue.

Hence we did a prospective study on the efficacy of mometasone nasal spray among children with adenoid hypertrophy at our institution.

MATERIALS AND METHODS

It was a hospital based longitudinal study conducted in the department of ENT, Govt. TD Medical College, Alappuzha, and Kerala, India from December 2018 to May 2020. The study subjects were the children of 4 to 14 years with adenoid hypertrophy who attended the outpatient department of ENT. Approval by the Institutional Ethics committee was taken (EC 59/2018) and the study was performed in accordance with the Helsinki Declaration of 1975. Informed consent was taken from the parents of the children and assent from the older children above 7 years.

OBJECTIVES

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1. To assess the effect of mometasone furoate intranasal spray in treating adenoid hypertrophy.
2. To identify the age group of children who most benefited on using mometasone nasalspray.

Sample Size Calculation

A total of 110 cases, children with chronic adenoid hypertrophy were enrolled. From a similar study conducted by Saleh Mohebbi et al[16] the adenoid size at the end of treatment was 38.2 +/- 20mm.Using the formula4SD2/d2whereSD=20, with precision, d = 20% of SD =4, minimum sample size (n) was calculated as 100, assuming a 10% drop out, the sample size was arrived at 110.

Inclusion Criteria

- Children between the age group of 4 and 14 years.
- With nasal obstruction/ habitual snoring/ mouth breathing for more than 3 months.
- Adenoid size grade II and above based on Clemens et al. clinical grading by doing a nasal endoscopy.[12,15]

Exclusion Criteria

- Use of nasal or systemic corticosteroid or antibiotics during the last 4 weeks.
- Those with idiosyncratic reaction to corticosteroids.
- Significant nasal septal deviation, choanal atresia, syndromic child, craniofacial and neuromuscular anomalies.
- Recurrent epistaxis with documented immunodeficiency conditions.
- Use of nasal or systemic corticosteroid or antibiotics during the last 4 weeks.

Study Procedure

A detailed history on adenoid hypertrophy symptoms and related problems was taken and documented by using a questionnaire to assess the symptoms like nasal blockade, mouth breathing, snoring, hyponasal speech, recurrent upper respiratory tract infections (URI), aural complaints, allergic features, nasal discharge, post nasal drip, headache, dry cough with a score system provided to each domain and the baseline symptom scores were recorded on a 0 to 3 scale in a diary. Scores of 0, 1, 2 and 3 were defined as absent (no symptom), mild (present, but not troublesome), moderate (frequently troublesome symptoms), and severe (daily symptoms). Flexible nasopharyngoscope and a 2.7 mm rigid 0 degree nasal endoscope were used to assess the nasopharynx for presence of adenoid tissue. Adenoid size was graded based on Clemens & McMurray Clinical grading[17] and recorded. Otoscopic evaluation was done for ear pathology. Soft tissue X-ray lateral view of the skull to view the nasopharynx was not taken as a routine procedure.

Study Variables

Quantitative variables: Age, symptom scores and grade of adenoid size.

Qualitative variables: Age subgroups, gender, associated allergic rhinitis, symptoms of adenoid enlargement, adenoid size grades.

Number of cases who required surgery at the end of the study period was considered as an outcome variable. Children were given mometasone furoate aqueous nasal spray 1 actuation (50mcg) in each nostril once daily (total 100 mcg per day) for two months. They were then reviewed for symptoms and the adenoid size at the end of one month and two months of initiating the treatment and after discontinuing the spray, they were reviewed again after 3 months.

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Directions for using the Intranasal Spray

Close one nostril by gently pressing with finger
Tilt the head slightly forward and keep the bottle upright
Gently insert the bottle tip into the other nostril.
Squeeze the bottle and breathe in deeply through that nostril.
Remove the bottle and sniff once or twice.
Do not spray directly onto the nasal septum.
Repeat steps1–6 in the other nostril. Avoid blowing of the nose for the next 15 minutes.

Statistical Analysis

Data collected was tabulated using Microsoft Excel sheets and the statistical analysis was done using SPSS (PASW Statistics 18) software. The quantitative variables were summarized using mean with standard deviation or median with inter-quartile range (IQR). For qualitative variables (age subgroups, gender, history of atopy, symptoms associated with adenoid enlargement, referred for adenoidectomy, ear complaints, category of adenoid size grade) data was analyzed for frequency and percentage. Chi-square test was used for testing the association between age subgroup and the improvement in symptoms/adenoid size category. The Fischer's exact test was applied if the expected count was less than five in any of the cells in chi-square test. Non-parametric test like Mann-Whitney U test and Friedman test were used as a test of significance for assessing ordinal data. Mann-Whitney U test was used for assessing the difference in total symptom scores between the two age sub-groups. Friedman test was used as the test of significance for assessing symptom scores and grades of adenoid size at different follow-up times. For all statistical evaluations, a calculated probability (p value) of $< 0.05$was considered significant.

RESULTS

Table 1 gives the distribution and dispersion of the patients according to the age and gender with the younger age group presenting with more symptoms of adenoid hypertrophy. The mean age of the study subjects was 8.1years and the standard deviation 2.6 years.

Distribution of symptoms related to adenoid hypertrophy is shown in figure 1. The patients in the 4-9 years of age group were more symptomatic than the 10-14 years of age group.

Age groups	Total no of patients	Percentage	Gender		Dispersion of age Mean Median			
			Male	Female	Minimum	Maximum	(SD)	(IQR)
4-6 years	41	37.3	21	20				
7-9 years	30	22.7	19	6	4	14	8.1(2.6)	8.0(5.0)
10-14 years	25	27.3	19	11				
12-14 years	14	12.7	9	5				
Total	110	100	68	42				

Table 1: Distribution and dispersion of the patients according to the age &gender

Individual symptom scores during pretreatment and follow up were compared in each age group and given in the table 2 and 3. There was a significant improvement in all the symptom domains ($p<0.001$) excepting ear complaints (p value 0.112). Among the older children statistically significant improvement was noted in all the symptoms excepting sleep disturbances and ear complaints as shown in table 3. On comparing the mean total symptom scores between pretreatment and follow up

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periods for the two age groups, reduction in symptoms was noted which was statistically significant, p value <0.001 (Table 4).

No significant difference in the median value of total symptom score was noted between the two age groups in any of the follow up phases (Table 5).

Good clinical response was observed in 54.5% of the cases with recurrence of symptoms in 29.6% of cases in the 4-9 year age group and 20.5% in the 10-14year age group.

Adenoid size at follow up visits was compared with pretreatment size and assessed endoscopically. Decrement in the grade of adenoid size at different follow up times was statistically significant in both the age groups (Table 6).

27 (24.5%) children required adenoidectomy at the end of 5 months, 19(26.8%) from the younger age group and 8 (20.5%) from the older age group but the difference was not statistically significant, p value was 0.466.

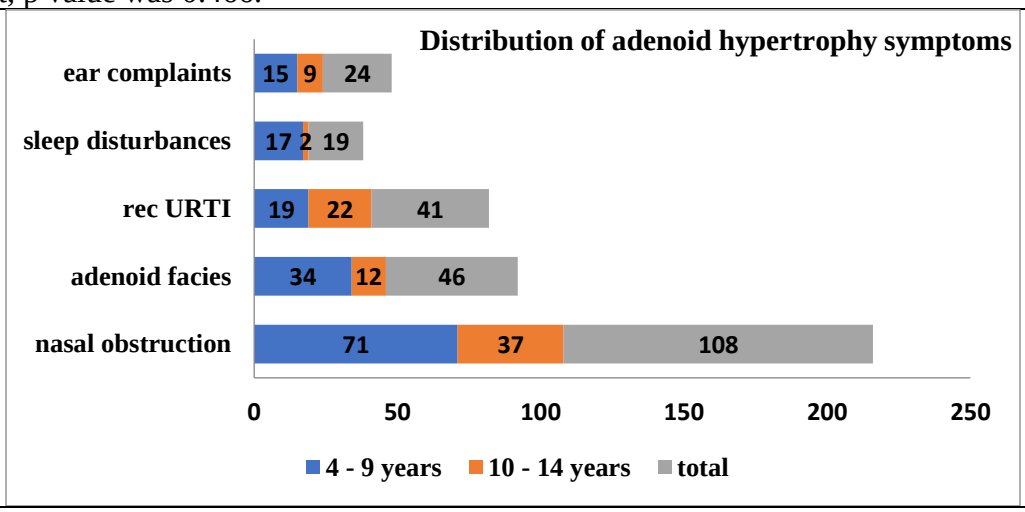

Figure 1: Distribution of adenoid symptoms

Symptoms	Treatment Schedule	Mean Score	Standard Deviation	Minimum Score	Maximum Score	Chi-Square	p- Value
Nasal obstruction	Pre T/T	5.54	1.263	2	7	166.342	<0.001
	1st month	3.77	1.267	1	7		
	2nd month	2.94	1.264	0	6		
	Post T/T	3.18	1.588	0	7		
Sleep disturbance	Pre T/T	0.89	1.65	0	5	27.471	<0.001
	1st month	0.7	1.44	0	5		
	2nd month	0.61	1.21	0	4		
	Post T/T	0.69	1.41	0	5		
Recurrent URI	Before T/T	0.48	0.83	0	2	35.056	<0.001
	1st month	0.32	0.58	0	2		
	2nd month	0.14	0.38	0	2		
	After T/T	0.28	0.59	0	2		
Ear complaints	Before T/T	0.38	0.8	0	3	6	0.112
	1st month	0.38	0.8	0	3		
	2nd month	0.35	0.79	0	3		
	After T/T	0.35	0.79	0	3		

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Chronic rhinosinusitis	Before T/T	1.13	1.82	0	6	48.769	<0.001
	1st month	0.92	1.61	0	6		
	2nd month	0.48	1.01	0	4		
	After T/T	0.75	1.37	0	5		
Allergic rhinitis	Before T/T	1.42	1.89	0	4	63.987	<0.001
	1st month	0.85	1.21	0	3		
	2nd month	0.24	0.62	0	2		
	After T/T	0.55	1.39	0	10		

Table 2: Comparison of Individual symptom scores during pretreatment and follow up in the age group of 4-9 years

*Friedman test ,d f=3

Symptoms	Treatment Schedule	Mean Score	Standard Deviation	Minimum Score	Maximum Score	Chi-Square	P- Value
Nasal obstruction	Pre T/T	5.46	1.36	2	7	92.676	<0.001
	1st month	3.69	1.38	1	7		
	2nd month	2.97	1.4	0	6		
	Post T/T	3.18	1.5	0	6		
Sleep disturbance	PreT/T	0.18	0.79	0	4	4.714	0.194
	1st month	0.15	0.71	0	4		
	2nd month	0.13	0.57	0	3		
	Post T/T	0.13	0.57	0	3		
Recurrent URI	Pre T/T	0.95	0.92	0	2	35.779	<0.001
	1st month	0.72	0.76	0	2		
	2nd month	0.36	0.58	0	2		
	Post T/T	0.51	0.76	0	2		
Ear complaints	Pre T/T	0.31	0.69	0	2	9	0.029
	1st month	0.31	0.69	0	2		
	2nd month	0.23	0.63	0	2		
	Post T/T	0.23	0.63	0	2		
Chronic Rhinosinusitis	Pre T/T	1.08	1.56	0	5	28.267	<0.001
	1st month	0.79	1.32	0	4		
	2nd month	0.23	0.62	0	3		
	Post T/T	0.64	1.15	0	4		
Allergic Rhinitis	Pre T/T	1.44	1.94	0	4	37.301	<0.001
	1st month	0.77	1.13	0	3		
	2nd month	0.36	0.77	0	3		
	Post T/T	0.44	0.85	0	3		

Table 3: Comparison of Individual symptom scores during pretreatment and follow up in the age group 10-14 years

*Friedman test, df =3

Age Group in Years	Follow up Period	Mean	Standard Deviation	Minimum	Maximum	Chi-Square	P Value
4-9 years	Pre t/t	9.65	3.833	3	19	174.124	0.<001

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N=71	1st m	6.9	3.226	2	16		
	2nd m	4.83	2.808	0	16		
	Post t/t	5.77	3.538	1	17		
10-14 years	Pret/t	9.74	3.282	5	17	96.9	0.<001
	1st m	6.51	3.016	2	15		
	2nd m	4.15	2.072	1	13		
	Post t/t	5.18	2.919	1	15		

Table 4: Comparison of total symptom score at different follow up time in each age group

Total Symptom Score	**4-9 Years N=71**	**10-14 Years N=39**	**p Value**
(Total Score=28)	**Median (IQR)**	**Median (IQR)**	
Before treatment	9.0(6.0)	9.0(4.0)	0.73
During 1 month follow up	6.0(5.0)	6.0 (4.0)	0.66
During 2 month follow up	4.0(4.0)	4.0(2.0)	0.25
After treatment	5.0(4.0)	4.0(4.0)	0.49
% change median score (before &after)	14.28%	17.85%	

Table 5: Comparison of the median value of the total symptom scores between the age groups (Mann- Whitney U test)

Age Group	**DNE Examination**	**N#**	**Adenoid Size Grading**		**Chi-Square**	**P Value**
			Median	**IQR**		
4-9 years	Before treatment	50	3	1		
	During follow up	50	2	0		
	After stopping treatment	50	2	1	74.722	<0.001
10-14 years	Before treatment	29	2	1		
	During follow up	29	2	1		
	After stopping treatment	29	2	1	36.594	<0.001

Table 6: Comparison of Grade of Adenoid size at different follow up period in each age group

*Friedman test, df=2 #number of subjects who underwent nasal endoscopy in all stages of follow up

DISCUSSION

The age distribution in our study was from 4 years to 14 years with a mean age of 8.1+/- 2.5 years with41 cases in the age group of 4-6 years (37.3%) and 14 cases in the 12-14 years which was similar to a study conducted on the Iraqi population with the highest incidence in the 3–5-year-oldage group (60%) and the lowest in the 9-12-year-old age group (18%).[18] Higher prevalence was also noted between 3-6 years in the study by Prestes Carneiro et al.[19]

The male to female ratio was 1.6:1 which was similar to the study by RenataC. DiFranceso et al.[20] with male to female ratio 1.57:1.

Nasal obstruction was seen in 98% of the cases and there was a statistically significant decrease in its severity with a change in mean score from 5.5 to 2.9 and then 3.1 on using the mometasone nasal spray. Saleh Mohebbi et al[16] in their study also had a statistically significant response to mometasone nasal spray with reduced snoring and mouth breathing.

37.3% of the cases in our study had associated recurrent URI, 11 % with tonsillar hypertrophy and 22.8% showed features of chronic sinusitis. With this treatment we noticed a marked decrease in

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the frequency of headache, episodes of dry cough, rhinorrhoea and post nasal dripping which was statistically significant (p value<0.001) with the number of attacks of URI reduced. There was a significant improvement in their mean allergic symptom scores (1.4+/- 1.2to 0.55+/-1.4). The results were comparable with the study conducted by Gupta V et al.[21]

We observed a statistically significant reduction in mean total symptom score in both age groups in all stages of follow up. The percentage change in the median symptom score before and after discontinuing the treatment was 14.28% in the younger age group and 17.85% in the older group but the comparison between the two age groups was not statistically significant (p value >0.05).

Good response outcome was observed for 54.5% and poor response in 19.1% of the cases. Symptoms recurred in 26.4%. The recurrence was found to be higher in the 4–9-year age group (29.6%) than in the 10-14-year age group (20.5%). There was a statistically significant reduction in the grade of adenoid size on follow up in both the age groups (p value <0.001) which was similar to the study by Rezende et al.[22]

27 children (24.5 %) required adenoidectomy atthe end of 5 months, the proportion of children being higher in the 4-9year age group, but the difference was not significant, p value 0.466.

Berlucchi noted adenoidectomy could be avoided in adenoid hypertrophy on a long-term use of intranasal mometasone furoate spray.[23]

Gupta V et al[21] reported few adverse effects like epistaxis and dry mouth during the treatment, but in our study no such adverse effects were reported.

From our study overall satisfying responses were obtained in both the age groups,in the improvement of symptoms and reduction in adenoid size, thereby minimizing the need for adenoidectomy. Intranasal mometasone is found to be effective in controlling the obstructive symptoms of adenoid enlargement in this short- term period of study.

LIMITATIONS OF THE STUDY

1. Our study was a longitudinal prospective one with no control group.
2. As it was a short -term period of study, the long -term effects of the nasal spray cannot be commented.
3. Only subjective assessment was done with the help of a questionnaire and recording the responses from the parents of the children. Objective assessment of the nasal airway patency was not done.

CONCLUSION

Mometasone nasal spray can be used as an effective alternative to surgery, especially in younger children while considering the surgical burden of adenoidectomy. However further studies should be done to study its long-term efficacy.

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