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LONG TERM USE OF MOMETASONE FUROATE AQUEOUS NASAL SPRAY VERSUS ADENOIDECTOMY IN THE MANAGEMENT OF ADENOID HYPERTROPHY IN CHILDRENS- A COMPARITIVE STUDY

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Conflicts of Interest: Nil

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Abstract:

Background: One of the common causes for nasal obstruction in children is adenoid hypertrophy which is a common indication for surgical removal due to associated diseases. Long term use of steroid spray also

Objectives: The aim of the current study was to compare invasive and noninvasive treatment modalities in the treatment adenoid hypertrophy in the children between 5-15 year ages.

Methods: a comparative prospective study conducted on 5-15 year old children with pre diagnosed adenoid hypertrophy. 30 patients each group was treated either by long term mometasone furoate (MF) nasal spray i.e. Group A and Adenoidectomy i.e. Group B. MF nasal spray was prescribed to the patients for 3 hourly everyday for 3 months. Adenoidectomy was performed under general anesthesia. Symptoms like Adenoid hypertrophy grading, nasal obstruction, snoring and interruption in mouth breathing were evaluated Pre and post treatment. Nasal obstruction was counted as mild, moderate and severe. Presence of snoring and interruption in mouth breathing were observed. The follow up was taken on 15th day, at the end of 1st month and 3rd month.

Results: Few common symptoms of adenoid hypertrophy were observed prior and after the treatment. Follow up period was evaluated on 15th day, 1 month and 3 month. Out of 60 patients, only 3 (10%) patients showed nasal obstruction by 3rd month, 6 (20%) patients had increase in adenoid size, 5 (16.66%) patients showed snoring and 3 (10%) patients showed interrupted mouth breathing. Out of 30 patients in Group B; only 2 (6.66%) patients showed nasal obstruction and snoring. There was no growth in adenoid size and obstruction in mouth breathing. All the findings were statistically significant. Interrupted mouth breathing was found to be more relieved symptom.

Conclusion: adenoidectomy and long term MF nasal spray treatment both has good efficacy in treatment of nasal obstruction due to adenoid hypertrophy. Long term non invasive local steroid therapy was used where surgery was contraindicated. Adenoidectomy was found to be more reliable as recurrence rate was minimal.

Keywords: adenoid hypertrophy, adenoidectomy, nasal obstruction, mometasone furoate (MF) nasal spray.

Introduction:

In conjunction with the palatine tonsils, lingual tonsils, and tubal tonsils, the adenoids make up the structure known as Waldeyer's Ring, a collection of mucosal-associated lymphoid tissue situated at the entrance of the upper aerodigestive tract. Blood supply to the adenoids includes the ascending pharyngeal artery, with some contributions from the internal maxillary and facial arteries.[1] the glossopharyngeal and vagus nerves provide sensory innervations to adenoids. Adenoid size tends to increase during childhood, usually reaching maximal size by age 6 or 7 before regressing by adolescence.[2] One of the common causes for nasal obstruction in children is adenoid hypertrophy.

One of the most frequent reasons of nasal obstruction and sleep apnea in pediatrics is adenoid hypertrophy. Remaining adenoid tissue can reoccur following hypertrophied adenoid removal and a second operation may be needed. Adenoidal hypertrophy (AH) and Adenotonsillar hypertrophy are common disorders in the pediatric population and can cause symptoms such as mouth breathing, nasal congestion, hyponasal speech, snoring, and obstructive sleep apnea (OSA), as well as chronic sinusitis and recurrent otitis media.[3] More serious long-term sequelae, typically secondary to OSA,

include neurocognitive abnormalities (e.g. behavioral and learning difficulties, poor attention span, hyperactivity, below average intelligence quotient); cardiovascular morbidity (e.g. decreased right ventricular ejection fraction, left ventricular hypertrophy, elevated diastolic blood pressure); and growth failure.[4]

Enlarged adenoids can become nearly the size of a ping pong ball and completely block airflow through the nasal passages. Even if enlarged adenoids are not substantial enough to physically block the back of the nose, they can obstruct air flow enough so that breathing through the nose requires an uncomfortable amount of work, and inhalation occurs instead through an open mouth. Adenoids can also obstruct the nasal airway enough to affect the voice without actually stopping nasal air flow altogether. Adenoid hypertrophy can occur because of infectious and non-infectious etiologies. Infectious causes of adenoid hypertrophy include both viral and bacterial pathogens. Viral pathogens associated with adenoid hypertrophy include adenovirus, coronavirus, coxsackievirus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), herpes simplex virus, human bocavirus parainfluenza virus, and rhinovirus.[5] Multiple non-infectious causes of adenoid hypertrophy have also been suggested including gastroesophageal reflux, allergies, and exposure to cigarette smoke.[7] In adults, adenoid hypertrophy can also be a sign of a more serious condition such as HIV infection , lymphoma, or sino-nasal malignancy.[5,6]

In acute and chronic infectious adenoid hypertrophy, medical management with antibiotics is an appropriate first step. Amoxicillin can be used for uncomplicated acute adenoiditis, however, a beta-lactamase inhibitor such as clavulanic acid should be included for chronic or recurrent infections. Clindamycin or azithromycin are considered as alternatives in patients with penicillin allergies.[10] Nasal steroids have been suggested as an additional option for medical treatment with some short-term success noted. Adenoid hypertrophy is generally a self-limiting condition which resolves as the adenoids atrophy and regress by adolescence. However, given the potentially serious complications and impact on patient quality of life, surgical management of adenoid hypertrophy is employed for many patients annually.[11,12]

This is more relevant in the developing countries where the burden of disease in the younger age is high and frequently a cause of running nose and snoring. It can also be useful where surgery is contraindicated in conditions like bleeding disorders, cleft palate and bifid uvula. Conservative treatment has the advantage of not having the complications of surgery like bleeding and hypertrophy of other components of Waldeyer's ring. It is useful to control concurrent conditions of the nose and PNS like allergic rhinitis and sinusitis, which have a significant contribution towards a running nose especially in children. A conservative attitude towards chronic adenoiditis

Topical nasal steroids most likely affect the anatomical component by decreasing inspiratory upper airway resistance at the nasal, adenoidal or tonsillar levels.[1,13] Corticosteroids, by their lympholytic or anti-inflammatory effects, might reduce adenotonsillar hypertrophy. Intranasal corticosteroids reduce cellular proliferation and the production of pro-inflammatory cytokines in a tonsil and adenoid mixed-cell culture system.[14] It is common indication for surgical removal in these patients due to multiple morbidities. In severe symptoms adenoidectomy is recommended, however there are limitations for surgery like cleft palate.[14,15] The safety of nasal steroid spray has been well reported. Adenoids rarely recur after surgery and where there were traces of adenoidal tissue, it did not manifest clinically. Nasal obstruction after the adenoidectomy is rhinogenic origin, not the cause of enlarged adenoids. Adenoidal recurrence more often occurs in children younger than five years old and in those patients who were treated postoperatively with antibiotics on numerous occasions. Nasal corticosteroids are utilized in order to reduce adenoid hypertrophy and eliminate adenoidectomy operation. The purpose of our study is to assess the effect of nasal corticosteroid administration after adenoidectomy on adenoid regrowth and symptom scores.

The aim of the current study is to compare the effectiveness of mometasone nasal spray versus adenoidectomy in the treatment of children with adenoid hypertrophy.

MATERIAL AND METHODS

This was a prospective study conducted in the department of ENT, Government Mohan

Kumarmangalam Medical College, Salem, and Tamilnadu; in the period of 6 months since January 2018 to June 2018. Study comprised about analysis of mometasone furoate (MF) nasal spray and Adenoidectomy for the treatment of adenoid hypertrophy on 60 children of age range between 5-15 years. The study was approved by the Institutional Research Ethics Committee and written informed consent was obtained from parents of all participants.

The inclusion criteria were as follows:
1. Patients aged between 5 to 12 years old,
2. Adenoid hypertrophy without tonsillar hypertrophy for a minimum of 12 months,
3. No sign of improvement despite medical treatment with antibiotics under parental control.
The exclusion criteria were as follows:
1. Use of any nasal or systemic steroid within the past 1 year.
2. Use of any nasal decongestant or anti-allergic medication within the past 2 weeks.
3. History of upper respiratory tract infection within the past 2 weeks.
4. History of one or more of the following conditions: genetic craniofacial, or neuromuscular syndromes, chronic epistaxis, immune disease, asthma, nasal surgery, septal perforation, nasal trauma within the last 3 months and hypersensitivity to MF.
Adenoid hypertrophy endoscopic classification according to its anatomical relationship with adjacent structures such as vomer, soft palate and torus tubaris.[23]

- Grade 1- the adenoid tissue contacts with the torus tubaris;
- Grade 2- the adenoid tissue contacts with torus tubaris and vomer;
- Grade 3- the adenoid tissue contacts with torus tubaris, vomer and soft palate in resting position.

Primary outcomes

- Adenoid size and presence as assessed by DNE.
- Improvement of signs and symptoms (Mouth breathing, snoring, nasal obstruction – Visual analogue score (VAS), recurrent cold, epistaxis, hyponasal speech)
- Recurrent & residual disease after treatment assessed by DNE.

Secondary outcomes

- Hearing Improvement-Pure tone audiogram (PTA)
- Earache-VAS
- Complications of treatment in any of the groups.
- Requirement for rescue medication.

Patients were randomly divided in 2 groups according to the treatment. Group A (n= 30) patients were prescribed with Mometasone Furoate nasal spray (Metaspray from Cipla Pharma) for 3 hourly everyday for 3 months and Group B (n=30), Adenoidectomy i.e. surgical removal of adenoids. Patients selected for surgical treatment were subjected to curettage adenoidectomy under general anesthesia by a single experienced surgeon. The same surgical protocol and postoperative management was followed in all surgeries. Intraoperative, complete clearance of adenoid was ensured by digital palpation and endoscopy after surgery. Patient was observed for 24 hours and then discharged.

Symptoms like Adenoid hypertrophy grading, nasal obstruction, snoring and interruption in mouth breathing were evaluated Pre and post treatment. Nasal obstruction was counted as mild, moderate and severe. Presence of snoring and interruption in mouth breathing were observed. The follow up was taken on 15th day, at the end of 1st month and 3rd month.

Statistical analysis: All the data was tabulated and transferred on MS excel sheet. Data analysis was carried out using statistical package for social science (SPSS, V 21) software. In all cases “p” value of less than 0.05 was indicative of statistical significance.

RESULTS

This was a prospective analytical study performed on 60 children suffering from adenoid hypertrophy. Children of age range between 5-15 years, were randomly selected and divided 30 in each group i.e. Group A patients were prescribed with Mometasone Furoate nasal spray and Group B, Adenoidectomy i.e. surgical removal of adenoids. Out of 60 patients 36 (60%) were male and 24 (40%) were female. Group A included 20 (33.33%) male patients and 10 (16.66%) female patients, Group B included 16 (26.66%) male patients and 14 (23.33%) female patients. According to the findings as shown in Table 1, male predominance was higher in both groups.

Few common symptoms of adenoid hypertrophy were observed prior to the treatment. 30 patients had mild, 20 patients had moderate and 12 patients had severe nasal obstruction. In Group A; Adenoid stage 1st grade was observed in 21 (70%) patients, 2nd grade in 7 (23.33%) patients and 3rd grade in 2 (6.66%) patients. Group B; Adenoid stage 1st grade was observed in 12 (40%) patients, 2nd grade in 15 (50%) patients and 3rd grade in 3 (10%) patients.

In Group A, Snoring was present in 23 (76.66%) patients. In Group B, Snoring was present in 27 (90%) patients. In Group A, Mouth breathing was found to be interrupted in 26 (86.66%) patients and in Group B, 28 (93.33%) patients showed same symptom. All the findings were statistically significant. According to Table 2, Snoring and mouth breathing were most predominant symptoms.

Follow up period was evaluated on 15th day, 1 month and 3 month. Out of 30 patients in Group A; only 3 (10%) patients showed nasal obstruction by 3rd month, 6 (20%) patients had increase in adenoid size, 5 (16.66%) patients showed snoring and 3 (10%) patients showed interrupted mouth breathing. Out of 30 patients in Group B; only 2 (6.66%) patients showed nasal obstruction and snoring. There was no growth in adenoid size and obstruction in mouth breathing. All the findings were statistically significant. Interrupted mouth breathing was found to be more relieved symptom in all group patients than any other symptoms i.e. 3 (10%) and 0 patients. All the findings were described as shown in Table 3.

Table 1: Demographic variables.

Groups	Male		Female	
	N = 36	%	N = 24	%
Group A (MF Spray)	20	33.33	10	16.66
Group B (Adenoidectomy)	16	26.66	14	23.33

Table 2: Pre operative Severity of symptoms

Group	Nasal obstruction			Adenoid stage grading			Snoring		Mouth breathing		p-value
	Mild	Moderate	Severe	1	2	3	Present	Absent	Normal	Interrupted	
Group A	30	20	12	21	7	2	23	7	4	26	0.002
Group B	30	24	21	12	15	3	27	3	2	28	0.001

Table 3: Follow up.

Symptoms	Follow up Period	Group A	Group B	p-value
Nasal obstruction	15th day	18	15	0.01
	1 month	12	11	
	3 month	3	2	
Adenoid size	15th day	16	0	0.001
	1 month	11	0	
	3 month	6	0	
Snoring	15th day	18	15	0.05
	1 month	10	10	
	3 month	5	2	
Mouth breathing	15th day	20	12	0.002
	1 month	12	4	
	3 month	3	0	

DISCUSSION

Adenoid hypertrophy (AH), which obstructs the nasal airway in patients, is associated with multiple symptoms including snoring, nasal discharge, nasal congestion, chronic mouth breathing, halitosis, hyponasal speech, restless sleep etc. It also plays a major role in chronic rhinosinusitis and otitis media with effusion (OME).[4,5] Adenoidectomy has been the definitive treatment for relief from upper airway obstruction and diseases complicated by or attributable to Adenoid Hypertrophy. Steroid spray has some low risk benefits and postoperative complications. Also, there is a fear of surgery in children's parents.[14]

In the previous study conducted by Demain JG et al[12] and Criscuoli G et al[28] in their study on aqueous nasal beclamethasone spray hypothesized that removal of adenoids may harm the immunologic system.

Our study was a prospective analytical study performed on 60 children suffering from adenoid hypertrophy. Children of age range between 5-15 year, were randomly selected and divided 30 in each group i.e. Group A patients were prescribed with Mometasone Furoate nasal spray and Group B, Adenoidectomy i.e. surgical removal of adenoids. Out of 60 patients 36 (60%) were male and 24 (40%) were female. Group A included 20 (33.33%) male patients and 10 (16.66%) female patients, Group B included 16 (26.66%) male patients and 14 (23.33%) female patients. According to the findings as shown in Table 1, male predominance was higher in both groups. Rezende RM et al,[13] Minshall E et al,[14] Cengel S et al[15] who studied mometasone furoate aqueous nasal spray and reported similar results. This finding was similar to the results in the previous study conducted by Gupta V. et al[11] in 2014 and Pai V. K. et al[25] in 2019 which found higher female predominance.

Minshall E et al,[14] describes the long term maintenance therapy of steroids. Voluntary suspension of maintenance therapy after surgery of this disorder can cause recurrence or regrowth, whereas its regular administration, may lead to successful results. Few common symptoms of adenoid hypertrophy were observed prior to the treatment. 30 patients had mild, 20 patients had moderate and 12 patients had severe nasal obstruction. In Group A; Adenoid stage 1st grade was observed in 21 (70%) patients, 2nd grade in 7 (23.33%) patients and 3rd grade in 2 (6.66%) patients. Group B; Adenoid stage 1st grade was observed in 12 (40%) patients, 2nd grade in 15 (50%) patients and 3rd grade in 3 (10%) patients. Similar results were also provided by Pai VK et al,[25] Berlucchi M et al[26] in their study performed on adenoidectomy versus mometasone furoate nasal spray.

Paulussen C et al[23] revealed that 45 patients were Grade 1 and 10 patients were Grade 2. Mouth breathing was found to be interrupted in 52 (72.22%) patients. All the findings were statistically significant. According to Table 2, Snoring and mouth breathing was the most predominant symptoms. A study done by Gupta et al[11] and Rezende RM et al,[13] on snoring due to adenoids showed a significant improvement in all domains of obstructive sleep apnea due to adenoid hypertrophy. Demain JG et al1[12] in 1995, showed intranasal budesonide to decrease the severity of respiratory distress and the size of the adenoids, although mildly, with 6 weeks of use in children with mild OSA. Minshall E et al,[14] Cengel S et al[15] in their study on mometasone furoate aqueous nasal spray showed that there were statistically significant differences between pre- and post-treatment values in every single group administered corticosteroids, and combined therapy ($P < 0.05$).

Follow up period was evaluated on 15th day, 1 month and 3 month. Out of 30 patients in Group A; only 3 (10%) patients showed nasal obstruction by 3rd month, 6 (20%) patients had increase in adenoid size, 5 (16.66%) patients showed snoring and 3 (10%) patients showed interrupted mouth breathing. Out of 30 patients in Group B; only 2 (6.66%) patients showed nasal obstruction and snoring. This finding was similar to the results provided by Rout MR[22] et al, Paulussen C et al.[23] There was no growth in adenoid size and obstruction in mouth breathing. All the findings were statistically significant. Interrupted mouth breathing was found to be more relieved symptom in all group patients than any other symptoms i.e. 3 (10%) and 0 patients. All the findings were described as shown in Table 3.

Adenoid hypertrophy is more common in children than in adults; the adenoids naturally atrophies and regress during adolescence. Rezende RM et al,[13] Minshall E et al,[14] Cengel S et al[15] also studied mometasone furoate aqueous nasal spray in adenoid hypertrophy patients. They mentioned about the benefits of local therapy as the there were higher risks to the curettage adenoidectomy. Rout MR[22] et

al, Paulussen C et al,[23] reported a significant improvement in snoring habit, regular breathing, frequent loss of sleep, mouth breathing and nasal discharge after 4 weeks of adenoid hypertrophy surgery in children.

A recent meta-analysis presented by Feres MF et al in 2013,[16] showed the prevalence of adenoid hypertrophy among children and adolescents was 34.46%. Pereira L et al[10] in 2018, in his meta-analysis, revealed that long term use of MF nasal spray found to be very effective in minimizing the obstructive symptoms caused by adenoid hypertrophy. Rezende RM et al,[13] Minshall E et al,[14] Cengel S et al[15] in their research on mometasone furoate aqueous nasal spray also concluded similar results. Bhat VK et al,[17] Pai VK et al,[25] Berlucchi M et al[26] in their study performed on Adenoidectomy versus mometasone furoate nasal spray found clinically significant results similar to our study.

CONCLUSION

Our randomized prospective comparative study was performed on 60 children having adenoid hypertrophy. Intranasal MF spray was prescribed for first group and adenoidectomy performed to curette nasal obstruction caused due to adenoid hypertrophy. Symptoms like Adenoid hypertrophy grading, nasal obstruction, snoring and interruption in mouth breathing were evaluated Pre and post-treatment. Nasal obstruction was counted as mild, moderate and severe. The presence of snoring and interruption in mouth breathing were observed. The follow up was taken on the 15th day, at the end of 1st month and 3rd month. All the symptoms were found to be milder in severity at the end of the 3rd month. So we can conclude that the long-term effect of intranasal MF spray may significantly improve nasal obstruction symptoms in children with moderate to severe adenoidal hypertrophy, and this improvement may be associated with a reduction of adenoid size.

In patients were adenoidectomy is contraindicated, long term MF nasal spray treatment has good efficacy in the treatment of nasal obstruction due to adenoid hypertrophy. This is a safer, simpler and painless alternative to surgery to achieve remissions in young children. As the number of patients in our study was limited, more sample sizes required to decide any definite conclusion.

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