Int.j.pathol.2022;20(2): 56-61

Original Article

Efficacy of Nasal Steroids in Treatment of Adenoidal Hypertrophy in Children

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ABSTRACT

Background: The Adenoids (Pharyngeal tonsils) undergo hypertrophy till 7 years of age, showing maximum enlargement at the age of 4 years, it atrophies/ vanishes by the time adulthood sets in. This study will assess the effect of intranasal steroids in the treatment of adenoidal hypertrophy in our population. Significant data has not been collected with regards to the efficacy of intranasal steroids in conservative management of Adenoid Hypertrophy in our population to prevent the burden of surgery in such patients.

Objective: To assess the efficacy of intranasal steroids in the treatment of hypertrophy of adenoids in children preventing the need for adenoidectomy.

Methodology: A Randomised Control Trial was conducted at the ENT department of Hayatabad Medical Complex over a period of 6 months on 444 patients. The patients were randomly assigned into two groups by consecutive non probability sampling: one which had received intranasal steroid (Mometasone Furoate 100umg per day for 8 weeks) and the other group was given only placebo (saline nasal spray).

Results: In Group A mean age was 7 years (SD ± 5.21) whereas in Group B mean age was 7 years (SD ± 5.57). In Group A 122 (55%) children were male while 100 (45%) were female whereas in Group B 127 (57%) children were male and 95 (43%) were female. Group A (Intranasal steroid) was effective in 195 (88%) children and was not effective in 27 (12%) children. In Group B (Saline nasal spray) was effective in 164 (74%) children and was not effective in 58 (26%) children.

Conclusion: Our study concludes that intranasal steroids are more effective than nasal saline spray in the treatment of hypertrophy of adenoids in children, preventing the need for adenoidectomy.

Key Words: efficacy, intranasal steroids, nasal saline spray, hypertrophy, adenoidectomy

Introduction

The Adenoids (Pharyngeal tonsils) are a mass of lymphoid tissue which are present in the nasopharynx on the roof and posterior walls. Adenoids undergo hypertrophy till 7 years of age, showing maximum enlargement at the age of 4 years, it atrophies/vanishes by the time adulthood sets in. Adenoids are a part of the Waldeyer's ring which consists of adenoids, palatine and lingual tonsils. This ring is considered to be the first immunocompetent anatomical structure. Adenoidal Hypertrophy (AH) in childhood is a common condition which has been found to be associated with chronic or recurrent upper respiratory tract infections or allergies which results in signs and symptoms ranging from Nasal obstruction to Obstructive Sleep Apnea.

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Though, AH is considered as an indication for adenoidectomy in children, several studies have been conducted to assess the efficacy of steroids in conservative management of AH.[1-4] In this study we will measure the efficacy of steroids in management of AH in children which would be a prospective, randomised, placebo-controlled trial. The anti-inflammatory effects of steroids can be used as an alternative to adenoidectomy to decrease the size of adenoids in children, thus reducing the need for surgery.

In children, nasal respiratory obstruction has most commonly been attributed to allergic rhinitis and adenoid hypertrophy. Obstructive adenoids lead to apnoea in 2-3% children and worldwide, allergic rhinitis affects 20-40% children.[5, 6] Adenoidectomies are considered to be the mainstay for the management of nasopharyngeal obstruction. Though, it has some negative impact on the immune system and has post-operative regrowth.[7, 8] Newer modalities being used in the management of adenoids is the use of intranasal

steroids which has been found to be significantly effective in children.[9-12] Studies show that the use of intranasal steroids has proven to be fruitful in 50-70% of the patients while the rest will still need surgery.[9, 11-13]

A review conducted at Faculty of Medicine, Federal University of Rio Grande, Rio Grande, RS, Brazil and Division of Paediatric Otolaryngology, BC Children's Hospital, Vancouver, Canada which comprised of 394 patients in 6 randomised trials in order to assess the efficacy of intranasal steroids in treatment of AH. 5 out of the six trials showed significant effect of steroids in reducing AH in children. A significant relief of nasal obstruction was evident in the patients being treated with intranasal steroids than in patients being given placebo. Only one trial did not show any significant decrease in adenoid size with the subsequent intranasal steroid therapy in children suffering from AH.[14]

Another randomised controlled study conducted in Naples, Italy which included 178 children suffering from AH showed that an 8-week period of intranasal steroid therapy in patients of AH greatly reduces the size of adenoids, thus preventing the need for surgery.[15]

A double-blind, randomised, crossover trial of steroids or placebo conducted in Kentucky which recruited 71 possible candidates (62 children with obstructive apnea confirmed through polysomnography) showed a significant relief with steroid therapy being monitored through polysomnography and measurement of the size of the adenoids.[16]Other studies on the contrary supports adenoidectomy as the treatment of choice in such patients.[17]

In Pakistan, the use of intranasal mometasone therapy for the treatment of Adenoid hypertrophy in children has not been assessed. The only mode of treatment being offered to the patients is adenoidectomy. Hence, this study would help in introducing the novel modality and assess the effect of intranasal steroids in the treatment of adenoid hypertrophy in our population. If intranasal mometasone is found to be effective in the treatment of adenoid hypertrophy, this can be used as an adjuvant therapy in treating children with adenoid hypertrophy thus reducing the need for adenoidectomy. Significant data has not been collected with regards to the efficacy of intranasal steroids in conservative management of AH in our population to prevent the burden of surgery in such patients.

Material and Methods

A Randomised Control Trial was conducted at the department of ENT, Hayatabad Medical Complex, Peshawar, Pakistan from 27th November 2019 to 27th May 2020.

Patients with the following findings were included in the study.

1. Children aged 3-12 years suffering from chronic adenoid hypertrophy and symptoms consistent with adenoid hypertrophy (such as snoring, hypo-nasal speech, bilateral nasal blockage, rhinorrhea and mouth breathing) for the last 6 months. Children having 3 out of the 5 signs and symptoms were included in the study.
2. X-ray evidence of adenoid tissue occluding 50-70% of the nasopharynx confirmed through nasal endoscopy. Patients with more than the aforementioned occlusion were referred for surgery.
3. No prior history of adenoidectomy.

Patients with any of the following conditions were excluded from the study.

1. Patients with a recent history (up to 3 months) of upper respiratory infection.
2. Sinonasal or nasal anomalies.
3. Craniofacial deformity.
4. Suffering from cardiovascular and neurological diseases.
5. Patient being exposed to topical intranasal or systemic steroid therapy in the last 4 months.
6. Patients not willing to participate in the study were excluded.
7. Concomitant hypertrophy of tonsils.
8. History of epistaxis.
9. Positive history of allergy and hypersensitivity to steroids.

After the study was approved by the Ethical and Research Board of the hospital, all consenting patients fulfilling the inclusion criteria were recruited. Patients were put on standard treatment for pneumonia. Data and detailed ENT history was obtained from the parents. Nasal obstruction and hypo-nasal speech was assessed clinically. A lateral X-ray nasopharynx for size estimation of adenoid hypertrophy was carried out and confirmed by nasal endoscopy.

The patients were randomly assigned into two groups using the coin flip method: one group which had received intranasal steroids (Mometasone Furoate 100 micrograms per day for 8 weeks) and the other group were given only placebo (saline nasal spray).

The X-ray evidence of adenoids along with the presenting complaints was noted at the time of presentation and on follow up after 8 weeks. Patients with a consequent mitigation in signs and symptoms of adenoid hypertrophy were called 'responders' and were considered for maintenance therapy. On the other hand, non-responders were considered for adenoidectomy.

Data was analyzed using SPSS version 21. Mean and standard deviations were calculated for continuous variables like age, size of adenoids hypertrophy on x-ray and duration of symptoms. Frequencies and percentages were calculated for categorical variables like gender and efficacy. Both groups were compared for efficacy using Chi square test. Efficacy was stratified among age, gender, duration of disease to control effect modification. Post stratification was done through using a chi square test to determine the difference in the proportion of patients between the two groups keeping the p-value of ≤0.05 for statistical significance.

Results

A total of 444 patients, divided into 2 groups, were included in the study. Group A patients were given intranasal steroids while Group B patients were given a placebo (saline nasal spray).

In Group A, 151 (68%) patients were in age between 3-7 years while 71 (32%) were in age between 8-12 years. Mean age was 7 years (SD ± 5.21). In Group B 155 (70%) patients were aged 3-7 years while 67 (30%) were between 8-12 years. Mean age was 7 years with SD ± 5.57. (Table 1)

In Group A, 122 (55%) patients were male while 100 (45%) were female. In Group B, 127 (57%) patients were male and 95 (43%) were female. (Table 1)

In Group A, 78 (35%) patients had duration of symptoms ≤1 year while 144 (65%) had duration of symptoms >1 year. In Group B, 84 (38%) patients had duration of symptoms ≤1 year while 138 (62%) patients had duration of symptoms >1 year. (table 1)

In Group A, the intranasal steroids were effective in 195 (88%) patients and ineffective in 27 (12%) patients whereas in Group B, saline nasal spray was effective in 164 (74%) patients and ineffective in 58 (26%) patients. (Table 2).

Stratification of efficacy with respect to age, gender, Duration of symptoms is mentioned in table 3.

Table-1. Demographic Data and Duration of Symptoms (n=444)

Age	**GROUP A**	**GROUP B**
3-7 years	151(68%)	155(70%)
8-12 years	71(32%)	67(30%)
Total	222(100%)	222(100%)
Gender	**GROUP A**	**GROUP B**
Male	122(55%)	127(57%)
Female	100(45%)	95(43%)
Total	222(100%)	222(100%)
Duration of Symptoms	**GROUP A**	**GROUP B**
≤ 1 year	78(35%)	84(38%)
> 1 years	144(65%)	138(62%)
Total	222(100%)	222(100%)
Mean and SD	10 months ± 4.77	12 months ± 3.41

T Test was applied and P value was 0.0000

TABLE 2. EFFICACY (n=444)

EFFICACY	**GROUP A**	**GROUP B**
Effective	195(88%)	164(74%)
Not effective	27(12%)	58(26%)
Total	222(100%)	222(100%)

Chi square T Test was applied and P value was <0.001.

Table-3: Stratification of Efficacy W.R.T Age Distribution, Gender Distribution and Duration of Symptoms

AGE	EFFICACY	GROUP A	GROUP B	P value
3-7 years	Effective	133	114	0.0012
	Not effective	18	41	
Total		**151**	**155**	
8-12 years	Effective	62	50	0.0565
	Not effective	9	17	
Total		71	67	
GENDER	**EFFICACY**	**GROUP A**	**GROUP B**	**P value**
Male	Effective	107	94	0.0061
	Not effective	15	33	
Total		**122**	**127**	
Female	Effective	88	70	0.0108
	Not effective	12	25	
Total		**100**	**95**	
DURATION OF SYMPTOMS	**EFFICACY**	**GROUP A**	**GROUP B**	**P value**
≤ 1 year	Effective	69	62	0.0178
	Not effective	9	22	
Total		**78**	**84**	
> 1 year	Effective	126	102	0.0037
	Not effective	18	36	
Total		**144**	**138**	

Discussion

In 1995, Demain introduced the treatment of adenoid hypertrophy in children using intranasal corticosteroids for the first time.[19] It has not yet been determined how the intra nasal steroids relieve obstruction of the nasal airway. It is, however, hypothesized that they bring about the aforementioned effect through their lymphocytic or anti-inflammatory effects.[20, 21]

The present study shows that the mean age for both the groups was 7 years. In Group A 122 (55%) children were male while 100 (45%) children were female. Whereas in Group B 127 (57%) children were male and 95 (43%) children were female. Mover over Group A (Intranasal steroid) was effective in 195 (88%) children and was not effective in 27 (12%) children. Whereas Group B (Saline nasal spray) was effective in 164 (74%) children and was not effective in 58 (26%) children. Similar demographics have been reported in other studies[22] with age range from 3 to 13 years (mean age = 5.89 years) which shows the age bracket in which adenoid hypertrophy is the most frequent. Further research should be conducted on the safety of intra nasal corticosteroid use in the fetal period. In the same study, the overall improvement among patients of group I (intranasal steroids) patients was 85.4%while the overall improvement among patients of group II (intranasal saline) was 76.1%.

A study conducted by Elbeltagy YM et al[23] on twenty-three relevant potential citations and identified nine articles that were suitable for these meta-analyses after screening. These included randomized controlled trials enrolled in five meta-analyses. Three meta-analyses showed significant improvement in adenoid size after the use of intra nasal corticosteroids with a risk ratio of 0.68, and standardized mean difference (SMD) of −2.97, −0.67 and −1.34. Two meta-analyses showed insignificant improvement in nasal obstruction symptoms with SMD=−1.53 and 0.67.

In another study conducted by Solmaz F et al [23,24] reported that flexible endoscopy performed before the treatment revealed that 20 patients were Grade 2, 11 patients were Grade 3 and 24 patients were Grade 4. Nasal endoscopies performed after 6 weeks of intranasal topical steroid therapy revealed that 45 patients were Grade 1 and 10 patients were Grade 2. A statistically significant difference was present between endoscopic grades before and after treatment ($p < 0.0001$). Nasal endoscopies performed after 6 weeks in a control group receiving saline solution treatment revealed Grade 2 in 7 patients, Grade 3 in 10 patients and Grade 4 in 3 patients. There was no statistically significant difference between the prior and later

grades of the control group (p = 0.3125). Moreover, they are of the view that the use of intranasal steroids (mometasone furoate) for 6 weeks in patients with paediatric chronic nasal obstruction due to adenoid hypertrophy may be an effective treatment modality in alleviating symptoms and decreasing adenoid volume without causing systemic side effects.

Conclusion

Our study concludes that intranasal steroids are effective in the treatment of hypertrophy of adenoids in children. It is a plausible treatment modality in reducing the symptoms and an alternative to surgery reducing the need for adenoidectomy.

Competing interests
The authors of the study have no conflict of interest.
Funding
Authors did not receive any funding for conducting this research.

References

1 Sakarya E, Muluk NB, Sakalar E, Senturk M, Aricigil M, Bafaqeeh S, et al. Use of intranasal corticosteroids in adenotonsillar hypertrophy. The Journal of Laryngology & Otology. 2017;131(5):384-90.
2 Chohan A, Lal A, Chohan K, Chakravarti A, Gomber S. Systematic review and meta-analysis of randomized controlled trials on the role of mometasone in adenoid hypertrophy in children. International journal of pediatric otorhinolaryngology. 2015;79(10):1599-608.
3 Bhargava R, Chakravarti A. A double-blind randomized placebo-controlled trial of topical intranasal mometasone furoate nasal spray in children of adenoidal hypertrophy with otitis media with effusion. American journal of otolaryngology. 2014;35(6):766-70.
4 Madisetti S, Muppidi V, Jadi L, Reddy KP, Batchu D. Does intranasal steroids reduce the need of adenoidectomy in adenoid hypertrophy. J Evid Based Med Healthc. 2017;4(47):2871-5.
5 Löfstrand-Tideström B, Hultcrantz E. The development of snoring and sleep related breathing distress from 4 to 6 years in a cohort of Swedish children. International journal of pediatric otorhinolaryngology. 2007;71(7):1025-33.
6 Bousquet J, Van Cauwenberge P, Khaltaev N. Allergic Rhinitis and its Impact on Asthma (ARIA) In collaboration with the World Health Organization. Executive Summary of the Workshop Report7-10 December 1999, Geneva, Switzerland. Allergy-Koebenhavn. 2002;57(9):841-55.
7 Paulussen C, Claes J, Claes G, Jorissen M. Adenoids and tonsils, indications for surgery and immunological consequences of surgery. Acta oto-rhino-laryngologica Belgica. 2000;54(3):403-8.
8 Buchinsky FJ, Lowry MA, Isaacson G. Do adenoids regrow after excision? Otolaryngology-Head and Neck Surgery. 2000;123(5):576-81.
9 Demain JG, Goetz DW. Pediatric adenoidal hypertrophy and nasal airway obstruction: reduction with aqueous nasal beclomethasone. Pediatrics. 1995;95(3):355-64.
10 Brouillette RT, Manoukian JJ, Ducharme FM, Oudjhane K, Earle LG, Ladan S, et al. Efficacy of fluticasone nasal spray for pediatric obstructive sleep apnea. The Journal of pediatrics. 2001;138(6):838-44.
11 Cengel S, Akyol M. The role of topical nasal steroids in the treatment of children with otitis media with effusion and/or adenoid hypertrophy. International journal of pediatric otorhinolaryngology. 2006;70(4):639-45.
12 Berlucchi M, Salsi D, Valetti L, Parrinello G, Nicolai P. The role of mometasone furoate aqueous nasal spray in the treatment of adenoidal hypertrophy in the pediatric age group: preliminary results of a prospective, randomized study. Pediatrics. 2007;119(6):e1392-e7.
13 Berlucchi M, Valetti L, Parrinello G, Nicolai P. Long-term follow-up of children undergoing topical intranasal steroid therapy for adenoidal hypertrophy. International journal of pediatric otorhinolaryngology. 2008;72(8):1171-5.
14 Zhang L, Mendoza-Sassi RA, César JA, Chadha NK. Intranasal corticosteroids for nasal airway obstruction in children with moderate to severe adenoidal hypertrophy. Cochrane Database of Systematic Reviews. 2008(3).
15 Ciprandi G, Varricchio A, Capasso M, Varricchio A, De Lucia A, Ascione E, et al. Intranasal flunisolide treatment in children with adenoidal hypertrophy. International journal of immunopathology and pharmacology. 2007;20(4):833-6.
16 Kheirandish-Gozal L, Gozal D. Intranasal budesonide treatment for children with mild obstructive sleep apnea syndrome. Pediatrics. 2008;122(1):e149-e55.
17 Schupper AJ, Nation J, Pransky S. Adenoidectomy in Children: What Is the Evidence and What Is its Role? Current Otorhinolaryngology Reports. 2018;6(1):64-73.
18 Animasahun B, Adekunle M, Gbelee H, Njokanma O. Echocardiographic Characteristics of Nigerian Children with Adenoidal Hypertrophy: A Multicenter Study. Transl Med (Sunnyvale). 2016;6(189):2161-1025.1000189.
19 Demain JG, Goetz DW: Pediatric adenoidal hypertrophy and nasal airway obstruction: reduction with aqueous nasal beclomethasone. Pediatrics. 1995, 95:355-64.
20 Brouillette RT, Manoukian JJ, Ducharme FM, Oudjhane K, Earle LG, Ladan S, Morielli A: Efficacy of fluticasone nasal spray for pediatric obstructive sleep apnea. J Pediatr. 2001, 138:838-44. 10.1067/mpd.2001.114474
21 Mlynarek A, Tewfik MA, Hagr A, Manoukian JJ, Schloss MD, Tewfik TL. Lateral neck radiography versus direct video rhinoscopy in assessing adenoid size. J Otolaryngol 2004;33:360- 5.

22 Sobhy TS. Role of intranasal steroid in the prevention of recurrent nasal symptoms after adenoidectomy. Int J Otolaryngol. 2013; 2013: 603493.
23 Elbeltagy YM, Ibrahim SA, Hasaballah MS, Sowilem OM. Efficacy of intranasal corticosteroids in improving nasal airway obstruction in children with symptomatic adenoidal hypertrophy: a meta-analysis and systematic review. Egypt J Otolaryngol 2019;35:30-6.
24 Solmaz F, Aşcıoğlu ME, Durgut O, Dikici O, Haksever M. Are nasal steroids effective in children with adenoid hypertrophy? The European Research Journal 2019;5(2):311-318

HISTORY	
Date received:	28-3-2022
Date sent for review:	21-4-2022
Date received reviewers comments:	13-5-2022
Date received revised manuscript:	26-6-2022
Date accepted:	18-7-2022

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A. Conception/Study/Designing/Planning
B. Active Participation in Active Methodology
C. Interpretation/ Analysis and Discussion