CHRONIC ADENOID HYPERTROPHY IN CHILDREN - IS STEROID NASAL SPRAY BENEFICIAL?

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ABSTRACT: Objectives: *To study the efficacy of nasal beclomethosone spray in the treatment of chronic adenoid hypertrophy in children.*
Method: *A randomized double-blind placebo-controlled study*
Setting: *Tertiary academic referral center*
Patients: *Aged 3-12 years diagnosed to have chronic nasal obstruction due to hypertrophied adenoids.*
Intervention: *Intranasal beclomethasone at the dose of 200 micrograms/day to one group and placebo to the other group in matched dispensers for 8 weeks.*
Outcome measures: *Reduction of symptoms due to hypertrophied adenoids and the size of enlarged adenoids. Variables were noted at the beginning and end of the study for symptoms score severity, X-ray and flexible nasal endoscopic findings.*
Results: *Analysis was done to find any significant improvement between the two groups. The Chi-square test was used to investigate the relationship between discrete variables. 26 children completed the study with 13 each in the drug and placebo group. There were 17 male and 9 female patients from 3 to 12 years of age. There was no significant difference in nasal obstruction, snoring or nasal discharge between the two groups. Comparison of x-rays and endoscopy also showed no significant difference between the 2 groups significant (P value =1.000 and P=0.0666 respectively).*
Conclusion: *This study indicates that intranasal beclomethasone therapy is not useful in treatment of chronic adenoid hypertrophy in the general pediatric population.*

Key Words: *children; adenoid hypertrophy; beclomethosone nasal spray*

INTRODUCTION

Abnormally large adenoids have been attributed to recurrent acute upper respiratory tract infection, although it has been suggested that allergic episodes also result in adenoidal hypertrophy. However, there is very little evidence to show that the adenoids act as a reservoir of infection as histological studies of adenoidal tissue show only hyperplasia of lymphoid follicles and very rarely show septic foci or micro abscesses. Enlarged adenoids can cause harmful effects like nasal obstruction with snoring, sleep apnea, sinusitis, otitis media with effusion, facial mal-development and adenoid facies in children.[1] The definitive treatment of upper airway obstruction due to adenoid hypertrophy has been surgical treatment with adenoidectomy. Medical management of enlarged adenoids is presently directed towards the control of harboured infection as infection could be a stimulant to hyperplasia of this reactive and inflammatory submucosal aggregate, thus treating concurrent infection and complications of adenoidal enlargement. Nasal obstruction is symptomatically treated with decongestant nasal drops.[2] Anti-allergics are used though there is little evidence supporting a significant role of tonsils or adenoids in allergic reactions.[3] The role of oral steroids in alleviating the symptoms due to adenoid enlargement is known. Systemic steroids produce dramatic but temporary decrease in adenoidal size but significant side effects preclude their chronic use.[4] Aerosol treatment is the most effective way to decrease the systemic adverse effects of corticosteroid therapy. Beclomethasone is a lipid soluble corticosteroid. Delivery of drug to the upper airway has minimal systemic absorption. The safety of nasal steroid spray in children has been reported[5,6,7]. No significant effects on adrenocortical function were observed after 6 weeks of triamcinolone acetonide acqueous nasal spray in children 6-12 yrs with allergic rhinitis.[5] Intranasal administration of 200 microgms of Mometasone furoate aqueous nasal spray once daily for 14 days was found to be safe and well tolerated in a study among 3-12 year age group.[6] Intranasal beclomethasone was also found to be a

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useful adjunct to antibiotic treatment of chronic middle ear effusion in children 3-11 years.[7] To date there has been only one study reporting the efficacy of intranasal beclomethasone[8] in children attending the Allergy – Immunology department who were diagnosed to have nasal airway obstruction due to adenoid hypertrophy. Hence this study was undertaken.

MATERIALS AND METHODS

Children aged 3-12 years who presented to ENT / Pediatric outpatient departments of Christian Medical College & Hospital at Vellore in India from December 1998 to August 1999, diagnosed to have adenoid hypertrophy were included in the study. The diagnosis was based on the symptoms (nasal obstruction, snoring and /or nasal discharge), and lateral cephalometric radiographs (enlarged soft tissue convex bulge in the roof of nasopharynx compressing the nasopharyngeal airway). Other inclusion criteria were:

- ·Residence in /near Vellore and who could come for monthly followup
- ·Accompanied by either parent or guardian who resided with the child and could supervise the usage of drug.

The exclusion criteria were :

- ·Use of intranasal or systemic steroids within the last 1 year.
- ·Use of any intranasal medication like decongestants, anti-allergens within 2 weeks of entering the study.
- ·Acute upper respiratory infection within 2 weeks of entering the study.
- ·History of chronic epistaxis, immunodeficiency disorders or hypersensitivity to beclomethasone.

Following detailed history, the symptoms were graded according to severity. X-ray and a flexible nasal endoscopy of the child was done and the adenoid enlargement graded by the co-investigator and investigator independently.

Symptoms: Nasal obstruction, snoring and discharge **:** These symptoms as given by parents were graded according to severity into Grade 0: none at all: Grade 1: occasional during colds: Grade 2: frequent: Grade 3: constant.

X-ray of the nasopharynx : The size of the adenoids was graded according to the palatal airway measured from the most convex point of the adenoid tissue to the soft palate, the narrowest distance between the nasopharyngeal soft tissues and the soft palate was taken.[9] Grade 1:>6mm, Grade 2: 4-6mm, Grade 3: 0-3 mm.

Nasal endoscopy was done with Olympus Type P3 scope under topical anaesthesia using 4% xylocaine with no decongestant. The size of the adenoid was observed and the distance of the adenoid tissue from the vomer was assessed.[10] It was graded as: Grade1 :distance > 1cm, Grade 2 : distance 0.5-1.0cm, Grade3 :distance < .5 cm. Audiogram and tympanometry were done for children with ear symptoms.

The children were then randomly divided into 2 groups, using block randomization, one received the drug; the other received placebo in matched dispensers in double blind manner. Both the groups were instructed to use1 puff in each nostril twice daily for 8 weeks. Intranasal beclomethasone was at the dose of 50 microgm/puff and the total dose per day was 200 microgm.

Fig.1a. Distribution of study variable (Sex)

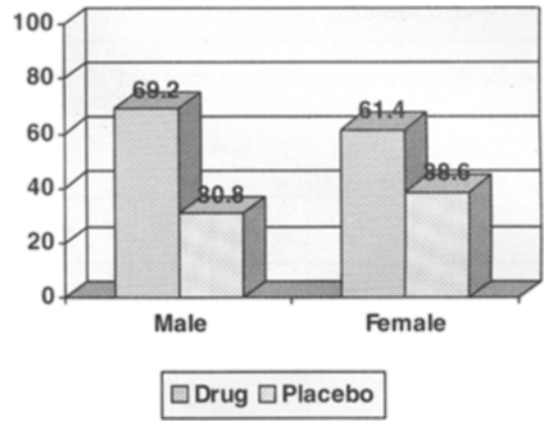
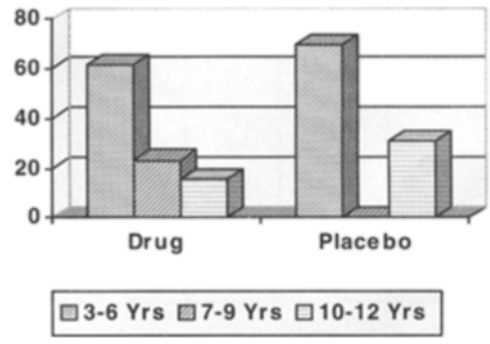


Fig.1b Distribution of Study Variable (Age)



In the 1st follow up after 4 weeks only the symptoms of the child was reassessed using questionnaire. This was repeated again at the completion of the study which was at the end of 8 weeks along with X-ray and nasal endoscopy for reevaluation of adenoid size. Children who required an audiometry and tympanogram in the first visit had these tests too repeated.

Table 1. Distribution of study variables

	Drug (n=13)		Placebo (13)	
	No.	%	No.	%
Nasal Block				
Gr 0	0	0	0	0
Gr I	3	23.1	2	15.4
Gr II	2	5.4	3	23.1
Gr III	8	61.5	8	61.5
Snoring				
Gr 0	1	7.7	0	0
Gr I	3	23.1	0	0
Gr II	0	0	3	23.1
Gr III	9	69.2	10	76.9
Nasal Discharge				
Gr 0	1	7.7	1	7.7
Gr I	3	23.1	4	30.8
Gr II	2	46.2	2	15.4
Gr III	3	23.1	6	46.2

Gr = Grade (See text)

RESULTS

A total of 31 children were taken into our study, out of which 5 were lost to follow up. Among the 5, 2 received the drug and 3 received placebo. 26 children aged 3-12 years came for follow up of which 13 children were in the drug and placebo group. All the children used nasal spray regularly, supervised by parents. There was no untoward effect of the spray and parents did not complain of any nasal bleed, stinging or allergies in either drug or placebo group. The pre and post treatment symptoms severity score, X-ray findings and endoscopic findings were graded (Table 1, 2a, 2b).

Statistical Analysis:

Statistical analysis was done using the SPSS/PC+ software. The Chi-square test was used to investigate the relationship between discrete variables. Analysis of variance was done

Table 2a. Comparing symptom score of visit 1 with visit 3 among drug and placebo

(visit I)	Drug Visit III					Placebo Visit III				
	Gr 0	Gr I	Gr II	Gr III	Row Total	Gr 0	Gr I	Gr II	Gr III	Row Total
Nasal Block										
Gr 0	0	0	0	0	0	0	0	0	0	0
Gr I	3	0	0	0	3	1	1	0	0	2
Gr II	2	0	0	0	2	3	0	0	0	3
Gr III	2	3	1	2	8	3	3	0	2	8
Snoring										
Gr 0	1	0	0	0	1	0	0	0	0	0
Gr I	3	0	0	0	3	0	0	0	0	0
Gr II	0	0	0	0	0	3	0	0	0	3
Gr III	3	2	1	3	9	3	3	2	2	10
Nasal Discharge										
Gr 0	1	0	0	0	1	1	0	0	0	1
Gr I	2	1	0	0	3	4	0	0	0	4
Gr II	3	1	2	0	6	1	1	0	0	2
Gr III	1	1	0	1	3	4	0	0	2	6

Gr = Grade (See text)

Table 2b. Comparing X-ray and Endoscopy score during the I Visit & III Visit among drug and placebo

	Drug Visit III						Placebo Visit III					
	Gr I		Gr II		Gr III		Gr I		Gr II		Gr III	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
X-Ray (Visit I)												
Gr I	2	100	0	0	0	0	1	100	0	0	0	0
Gr II	2	40	2	40	1	20	0	0	1	100	0	0
Gr III	0	0	0	0	6	100	0	0	3	27.3	8	72.7
Endoscopy												
Gr I	2	100	0	0	0	0	1	100	0	0	0	0
Gr II	2	66.7	1	33.3	0	0	0	0	1	100	0	0
Gr III	0	0	3	37.5	5	62.5	0	0	1	9.1	10	90.9

Gr = Grade (See text)

Table 3a. Analysis of symptoms scores - Drug Vs Placebo

	Drug (n=13)		Placebo (n=13)		
	Mean	SD	Mean	SD	P value
Nasal Block	-1.5385	.9674	-1.6923	1.1094	.7096
Snoring	-1.3077	1.1821	-1.7692	1.0127	.2957
Nasal Discharge	-1.0769	1.0377	-1.4615	1.1983	.3903

Table 3 b. Analysis of the X-ray & Endoscopy scores Drug Vs Placebo

	Drug (n=13)		Placebo (n=13)		
	Mean	SD	Mean	SD	P value
X-ray	-.0769	.4935	-.2308	.4385	1.000
Endoscopy	-.3846	.5064	-.0769	.2774	.0666

to assess significant difference between the two groups. The distribution and baseline variables of both the drug and placebo groups were equal. There were 9 males and 4 females in the drug which was comparable to 8 male and 5 females in the placebo group (fig.1a). The children were equally distributed according to age between 3-12 years (fig.1b). All the children were of Asian Dravidian origin and living with their parents. This shows that there were no confounding factors in the baseline variables. Comparison of scores between drug and placebo groups were made at the end of the study. There was no significant difference in nasal obstruction, snoring and nasal discharge (Table 3a) between the 1st and 3rd visits of drug and placebo groups. Comparison of X-rays and endoscpic examination of the 1st and 3rd visits among drug and placebo also showed no significant difference (3b).

DISCUSSION

To date there has been one randomized double blind placebo controlled cross over study of beclomethasone nasal spray for the treatment of adenoid hypertrophy[8]. It included 17 children aged 5-11 years treated for period of 8 weeks (338 microgm/day) followed by 16 weeks on

a lower daily drug dose (168 microgm/day). In our study there were 31 children aged 3-12 yrs of which 5 were lost to follow up.13 children in each limb, drug and placebo took a supervised daily dose of 200 microgm of topical intranasal beclomethasone for 8 weeks. The maximum dose of beclomethasone received over an 8 week period was 12mg in our study with no major side effects as compared to maximum dose of 30.2 mg of beclomethasone received over a 24 week period in the previous study[8] where significant side effects of epistaxis, stinging and sneezing were reported. None of the children in our study had history of atopy while history of atopy were present in significant number of children (7/17) from the earlier study[8] with two of them already using medication for asthma at entry into the study. All subjects in their study responded to beclomethasone treatment at the end of 8 weeks with a decrease in adenoid size, as compared to a mixed response to placebo along with improvement of adenoidal obstruction and total symptoms score over the 24 weeks of study. By 24 weeks, an 82% reduction in mean nasal obstruction symptom score accompanied a 29% mean reduction in adenoid/choana ratio. This result was not seen in our study where there was no significant improvement in symptoms score, X-ray and endoscopy among the drug and placebo group after 8 weeks intranasal beclomethasone. The power of the study with nasal block as outcome was nearly 6%. This implies that the effect in nasal block in the drug arm is similar to the placebo group. Based on the P value and the power it is evident that the increase in sample size is unlikely to provide clinically meaningful difference in the effect between the two groups. The earlier study was conducted among children attending the Allergy - Immunology department and the role of allergy in adenoid hypertrophy, may be a possible explanation for the discrepancies in the results of the two studies.

CONCLUSION

There was no significant difference in the symptoms of nasal obstruction, nasal discharge and snoring in children with adenoid hypertrophy in the beclomethasone nasal spray group and the placebo group. The X-rays of children pre and post treatment in the drug and placebo group did not show significant difference. The endoscopic findings in the drug group was better after treatment than placebo group though this was not statistically significant (P<.06). Intranasal beclomethasone therapy does not appear to be useful in the treatment of adenoid hypertrophy in the general pediatric population.

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