IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 7 Ver. III (July. 2017), PP 101-106
www.iosrjournals.org

EFFICACY OF INTRANASAL MOMETASONE FUROATE AS AN ADD ON THERAPY IN THE TREATMENT OF ADENOIDAL HYPERTROPHY IN ADOLESCENTS

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ABSTRACT :
Objective: *Treatment with intranasal mometasone furoate spray is proposed as alternative to surgery in adolescents with adenoidal hypertrophy. Hence we compared the efficacy and tolerability of intranasal mometasone furoate as an add-on therapy with existing standard treatment in a randomized, open label comparative study.*
Design: *A Prospective, randomized, open label, comparative study in patients with grade I and II adenoidal hypertrophy. Patients were divided into two groups to receive intranasal mometasone therapy and intranasal saline plus existing standard treatment with amoxycillin, paracetamol and levocetrizine. Improvement in symptoms like nasal obstruction, rhinorrhoea, cough, snoring and quality of life were assessed by a questionnaire at 2, 4, 6 and 8 weeks and by an endoscopic scoring at baseline and 8 weeks.*
Results: *At the end of 8 weeks the percentage reduction of nasal obstruction in mometasone furoate and saline were 81.5% and 39% respectively, rhinorrhoea was 89.66% and 37.93% , cough was 97% and 41.4% snoring symptoms were 95.4% and 35.71%, quality of life was 96.2% and 39.29% . In Endoscopic scoring, there was reduction in size of adenoids attributed to 61.98% in mometasone and 14.81% in saline group.*
Conclusions: *Intranasal mometasone furoate is an effective alternative to surgery in the management of grade I and II adenoid hypertrophy in adolescents.*
Keywords: *Adenoid hypertrophy, Intranasal steroids, Mometasone furoate, Adolescents*

I. Introduction

The adenoid, or nasopharyngeal tonsil is situated in the nasopharynx[1] and it forms a part of Waldeyer's ring of lymphoid tissue. The adenoids gets inflammed and hypertrophied as a result of allergy and infection between the age of 8 to 15 years. Normally the adenoids regress by the age of 18 years. Adenoid hypertrophy usually present with nasal obstruction, nasal discharge and sneezing which are milder symptoms. Nasal endoscopy[2] has also guided in the diagnosis of adenoid hypertrophy. Surgical removal was the primary mode of treatment in chronic cases of adenoid hypertrophy. With expanding knowledge about the disease process and the immunological importance of adenoids, conservative management of adenoids was tried and various studies support this.

Literature on the prevalence and approach to management of adenoidal hypertrophy[3] in adolescents is scarce and it underestimated. Previous studies[4] suggested nasal obstruction as the commonest presenting symptom in adolescents referred to otorhinolaryngology clinic. It also suggested intranasal steroids reduce the symptoms of adenoidal hypertrophy except rhinorrhoea. The objective of this study is to find out the efficacy of intranasal mometasone furoate[5] as an add on therapy in the treatment of adenoidal hypertrophy in adolescents with the existing standard treatment in reducing the size of adenoids in adolescent patients for reduction in symptoms as compared to intranasal saline spray.

II. Methods

2.1 Study participants

This study was approved by the Institutional Ethics Committee of Stanley Medical College and Hospital, Chennai, India. Informed consent was obtained from legally authorized representatives. The screening procedure consisted of a detailed medical history, clinical examination, laboratory investigations, endoscopic examination. Eligible patients were adolescents between 12 to 18 years of age and their primary diagnosis was adenoidal hypertrophy both clinically and by endoscopic examination. 90 patients were screened, 60 patients

whose endoscopic examination revealed adenoid hypertrophy were included in the study. 30 patients were excluded. The 60 patients were randomized into 2 groups. 30 patients were allotted in each group using a 1:1 ratio randomization. Informed consent was obtained from the legal caregivers. The inclusion criteria included: (1) Patients between 12 to 18 years of age of both sex. (2) Patients who had symptoms of nasal obstruction for atleast 6 months. (3) Patients who had adenoidal hypertrophy Grade I and II as assessed by nasal endoscopy. (4) Patients not willing to undergo surgery or deny surgery. Exclusion criteria was presence of any of the following - patients who had systemic infections, nasal or paranasal infections within 2 weeks, nasal trauma, nasal surgery, nasal septum perforation, hypersensitivity to mometasone furoate, patients undergoing immunosuppressant therapy, patients on inhalational or systemic corticosteroid therapy, chronic epistaxis and patients who are not willing to give written informed consent.

2.2 Study Design

This was a Prospective, randomized, single blinded, comparative study performed by Department of Pharmacology and done in the Department of Otorhinolaryngology, Stanley Medical College & Hospital. Eligible patients were done a clinical examination and nasal endoscopy and were allocated randomly into two groups. Group A to receive Mometasone furoate nasal spray 200µg/day, 50µg twice daily in each nostril for 6 weeks + existing standard treatment, C.Amoxycillin 250 mg tid for 7 days and T.Levocetrizine 5 mg HS for 7 days. Group B to receive saline nasal spray 1 puff twice daily in each nostril for 6 weeks + existing standard treatment, C.Amoxycillin 250 mg tid for 7 days and T.Levocetrizine 5 mg HS for 7 days. The study protocol is outlined in Fig.1.

2.3 Assessment of patients

Assessment of patients in the study included history, clinical examination, nasal endoscopy and a parental questionnaire. Patient history included age, gender, history of allergy or atopy in family and drug allergies, if any in the past. Improvement of symptom such as nasal obstruction, rhinorrhoea, cough, snoring and disruption of quality of life in general will be evaluated at each visit at the baseline, 2weeks, 4 weeks, 6 weeks and 8 weeks after treatment by using a clinical scoring system[6] ranging from 0 to 3. [0-absent;1-occasional;2-frequent;3-daytime and nighttime symptoms]. An overall total symptom score was obtained for each patient. Nasal endoscopy was performed to evaluate the size of adenoids and for grading. At the baseline and at the end of 8 weeks, the findings was estimated by endoscopic grading [7]. [1-Adenoid occupying less than 25% of choanal area; 2-Adenoid occupying 25-50% of choanal area; 3-Adenoid occupying 50-75% of choanal area; 4-Adenoid occupying 75-100% of choanal area]. Adverse effects like nasal bleeding and burning sensation in the nose was recorded at each visit.

2.4 Outcomes

The primary outcomes were improvement in symptoms by a scoring of symptoms - as nasal obstruction, rhinorrhoea, cough, snoring and disruption of quality of life and reduction in size of adenoids by endoscopic grading. Secondary outcomes were frequency of adverse effects and treatment compliance.

2.5 Statistical methods:

The statistical analysis was performed using SPSS (Statistical Package for Social Sciences) for Windows version 17. Data were expressed as mean and standard deviation. Student independent 't' test was used to compare quantitative data between two groups. Pearson's chi square test is used for gender difference.

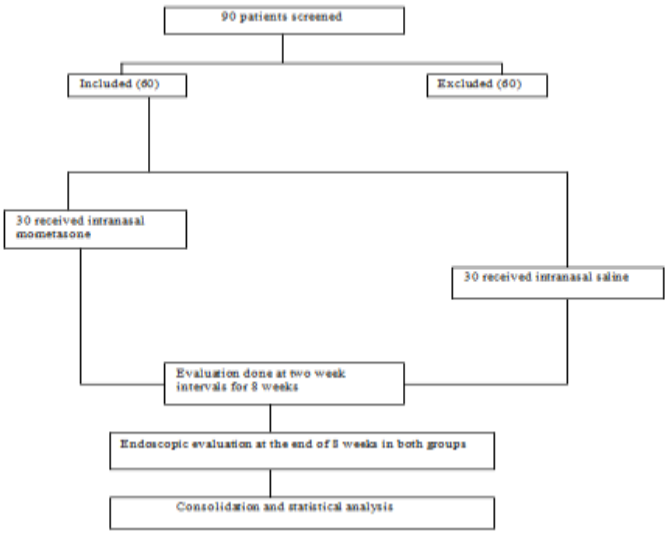

Fig.1. Trial profile.

2.6 Materials used during the study

- Carl storz nasal endoscope
- Cold light source
- Watec endoscope camera with auto iris
- Topical nasal decongestants
- 4% Lignocaine topical
- Tilley's forceps
- Oral amoxycillin and oral levocetrizine
- Mometasone furoate nasal spray and saline nasal spray.

III. Results

3.1. Trial population

Thirty adolescent patients in each group were enrolled and assigned randomly to receive mometasone furoate and saline nasal spray. Mean age distribution was 14.83 for Group A and 14.77 for Group B, done using student independent 't' test showing '*p'* = 0.8344. Sex distribution was using Chi Square test showed '*p*' value of 0.0384. All patients completed the study and there was no dropouts and all patients were followed for 8 weeks after treatment. No patients had history of cigarette smoking. Nasal endoscopy was tolerated well by all the patients. There was no complications during the diagnostic nasal endoscopic examination before and after treatment.

Table 1 Mean scoring of mometasone and saline nasal spray

	Group A		Group B		'*p*' value for difference in treatment
	Before MF	After MF	Before saline	After saline	
Nasal obstruction	2.70	0.50	2.80	1.70	0.0000
Rhinorrhoea	2.90	0.30	2.90	1.80	0.0000
Cough	2.60	0.07	2.90	1.70	0.0000
Snoring	2.83	0.13	2.80	1.80	0.0000
Quality of life	2.63	0.10	2.80	1.70	0.0000

At the start of the study, there was no difference between the mean of the sinonasal symptoms (nasal obstruction, rhinorrhoea, cough, snoring and quality of life) between the two treatment groups. The mean value of nasal obstruction scoring in Group A was 2.7 and in group B was 2.8 in the baseline.('*p*' value=0.3797; not significant). At the end of 8th week , mean value of nasal obstruction scoring in group A was 0.50 and in Group B was 1.70. ('*p*' value=0.0000, is significant). The mean value of rhinorrhoea scoring in Group A was 2.9 and in group B was 2.9 in the baseline.('*p*' value=0.2863; not significant). At the end of 8th week , mean value of rhinorrhoea scoring in group A was 0.30 and in Group B was 1.80. ('*p*' value=0.0000, is significant). The mean value of cough scoring in Group A was 2.60 and in group B was 2.90 in the baseline.('*p*' value=0.0071 significant). At the end of 8th week , mean value of cough scoring in group A was 0.07 and in Group B was 1.70. ('*p*' value=0.0000, is significant). The mean value of snoring scoring in Group A was 2.83 and in group B was 2.80 in the baseline.('*p*' value=0.7438; not significant). At the end of 8th week , mean value of snoring scoring in group A was 0.13 and in Group B was 1.80. ('*p*' value=0.0000, is significant). The mean value of quality of life scoring in Group A was 2.63 and in group B was 2.80 in the baseline.('p' value=0.1574; not significant). At the end of 8th week , mean value of quality of life scoring in group A was 0.10 and in Group B was 1.70. ('*p*' value=0.0000, is significant).

Table 1 summarizes the comparison of means of symptom scoring of patients of two groups. There were significant improvement in symptom scoring from 2 weeks and upto 8 weeks. Analysis of symptoms revealed all symptoms improved significantly with the use of mometasone compared to saline nasal spray.The mean value of endoscopic scoring in Group A was 2.63 and in group B was 2.70 in the baseline.('*p*' value=0.5914; not significant).At the end of 8th week, mean value of endoscopic scoring was 1.00 in Group A and Group B was 2.30 ('*p*' value=0.0000; significant). The percentage reduction from the endoscopic scoring at at the end of 8th week was 61.98% in Group A and 14.81% in Group B.

Table 2 Nasal endoscopy scoring

	Group A		Group B		'*p*' value for difference in treatment
	Before MF	After MF	Before saline	After saline	
Nasopharynx Endoscopy scoring	2.63	1.00	2.70	2.30	0.0000

3.2 Adverse events

In group A, one patient had disturbances of taste, two patients had candidiasis of oropharynx and one patient had nausea. In group B, four patients had disturbances of taste, four patients had candidiasis of oropharynx, two patients had nasal discharge, three patients had nausea, two patients had headache.

IV. Discussion

Adenoid hypertrophy usually present with nasal obstruction, rhinorrhoea, sneezing and snoring. This leads to emotional distress in affected children and associated with marked reduction in quality of life. Complications associated with adenoid hypertrophy are otitis media with effusion (OME) and obstructive sleep apnea (OSA). The standard treatment previously was surgery alone. With the introduction of endoscopic procedures and grading of size of adenoids by endoscopy, grade I and grade II patients can be treated with intranasal steroids avoiding surgery. The effects of intranasal mometasone furoate in group A patients with adenoid hypertrophy were compared with intranasal saline in group B patients, in addition to the existing standard treatment. The results were highly encouraging than the previous studies done with intranasal mometasone therapy in adenoidal hypertrophy. From the results it was found that intranasal mometasone furoate has greater effects clinically and statistically in reducing the size of adenoids, also with reduction in symptoms like nasal obstruction, rhinorrhoea, cough and snoring. The mean age of patients in group A was 14.77 and group B was 14.83 respectively. The sex distribution of the patients in group A and group B showed a male preponderance.

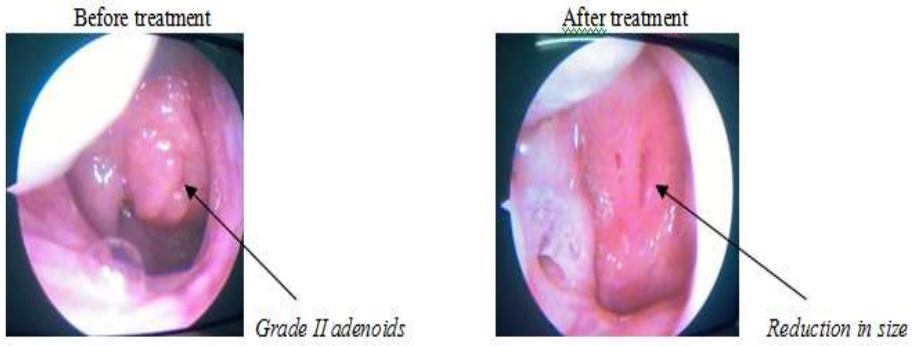

Fig. 2 Group A [Mometasone group]

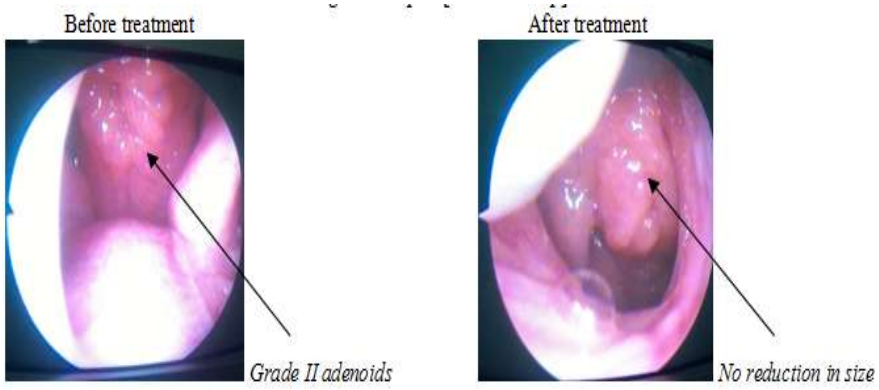

Fig. 3 Group B [Saline Group]

4.1 Nasal obstruction

The percentage reduction from the baseline of nasal obstruction scoring at the end of 2nd week was 23.95% in group A and 3.57% in Group B, at the end of 4th week the % reduction was 34.22 % in Group A and 10.71% in Group B, at the end of 6th week the % reduction was 68.44% in group A and 21.43% in Group B and at the end of 8th week was 96.2% in Group A and 39.29% in Group B. In the study of Zhang *et al*[8] and Demirhan *et al*[9] , it was suggested that intranasal steroids significantly improved nasal obstruction symptoms in children with adenoidal hypertrophy and subsequently reduction in size of adenoids on long term treatment. Our study suggest that in 30 patients treated with intranasal mometasone furoate there was

improvement in nasal obstruction at the end of 2nd week itself and from the end of 4th week, the subjects had no symptoms at all.

Table 3 Adverse effects of study patients

	Mometasone group		Saline group	
	N	%	N	%
1. Disturbances of taste	1	3.3	4	13.3
2. Candidiasis of oropharynx	2	6.6	4	13.3
3. Nasal discharge	0	0	2	6.6
4. Nausea	1	3.3	3	10
5. Headache	0	0	2	6.6

4.2 Rhinorrhoea

The mean value of rhinorrhoea in group A and group B at baseline was 2.90 and 2.90, at the of 2nd week was 2.33 and 2.80, 2.00 and 2.60 at the end of 4th week, 1.00 and 2.20 at the end of 6th week and 0.30 and 1.80 at the end of 8th week respectively. There were statistically significant differences in mean rhinorrhoea scoring between group A and group B. In the study of H.B.Yilmaz *et al*[10], it was suggested that intranasal mometasone furoate does not improve rhinorrhoea in adolescents. Our study showed improvement in rhinorrhoea also at the end of 2nd week itself (p=0.0002).

4.3 Cough

The mean value of cough in group A and group B at baseline was 2.60 and 2.90, at the of 2nd week was 2.17 and 2.60, 1.90 and 2.37 at the end of 4th week, 0.50 and 2.20 at the end of 6th week and 0.07 and 1.70 at the end of 8th week respectively. There were highly statistically significant differences in mean cough scoring at the end of 6 weeks (p=0.0000) between group A and group B.

4.4 Snoring

The mean value of snoring in group A and group B at baseline was 2.83 and 2.80, at the of 2nd week was 2.50 and 2.40, 1.80 and 2.20 at the end of 4th week, 0.57 and 2.10 at the end of 6th week and 0.13 and 1.80 at the end of 8th week respectively. There were highly statistically significant differences in mean snoring scoring at the end of 4 weeks (p=0.0003) between group A and group B.

4.5 Quality of life

The percentage reduction from the baseline of quality of life scoring at the end of 2nd week was 23.95% in group A and 3.57% in Group B, at the end of 4th week the % reduction was 34.22 % in Group A and 10.71% in Group B, at the end of 6th week the % reduction was 68.44% in group A and 21.43% in Group B and at the end of 8th week was 96.2% in Group A and 39.29% in Group B.

4.6 Endoscopic scoring:

20 patients who had grade II adenoid hypertrophy in group A (mometasone group) showed marked reduction in size of adenoids at the end of 8 weeks and 10 patients who had grade I adenoid hypertrophy in group A also showed significant decrease in the size of adenoids at the end of 8 weeks. 21 patients having grade II adenoid hypertrophy in group B (saline group) and 9 patients having grade I adenoid hypertrophy in group B does not show significant reduction in size of adenoids. There were also statistically significant differences in mean endoscopic scoring between group A and group B. H.B.Yilmaz[12] *et al* in their study concluded that there was no significant difference in reduction in the size of adenoids by nasal endoscopic examination in patients treated with mometasone furoate. Our study showed significant reduction in size of adenoids by nasal endoscopic examination clinically and showed high statistical significance in endoscopic examination at the end of 8th week (‘p’=0.0000) as compared to endoscopic examination in baseline. Thus intranasal mometasone furoate is proved to be an alternative therapy to surgery in reducing the size of adenoids, in patients with grade I and II adenoid hypertrophy.

Intranasal mometasone reduce the size of adenoids by lympholytic action and may reduce adenoid inflammation by its anti-inflammatory effects. The current study was done in 30 patients to evaluate the efficacy of intranasal mometasone furoate as an add on therapy in adenoidal hypertrophy in adolescents. This study can form a basis for a larger study in our set-up to define the precise role of intranasal mometasone furoate alone in adolescent patients. The high incidence of adenoid hypertrophy in adolescent age group makes the treatment of this disease an important public health issue. Conservative management for adenoid hypertrophy gains importance to the previous modality of treatment (i.e.) surgery and can rightfully command interest.

V. Conclusion

From this study, it is concluded that intranasal mometasone furoate is an effective alternative to surgery in the management of grade I and II adenoid hypertrophy in adolescents.

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*Sam Anbu Sahayam J. "Efficacy of Intranasal Mometasone Furoate As An Add on Therapy in the Treatment of Adenoidal Hypertrophy In Adolescents." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) 16.7 (2017): 101-06.