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The Effect of Steroidal Nasal Spray Mometasone Furoate on Adenoid Hypertrophy and its Related Complications

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ABSTRACT

INTRODUCTION:The treatment for the majority of children with uncomplicated AH is by adenoidectomy that is curative nevertheless,significant risks and problems are associated with this operation . In such instances surgical procedure could be replaced by non surgical methods. OBJECTIVE:We evaluated the efficacy of mometasone furoate aqueous nasal spray in decreasing adenoid size and reducing the severity of chronic nasal obstruction symptoms in children affected by adenoidal hypertrophy.METHODS:In the first stage, after a primary clinical evaluation and nasal endoscopy (time 0), children were assigned randomly to receive a single intranasal administration in each nostril of either MF aqueous nasal spray two puffs daily (group 1) or a placebo saline solution nasal spray (group 2) for 8 wks. At the end of the first 8wks

, both groups were reassessed, to evaluate the efficacy of treatment. Patients in group A showed improvements in clinical findings were considered responders. score was assigned to each nasal symptom in relation to their severity. All scores were summed obtaining an overall symptom

score for each patient before and after therapy . AH size was assessed by means of nasal endoscopy.

RESULTS: The use of MF (group 1) was associated with reduction in adenoid size and the mean overall symptom scores . On the contrary, in group 2 no significant reduction in adenoid size and the mean overall symptom scores

CONCLUSIONS: Mometasone furoate aqueous nasal spray may be considered useful in decreasing adenoid pad size and the severity of symptoms related to adenoidal hypertrophy. Children with adenoidal hypertrophy that is not associated with tonsillar hypertrophy should be considered for intranasal mometasone treatment before surgery is planned.

KEYWORDS :

INTRODUCTION

Nasal obstruction is a common symptom in children & is one of the main symptoms of adenoid hypertrophy; they are also presented with chronic rhinorrhea, snoring, hyponasal speech, and obstructive sleep disorder (1). The term adenoids describes lymphoid tissue on the superior and posterior walls of the nasopharynx,and their hypertrophy is a common condition of childhood (2). Adenoidal hypertrophy(AH) reprensents one of the most frequent indications for surgery in children .The obstructive sleep aponea syndrome affects approximately 2% of pre -school children and can result in serious complications, including neuro-cognitive disabilities,failure to thrive,and corpulmonale. However, the treatment for the majority of children with uncomplicated AH is by adenoidectomy that is curative nevertheless,-significant risks and problems are associated with this operation (3) Adenoidectomy remains a commonly performed procedure, although it produces short-term benefits (4). There are 2 difficulties that have been described to prevent complete adenoidal removal. Firstly, lymphoid tissue in the pharyngeal recess is considered by all authors as difficult to remove (5). The second difficulty is the bulging adenoidal tissue into the posterior choanae, which was addressed by Pearl and Manoukian (6); they found choanal adenoids in 9% of their study group,also e.g. in cleft palate adenoidectomy may lead to velopharyngeal insufficiency or in bleeding tendency there is risk of hemorrhage after surgery.Thus there are some limitations for surgery as the main route of therapy . In such instances surgical procedure could be replaced by non surgical methods. As the etiology of AH is unknown, but inflammatory mechanisms may play an important role. Local and systemic inflammatory markers and pro-inflammatory cytokines are increased in these children; these promote lymphoid tissue proliferation. Proper treatment of this condition is essential for controlling nasal obstructive symptoms. Thus, systemic or topical anti-inflammatory agents have been suggested to have a role in the treatment of AH(7,8,9)

Thus, in this study, we sought to assess the efficacy of topical steroids, which has anti-inflammatory properties, on symptoms and the size of adenoid tissue in children complaining of nasal obstruction. In addition,AH is associated with significant morbidity ranging from nasal obstruction,recurrent otitis media to obstructive sleep aponea.. Surgery treatment is indicated in severe forms.

Some professionals recommend antibiotic therapy to decrease the adenoid size(10). However, it has been recently reported that treatment with intranasal steroids can decrease the size of AH

Adenoidectomy can reduce both nasal obstructions and upper respiratory infections. However, some patients display clinically significantly persistent nasal symptoms even after surgery. Symptoms, such as nasal obstruction or recurrent upper respiratory infections, persist in 19–26% of patients (11) Although there are few nonsurgical alternative treatment options, these may be considered in less serious cases.

MATERIALS AND METHODOLOGY

This study was a prospective clinical study. The study was approved by the Institutional Ethical committee and was conducted during the period from 2014 to 2016 in the department of pediatrics and torhinolaryngology. Sixty children that had been examined in our clinic with a prediagnosis of AH. All the children were assessed clinically, endoscopically, and radiologically. The study included 2 groups; Group 1 and Group 2. Written informed consents from the parents were taken about the participation of their children in the study.The diagnosis was based on the following symptoms: nasal obstruction, nasal discharge, and/or snoring and lateral radiographs (enlarged convex bulge in the roof of the nasopharynx compressing the nasopharyngeal airway). Inclusion criteria were: a history of habitual snoring for at least the previous 3 months and adenoidal hypertrophy confirmed by simple X-ray findings or an endoscopic examination by an otolaryngologist. Allergic rhinitis was diagnosed when a child had typical allergic symptoms and showed positive result in skin prick test. . Those who had a previous adenoidectomy history and positive history of allergy or atopy, the use of intranasal or systemic steroids within the last 1 year, use of any intranasal medication within the previous 2 weeks of entering the study, acute URTI within 2 weeks of entering the study craniofacial malformations including labiopalatal clefts and genetic diseases (eg, Down syndrome), neurologic disorders, cardiovascular diseases, acute infections in the nose, palate or nasopharynx and history of chronic epistaxis, immunodeficiency disorders or hypersensitivity to topical steroids, were excluded from the study.

Each child underwent a routine ear nose throat examination and nasal endoscopy; a clinical history was obtained from parents using

a questionnaire. Patient history included age, gender, personal and family history of atopy, and use of drugs. Diagnosis of AH was confirmed by nasal endoscopy and lateral radiograph. Each cephalometric graph was evaluated by a blinded author. Effectiveness of the therapy was assessed by the change in symptoms and adenoid tissue, evaluated by nasal endoscopic examination and the adenoid/nasopharynx ratio on a lateral radiographic image before and at the end of therapy. After a 4-week course of therapy, all patients were reassessed to evaluate the efficacy of treatment.

Nasal obstruction, rhinorrhea, cough, snoring, and obstructive sleep apnea were the symptoms evaluated. These symptoms were graded according to severity.The lateral view nasopharyngeal radiograph, 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. Nasal endoscopy was performed to estimate adenoid size. After application of topical anesthesia in both nostrils (lidocaine 2%) and without decongestion, an endoscopic examination was conducted using a endoscope. The size of the adenoid was determined and the distance of the adenoid tissue from the vomer was assessed (13) and graded as: Grade I: distance > I cm, Grade 2: distance 0.5-1.0 cm, Grade 3: distance 0.5cm.

A lateral nasopharyngeal X-ray was performed in all patients in the supine position during nasal inspiration with the necks slightly extended and the mouth closed at a distance of 1;m from the radiation tube. Using the reference points and lines on lateral radiographs of the nasopharynx, adenoid size and nasopharyngeal depth were calculated from all X-rays.

Adenoidal measurement (A) used the line beginning from the most convex point of adenoid tissue and extending to the anterior line of the basioccipital part of the occipital bone. The nasopharyngeal space (N) was the line extending from the posterior edge of the hard palate and anteroinferior side of the sphenobasioccipital synchondrosis or from the posteroinferior side lateral pterygoid plate to the bony part of the nasopharynx . As adenoidal-nasopharyngeal ratio (A/N ratio) was defined the ratio of adenoid size/nasopharyngeal depth and A/N ratio pre- treatment and post-treatment may be compared as well.

Statistical Analysis. The collected data was revised, coded, tabulated, and introduced to a PC using statistical package

RESULTS

62 children were enrolled in the study and were assigned randomly to receive a single intranasal administration in each nostril of either MF aqueous nasal spray two puffs daily for 8 weeks (group I; n = 62, 35 males and 27 females) . GROUP II receive a single intranasal administration in each nostril of a placebo saline solution nasal spray for 8 wks .The mean age of the subjects was 7.25 ± 2.19 years, 56.45% of patients were male and 43.54% of them female(table 1). At time 0 , there were no significant differences between study groups with regard to demographic features or symptoms such as rhinorrhea, cough, and snoring, whereas nasal obstruction and obstructive sleep apnea were more severe in group A.The chief complaints of the patients at the time of refer were night snoring , mouth breathing , conductive hearing Loss , nasal stuffiness and recurrent upper respiratory infections . Radiographic findings revealed that adenoid size (antero-posterior diameter) after treatment was significantly less than its size before treatment and adenoid – soft palate space (airway diameter) after treatment was significantly more than before treatment . In regarding to symptoms related to nasal obstructive findings showed that after intervention severe and moderate forms of hyponasal speech, day time sleepiness, nasal stuffiness, and night snoring were significantly less frequent than before intervention (table 2). The use of MF (group A) was associated with significant reduction in adenoid size .and the improvement in mean overall symptom scores . On the contrary, in group B no significant reduction in adenoid size i (TABLE 2) and the mean overall symptom scores .

Table 1: **Gender distribution of the 62 childrens with adenoidal hypertrophy that were included in the study.**

	GROUP I	GROUPII
MALES	35	33
FEMALES	27	23

Table 2: frequency of symptoms related to air way obstruction in patients before and after treat

symptoms		severe	moderate	mild	absence
Hyponasal speech	before	10	38	14	0
	after	0	18	20	24
Uncomfortable speech	before	4	30	28	0
	after	0	8	26	28
Daytime sleepiness	before	8	20	16	18
	after	0	0	22	40
Nasal stuffiness	before	16	34	10	2
	after	0	6	26	30
Nasal snoring	before	12	46	4	0
	after	0	6	32	24

Table 3:**The evaluation of the pre-treatment and post-treatment endoscopic grades of the 62 childrens with adenoidal hypertrophy that were included in the study.**

	PRE-TREATMENT			POST-TREATMENT		
ENDOSCOPIC EXAMINATION	GRADE 1	GRADE 2	GRADE 3	GRADE 1	GRADE 2	GRADE 3
	8	18	36	18	21	23

There was a significant decrease in adenoid size endoscopically at the end of the therapy

DISCUSSION

AH is one of the most frequent pathological conditions in the pediatric age group, the clinical manifestations of which differ according to adenoid size. Bilateral nasal obstruction is a primary complaint that can be associated with various sleep disorders, ranging from snoring to OSA(16)

AH is also one of the most frequent indications for surgery in childhood and adenoidectomy is generally considered the definitive treatment for nasopharyngeal obstruction. As adjunctive treatments, few non-surgical alternatives that reduce adenoid size are available. Several authors have proposed the use of topical nasal steroids to decrease AH, with the intention of preserving immunologically active tissue and avoiding the risks of anesthesia and surgery inherent in adenoidectomy (8,12,17,18) In this study, we aimed to assess the effects of mometasone therapy in children with adenoid hypertrophy. The use of a topical treatment has many advantages over a systemic treatment-(19) .First, with a nasal spray, medication can be delivered directly to the site of the allergic inflammation. Second, higher concentrations of antihistamines can be achieved in the nasal mucosa by topical versus oral administration-(19).The rational for using topical steroids is that they have limited or absent side effects and exert their anti-inflamatory activity locally on the upper airways.Moreover, a recent study provided evidence that treatment with nasal steroids could represent for some children an effective means of avoiding adenoidectomy(20). Successful use of intranasal steroid treatment in children with adenoid hypertrophy was introduced by Demain and Goetz (17). In 2001, Brouillette et al tested the efficacy of another intranasal steroid treatment for OSAS in a randomized, triple-blind, placebo-controlled, parallel-group trial investigating , the use of fluticasone propionate nasal spray versus placebo for 25 children affected by OSAS, as demonstrated with polysomnography.The present study showed that the use of intra nasal steroids was beneficial to relieve nasal obstruction. Steroids are generally well tolerated in children. Studies showed only one case of episodic nasal bleeding (21) The effect of intranasal steroids on growth was studied by Allen and his colleagues in (22), in a randomized, double-blind, placebo-controlled study. The growth rate in pre-puberty children who had used intranasal steroids for 1 year was reported to be equal to the growth rate of the placebo control group.

Three main trials succeeded to demonstrate the improvement of nasal obstruction with reduction of adenoid size with the use of in-

tranasal steroids (12,17,23). It was reported that treatment with intranasal steroids can decrease the size of adenoid hypertrophy, using beclomethasone (17), fluticasone (3), and mometasone (24). Among several commercially available steroid nasal sprays, we selected mometasone furoate for this study. we chose to test MF for 4 reasons, namely, (1) the drug had been reported previously not to cause any adverse tissue changes in the nasal mucosa of patients treated for long periods, (2) it has no effects on growth in children, (3) it has no effects on the hypothalamic-pituitary-adrenal axis, and (4) the systemic availability of the drug after topical administration is lower than that of other steroids. (25)

Ciprandi and coworkers in (26)_found that the use of intranasal flunisolide was associated with a significant reduction of adenoid hypertrophy in 72.6 % of the children. On the contrary, isotonic saline solution was associated with a nonsignificant improvement of adenoid hypertrophy as reported in 30.7% of children. A recent study provided evidence that treatment with nasal steroids could represent for some children an effective means of avoiding adenoidectomy (20). The current study also clarified similar results as Ciprandi and his colleagues (26), as there was significant reduction in the size of the adenoid in lateral radiographs after 1 year .In 2003, Criscuoli et al, studying 53 children, reinforced the conclusions reached by Demain and Goetz.1 For the first time, they reported on the long-term outcomes of treatment with aqueous nasal beclomethasone for patients with adenotonsillar hypertrophy. Twenty-four patients exhibited improvement after 2 weeks of steroid treatment, and an additional 24 weeks of therapy at a lower steroid dose maintained clinical improvement at 52 and 100 weeks for 45.8% of those patients

The duration of treatment with intranasal steroids in previous studies varied from 8 to 24 weeks. None of these trials established the optimal duration of treatment in children. The effects are expected after 2 weeks of the initiation of the treatment as described by Criscuoli et al. (20)

To date, no standard indications regarding dosage and duration of topical intranasal steroid therapy for the treatment of Adenoidal Hypertrophy have been established. Compared with the aforementioned trials, we chose to administer a lower daily steroid dose in each nostril but for a longer time (first treatment period: 60 days). A single low dose of intranasally administered steroid was well accepted by parents/legal guardians and children, thereby increasing compliance Although group 1 had more-severe clinical findings than group 2 at time 0, children treated with MF showed significant improvements in symptoms and significant reductions in adenoid size after the first 8 wks of treatment, thus avoiding adenoidectomy. However, it is difficult to attribute the true value to these results because of the small number of patients studied. Although at our knowledge there are no publications in the literature supporting or criticizing a low topical steroid dosage for the treatment of Adenoidal Hypertrophy. By obstructing the postnasal space, adenoids prevent steroids from acting on the palatine tonsils. Because the steroid nasal spray acts especially in the nasal fossa and nasopharynx, we tested the effects of intranasal MF therapy on patients affected exclusively by Adenoidal Hypertrophy , with no tonsillar hypertrophy. Several mechanisms, such as direct lympholytic action, inhibition of inflammation, and alteration of adenoid bacterial flora, have been suggested to explain how steroids decrease adenoid pad volume and improve symptoms of Adenoidal Hypetrophy, although none has yet achieved widespread acceptance. (17)

There have been various studies of finger palpation, transoral mirror adenoid examination, baseline lateral soft-tissue radiographs of the nasopharynx, and nasal endoscopy; these are commonly used to assess adenoid size.(16,27-31) In recent decades, technological advances have resulted in the development of flexible and rigid endoscopes with small diameters (2.7mm), which enable accurate nasal endoscopic examination with fewer complications. Nasofiberendoscopy is currently considered as the "gold standard" examination for the evaluation of adenoid hypertrophy(29). Fiberoptic and rigid endoscopic examinations is more effective in identifying AH(32). In some children, it is impossible to examine the nasopharynx due to patient non-cooperation(33). Fujioka et al(15)·described the A/N ratio as an indicator of adenoidal size in 1979, and this method has since been adopted in many studies(34). Thus, lateral nasopharyngeal radiography can be used to assess adenoidal size in children who will not cooperate with an endoscopic examination. Mlynarek et al (35) reported that direct video rhinoscopy was better correlated with the severity of symptoms than values obtained by lateral neck radiography. Office nasal endoscopy offers several advantages over the lateral skull radiograph in the evaluation of adenoid hypertrophy. We examinated the correlation between lateral nasopharyngeal X-ray, nasal endoscopy and subjective symptoms. The results of lateral neck X-ray and nasal endoscopy showed good correlation with actual adenoid size. Caylaklı (36) revealed significant correlation between A/N ratio and nasal endoscopic examination findings

Our data indicate significant improvements in symptom scores & endoscopic findings in children with AH and allergic rhinitis after a 8-week trial of intranasal MF. Nasal obstruction, rhinorrhea, cough, snoring, and obstructive sleep apnea improved significantly.In our study differences were seen in symptom scores, X-ray findings (A/N ratio), and nasal endoscopic grade in children with AH. These findings suggest that Mometasne furoate is a suitable treatment choice in selected patients.

limportant limitation in our study was the lack of long term follow up. Patients were followed up for 2 months after they completed therapy. Therefore we can claim that MF can be used to delay operation date in necessary situations .There were other limitatins too like; we could not perform endoscopy for all children, because of the noncompliance of the children ;the noncompliance of the children to the intranasal steroids which is observed mainly in the young children. Further studies with longer follow-up periods on the study patients should elicit a more informative data.

CONCLUSION

This study reported the efficacy of mometasone nasal spray for the treatment of AH in children. Intranasal mometasone therapy appears to be useful in the treatment of AH in the general pediatric population .Thus can be considered a good therapeutic option to decrease Adenoidal hypertrophy as this treatment works effectively regardless of allergic status, sinusitis, and obesity .However, Factors influencing the outcome of intranasal steroids therapy have not been identified. The most appropriate drug, the most efficient dose, and optimal treatment duration need to be investigated and determined.

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