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The Effect of Mometasone Furoate Nasal Spray on Adenoid Hypertrophy and Its Related Obstructive Sleep Apnea in Pediatric Age Group

KEYWORDS: Mometasone furoate, adenoidal hypertrophy, choanal obstruction

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ABSTRACT *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.We evaluated the utility of mometasone furoate aqueous nasal spray in children with 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 A) or a placebo saline solution nasal spray (group B) 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. In the second stage, responders underwent "maintenance therapy" for 6 months and were divided randomly into 3 subgroups; (1) patients in group A1 received intranasal MF treatment on alternate days for the first 2 weeks per month.(2) group A2 continued daily topical steroid treatment for the first 2 weeks per month (3) group A3 received intranasal MF treatment on every alternate days. Chronic nasal obstructive symptoms were evaluated using a clinical score ranging from 0 to 3 (0 =absent; 1 = occasional; 2 = frequent; 3 = daytime and nightime symptoms).Thus, a 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 maintenance therapy . AH size was assessed by means of nasal endoscopy. Results: The mean overall symptom scores were 12 for group A and 10 for group B. The use of MF (group A) was associated with significant reduction in adenoid size i.e (76.6 to 39.7%) and the mean overall symptom scores i.e(12 to3). On the contrary, in group B no significant reduction in adenoid size i.e(68.6 to 65.82%) and the mean overall symptom scores i.e (10 to 8). In the second stage, 16 of 60 patients in group A1 received intranasal MF treatment on alternate days for the first 2 weeks per month, 19 of 60 patients in group A2 continued daily topical steroid treatment for the first 2 weeks per month while as 25 of 60 patients in group A1 received intranasal MF treatment on alternate days for 6 month. The mean overall symptoms scores and choanal obstruction showed insignificant difference among these groups. Conclusions: This study concludes that mometasone furoate aqueous nasal spray treatment is a good therapeutic option for adenoidal hypertrophy.*

INTRODUCTION

The term adenoids describes lymphoid tissue on the superior and posterior walls of the nasopharynx,and their hypertrophy is a common condition of childhood (1). Adenoidal hypertrophy(AH) reprensents one of the most frequent indications for surgery in children.In addition,AH is associated with significant morbidity ranging from nasal obstruction,recurrent otitis media to obstructive sleep aponea. 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 (2) . Surgery treatment is indicated in severe forms. However there are some limitations for surgery as the main route of therapy, e.g. in cleft palate adenoidectomy may lead to velopharyngeal insufficiency or in bleeding tendency there is risk of hemorrhage after surgery. In such instances surgical procedure could be replaced by non surgical methods. Some professionals recommend antibiotic therapy to decrease the adenoid size(3). However, it has been recently reported that treatment with intranasal steroids can decrease the size of AH (2

METHODS

In this study, we investigated whether intranasal steroids could result in 1) improvement of lateral neck radiographic and or fiberoptic endoscopic findings related to adenoid hyperpleasia and 2) decreasing airway obstruction symptoms. children affected by AH are referred for exclusive adenoidectomy were recruited at the Department of Otorhinolaryngology, Skims medical college bemina. Informed consent was obtained from either the parents or legal guardian of all study participant. At enrollment, patients needed to meet the following inclusion criteria: (1) 3 or 4 degree adenoid hypertrophy as determined with nasal endoscopy; (2) age between 3 and 8 years; (3) symptoms consistent with AH lasting ≥12 months; and (4) no previous adenoidectomy. Children with concomitant tonsillar hypertrophy, positive history of allergy or atopy, upper respiratory infection within the past 2 weeks, nasal anatomic anomalies (eg, nasal septum deviation) or sinonasal diseases such as hypertrophy of inferior turbinates and/or nasal polyposis, craniofacial malformations including labiopalatal clefts, genetic diseases (eg, Down syndrome), neurologic disorders, cardiovascular diseases, immunodeficiency, history of epistaxis, hypersensitivity to steroids, or intranasal, topical, or systemic steroid or antibiotic treatment within the past 4 weeks were excluded.

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 A) or a placebo saline solution nasal spray (group B) for 8 wks. At the end of the first 8wks period , both groups were reassessed,

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to evaluate the efficacy of treatment. Patients in group A who showed improvements in clinical findings and decreases in adenoid pad size, such that adenoidectomy could be avoided, were considered responders. In the second stage, responders underwent "maintenance therapy" for 6 months and were divided randomly into 3 subgroups; (1) patients in group A1 received intranasal MF treatment on alternate days for the first 2 weeks per month.(2) group A2 continued daily topical steroid treatment for the first 2 weeks per month (3) group A3 received intranasal MF treatment on every alternate days. Chronic nasal obstructive symptoms were evaluated using a clinical score ranging from 0 to 3 (0 =absent; 1 = occasional; 2 = frequent; 3 = daytime and nighttime symptoms).Thus, a 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 maintenance therapy . AH size was assessed by means of nasal endoscopy. Compliance with drug administration, side effects, and health status of their children was assessed with parents. Moreover, the occurrence of any disease and related therapy were recorded.

Results

112 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 (group A) or a placebo saline solution nasal spray (group B) for 8 wks (group A; n = 60, 33 males and 27 females) or placebo (group B; n = 52, 30 males and 22 females)

At time 0, (TABLE 1)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 mean overall symptom scores were 12 for group A and 10 for group B.After endoscopy and/or lateral neck radiography at recruitment, the mean choanal obstruction was 76.6% in group A and 68.6% in group B. The use of MF (group A) was associated with significant reduction in adenoid size i.e (76.6 to 39.7%) and the mean overall symptom scores i.e(12 to3). On the contrary, in group B no significant reduction in adenoid size i.e(68.6 to 65.82%) (TABLE 2) and the mean overall symptom scores i.e (10 to 8). In the second stage, 16 of 60 patients in group A1 received intranasal MF treatment on alternate days for the first 2 weeks per month, 19 of 60 patients in group A2 continued daily topical steroid treatment for the first 2 weeks per month while as 25 of 60 patients in group A3 received intranasal MF treatment on alternate days for 6 month. The mean overall symptoms scores and chonal obstruction showed insignificant difference among these groups(TABLE 3)

No complications were observed during nasal endoscopy, which was well tolerated by all children.Throughout the study period, all patients suffered only from symptoms that were treated with anti-inflammatory and anti-pyretic drugs, whereas systemic steroids were never administered. No side effects was observed after a follow-up of 6months.

TABLE 1: SHOWS DIFFERENCES BETWEEN STUDY-GROUPS WITH REGARD TO SYMPTOMS(AT TIME 0)

SCORE	GROUP A(receive a single intranasal administration in each nostril of MF aqueous nasal spray two puffs daily)for 8 wks(TOTAL SCORE 12)	GROUP B(receive a single intranasal administration in each nostril of a placebo saline solution nasal spray for 8 wks (TOTAL SCORE 10)
Nasal Obstruction	4	3
Obstructive Sleep apnoea	3	2
Snoring	2	2
Nasal discharge	2	2
Cough	1	1
Mean Choanal Obstruction	76.6%	68.6%

TABLE 2: SHOWS DIFFERENCES BETWEEN STUDY-GROUPS WITH REGARD TO SYMPTOMS(AFTER 8 WEEKS)

SCORE	GROUP A(TOTAL SCORE 3)	GROUP B(TOTAL SCORE 8)
Nasal Obstruction	1	3
Obstructive Sleep Apnoea	1	2
Snoring	-	2
Nasal discharge	-	1
Cough	1	-
Mean Choanal Obstruction	39.7%	65.82%

TABLE 3: SHOWS RESPONSE IN GROUP A(RESPONDERS) WITH DIFFERENT SCHEDULES OF TREATMENT ON-MAINTENANCE THERAPY

GROUP	AT MAINTENANCE THERAPY	AFTER TREATMENT
A1(received intranasal MF treatment on alternate days for the first 2 weeks per month for 6 months)	40.2%	19%
A2(received daily topical steroid treatment for the first 2 weeks per month for 6 months	39.3%	21.2%
A3(received intranasal MF treatment on alternate days for 6 months)	39.6%	20.5%

DISCUSSION

Adenoidal Hypertrophy (AH) is most common cause of obstructive sleep apnea and the cardiopulmonary syndrome,with severe complication (4,5). Adenoidal Hypertrophy is one of the most frequent indications for surgery in childhood, and adenoidectomy commonly is considered definitive treatment for nasopharyngeal obstruction (6.)

Systemic steroids produce a prompt,but temporary,decrease in adenoid size. Hower,significant side effects preclude their prolonged use to suppress Adenoidal Hypertrophy (7).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(8).

In 1995,Demain and Goetz described the first successful use of intranasal steroid therpy for Adenoidal Hypertrophy in pediatric patients (9) .In 2001, Brouillette et al[2] 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. Thirteen of 25 patients underwent topical intranasal fluticasone therapy (50 µg of active drug) with 1 spray per nostril twice daily for the first 7 days and then once daily for an additional 5 weeks. The remaining 12 children received placebo. After treatment, the mixed/obstructive apnea/hypopnea index, frequency of hemoglobin desaturation, and respiratory movement/arousals decreased more in the fluticasone-treated group, compared with the placebo-treated group. Moreover, improvements in symptom scores were observed for 69% of children who received fluticasone (6.)

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

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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. Among several commercially available steroid nasal sprays (beclomethasone dipropionate, budesonide, flunisolide, fluticasone propionate, MF, and triamcinolone acetonide), 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. 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: 40 days). A single low dose of intranasally administered steroid was well accepted by parents/legal guardians and children, thereby increasing compliance

Although group A had more-severe clinical findings than group B 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. Interestingly, among the analyzed factors (ie, age, gender, weight, symptoms, and choanal obstruction), only obstructive sleep apnea was statistically significant in discriminating between responders and nonresponders. 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, It is critical to highlight that we obtained these successful results for children with only Adenoidal Hypertrophy . By obstructing the postnasal space, adenoids prevent steroids from acting on the palatine tonsils. In the study by Demain and Goetz,[9] no evident tonsillar changes were observed for 7 children who showed, besides Adenoidal Hypertrophy, moderate tonsillar hypertrophy. 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.[9]

CONCLUSION

Topical intranasal Mometasone Furoate therapy can be considered a good therapeutic option to decrease Adenoidal hypertrophy as this treatment works effectively regardless of allergic status, sinusitis, and obesity. Daily use for 2 weeks per month after an initial 40-day-period treatment seems to be the ideal maintenance schedule. Voluntary suspension of maintenance therapy seems to favor surgical treatment of Adenoidal Hypertrophy . Such long- term therapy is safe and well tolerated by pediatric patients so under close medical control we may obtain successful results

REFERENCE

1 Chadha NK, Zhang L, Mendoza-Sassi RA, César Using nasal steroids to treat nasal obstruction caused by adenoid hypertrophy: does it work? Otolaryngol Head Neck Surg. 2009 Feb;140(2):139-47. doi: 10.1016/j.otohns.2008.11.008. | 2 Brouillette RT, Manoukian JJ, Ducharme FM, et al. Efficacy of fluticasone nasal spray for pediatric obstructive sleep apnea. J Pediatr.2001;138 :838– 844 | 3 Berjis N, Okhovat A, Rogha M, Abdeyazdan Z, Khalaj Mμ, Kabiry Mα. The Effect of Beclomethasone Nasal Spray on the Size of Adenoid and its Related Obstructive Symptoms in Children with Adenoid Hypertrophy. Shiraz E-Medical Journal | Vol. 10, No. 1, January 2009 . | 4 Wiatrak BJ, Woolley AL. Pharyngitis and Adenotonsillar Disease.In: Cummings CW,et al,editors. Otolaryngology Head & Neck Surgery. 4th Edition. Philadelphia: Elsevier Mosby 2005; 3: 4152 | 5 Yonkers j.w. and Spaure r.c. Upper airway obstruction and the pharyngeal lymphoid tissue. Otolaryngol. Clin.North Am. 1987,20;235 | 6 Marco b, Luisa v, Giovanni p, Piero n.Long term follow up of children undergoing topical intranasal steroid therphy for adenoidal hypertrophy. International journal of pediatric otorhinolaryngology 2008;72;1171-5. | 7. Demain JG, Goetz DW, Pediatric adenoidal hypertrophy and airway obstruction: reduction with aqueous nasal beclomethasone. Pediatrics 1995; 95 (3): 355-384. | 8 Criscuoli G, D'Amora S, Ripa G, et al. Frequency of surgery among children who have adenotonsillar hypertrophy and improve after treatment with nasal beclomethasone. Pediatrics.2003;111 :236– 238 | | 9Brouillette.r.t, Manoukian.j.j, Ducharme. F.m,et al.Efficacy of fluticasone nasal spray for pediatric obstructive sleep apnea,J.pediatr,2001, 138,838_4. | | 10 Cassano P, Gelardi M, Cassano M, Fiorella MC, Fiorella R. Adenoid tissue rhinopharyngeal obstruction grading based on fibroendoscopic findings: a novel approach to therapeutic management. Int J Pediatr Otorhinolaryngol.2003;61 :1303– 1309. |