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MAIN ARTICLE

Is the effect of topical intranasal steroids on obstructive adenoids transient or long-lasting? Case series and systematic review of literature

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Abstract

Objectives: To study and review the short- and long-term effects of intranasal steroids on obstructive adenoids.

Methods: In this prospective cohort study, 19 children previously treated with mometasone furoate for 3 months were contacted at 3, 6 and 12 months after cessation of treatment. Main outcome measures included: change in severity of nasal obstruction, allergic rhinitis and obstructive symptoms. A systematic review of literature was also performed.

Results: By one year, 25 per cent of patients required adenoidectomy; the remaining children had no significant change in clinical score ($p = 0.464$), obstruction severity ($p = 0.191$) or allergic symptoms ($p = 0.284$). Fourteen pertinent studies were identified; all but one study showed improvement in the patients' symptoms and/or degree of obstruction. Two studies with follow up reaching 25 months showed positive effects.

Conclusion: The short-term positive effect of some intranasal steroids on obstructive adenoids seems to persist in a significant number of patients after the cessation of treatment.

Key words: Adenoid; Nasal Obstruction; Intranasal Drug Administration; Steroids; Follow-Up Studies; Mometasone Furoate

Introduction

Medically treating children with obstructive adenoids to relieve their symptoms has been practised for more than 15 years.[1] According to a review of randomised, controlled trials studying the use of topical intranasal steroids in children with obstructive adenoids, this treatment may significantly improve nasal obstruction symptoms.[2]

The use of mometasone furoate monohydrate nasal spray in that context has been studied previously, with good outcomes.[3–5] However, these studies had a relatively short-term follow up, and they reported symptom improvement while the patients were still on treatment. Cengel and Akyol[4] used a total treatment time of six weeks, which was beneficial in 67.2 per cent of patients. Berlucchi *et al*.[3] gave their patients 40 days (approximately 6 weeks) of treatment. They followed this with a maintenance therapy for responders (77.7 per cent of the subjects), for a period of three months, using either alternate days of therapy for the first two weeks of each month, or daily use of the medication for the first two weeks of each month.[3] They subsequently reported a 28-month follow up of their patients, but these patients were still on maintenance therapy.[6] In our previously published pilot study, a three-month treatment duration was used, with a response rate of 89 per cent.[5]

This study aimed to analyse the long-term effect of mometasone furoate monohydrate on obstructive adenoids in children, after the cessation of three months of treatment. We also performed a systematic review of the English literature regarding the short- and long-term effects of intranasal topical steroids on obstructive adenoids.

Materials and methods

Nineteen children, who were previously enrolled in a pilot study,[5] and who completed a three-month treatment period with mometasone furoate nasal spray,

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were included in this prospective cohort study. The study was approved by the institutional review board at the American University of Beirut, and written consent was obtained from the respective parents or guardians of enrolled patients.

The patients' caregivers were contacted by telephone at 3 months, 6 months and 12 months after the cessation of treatment, to assess: any present allergic rhinitis symptoms, the severity of nasal obstruction and the degree of obstructive symptoms caused by the adenoids.

Allergic rhinitis symptoms included rhinorrhoea or post-nasal drip, nasal congestion, nasal itching, sneezing, and eye symptoms (e.g. redness, itching or hyperlacrimation). Symptom severity was recorded according to the following scale: 0 (none) = no symptom evident; 1 (mild) = symptom is present but with minimal awareness and is easily tolerated; 2 (moderate) = definite awareness of symptom which is bothersome but tolerable; and 3 (severe) = symptom is hard to tolerate and causes interference with activities of daily living and/or sleeping. Allergic rhinitis was classified as mild or moderate to severe, and intermittent or persistent, as per the Allergic Rhinitis and its Impact on Asthma guidelines.[7] Allergic rhinitis is considered moderate to severe if it affects sleep, daily activities or performance at school; otherwise, it is classified as mild. If the symptoms occur more frequently than 4 days per week, or if they have been present for more than 4 consecutive weeks, the allergic rhinitis will be considered persistent; otherwise, it will be classified as intermittent.[7]

The severity of nasal obstruction in general was assessed using the above scale, while the clinical score included the following symptoms: mouth breathing, snoring, restless sleep, frequent waking up at night (at least three times per night because of respiratory discomfort or distress) and obstructive breathing during sleep. Each symptom received a score of 0 (if absent) or 1 (if the parents confirmed its presence during sleep) to generate a final clinical score out of 5. This score has been previously validated against lateral nasopharyngeal X-ray and intra-operative findings.[8]

The above variables were compared at each point of follow up with the baseline values (obtained at the end of the previous treatment) using the Wilcoxon signed-rank test for non-parametric samples. The mean value of each variable was also reported.

To ensure the absence of any emergent causes of nasal obstruction during the intervals between the telephone calls, the parents were asked about any current or recent upper respiratory tract infection, and any recent history of trauma to the nose or nasal surgery.

A systematic review of the English literature was performed using Medline and Embase databases and the Cochrane Library. The terms 'intranasal', 'topical', 'steroid', 'corticosteroid', 'spray', 'drops' and 'adenoid' were used in various combinations to identify relevant articles published between 1970 and 2014. The results of the included studies were analysed regarding the short- and long-term effects of such treatment, and our results were compared to theirs.

TABLE I
OBSTRUCTIVE AND ALLERGIC SYMPTOM CHANGES OVER FOLLOW-UP PERIOD

Variable	Baseline*	3 months†	6 months†	12 months†
Clinical score				
– Mean	1.38	1.25	1.33	1.50
– Median	1.00	1.00	1.00	1.00
– Range	0–4.00	0–4.00	0–5.00	0–4.00
– $p^{\ddagger}$		0.671	0.666	0.464
Obstruction severity score				
– Mean	0.94	0.94	1.13	1.36
– Median	1.00	1.00	1.00	1.00
– Range	0–2.00	0–2.00	0–3.00	0–2.00
– $p^{\ddagger}$		1.000	0.331	0.191
Allergic rhinitis score				
– Mean	1.63	1.19	0.93	0.79
– Median	1.00	0	0	0
– Range	0–5.00	0–6.00	0–7.00	0–4.00
– $p^{\ddagger}$		0.310	0.361	0.284

*Baseline refers to the end of the previous three-month treatment period. †After the cessation of treatment. ‡Compared with values at baseline (using the Wilcoxon signed-rank test)

Results

Nineteen children (8 females and 11 males), with a mean age of 4.24 years (range, 2.25–8.50 years; median age of 4.00 years) completed the previous treatment. Their caregivers were subsequently contacted by telephone.

The patients had an initial mean clinical score of 3.89, mean symptom severity score of 2.37, mean obstruction on endoscopy of 85 per cent and mean allergic rhinitis score of 4.05.[5] At the end of treatment, these decreased to 1.26, 0.79, 61 per cent and 1.42, respectively. Overall, 89 per cent (17 out of 19) of the enrolled patients significantly improved.[5] Three months later, 94.12 per cent (16 of 17) had no worsening of their symptoms, while 1 patient needed adenoidectomy; 2 patients were lost to follow up (Table I). At 6 months' follow up, 88.24 per cent (15 of 17) of patients had stable symptoms, and 1 more patient required adenoidectomy. By one year, three patients had been lost to follow up. Twenty-five per cent (4 of 16) of the patients required adenoidectomy, while the remaining patients (12 of 16) had no significant change in: clinical score ($p = 0.464$) nasal obstruction symptoms ($p = 0.191$) or allergic rhinitis ($p = 0.284$) (Figure 1). Two patients used mometasone furoate monohydrate when needed to relieve transiently reappearing obstructive symptoms.

We identified 14 studies (comprising 856 children) reporting the use of intranasal topical steroids for obstructive adenoids (Table II).[1,3–6,9–17] The most commonly used steroid was mometasone furoate monohydrate, used in 6 studies (comprising 311 children), followed by beclomethasone (3 studies) and

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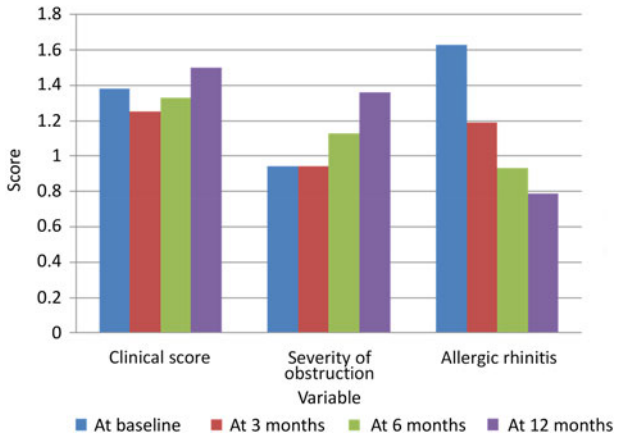

FIG. 1

Graph showing a slight but non-significant rise in the severity of nasal obstruction and obstructive symptoms over time, with a non-significant decrease in allergic rhinitis symptoms.

flunisolide drops (2 studies). All but one study (Lepcha *et al.*[10]) showed a positive effect of intranasal steroids on the obstructive adenoid symptoms.

In addition to the variety of steroids used, the various studies employed different treatment regimens. There was variability in terms of the duration of treatment, which ranged from 4 to 112 weeks; the duration of continuous daily treatment ranged from 4 to 28 weeks.

Most studies relied on a symptom score (11 studies) and nasal endoscopy (10 studies) to evaluate the response to treatment. Others relied on X-rays (4 studies) and polysomnography (2 studies). The variability of the symptom scores, duration of treatment and type of steroid used precluded performing a meta-analysis.

Most studies investigated the effects of the steroid while the patients were taking the medication and the short-term effects (one to six months) post-treatment. The long-term effect was investigated in only 3 previous studies; these had a follow-up period of 12 to 28 months.[6,11,14] The current study, with a follow-up period of 12 months, may add information to the scarce literature regarding the long-term effects.

Discussion

In 1995, Demain and Goetz[1] described the first successful use of intranasal steroid therapy (beclomethasone) for obstructive adenoids in paediatric patients. Since then, other authors have reported encouraging results utilising different steroids (Table II). All but one study (Lepcha *et al.*[10]) showed improvement in the treated patients. Lepcha *et al.*[10] attributed the lack of improvement in their group to the absence of a history of atopy among their studied patients. However, they did not perform any objective testing to rule out the presence of allergy in their patients, and the presence of allergic rhinitis or atopy was not among their exclusion criteria.

The short-term effect of intranasal steroids on obstructive adenoids is encouraging, especially given that this effect was observed using a variety of steroids. The optimal treatment duration is not known. A positive effect has been reported with a treatment duration as short as four weeks, but others have given a treatment time as long as seven months. In our previous published study, we observed that no additional effect was gained after six weeks of treatment with mometasone furoate spray.[5] The optimal duration is yet to be determined.

Another issue for future consideration is the methodology of evaluating responses to treatment in children with obstructive adenoids. There should be standardisation of symptom scores, in addition to the endoscopy and radiological studies performed. This will allow a meta-analysis to be performed on this subject.

Among the steroids used in the various reviewed trials, mometasone is the most studied. However, none of the previous studies investigated the long-term effect of this treatment. In the present study, we demonstrated a persistence of the improvement in 75 per cent of the patients who continued to attend follow up, one year after the cessation of treatment. To our knowledge, this is the first long-term follow-up study on patients previously treated with mometasone furoate monohydrate. Although Berlucchi *et al.*[6] reported a long-term follow up for patients previously treated with mometasone furoate, their patients were kept on maintenance therapy using mometasone furoate nasal spray (100 mcg/day) for the first 2 weeks of every month, for up to 28 months.

Regarding those studies that used other steroids, we could identify two studies with long-term follow-up periods. Criscuoli *et al.*[11] reported the use of beclomethasone (400 mcg/day) in 53 children with adenotonsillar hypertrophy in a randomised, single-blind, placebo-controlled, cross-over study, and then followed them up in an 'open-label' study for 24 weeks. One hundred weeks later, it was found that the initial responders (45 per cent of the patients) had clinical improvement and a reduction of adenotonsillectomy compared to the non-responders. The only drawback of using this study for comparison was the inclusion of patients with adenotonsillar obstruction and not with isolated obstructive adenoids. In the other study, Varricchio *et al.*[14] reported a 12-month follow up of 139 children who received flunisolide drops for 8 weeks. They found that the long-term effect was maintained mainly in the allergic patients, while almost all the non-allergic patients relapsed.

This long-term improvement only in allergic patients raises the question of whether the true effect of the intranasal steroids is through suppression of a present allergic condition or a real decrease in the volume of the adenoid tissue. Our observed short-term improvement, and the persistence of this improvement in most patients, was not found to be influenced by the presence or absence of allergic rhinitis or atopy.

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TABLE II
TOPICAL INTRANASAL STEROIDS USED IN TREATING OBSTRUCTIVE ADENOIDS

Authors	Year	Study type	Pts (*n*)	Medication	Pathology	Duration of treatment & follow up	Assessment	Results
Demain & Goetz[1]	1995	Randomised, double-blind, placebo-controlled, cross-over, followed by open-label part	17	Beclomethasone spray (336 mcg/day), then (168 mcg/day)	AH	8 wks, then 16 wks open-label	Symptoms score, nasal endoscopy	Decrease in degree of obstruction & symptoms score
Brouillette *et al.*[9]	2001	Randomised, triple-blind, placebo-controlled	25	Fluticasone propionate spray 200 µg daily for 1 wk, then 100 µg daily for 5 wks	ATH	6 wks	Polysomnography, X-ray, tonsillar size, symptoms score	Decrease in severity of OSA, no change in adenotonsillar hypertrophy or symptoms score
Lepcha *et al.*[10]	2002	Randomised, double-blind, placebo-controlled	26	Beclomethasone spray (200 mcg/day)	AH	8 wks	Symptoms score, X-ray, nasal endoscopy	No significant improvement
Criscuoli *et al.*[11]	2003	Randomised, single-blind, placebo-controlled, cross-over, followed by open-label part	53	Beclomethasone spray (400 mcg/day)	ATH	4 wks, then 24 wks open-label, with 100 wks follow up	Symptoms score	Decrease in score & need for surgery
Cengel & Akyol[4]	2006	Randomised, controlled	122	Mometasone furoate spray	AH	6 wks	Symptoms score, nasal endoscopy	Decrease in score & degree of obstruction
Berlucchi *et al.*[3]	2007	Randomised, placebo-controlled	57	Mometasone furoate spray	AH	40 days, then maintenance for 3 mths (alternate days for first 2 wks per mth, or daily for first 2 wks per mth)	Symptoms score, nasal endoscopy	Decrease in score & degree of obstruction
Ciprandi *et al.*[12]	2007	Randomised, placebo-controlled	178	Flunisolide drops (500 mcg/day)	AH	8 wks	Nasal endoscopy	Decrease in degree of obstruction
Kheirandish-Gozal & Gozal[13]	2008	Randomised, double-blind, placebo-controlled, cross-over	62	Budesonide spray (64 µg/day)	AH	6 wks, with 8 wks follow up	X-ray, polysomnography	Decrease in polysomnographic measures & adenoid size
Berlucchi *et al.*[6]	2008	Follow up on responders	21	Mometasone furoate spray	AH	First 2 wks of every mth for mean of 28 mths	Symptoms score, nasal endoscopy	Improvement or maintenance of initial improvement in those who continued treatment
Varricchio *et al.*[14]	2009	Randomised, single-blind, placebo-controlled	139	Flunisolide drops (number of drops = 0.5 × kg)	AH	8 wks, with 12-mth follow up	Nasal endoscopy	Decrease in degree of obstruction
Demirhan *et al.*[15]	2010	Randomised, placebo-controlled	45	Fluticasone propionate nasal drops (400 mcg/day)	AH, tonsillitis	8 wks	Symptoms score, nasal endoscopy	Decrease in symptoms score & degree of obstruction
Jung *et al.*[16]	2011	Prospective	41	Mometasone furoate spray	AH	4 wks	OSA-18, X-ray	Decrease in OSA-18 score & adenoids/nasopharyngeal ratio
Rezende *et al.*[17]	2012	Prospective	51	Mometasone furoate spray	AH	40 days using normal saline, then 40 days using mometasone furoate	Symptoms score, nasal endoscopy	Decrease in score & degree of obstruction
Bitar *et al.*[5]	2013	Prospective, controlled	19	Mometasone furoate spray	AH	3 mths	Symptoms score, nasal endoscopy	Decrease in score & degree of obstruction
Current study	2016	Prospective	19	Mometasone furoate spray	AH	No treatment or just when needed, for 12 mths	Symptoms score	No change – persistence of previous decrease in score

Pts = patients; AH = adenoid hypertrophy; wk = week; ATH = adenotonsillar hypertrophy; OSA = obstructive sleep apnoea; mth = month; OSA-18 = 18-item obstructive sleep apnoea quality-of-life survey

TABLE III
STUDIES THAT DID NOT EXCLUDE PATIENTS WITH ATOPY OR ALLERGIC RHINITIS

Study	Atopy or AR (%)	Effect/remarks
Demain & Goetz[1]	53	No effect of atopy on results
Brouillette *et al.*[9]	16	No comment on AR
Criscuoli *et al.*[11]	17	Atopy was distributed equally between both groups
Cengel & Akyol[4]	9	Atopic patients had better response
Ciprandi *et al.*[12]	NR	No effect of atopy
Kheirandish-Gozal & Gozal[13]	37	No effect of AR on results
Varricchio *et al.*[14]	60	Long-term effect is more maintained in atopic patients
Jung *et al.*[16]	46	No effect of allergy on results
Rezende *et al.*[17]	47	Effect of allergy eliminated by environmental control against relevant allergens
Bitar *et al.*[5]	53	No effect of allergy on results

AR = allergic rhinitis; NR = not reported

However, our patients initially had mild intermittent allergic rhinitis symptoms, and thus did not have nasal obstruction related to inferior turbinate hypertrophy or congested nasal mucosa in general.

We examined the potential influence of allergic rhinitis and/or atopy as reported in the studies reviewed (Table III). All but four studies[3,6,10,15] included patients with atopy or allergic rhinitis. In the short-term, only Cengel and Akyol[4] reported an influence of atopy on their results. The atopic patients in their study group showed significant improvements (while on treatment) in terms of the degree of obstruction ($p < 0.05$), as compared to atopic patients in the control group who did not show any difference ($p = 0.221$). In that study, the incidence of atopy was the same in both the study group (8.9 per cent) and the control group (9 per cent).

In contrast, Demain and Goetz,[1] Bitar *et al.*,[5] Ciprandi *et al.*,[12] Kheirandish-Gozal and Gozal,[13] and Jung *et al.*[16] did not find any effect of allergy on the obtained results. In some studies, although allergy was present in the patients, its effect was not studied or commented on (Brouillette *et al.*[9]), nor its effect eliminated by environmental control of the causative allergens (Rezende *et al.*[17]).

In the long-term follow-up studies, one investigation excluded the atopic patients (Berlucchi *et al.*[6]), another had the incidence of atopy equally distributed between subjects and controls (Criscuoli *et al.*[11]), while in the third study, atopy had a positive effect on maintaining the initial response (Varricchio *et al.*[14]). Although most previous studies showed no significant effect on the observed results, the heterogeneity of the studied population makes one careful in drawing a definite conclusion regarding the suspected influence. In principle, patients with moderate-to-severe or persistent allergic rhinitis symptoms should not be included in such studies, as the resultant allergic inflammation will be a significant confounding variable affecting the results. Therefore, it would be necessary to exclude patients with atopy or allergic rhinitis, or to include only patients with mild and intermittent allergic rhinitis, to avoid the presence of nasal obstruction caused by allergic nasal congestion.

- **Children with obstructive adenoids have been medically treated to relieve symptoms for more than 15 years**
- **Most previous studies have focused on benefits of topical intranasal steroids during treatment**
- **There are no studies on the long-term effect of mometasone spray after cessation of treatment**
- **Intranasal steroids are an effective treatment for children with obstructive adenoids, in the short- and long-term**
- **The short-term effect appears to persist in a number of patients after cessation of treatment**
- **The evaluation process of treated children needs standardising to obtain more coherent results**

One important factor to keep in mind when observing the long-term effect of topical intranasal steroids used in children with obstructive adenoids is the fact that, as the children grow, their nasopharyngeal space enlarges and their obstructive nasal symptoms improve. This may be an important confounding variable if an extended period of follow up is contemplated (e.g. more than 12 months). It may be useful in future investigations to obtain cephalometric studies during the follow-up period to assess the degree of nasopharyngeal growth; however, a concern will be raised against exposing children to unnecessary radiation. Other future studies might focus on endoscopic assessment of adenoidal impact on the posterior choanae, or the use of magnetic resonance imaging in calculating the adenoidal size and its impact on the posterior nasal choana.

Conclusion

Intranasal steroids are an effective treatment for children with obstructive adenoids, in both the short-term and the long-term. Various steroids have been shown to be effective. There is a need to standardise the evaluation process of the treated children in order to obtain more coherent results. This will help in deciding on the optimal treatment regimen. Further studies are needed to contemplate the observed long-term effect of such treatment.

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