Efficacy of Intranasal Beclomethasone in the Treatment of Children with Otitis Media with Effusion and/or Adenoid Hypertrophy

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ABSTRACT:

BACKGROUND:

Adenoid hypertrophy and otitis media with effusion are very frequent indications for surgery in children. Otitis media with effusion is the commonest cause of their hearing difficulty.

A potential role of corticosteroids in the treatment of both diseases has emerged "6". Short-term use of systemic steroids provides a temporary improvement but long-term use of systemic steroids is not appropriate in children due to severe side-effects. On the other hand, topical nasal steroids without systemic side-effects might be used"7" .

OBJECTIVE:

To prove that intranasal steroid treatment can be a useful alternative to surgery in the treatment of children with otitis media with effusion and/or adenoid hypertrophy

PATIENTS AND METHODS:

A total of 68 children (4–14-year-old) on the waiting list for an adenoidectomy and/or myringotomy with or without ventilation tube placement were enrolled into the study and control groups. The study group (38 patients with adenoid hypertrophy, 19 of them with otitis media with effusion) received intranasal beclomethasone dipropionate (aqueous suspension) 168 mcg daily, and the control group (30 patients with adenoid hypertrophy, 16 of them with otitis media with effusion) was followed up without any treatment. All patients were evaluated at 0 and 8 weeks. The assessment of each patient included history, a symptom questionnaire, a tympanogram, a pure tone audiogram, and otoscopic examination and a plain radiograph (lateral soft tissue X-ray of postnasal space). The size of adenoid tissue was graded as a percentage according to obliteration of the airway of the postnasal space. The adenoid/postnasal (A/P) airway ratio was recorded for each patient. Symptoms were scored as 0 (absent), 1 (intermittent/periodic), or 2 (continuous). The data were analyzed with the "Statistical Package for the Social Sciences" (SPSS 9.0).

RESULTS:

Resolution of otitis media with effusion in the study group (41.6%) was significantly higher than that in the control group (13.3%) ($p < 0.001$). Twenty -six patients (68.4%) with adenoid hypertrophy in the study group showed a significant decrease in adenoid size according to the plain radiograph evaluation compared to the control group ($p < 0.001$). A significant improvement in obstructive symptoms was seen in the study group ($p < 0.001$). The radiographically measured adenoid/postnasal airway ratio and degree of obstructive symptoms showed a significant correlation ($r = 0.838$ $p < 0.001$, $r = 0.879$ $p < 0.001$, $r = 0.838$ $p < 0.001$, $r = 0.879$ $p < 0.001$).

CONCLUSION:

Nasal beclomethasone dipropionate treatment can significantly reduce adenoid hypertrophy and eliminate obstructive symptoms. It is a useful alternative to surgery (in good percentage of cases), at least in the short term (8weeks), for otitis media with effusion.

KEYWORDS: otitis media with effusion (ome), adenoid (ad),adenoid/postnasal (a/p) ratio

INTRODUCTION:

Adenoid hypertrophy and otitis media with effusion(OME) are one of the most frequent indications for surgery in children. OME is the commonest cause of hearing difficulty in children. Hearing loss is the most common presentation in OME in children , this may cause educational , behavioral and speech problems.(1)Pneumatic otoscopy is the primary

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method of dignosis of OME [2], when dignosis is uncertain tympanometry should be considered as an adjunct to pneumatic otoscopy .[3]

The treatment of OME varies widely and should depend not only on the duration and severity of the condition but also on the age and general condition of the child "1".Some of the cases resolve spontaneously, others need medical treatment including antimicrobial therapy, antihistamine, decongestant and corticosteroid (systemic or local).The surgical treatment include myringotomy with or without insertion of ventilation tube and adenoidectomy.[4]

The symptoms and signs of Ad hypertrophy are nasal obstruction, mouth breathing, snoring ,development of adenoid faces ,deafness(due to Eustachian tube obstruction) nasal discharge, postnasal drip and nocturnal enuresis. Diagnosis depend on the above clinical feature and examination of postnasal space by mirror. Narrowing of the nasopharyngeal air space may be seen by the lateral soft tissue view on an X-ray film. Treatment either conservative, when the symptoms are not marked, includes non-irritant decongestant nasal drops may give relieve, treatment of sinusitis and nasal allergy, or surgical (adenoidectomy).[5]

Systemic corticosteroids produce a prompt, temporary decrease in adenoid size and resolution in middle ear effusion but significant side-effects cause avoidance of its chronic use in children [6]. Compared with systemic steroids, topical nasal steroids have limited systemic effects and would be expected to exert their anti-inflammatory effects locally on the nose, nasopharynx, and Eustachian tube [7]). While systemic steroids have been extensively studied, the intranasal nasal steroids as the sole treatment of OME and adenoid hypertrophy have not been adequately evaluated.

Oral steroids stabilize membrane phospholipid breakdown and prevent the formation of inflammatory mediators. They also promote shrinkage of peritubular lymphoid tissue, enhance secretion of Eustachian tube surfactant, and reduce the viscosity of middle ear fluid [7]. By these mechanisms, they aid middle ear resolution. Reduction in adenoid size may be due to a direct lympholytic action and to a general anti-inflammatory effect in respiratory tissues [8]. Relief of nasal obstruction occurs as a result of decreased inflammation and reduction of adenoid size. An additional cause may be decreased significance of the adenoid tissue as a reservoir for infection. In contrast to oral steroids, steroids exert their effects only locally, therefore having limited systemic side-effects[7].

A potential role of corticosteroids in the treatment of both diseases has emerged [6]. Short-term use of systemic steroids provides a temporary improvement but long-term use of systemic steroids is not appropriate in children due to severe side-effects. On the other hand, topical nasal steroids without systemic side-effects might be used[7] .

AIM OF THE STUDY:

To evaluate the role of intranasal steroids (Beconase nasal spray) in the treatment of children with otitis media with effusion and/or adenoid hypertrophy.

PATIENTS AND METHODS:

Patients: A total of 68 children (4–14-year-old) scheduled for the surgical treatment for adenoidectomy and/or myringotomy with or without ventilation tube placement were enrolled into the study and control groups. There were no statistical differences between groups in terms of age, sex, history of allergy or family history . There was also no difference between groups in the term of season during the study. The study group (38 patients with adenoid hypertrophy, 19 of them with otitis media with effusion) received intranasal beclomethasone dipropionate (aqueous suspension) 168 mcg/day, one spray in each nostril twice a day for 8 weeks . The control group (30 patients with adenoid hypertrophy, 16 of them with otitis media with effusion) was followed up without any treatment. No other medication was allowed during the study in either group.

The standard criteria for otitis media with effusion in the study were as follows: (1) documented persistent middle ear effusion by otoscopic examination for a minimum of 3 months at the time of entry into the study, (2) middle ear pressure less than −250 mm H_2O, and conductive hearing loss in audiometry supporting the diagnosis of otitis media with effusion and (3) treatment with appropriate antibiotics at least twice before (2 courses each coarse with amoxicillin for 10 days). Each ear was evaluated separately. The criterion for adenoidal hypertrophy was chronic nasal obstruction unexplained by any reason other than adenoidal hypertrophy which is proved by lateral soft tissue X-ray of postnasal space.

Subjects were excluded if they met any of the following criteria: (1) surgery for these illnesses, (2) active upper airway infections in the previous 2 weeks, (3) history of immunodeficiency,

hypersensitivity to beclomethasone dipropionate, or any systemic and local contraindication against corticosteroids, [4] a craniofacial anomaly, and [5] presence of systemic disease.

Evaluations and patient management: All patients were evaluated at 0 and 8 weeks. Assessment of each patient included history, a symptom questionnaire, ENT examination, an otoscopic examination, a tympanogram (MADSEN otoflex)(A middle ear pressure less than −200 mm H_2O (type C2) and type B flat tympanograms were considered to support the diagnosis of otitis media of effusion), if possible a pure tone audiogram(MADSEN Astera) and a radiological examination.

Radiological assessment: Plain radiographs of lateral view of the postnasal space soft tissue gave us good ideas about the size of the adenoids. We did not take the size of adenoids as an absolute measurement but we put it as a ratio of percentage to the width of the airway of the postnasal space.

The symptom questionnaire was filled in at initial enrollment and after 8 weeks. It consisted of a parental assessment of the patient's ear pain, ear popping, hearing loss, nasal obstruction, nasal discharge, snoring and mouth breathing. The obstructive symptoms were scored as 0 (absent), 1 (intermittent/periodic), or 2 (continuous). Subsequently, the scores of each patient were added up and the overall score was used for comparison at the end of the study. Each symptom was also compared separately between two evaluations.

The data were analyzed with the "Statistical Package for the Social Sciences" (SPSS 9.0).

RESULT:

In our study, which involved 68 patients (38 in the study group and 30 in the control group), in the study group the patients ages range from 4 to 14 years.Otitis media with effusion was present in 19 patients in the study group (50%) and in 16 patients in the control group (53.3%). Seventeen patients in the study group and 14 in the control group had bilateral otitis media with effusion, whereas 2 patients in the study group and 2 in the control group had unilateral otitis media with effusion (36 ears in the study group and 30 ears in the control group),see (table1&2).

Table 1: Distribution of patients and there involvement with OME.

	Study Group	Control Group	Total
Number Of patient	38	30	68
Patient with OME	19	16	35
Percentage	50%	53.3%	51.4%

Table 2: Distribution of ears.

	Study Group	Control Group	Total
Unilateral OME	2	2	4
Bilateral OME	17	14	31
Number of ears	36	30	66

Table (3) summarizes the patient's improvements in OME(hearing), A/P ratio and obstructive symptoms according to group at entry (week 0) and at the end of the study. The rate of the improvement of OME in the study group (41.7%) was significant higher than that in the control group (13.3%) ($p < 0.001$).

Table 3: Distribution of the patients and improvement rates in the groups.

	Study group (week 0)	Study group (week 8)	Control group (week 0)	Control group (week 8)	
OME	36	21	30	26	P<0.001**
	P<0.05*		P=0.5*		
A/P ratio Mean %	80	40	70	80	P<0.001**
	P<0.001*		P=0.013*		

A/P ratio = adenoid / postnasal airway ratio (by X-ray)

Symptom scores of patients treated with intranasal steroid were also significantly improved at the end of study ($p < 0.001$). There were no significant spontaneous improvements in the control group ($p = 0.134$). Improvements in the study group were significantly higher than those in the control group ($p < 0.001$).

Table 4: Distribution of the patients and improvement rates in the obstractive symptom.

	Study group (week 0)	Study group (week 8)	Control group (week 0)	Control group (week 8)	
Mouth breathing	Absent 2	13	2	3	P<0.001**
	Intermittent 8	19	14	10	
	Continuous 28	6	14	17	
	P<0.001*		p>0.05*		
Snoring	8	24	6	7	P<0.001**
	9	11	11	6	
	21	3	13	17	
	P<0.001*		p>0.05*		
Nasal Obstruction	2	21	3	2	P<0.001**
	15	15	17	16	
	21	2	10	12	
	P<0.001*		p>0.05*		
Nasal Discharge	32	36	26	26	
	4	2	4	3	
	2	0	0	1	

* Statistics within the same group.
** Statistics between the study and control groups

A/P ratios were graded as grade I (0–25%), II (26–50%), III (51–75%) and IV (76–100%) to make measurements more objective.

Table 5: Adenoid /postnasal airway ratio in the study group.

Last A/P ratio	First A/P ratio				
	I	II	III	IV	N
I	1	1	1	1	4
II	--	3	8	6	17
III	--	--	2	9	11
IV	--	--	--	6	6
N	1	4	11	22	38

There was also a statistically significant improvement in the graded A/P ratio of the study group ($p < 0.001$). Although 22 patients (57.8%) were evaluated as grade IV at entry, 6 patients (15.7%) remained at this grade after treatment with intranasal steroid. Sixteen patients (42.1%) showed good improvement according to both A/P ratio and symptoms. The overall A/P ratios of 26 patients (68.4%) showed regression to a lower grade. This improvement in the A/P ratio in the treatment group was statistically significant when compared with the control group ($p < 0.001$). Patients who did not improve after nasal steroid treatment were operated on as planned before, see (table 5&table 6).

Table 6: Adenoid /postnasal airway ratio in the control group.

Last A/P ratio	First A/P ratio				
	I	II	III	IV	N
I	2	--	--	--	2
II	--	4	2	--	6
III	--	--	5	--	5
IV	--	--	6	11	17
N	2	4	13	11	30

As the A/P ratios of the patients decreased with treatment the obstructive symptoms improved in the study group, whereas neither the A/P ratios nor the obstructive symptoms improved in the control group ($p < 0.001$).

Table 7 :The air-bone gap(in dB) in the study group at 0&8 week.

Last A-B gap(dB)	First A-B gap(dB)							
	0-4	5-9	10-14	15-19	20-24	25-29	30-35	N
0-4			1	2	1	1		5
5-9				2	2	1	1	6
10-14			3		1	1	1	6
15-19				4			1	5
20-24					6			6
25-29						5		5
30-35							3	3
N	0	0	4	8	10	8	6	36

The air-bone(A-B) gap measured (in dB) at 0 week (pre-treatment) and 8 week (post-treatment).In the study group, although 6 ears were evaluated as having 30dB air-bone gap at entry, 3 ears remained at this level after treatment with intranasal steroid. Fifteen ears (41.7%) showed improvement according to both A-B gap and symptoms. This improvement in the A-B gap in the treatment group was statistically significant when compared with the control group(13.3%) ($p < 0.001$). Ears who did not improve after nasal steroid treatment were operated on as planned before, see (table 7&table 8).

Table 8: The air-bone gap in the control group at 0&8 week.

Last A-B gap(dB)	First A-B gap(dB)							
	0-4	5-9	10-14	15-19	20-24	25-29	30-35	N
0-4					1			1
5-9					1	1		2
10-14			3			1		4
15-19				5				5
20-24					6			6
25-29						6		6
30-35						1	5	6
N	0	0	3	5	8	9	5	30

The correlation between obstructive symptom scores and adenoid/postnasal airway ratio (A/P ratio) measured by X-ray was statistically significant in both groups in the first and consecutive evaluations, see (table 9).

Table 9: The correlation between obstructive symptom scores &A/P ratio.

	0 week		8 week	
Study group	r= 0.838	P<0.001	r= 0.879	P<0.001
Control group	r= 0.838	P<0.001	r= 0.879	P<0.001

r= relation

DISCUSSION:

Several reports have analyzed the value of intranasal steroids in the treatment of OME.

Shapiro in 1982 compared dexamethasone nasal spray to placebo in a blinded study of 45 children (with OME)with a minimum of 4-week duration. In first 3 weeks, dexamethasone showed more efficacy than the placebo but in the third week there was no difference between them[9]. Tracy et al. in 1998 reported a double-blind, placebo-controlled randomized study of nasal beclomethasone "10". Patients were randomized into three groups: (1) prophylactic antibiotics, (2) prophylactic antibiotics plus intranasal beclomethasone and (3) prophylactic antibiotics plus intranasal placebo. The beclomethasone plus antibiotics group improved more rapidly than did the others. Anwar et al. in 2015 compared the effectiveness of intranasal mometason and oral steroid in the treatment of OME in 100 patient, they conclude that both are effective medical therapy in the treatment of OME in children with no significant difference between the two methods"11 ".

In our study, intranasal steroids were used in the treatment of OME as the only medication for 8 weeks, and 41.7% of the patients recovered completely. All the patients before participating in our study had undergone 3 months of follow up for OME and during this period they received antibiotic therapy at least twice. Patients unresponsive to antibiotic treatment and waiting for surgery were included in the study. Therefore, the 41.7% recovery rate without any other simultaneous medication appears more significant. Another important point is that recovery occurred in patients in whom medical therapy had failed and who were scheduled for surgery.

The role of intranasal nasal steroid use has also been evaluated in the treatment of adenoid hypertrophy. Demain and Goetz in 1995 reported a double blind, placebo-controlled crossover study of standard dose aqueous nasal beclomethasone in the treatment of 17 patients with adenoid hypertrophy [12]. An 82% reduction in the mean nasal obstruction symptom score accompanied a 29% mean reduction in the adenoid/choana ratio. Brouillette et al. in 2001 studied nasal fluticasone in pediatric obstructive sleep apnea patients and reported a decrease in

the number of obstructive and mixed apnea and hypopnea [13]. However, the size of adenotonsillar hypertrophy was not regressed significantly.Rezende et al. in 2012 used the mometasone with saline irrigation and found the combination useful in decreasing the adenoid size and improving symptoms[14].

In our study, 16 patients (42.1%) showed complete improvement according to both the A/P ratio and symptoms. The overall A/P ratios of 26 patients (68.4%) showed regression to a lower grade. As the patients' A/P ratios decreased with treatment, the obstructive symptoms also improved.

One of the main problems of intranasal steroid therapy is the duration and dosage because there is no consensus in the literature. The dose used in our study for Ad hypertrophy and OME is equal to that used in allergic rhinitis in the prescription of the drug. The safety of at least 1-year long use of topical steroids for children with allergic rhinitis is well known in the literature. Therefore, we think that long-term nasal steroids can be used in a routine dose for adenoid hypertrophy and OME.

Our study concerns the short-term follow-up of the patients. The demonstrated efficacy of the intranasal steroid treatment in the control of OME and nasal obstruction due to adenoid hypertrophy during its use does not give us any hint about the duration of this control. Therefore, the middle- (months) and long-term (years) effects of the drug in the control of OME and adenoid hypertrophy must be studied.

CONCLUSION:

The result of our study indicate that intranasal beclomethasone dipropionate treatment can significantly reduce Ad hypertrophy and obstructive symptoms. It seems to be a useful alternative to surgery (in good percentage of cases) for OME. Intranasal steroid (beclomethasone dipropionate) seems to be useful in the treatment of otitis media with effusion and adenoid hypertrophy. However, these results are only short-term; a long-term follow-up is necessary.

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