Treatment and Outcome of Intra Nasal Steroids Spray on Pediatric Sleep Disordered Breathing Due to Enlarged Adenoids

KHANAM A[1], AKHTAR G[2], RAHMAN MA[3], DEBNATH TK[4], KARIM MR[5], AHMED N[6], NASREEN L[7]

Abstract

Introduction: *Sleep disordered breathing (SDB) in children is described as a spectrum of respiratory abnormalities ranging from loud snoring to obstructed sleep apnea. Common symptoms include snoring, mouth breathing, daytime sleepiness, fatigue, mood disturbance and irritability. Complications of SDB are multi system like cardio-respiratory, neuro-cognitive, endocrine and metabolic disturbances. Adenotonsillar hypertrophy is the commonest cause of SDB and choice of treatment is adenotonsillectomy under general anesthesia. This study was done to diagnose SDB caused by adenoid hypertrophy and evaluation of impact of the disease on quality of life (QOL) in children and to evaluate the efficacy of intranasal steroid (fluticasone furoate) spray in pediatric SDB with QOL by using OSA-18 questionnaires.*

Methods: *It is a prospective observational study conducted among 52 children (2-12 years old). All patients received intra nasal fluticasone furoate spray (27.5 microgram) in each nostril once daily for 8 weeks. They were evaluated at pretreatment and post treatment with obstructive sleep apnea (OSA-18) quality of life questionnaire. Study was done during 1-year period of time in a tertiary care center, Green Life Medical College, Dhaka.*

Results: *Statistically significant improvement ($p<0.000$) in QOL was observed in 73.1% patients who were recruited for the study. The mean pre medication OSA-18 total score showed 78.3 improvement to 46.83 in post medication.*

Conclusion: *Medical treatment with intranasal steroid (fluticasone furoate) nasal spray for 8 weeks can be an effective treatment option in pediatric SDB patients due to enlarge adenoid without significant complications. OSA-18 questionnaires are quick, validated survey procedure of evaluating sleep disordered breathing in children as well as assessment of quality of life. So medical treatment can be an alternative to surgical treatment in children with mild to moderate SDB and surgical management is only indicated in severe cases when medical treatment fails.*

Keywords: *Adenoid hypertrophy, Fluticasone furoate, sleep disorder breathing, Obstructive sleep apnea, Quality of life*

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1. Afroza Khanam, Professor, Department of ENT, Green Life Medical College, Dhaka
2. Gulshan Akhtar,Professor, Department of Pediatrics, Green Life Medical College, Dhaka
3. Mohammad Abdur Rahman, Assistant Professor,Department of Cardiology,Shaheed Suhrawardy MedicalCollege, Dhaka
4. Timir Kumar Debnath, Assistant Professor, Departmentof ENT, Green Life Medical College, Dhaka
5. Mohammad Rezaul Karim, Assistant Professor, Department of ENT, Green Life Medical College, Dhaka
6. Nur Ahmed, Registrar, Department of ENT, Green Life Medical College, Dhaka
7. Lubana Nasreen, Medical Officer, Department of ENT, Green Life Medical College, Dhaka

Address of Correspondence: Afroza Khanam, Professor, Department of ENT, Green Life Medical College, Dhaka, email: afrozakhanam85@gmail.com

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Introduction:

Pediatric sleep disorder breathing (SDB) is a general term for breathing difficulties during sleep. SDB can range from loud snoring to obstructive sleep apnea (OSA), a condition where a part of upper airway is blocked repeatedly during sleep and produce temporary cessation of respiration.[1] SDB was first documented in 1976 by Guillemin Ault et al.[2] It represents a group of patho-physiological condition that is characterized by an abnormal respiratory pattern during sleep that can be isolated or coexist with respiratory, nervous, CVS and endocrine diseases. SDB is now well-known breathing problem and widely distributed in general pediatric population about 6-10%.[1,3] It is responsible for contribution to numerous problems ranging from fragmental sleep pattern to hypertension, growth retardation, neuro-cognitive disorder, cardiac arrhythmia and even death.[4,5]

There are numerous factors affecting upper airway size and patency. Among them, enlarged adenoid is the most common cause. Adenoid is a pad of lymphoid tissue present at the junction of roof and posterior wall of nasopharynx. When sufficiently enlarged due to infection, allergy or asthma it produces bilateral nasal obstruction, sleep disordered breathing ranging from primary snoring to OSA syndrome.[5,6]

Polysomnography (PSG) is a gold standard test for diagnosis of OSA or SDB, but pediatric PSG is not widely and easily available, more over it is costly and time consuming. In our current study, SDB was diagnosed on basis of clinical features, nasal endoscopy or x-ray nasopharynx lateral view and quality of life due to SDB by OSA-18 Questionnaires.[6,7]

Adenoidectomy is the choice of treatment in SDB due to adenoid hypertrophy and is well demonstrated but it may recur after incomplete surgery or by Coblation surgery in 8-12% cases.[7,8] Again some parents do not want to undergo surgery due to intra operative and post-operative complications. Some patients may have contraindication to surgery under general anesthesia.

Thus alternate, non-surgical approaches are well thought and topical nasal steroids were proposed by many authors from the past decade.[9,10,11]In our current study we planned to see the clinical efficacy of intra nasal steroid spray (fluticasone furoate) for 8 weeks in reducing enlarged adenoid size, increase patency of nasopharynx and also symptomatic healing of SDB with increase quality of life (QOL) according to OSA-18 questionnaires score.[12,13,14]

Methods:

This is a prospective observational study, conducted among total 52 pediatric patient (male 32, female 20) ranging from 2 to 12 years old attending ENT / pediatric outpatient department of Green Life Medical College Hospital Dhaka from 2020 to 2021 and diagnosed as sleep disorder breathing (SDB) due to enlarged adenoid, insufficiently upper airway and clinical sign symptoms.

The diagnosis was based on symptoms like: bilateral nasal blockage, loud snoring for last three months or more, mouth breathing, nasal discharge, problem during sleep, repeated middle ear infection, otitis media with effusion and growth retardation. Among the study population, X-ray nasopharynx (lateral view) showed enlarged adenoid of different grade and compromised air way. Patients who attended as a diagnosed case of SDB with enlarged adenoid of different grade for adenoidectomy were also included in this study.

Children who used topical or systemic steroid within last 6 months, children with history of nasal bleeding, immunodeficiency disorder, cranio-facial, neuromuscular or genetic disorder, nasal obstruction due to gross deviated nasal septum or sinusitis, with upper respiratory tract infections within 2 weeks of enrollment in this study, presence of grade 4 adenoid hypertrophy and have systemic complications were excluded from the current study

Counseling of parents or caregiver of each patient was done followed by obtaining informed consent for participation in this study. Instructions were given regarding how to fill up OSA-18 questionnaire and how to use fluticasone furoate nasal spray.

OSA-18 questionnaire was filled before and after use fluticasone furoate nasal spray to observe improvement in symptoms. The study population used fluticasone furoate, one spray (27.5 microgram) in each nostril daily for 8 weeks. Then again fill up the OSA-18 questionnaire to assess improvement of QOL of the children having sleep disorder breathing.

OSA-18 questionnaires survey is a trusted validated and sensitive QOL measurement tools used primarily in children with SDB, obstructive sleep apnea and adenoid / tonsillar hypertrophy. It was developed by Franco et al. in 2000. The survey includes 18 items divided into 5 domains: Each item score ranges from 1 to 7 (1- no problem and 7- worst possible problem). Total score range: 18 to 126. Score range < 60 indicate mild impact on QOL, score of 60-80 has moderate impact and score > 80 it has severe impact on QOL.

Results:

The study population consists of 52 children, of which 61.5% (n=32) were male. The mean age at inclusion into the study was 7.54 years (SD=3.638). The OSA-18 survey was answered by their parents (the mother in over 59.6% of cases). About 65.5% of the children slept in the same bedroom with their parents.

Table I

Characteristics of study population

Variables	Values
Number of subjects	52
Age (in years)	7.54±3.638
Gender (Female/Male)	20 (38.5%)/32 (61.5%)
Height (in meter)	1.2115±0.23253
Weight (in kg)	26.21±11.012
BMI (in kg/m^2)	26.25±10.994
Previous History of Disease	
Asthma	24 (45.3%)
Laryngitis	20 (37.7%)
Urticaria	8 (15.1%)

Table I summarizes the demographic data including the patient's age, gender, height, weight, BMI and history of disease.

Table II

Frequency of symptoms in children with Sleep Disorder Breathing (SDB) in the pre-medication assessment (during their first visit before giving Fluticasone Nasal Spray)

Symptoms	Frequency n (%)
Nasal obstruction	41 (78.8)
Snoring	43 (78.8)
Restless sleep	42 (80.8)
Apnoea	42 (80.8)
Rhinorrhoea	38 (73.1)
Sialosis	35(68.2)
Frequent Sneezing	36(69.3)
Repeated upper airway infection	40(77.0)
Repeated otitis	33(63.5)

Clinical assessment of patients during first visit presenting with nasal obstruction symptoms such as snoring, restless sleep, apnea during sleep, rhinorrhoea, frequent sneezing, sialosis, repeat upper airway infection, repeat otitis, during the pre-medication assessment, are shown in Table II.

Table III shows the total OSA-18 items in pre-medication and post-medication assessment. The pre-medication OSA-18 survey demonstrated small impact on the QOL in 4 children(7.7%), moderate impact in 31 children (59.6%), and severe impact in 17 children (32.7%).The mean time between administration of fluticasone furoate nasal spray and the follow-up visit was 56 days (SD= 12.92). A correlation of the medical assessment after 8 weeks of fluticasone furoate nasal spray administration with the impact on QOL according to the post-medication OSA-18 survey revealed that 38 (73.1%) of children were classified as having mild or low or small impact.

Table III

Total OSA-18 items' scores category on the pre-medication and post-medication assessment

Category	Pre-medication (n, %)	Post-medication (n, %)
Small impact on health-related quality of life	4 (7.7)	38 (73.1)
Moderate impact on health-related quality of life	31 (59.6)	10 (19.2)
Severe impact on health-related quality of life	17 (32.7)	4 (7.7)

Table IV

Total and domain pre and post-medication scores with level of significance by Linear Regression

Domain	Mean of pre-medication OSA-18 survey	Mean of post-medication OSA-18 survey	Mean differences between the pre-medication & post-medicatio means (CI 95%) Post-medication	p value
Sleep disturbances	17.74	10.32	7.42	
…loud snoring?	4.33	2.90	1.43	0.005
...periods in which breathing stopped or air seemed trapped during the night?	5.12	2.63	2.49	0.017
...choking noise or breathlessness while sleeping?	4.25	2.69	1.56	0.005
...restless sleep or frequent awakening during sleep?	4.04	2.10	1.94	0.230
Physical suffering	17.87	10.68	7.19	
...mouth breathing due to nasal obstruction?	4.17	3.37	0.8	0.001
...frequent common colds or upper airway infection?	4.27	2.48	1.79	0.121
...nasal secretion or runny nose?	4.81	2.31	2.5	0.857
...eating difficulties?	4.62	2.52	2.1	0.000
Emotional distress	13.46	7.08	6.38	
...change in humour or rage?	4.15	2.31	1.84	0.011
...aggressive or hyperactive behaviour?	4.98	2.25	2.73	0.000
... problems with discipline?	4.33	2.52	1.81	0.129
Daytime problems	11.68	8.23	3.45	
...drowsiness or excessive daytime naps?	4.04	2.52	1.52	0.000
...poor concentration or attention?	3.62	2.90	0.72	0.000
...difficulty to wake up in the morning?	4.02	2.81	1.21	0.001
Caretaker concern	17.55	10.52	7.03	
...leave you worried about the general health of your child?	4.50	2.27	2.23	0.045
...created a concern that your child is not breathing enough air?	4.29	2.33	1.96	0.002
...interfered in your ability to carry out your daily activities?	4.38	2.50	1.88	0.000
...made you feel frustrated?	4.38	3.42	0.96	0.000
Total OSA	78.3	46.83	31.47	

Table IV shows the mean pre-medication and post-medication the OSA-18 survey by linear regression. The mean pre-medicated total score was 78.30 (SD=8.091), and mean post-medication total score 46.83 (SD = 7.998), with a statistically significant p Value (p=0.000). Each domain of this survey significantly shows the difference before and after treatment. All total domain mean difference the pre-medication and post- medication is 31. 47, and domain scores (before and after medication) were statistically significant (p= 0.000).

Table V

Correlation between change in OSA-18 parameters and change in adenoid size (%)

	p value
Sleep disturbance	0.002
Physical suffering	0.001
Emotional distress	0.003
Daytime function	0.016
Caretaker concerns	0.021

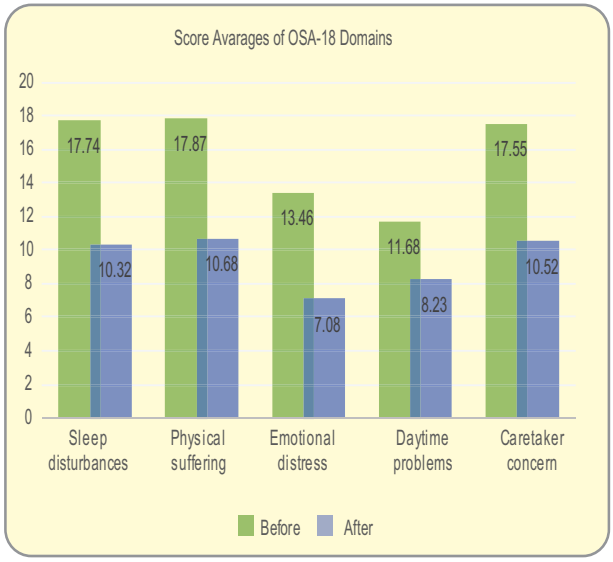

Figure 1: Comparison of symptom score between before and after 8 weeks course of Fluticasone furoate nasal spray

Table VI

Pre and post medication adenoid category with level of significance by Linear Regression

Adenoid Category	Mean of pre-medication	Mean of post-medication	Mean differences between the pre-medication and post-medication means (CI 95%)	p value Post-medication
Adenoid Size	64.4	30.7	33.7	0.014
Adenoid Grade	3.28	2.12	1.16	0.008

Table 6, show the adenoid category on the pre- medication and post medication assessment. The mean adenoid size occupying percentage of the space was 64.4+-12.3% (p=0.215 before medication and 30.7+-14.6 (p=0.014) after medication. The mean adenoid grade was 3.28+-0.54 (p=0.192 before medication and 2.1222+-0.43 (p=0.008) after medication.

Discussion:

Adeno-tonsillar hypertrophy is the common cause of pediatric sleep disorder breathing. In this prospective study we observed significant decrease in adenoid size and improvement in QOL by adopting OSA-18 questionnaires survey score in children treated with Fluticasone Furoate nasal spray (Glucocorticoid) once daily for 8 weeks. Among the OSA-18 questionnaires survey main items; sleep disturbance, physical suffering and emotional distress result were improved significantly while caregiver concern result was also improving but not significantly.

In our study we chose Fluticasone furoate glucocorticoid nasal spray among many other commercially available glucocorticoid nasal spray (Beclomethasone propionate, Budesonide, Mometasone furoate and Triamcinolone acetonide) for short time use. Because it has high potency, very low systemic absorption, well tolerated, no effect on the hypothalamic pituitary adrenal axis, no effect on growth in children. Moreover, it has anti-inflammatory, anti-edematous, anti-allergic property and has no local side effect like dryness of nose, nasal bleeding or nasal septum perforation.[15,16,17,18]

There are many studies evaluating intra nasal steroid effect on adenoid size. First study was done in 1995 in which they used Beclomethasone nasal spray for adenoid hypertrophy. After 8 weeks of treatment, the adenoid size mean reduction in adenoid choana ratio was 29% and 82% reduction in group mean nasal obstruction score.[19]

Berlucchi et al 2008 assessed the efficacy of an intranasal steroid (Mometasone Furoate) in the treatment of adenoid hypertrophy for 40 days treatment duration and 77.7%

children significantly decrease adenoid size and improve in their day-to-day symptoms.[13]

In other study of Hason Demirhan et al 2010 use fluticasone propionate nasal drops at 400 micro gram per day for enlarged adenoid for 8 weeks duration and showed a dramatic decrease in total symptom score from- 13.7 to 2.96. This difference was statistically significant ($p<0.05$). And the average adenoid / nasopharyngeal choana (A/C) ratio dropped from – 87% to 56 %. About 76% of treated children didn't require surgical intervention.[20] This study is similar to our study. OSA-18 questionnaires survey of quality of life assessment is well established in such studies, though Demirhan did not report it specifically.

In most recent study by Md.Mazharul Islam et al, 2018 on adenoid related SDB, use of Fluticasone Furoate intra nasal spray for 4 weeks duration to assess improvement of clinical symptom and QOL by OSA-18 questionnaires.[21] The average total score showed improvement from 60.95 to 46.37, which is also similar to our study.

In our study patients showed decrease adenoid size occupying percentage of the choanal area was 52.2#13.4% before medication and 34.6 #12.8 after medication. The mean adenoid grade was 2.98 #0.44 before medication and 2.32 # 0.51 after medication.

The pre mean pre medication and post medication scores and their difference based on OSA-18 survey by linear regression the mean pre medicated total score was 78.30 (SD= 8.091) and the post meditational total score 46.83(SD=7.998) a statically significant difference (P=0.000)

Total OSA-18 items scores following medication, compared to the classification of the impact on QOL seen in pre medication assessment and also post OSA-18 survey changed from 59.6% to 19.2% in children with moderate impact on the QOL and from 32.7% to 7.7% in children with severe impact on the QOL.

Several methods (x-ray nasopharynx lateral view, Nasal endoscopy, CT scan) have been used to evaluate adenoid size and patency of nasopharyngeal airway.[22,23]

CT scan is costly, nasal endoscopy is safe, reliable and simple method but not easy to perform in children. So, we choose X-ray nasopharynx (L/V) to see adenoid size and grade. Adenoid nasopharyngeal ratio(AN ratio) was obtained by dividing the measurement for A by value of N for each of the ratio. Graphs the AN ratio was computed according to the method of Fujioka et el .[22]

We have used the OSA-18 survey for evaluating the efficacy of short time intranasal steroid (fluticasone furoate) spray in symptomatic improvement of SDB and QOL. In our study highest improvement was noticed in sleep disturbance domain followed by physical suffering and parental or caretaker concern. The OSA-18 questionnaires survey was used in several studies as a determiner of the efficacy of treatment and its outcome [24,25,26,27]. It is convenient and easily practicable. In our study there is a significant improvement in OSA-18 score after treatment with fluticasone furoate nasal spray for 8 weeks. There are some limitations of this study which included: absence of control group, lac of long-term follow-up and not using nasal endoscopy to assess adenoid size.

Conclusion:

Medical management with intranasal steroid (Fluticasone furoate) spray for 8 weeks can be an effective treatment option in pediatric SDB patients due to enlarge adenoid without significant complications. OSA-18 questionnaires are a quick, easily reproduce, disease specific and QOL evaluator subjective survey. Being subjective survey, it should be used in conjunction with clinical and radiological assessment to diagnosis SDB and improvement of symptoms with quality of life. Thus, we can conclude this medical treatment can be provide an alternative to surgical treatment in children with mild to moderate SDB and surgical management is indicated in severe cases where intranasal steroid treatment did not work.

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