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Topical nasal steroid for management of adenoid hypertrophy in children

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Abstract
Background: Adenoid hypertrophy is a common issue observed in childhood, with an estimated prevalence of 34.46% in children. This study aimed to objectively assess the impact of the topical nasal steroid Mometasone furoate on adenoidal hypertrophy in children.
Methods: This observational prospective study was done on 106 patients aged from 4 to 8 years old, both sexes, presented with nasal obstructive symptoms and diagnosed with adenoid hypertrophy based on lateral x-ray nasopharynx with A/N ratio >0.73 using Fujioka method.
Results: A/N ratio before intervention with Mean ± SD = 0.78±0.45, while after intervention with Mean ± SD= 0.70±0.47, with high significance between 2 measurements. There was no impact of sex and age on intervention efficacy in A/N ratio reduction after and before intervention. SNOT22 score before intervention was reduced after intervention with high significance (p<0.001). There was high statistical significance (p<0.001) between 2 measurements regarding change of nasal obstruction in SNOT22 score values.
Conclusions: Topical nasal steroid intervention led to a significant reduction in adenoid size and symptoms associated with adenoid hypertrophy and improvement in the quality of life. Age and sex did not significantly impact the intervention's effectiveness. Additionally, no adverse events were reported, indicating the safety of the intervention.

Keywords: Topical nasal steroid, mometasone furoate, adenoid hypertrophy, SNOT22 score, x-ray nasopharynx

Introduction
Adenoid hypertrophy is a common issue observed in childhood, with an estimated incidence of 2%-3% in children [1]. Typically, hypertrophy follows upper respiratory tract infections, and the adenoids undergo pathological and physiological changes, resulting in chronic or recurrent infections [2].
Nasal obstruction, mouth breathing, snoring, rhinorrhea, postnasal leak, wheezing, parched mouth, halitosis, difficulty swallowing, hyponasal voice, disturbed sleep, enuresis, and morning migraines are all potential symptoms of obstructive adenoids. They may even induce craniofacial growth abnormalities, obstructive sleep apnea, and otitis media with effusion in severe cases [3].
Various diagnostic techniques are used to evaluate adenoid enlargement, such as lateral head radiography, video fluoroscopy, and nasal endoscopy. Among these options, the procedures that have been shown to be most successful are lateral radiography and nasal endoscopy [4].
Adenoidectomy is a frequently performed surgical intervention in pediatric patients, but with potential consequences including primary or secondary bleeding (4%-5%), adenoid tissue regrowth (10%-20%), and postoperative difficulty breathing (27%) [1]. Anaesthesia risks also need to be considered during the procedure [5]. As a result, conservative treatments for managing adenoid hypertrophy are being investigated and researched [6].
The administration of intranasal corticosteroids has a notable influence on the function and synthesis of several proinflammatory agents, such as T lymphocytes, cytokines, adhesion molecules, mast cells and eosinophils. It is widely postulated that these effects manifest mostly inside the nasal mucosa at a localized level. In addition to their known effects, intranasal corticosteroids have the capacity to decrease edema and vascular permeability.

This property may contribute to the alleviation of immunological activation seen in hypertrophied adenoid tissue [7].

The efficacy of intranasal corticosteroids has been shown in the reduction of nasal symptoms, adenoid size or adenoid/choana ratio, as well as the improvement of otitis media with effusion and obstructive sleep apnea [8].

Mometasone is a powerful corticosteroid with a 17-heterocyclic structure. When delivered intranasally, it has a strong affinity for corticosteroid receptors, a low systemic concentration (0.1%), and undergoes significant first-pass metabolism. At typical intranasal dosages, there is no observed suppression of the hypothalamo-pituitary axis [9].

This research aimed to objectively assess the impact of topical nasal steroid on adenoidal hypertrophy in children.

Materials and Methods

This observational prospective case series study was carried out on 106 patients aged from 4 to 8 years old, both sexes, presented with nasal obstructive symptoms and diagnosed with adenoid hypertrophy based on lateral x-ray nasopharynx with A/N ratio >0.73 using Fujioka method. It is noteworthy that 45 patients discontinued the study for varies reasons.

The research was conducted between October 2021 and September 2022 subsequent to obtaining clearance from the Ethical Committee of Tanta University Hospitals, located in Egypt. Relatives of the patients were procured with an informed written permission.

Exclusion criteria were history of adenoidectomy, chronic rhinosinusitis, history suggestive of allergic rhinitis, use of topical or systemic corticosteroid, antihistamine or antibiotics for at least two months at first consultation, immunocompromised state, nasal septal deviation, systemic diseases that may affect airway mucosa, such as cystic fibrosis, developmental facial malformations and subjects who discontinued the medication and those who presented with upper airways infection during the whole period of evaluation.

All patients were subjected to: history taking, clinical examination, lateral x-ray nasopharynx was done to confirm diagnosis and measure A/N ratio, SNOT22 questionnaire was filled by the parents, mometasone furoate nasal spray (50 mcg per nostril) once daily for 40 days, lateral x-ray nasopharynx was done post intervention and SNOT22 questionnaire was filled again by the parents.

X-ray protocol

The standard imaging position was lateral view while the patient is typically standing upright, while the X-ray machine is set at a focal distance of 140 cm, using 70 kV and 12 mA without a grid. The X-ray beam is directed towards the nasopharynx region. During the procedure, patients are instructed to close their mouths and breathe in through their noses. After capturing the image, Fujioka measurement method is utilized to assess the enlargement of the adenoid. Figure 1

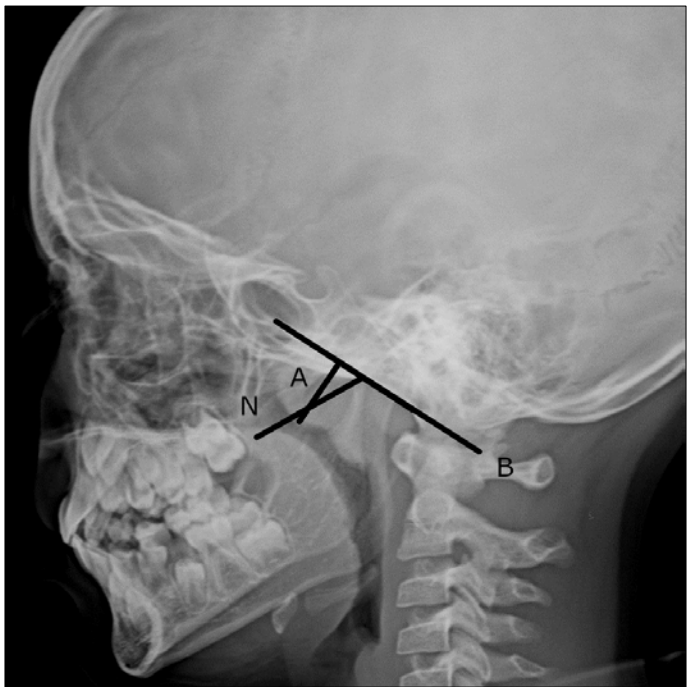


Fig 1: Soft-tissue lateral x-ray nasopharynx of one of the cases showing radiological parameters for Fujioka measurement method. A, adenoid; N, nasopharyngeal space; B, line through spheno-basioccipital synchondrosis

Data were collected at baseline and at the end of the 40-day intervention period. Adenoid size was measured by a radiologist who was blinded to the intervention. SNOT22 score was filled by the parents and assessed by the researcher. Data were analyzed using descriptive statistics and paired t-tests to compare baseline and post-intervention measures.

Standardized measurement protocols for measuring adenoid size on x-ray images included

- **Standardized positioning:** The patients were positioned in a standardized manner for the x-ray imaging, with the head in a neutral position and the mouth closed to ensure that the adenoid tissue was in a relaxed state.

- **Standardized landmarks:** The landmarks used for measuring the adenoid size were standardized, such as the C1 vertebra for the A/N ratio (Fujioka) method.
- **Standardized measurement tools:** The measurement tools used for measuring the adenoid size were standardized, such as specialized software or calibrated rulers.
- **Blinding:** The reader who measured the adenoid size was blinded to the intervention (mometasone furoate nasal spray) and the timepoint of the x-ray image (baseline or post-intervention) to minimize potential biases.
- **Quality control:** Quality control measures, such as inter- and intra-rater reliability tests, were performed periodically to ensure that the measurements were consistent and accurate.

The SNOT22 was a validated questionnaire used to assess the symptoms and quality of life related to sinonasal conditions, including adenoid hypertrophy. The SNOT22 questionnaire consisted of 22 items that addressed different aspects of sinonasal symptoms, such as nasal obstruction, rhinorrhea, facial pain, and sleep disturbance. Each item was scored on a 0-5 scale, with higher scores indicating greater symptom severity or worse quality of life. Validated Arabic translation was.

The primary outcome measure was the change in adenoid size assessed by x-ray nasopharynx (Fujioka measurement method) at the end of the intervention period. The secondary outcome measures included the change in SNOT22 score and the incidence of adverse events related to the intervention.

Statistical analysis

The data was gathered, collated, and subjected to statistical analysis using Microsoft Excel 16.0 for Windows. Quantitative statistics were used to depict qualitative information via the use of numerical values and percentages. The quantitative data were characterized using several statistical measures, including the range (Consisting of the lowest and highest values), the mean, the standard deviation, and the median. All statistical comparisons were conducted using a two-tailed approach, taking into account the significance level. A p-value equal to or less than 0.05 is considered to be indicative of statistical significance, although a p-value less than 0.001 suggests a very significant difference. Conversely, a p-value greater than 0.05 suggests a lack of statistical significance. The statistical test used in this study was the Paired T-test, which was utilized to assess the differences between two measurements of the same variable within a single group, using parametric quantitative data.

Results

The demographic data of the study participants presents. The average age of the participants was 6.0±1.17 years, with a range of 4 to 8 years. Among the 61 participants, 31 (50.8%) were males, and 30 (49.2%) were females. Table 1

Table 1: Demographic criteria of participants

Variable		Estimate
Age (years)		6.0±1.17
Gender	Male	31 (50.8%)
	Female	30 (49.2%)

Data are presented by Mean ± SD or number (%).

A/N ratio before intervention with Mean ± SD = 0.78±0.45, while after intervention with Mean ± SD= 0.70±0.47, with high significance (p<0.001) between the two measurements. Table 2.

Table 2: Change in A/N ratio

A/N ratio	Values	P value
Before intervention	0.78±0.045	0.001*
After intervention	0.70±0.047	

Data are presented as Mean ± SD.

A/N ratio after and before intervention was no significance regard sex and age. There was no impact of sex and age on intervention efficacy in A/N ratio reduction before and after intervention. Table 3

Table 3: Change in A/N ratio, comparison between both gender of children, pre-school age and after school age.

A/N ratio	4-6 years	6-8 years	P value
Before intervention	0.79±0.048	0.77±0.042	0.19
After intervention	0.70±0.050	0.69±0.043	0.23
Difference	0.08±0.023	0.08±0.019	0.87
	Male	**Female**	
Before intervention	0.78±0.048	0.78±0.043	0.73
After intervention	0.70±0.050	0.69±0.043	0.24
Difference	0.08±0.021	0.09±0.021	0.06

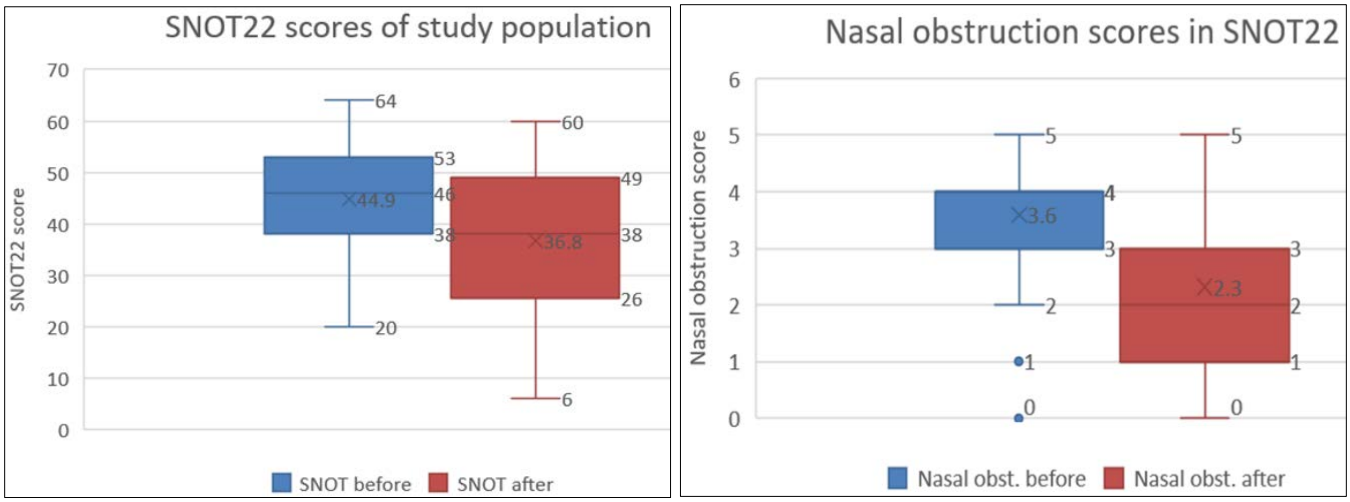
Data are presented as Mean ± SD.

SNOT22 score before intervention with Mean ± SD = 44.90±10.41, while after intervention with Mean ± SD = 36.75±12.94, with high significance between 2 measurements. Regarding change of nasal obstruction in SNOT22 score values before intervention with Mean ± SD = 3.59±1.189, while after intervention with Mean ± SD = 2.31±1.218, with high significance (p<0.001) among 2 measurements. Table 4, Figure 2.

Table 4: Alteration in SNOT22 Score and nasal obstruction in SNOT22 Score

Nasal obstruction	Values	P value
Before intervention	44.9±10.41	<0.001*
After intervention	36.75±12.94	
Change of nasal obstruction in SNOT22 Score		
Before intervention	3.59±1.189	<0.001*
After intervention	2.31±1.218	

Data are presented as Mean ± SD.



A B

Fig 2: Boxplot showing A) SNOT22 scores of study population before and after intervention, B) nasal obstruction scores in SNOT22 of study population before and after intervention

Discussion

The adenoids are a form of lymphoid tissue that may be seen in the nasopharynx. Adenoidal hypertrophy, a prevalent condition throughout childhood, may give rise to a range of symptoms including nasal blockage, snoring, coughing, and other related manifestations. In cases of significant severity, it may potentially lead to the development of obstructive sleep apnea, otitis media with effusion, and craniofacial anomalies [10].

The SNOT22 was a validated questionnaire used to assess the symptoms and quality of life related to sinonasal conditions, including adenoid hypertrophy. The SNOT22 questionnaire consisted of 22 items that addressed different aspects of sinonasal symptoms, such as sleep disturbance, nasal obstruction, rhinorrhea and facial pain. Each item was scored on a 0-5 scale, with higher scores indicating greater symptom severity or worse quality of life. Validated Arabic translation was used [11].

Our study results showed a significant reduction in the size of adenoid after the intervention (p<0.001). The A.78/N ratio before intervention ranged from 0.73 to 0.88, while after intervention, it ranged from 0.63 to 0.83. The analysis based on age groups (4-6 years and 6-8 years) did not reveal any significant difference in the A/N ratio before or after intervention (p>0.05).

The reduction in A/N ratio did not vary significantly between the two age groups (p = 0.87). The reduction in A/N ratio also did not significantly differ between the two sexes (p = 0.06). The SNOT22 score, which assesses the quality of life and symptoms associated with adenoid hypertrophy, showed a significant improvement after the intervention (p<0.001). The SNOT22 score before intervention ranged from 20 to 64, while after intervention, it ranged from 6 to 60.

These results indicate that the topical nasal steroid intervention for the adenoid hypertrophy management in children showed promising outcomes. The intervention led to a significant reduction in adenoid size, as indicated by the A/N ratio, and improvement in the quality of life and symptoms associated with adenoid hypertrophy, as assessed by the SNOT22 score.

Numerous studies in literature have examined the impact of nasal steroids, specifically intranasal mometasone furoate, for the treatment of adenoid hypertrophy.

Berlucchi *et al.* [12] concluded that the use of mometasone furoate aqueous nasal spray has shown potential in reducing the size of adenoid pad and alleviating symptoms associated with adenoidal hypertrophy. It may be beneficial to consider administering intranasal mometasone treatment to children with adenoidal hypertrophy, particularly in cases where tonsillar hypertrophy is not present, as a non-surgical alternative. This approach should be considered before deciding to proceed with surgical intervention.

In their study, Bhargava and Chakravarti [3] conducted a double-blind randomized placebo-controlled trial to evaluate the efficacy of topical intranasal mometasone furoate nasal spray in children with adenoidal hypertrophy and otitis media with effusion. Their findings suggest that the use of Mometasone nasal spray may be an effective treatment option for patients with otitis media with effusion who also have adenoidal hypertrophy.

The study conducted by Rezende *et al.* [13] aimed to examine the potential impact of atopy on the efficacy of mometasone furoate therapy for adenoid hypertrophy. The researchers reached the conclusion that the application of topical mometasone furoate resulted in a considerable reduction in the size of the adenoid tissue and also contributed to an additional enhancement of nasal symptoms. The observed improvement exhibited similarities across both atopic and nonatopic individuals.

A meta-analysis and systematic review conducted by Chohan *et al.* [8] recommended further randomized controlled trials (RCT) with varying doses and durations of mometasone administration to assess its safety and efficacy more comprehensively in children with adenoid hypertrophy.

In a separate systematic review and meta-analysis done by Elbeltagy *et al.* [14], the included articles were used in five meta-analyses that investigated the relationship between adenoid size and its related symptoms. Among the studies included, three meta-analyses have shown a statistically significant decrease in adenoid size subsequent to the administration of intranasal corticosteroids (INCS). Nevertheless, the two remaining meta-analyses failed to demonstrate a statistically significant improvement in nasal obstruction symptoms, despite the fact that the individual trials included within these meta-analyses reported favorable outcomes in terms of relieving obstruction symptoms.

One of the studies included in El beltagy *et al*. [14] study is the study conducted by Yilmaz *et al*. [15] using a randomized double-blind placebo-controlled cross-over study design, on subjects who were older than 12 years and younger than 18 years, the study observed a significant improvement in total subjective symptoms when mometasone furoate was used for adenoidal hypertrophy. Specifically, mometasone furoate showed significant improvements in nasal obstruction, coughing, snoring, and quality of life in adolescents with adenoidal hypertrophy.

However, no significant advantage of mometasone furoate over placebo was found for rhinorrhea in this patient group. The study did not find any difference between mometasone furoate and placebo in reducing the size of adenoid hypertrophy as observed during nasopharyngeal endoscopic evaluation. Study has two limitations.

Firstly, the current body of research exhibits a dearth of extended-term monitoring to ascertain the enduring beneficial impacts of mometasone furoate on nasal symptoms in individuals with adenoid hypertrophy. Furthermore, the analysis of the results in this research did not take into account the allergic status of the participants. The authors underscore the need of conducting more RCT on a wide scale and over an extended period of time, specifically focusing on the teenage demographic, in order to substantiate the conclusions drawn from this investigation.

INCS, or intranasal corticosteroids, have potent anti-inflammatory effects in the upper airway. They work by inhibiting the production of cytokines involved in the inflammatory process, such as GM-CSF, IL-6, and IL-8, by upper airway epithelial cells [16]. This leads to a reduction in T lymphocytes in the surface epithelium. INCS also reduce the expression of adhesion molecules, such as ICAM-1 and VCAM-1, which play a role in eosinophil and basophil adhesion and migration to sites of inflammation [17]. Additionally, INCS inhibit the production of chemotactic cytokines, like MCP-1 and MCP-4, which attract inflammatory cells to the inflamed area. Moreover, INCS can prevent the redistribution and decrease the number of mast cells in the nasal mucosa [7]. These mechanisms collectively contribute to the anti-inflammatory effects of INCS in various nasal conditions, including adenoidal hypertrophy.

The findings of our study suggest that the topical nasal steroid treatment can be considered as a viable therapeutic option for managing adenoid hypertrophy in children. The reduction in adenoid size indicates the potential of intervention to alleviate the physical obstruction caused by hypertrophic adenoids. Additionally, the improvement in the SNOT22 score reflects a positive impact on the overall symptoms experienced by the children, indicating an enhancement in their quality of life.

Our study employed a prospective design, which allows for the collection of data over time and enhances the validity of the findings. The use of objective measures, such as x-ray scans, adds to the robustness of the study. Furthermore, the study utilized a well-defined and homogeneous sample of participants with confirmed adenoid hypertrophy, ensuring that the results are applicable to the target population. The inclusion and exclusion criteria were clearly outlined, which enhances the internal validity of the study.

The study also considered potentially confounding factors by excluding participants with certain medical conditions or prior treatments that could affect the outcomes. This strengthens the ability to attribute the observed changes to the intervention itself.

Lastly, the study conducted thorough data analysis, including appropriate statistical tests to evaluate the significance of the results.

Among limitations of our study, its design was observational, which means that causal relationships cannot be established. It would be beneficial to conduct randomized controlled trials to further investigate the effects of the intervention. Another limitation is the relatively short duration of the intervention. The study followed participants for 40 days, and it would be valuable to assess the long-term effects of the treatment beyond the duration of the study. Long-term follow-up studies can provide a more comprehensive understanding of the intervention's effectiveness and its sustainability over time.

Further research with larger sample sizes, randomized controlled designs, longer durations, and objective outcome measures would be beneficial to address these limitations and strengthen the evidence base in this area. While the study's strengths lie in its prospective design, objective measures, well-defined sample, consideration of confounding factors, and rigorous data analysis. These strengths contribute to the credibility and reliability of the study's findings.

Conclusion

Topical nasal steroid intervention led to a significant reduction in adenoid size and symptoms associated with adenoid hypertrophy and improvement in the quality of life. Age and sex did not significantly impact the intervention's effectiveness. Additionally, no adverse events were reported, indicating the safety of the intervention.

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Conflict of Interest: Nil

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