
**“TO COMPARE THE EFFICACY OF ADDITION OF
MOMETASONE NASAL SPRAY TO THE STANDARD
MEDICAL TREATMENT IN REDUCTION OF ADENOID
HYPERTROPHY IN CHRONIC ADENOIDITIS: A ONE
YEAR RANDOMISED CONTROL STUDY”**

BY
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Dissertation

*Submitted to the KLE Academy of Higher Education and
Research, Belagavi, Karnataka*

*In Partial Fulfilment
of the Requirements for the Degree of*

M.S
IN
OTORHINOLARYNGOLOGY
AND HEAD AND NECK SURGERY

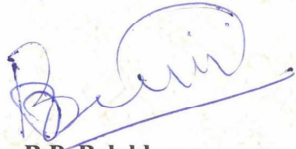
**DEPARTMENT OF OTORHINOLARYNGOLOGY AND
HEAD AND NECK SURGERY**
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELAGAVI, KARNATAKA

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With reference to the above, we wish to inform you that your proposed research project titled
“TO COMPARE THE EFFICACY OF ADDITION OF MOMETASONE NASAL SPRAY
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CONTROL STUDY”, is ethical and justifiable. The proposed research project has been cleared
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LIST OF ABBREVIATIONS

AH	Adenoid Hypertrophy
GABA	group A beta- haemolytic streptococci
ANR	Adenoid Nasopharyngeal Ratio
VAS	visual analogue scale
SPSS	Statistical Package for Social Sciences
OSA	Obstructive Sleep Apnea
CPAP	Continuous Positive Airway Pressure
HPA	Hypothalamic Pitutary Adrenal
MFNS	Mometasone Furoate Nasal Spray

ABSTRACT

Background: Adenoid hypertrophy (AH) is a common disorder in children , which has a major impact on child's growth and development ^[1]. Long term complications and sequelae of adenoidectomy such as alteration of immunological system, post operative bleeding, recurrence of adenoids and expenditure of the surgery are objects of criticism., hence this study will aim to reduce the need for the surgery by the addition of mometasone nasal spray in medical management of adenoid hypertrophy

Objectives: The objective of the study is to determine if adding intranasal corticosteroids to the standard medical regimen has a better efficacy in treating chronic adenoiditis so as to avoid the need for surgery.

Material and methods: This randomized control single blinded study was conducted in the department of Otorhinolaryngology and Head and Neck Surgery and Department of Anatomy of KAHER's Jawaharlal Nehru Medical College and KLES Dr.Prabhakar Kore Hospital and Medical Research Center, Belagavi from January 2021 to December 2021. 48 patients with clinically confirmed diagnosis of chronic adenoiditis underwent Clinical symptom evaluation by eliciting response from parent/child in a pre-structured questionnaire and were documented.

Results: 33 Male & 15 Female were studied. A statistically significant reduction in nasal obstruction index and other symptoms were noted at the end of 2 weeks follow up.

Conclusion: In present study, there is a significant improvement of symptoms and quality of life in chronic adenoiditis patients after the addition of corticosteroids to the standard medical regimen .Thereby avoiding the requirement for surgery as well as the long term complications and sequelae such as alteration of immunological system, post operative bleeding, recurrence of adenoids and expenditure of surgery.

Key words - : Adenoid hypertrophy, Mometasone furoate, Nasal obstruction index,

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INTRODUCTION

One of the prevalent conditions in children is adenoidal hypertrophy (AH), that has an impact on child growth .^[1]

The adenoids anatomically is pyramid shaped , lymphoid tissue aggregation with the apex of the structure in direction pointing to the nasal septum and the base is at the level of posterior wall of the nasopharynx and the roof^[2]

This lymphoid tissue , which is present at birth, continues hypertrophy until the age of 7 ,after reaching its maximal size, it starts to atrophy until it virtually vanishes in adulthood. The pharyngeal tonsil is a component of Waldeyer's ring,that includes the adenoid pad, , tubal, palatine and lingual tonsils and is located near the entrance to the aerodigestive tract^[2]

Conservative line of management for treatment in alleviating symptoms has been tried. There is reasonable amount of evidence concluding that medical management of adenoid hypertrophy has helped in alleviating nasal obstruction symptoms due to adenoid hypertrophy.

Steroid preparations in the form of topical and intranasal forms and antibiotics have been proven effective in the literature.^[3] Treatment with a 30 day course of amoxicillin + clavulanate potassium significantly reduced the need for adenoidectomy.^[4]

In 1995 At the conclusion of 24 weeks of treatment, Demain et al was one of the first to report the success of using intranasal form of steroid therapy and

discovered a significant reduction in the symptom score for nasal obstruction and a decreased adenoid-choana ratio.^[5]

Even when used for extended periods of time, mometasone furoate does not result in any adverse effect on nasal mucosa .^[6] It has no impact on a child's ability to grow, the hypothalamic-pituitary-adrenal axis is unaffected, and has a low level of systemic availability^[7,8].

As a result, mometasone furoate is chosen above other steroids. Adenoidectomy's long-term complications and sequelae, such as altered immune function, postoperative bleeding, reoccurrence of adenoids, and cost of the procedure, have drawn criticism.

As a result, the goal of this study is to reduce the need for surgery by addition of mometasone nasal spray into the medical management of adenoid hypertrophy.

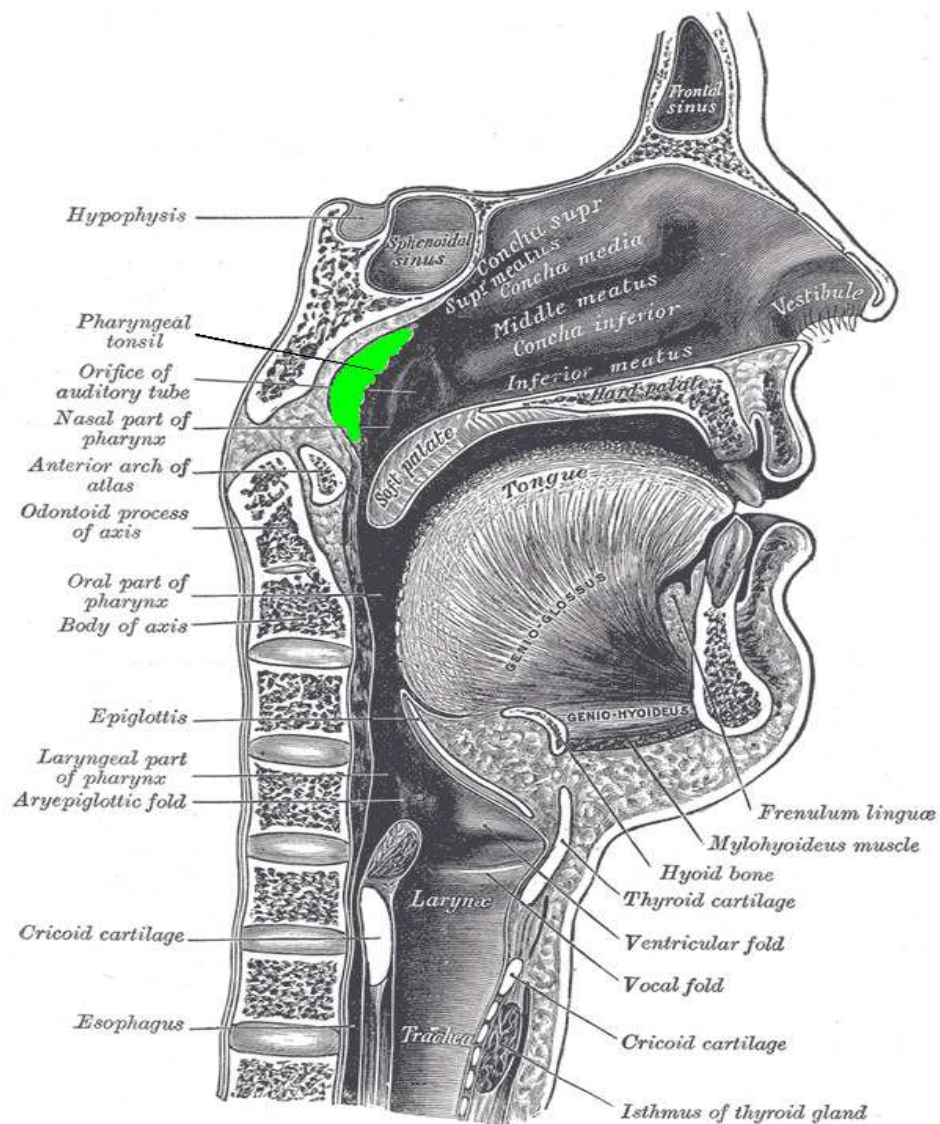
OBJECTIVES

The objective of the study is to compare and assess the efficacy of intranasal corticosteroids for improving nasal airway obstruction in children with chronic adenoidal hypertrophy

REVIEW OF LITERATURE

ANATOMY OF ADENOIDS:

Adenoid is a truncated pyramid shaped lymphoid tissue situated in the roof and posterior wall of nasopharynx, its apex lies at nasal septum and base at the roof of nasopharynx. [9]



Median sagittal section through the head and neck

It's a lymphoid tissue in the roof and posterior wall of nasopharynx is prominent in children and disappears during adulthood .

Similarly lymphoid accumulations in the children in the posterior lip of ostium of the auditory tube are called the tubal tonsil. When the pharyngeal and tubal tonsils are enlarged, they are called adenoids. This causes difficulty in breathing due to mechanical obstruction of nasopharynx, and if the ostium of the tube is occluded, there may be hearing loss because of absorption of air in middle ear cavity . The most common complaints are acute and chronic airway obstruction due to adenoid and tonsillar hypertrophy. The hypertrophy of adenoids commences in the paediatric age group and continue to adolescent age group and rarely in young adults also.

The main symptoms of adenoid hypertrophy are :

- Snoring
- Nasal obstruction
- Mouth breathing
- Cough
- Apnea

The less common symptoms of adenoid hypertrophy are:

- Hyponasal speech
- Sleep disturbances
- Nocturnal enuresis
- Growth disturbances
- Failure to thrive

AGENTS INVOLVED IN AETIOLOGY OF ADENOIDITIS^[10]

1. Viruses:

Viruses play an important role in mucosal inflammation, crypt obstruction and ulceration thereby leading to bacterial superinfection. The viruses involved are rhinovirus, coronavirus, adenovirus, herpes simplex virus, parainfluenza virus, epstein barr virus, and cytomegalovirus.

2. Bacteria

The organisms involved are alpha and gamma-haemolytic streptococci, haemophilus influenza, staphylococcus aureus, group A beta- haemolytic streptococci (GABA) and Moraxella catarrhalis. Anaerobic organisms include peptostreptococcus, and fusobacterium.^[11] Also included are group C beta-haemolytic streptococci, neisseria gonorrhoeae, corynebacterium diphtheria, and mycoplasma pneumonia.^[11]

These infections may also present with anterior cervical lymphadenitis.

CLINICAL FEATURES: Symptoms and signs of adenoid hypertrophy depend on two factors^[11].

- Size of adenoid tissue.
- Space available in the nasopharynx.

Adenoid hypertrophy causes nasal, aural and general symptoms.^[10]

1. NASAL SYMPTOMS

Nasal obstruction and obstructive sleep apnoea^[12] are the commonest symptoms.

This obstruction manifests as mouth breathing and interferes with feeding or suckling in a child.^[13] Both respiratory obstruction and feeding difficulty leads to failure to thrive. This airway obstruction produces decreased arterial PaO₂ and increased PaCO₂.^[14]

2. *Nasal discharge or rhinorrhoea* The causes for nasal discharge are:

- a) Choanal obstruction^[15] wherein the nasal secretions from nasal cavity cannot drain posteriorly into the nasopharynx.
- b) Pre-existing chronic rhinitis.

3. *Sinusitis*

Adenoid hypertrophy is associated with chronic maxillary sinusitis. This is due to persistent nasal discharge and infection.

4. *Epistaxis*

In acute inflammation of adenoids if the child blows forcefully epistaxis may occur.

5. *Voice changes* Due to the nasal obstruction, nasal quality of voice is lost and the voice become toneless.

6. *Olfaction*

Olfaction is decreased due to the adenoid hypertrophy. This is an indirect cause for the poor appetite, affecting children with adenoid hypertrophy.

2. AURAL SYMPTOMS

- ***Tubal Obstruction***

Due to obstruction to the eustachian tube by the enlarged adenoids, the tympanic membrane gets retracted and leads to conductive hearing loss

- ***Recurrent attacks of acute otitis media***

This may occur due to spread of infection from nasopharynx to middle ear via the eustachian tube.

- ***Chronic suppurative otitis media*** -This condition may persist and does not resolve due to infection of adenoids. It is due to a partial selective IgA deficiency and is a causative factor in these otitis prone patients ^[11]

- ***Serous otitis media*** This condition is most commonly seen in children. The important finding seen in this condition is fluctuating hearing loss due to intermittent obstruction to eustachian tube due to increase and decrease in size of adenoids.

3. GENERAL SYMPTOMS

- ***Adenoid facies***

This appearance typical for adenoid hypertrophy is due to chronic nasal obstruction and mouth breathing. The child has an elongated face with dull expression, open mouth, prominent and crowded upper teeth and hitched up upper lip. Nose has a pinched in appearance due to disuse atrophy of alae nasi. High arched palate is present.

1. Incompetent lip seal
 2. Narrow upper dental arch
 3. Increased anterior face height
 4. Steep mandibular plane angle
 5. Retrognathic mandible
- ***Pulmonary hypertension***-Pulmonary hypertension and cor pulmonale is due to long standing nasal obstruction.
 - ***Aprosexia***-Lack of concentration is also seen in long standing cases.
 - ***Neoplasia*** -Neoplasia of adenoid in childhood is very rare, but non hodgkin's lymphoma has been reported.

ASSESSMENT AND MANAGEMENT: CLINICAL HISTORY ^[16] :

In paediatric and adolescent patients ,the clinical history is a crucial component of the patient's treatment. Special attention is paid to the middle ear illness and nasal obstruction symptoms when gathering a patient's medical history. ^[17]

ANTERIOR RHINOSCOPY :

Behind the patient's left shoulder a bull's eye lamp is placed and light is reflected off a concave mirror placed on the forehead of the examiner's . The centre of the mirror has a hole through which examiner looks and the patient's nostrils is dilated with a nasal speculum. Anterior part of the nasal cavity is seen in this examination, nasal mucosa is decongested for better view.

POSTNASAL EXAMINATION^[18]:

A small angled mirror (St Clair Thompson's) can be used to view nasopharynx which is held in the oropharynx and is directed upwards and light source is directed towards it . Tongue should be held down using a tongue depressor and the mirror should be preheated . This test is difficult to perform as their mouth is open soft palate cant be relaxed. Patient should be encouraged to breathe through the nose.

CLINICAL GRADING OF ADENOID SIZE^[16]

Grade I - Adenoid tissue filling one-third of the choanae

Grade II - Adenoid tissue filling from one-third to two-thirds of the choanae

Grade III - From two-thirds to nearly complete obstruction of the choanae

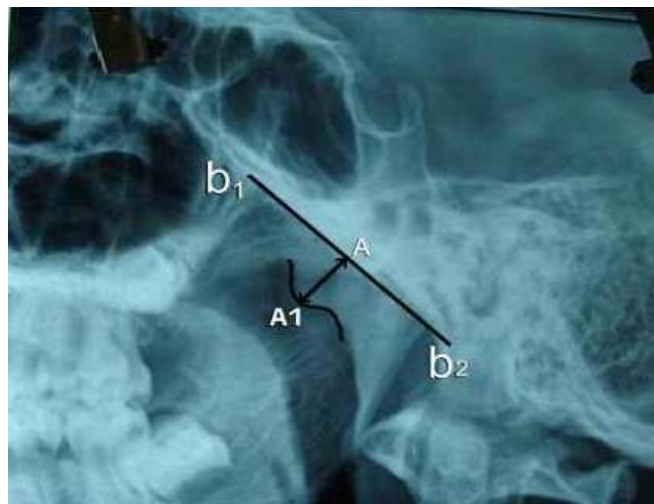
Grade IV- Complete choanal obstruction

RADIOLOGY:^[19] The best view for adenoids is the “X- ray neck – Lateral view,” which is the useful for evaluating adenoid size and patency of airway.They are straightforward, easily accessible.

The Adenoid Nasopharyngeal Ratio (ANR) which compares the amount of lymphoid tissue in the nasopharynx to the size of nasopharyngeal airway was first described by Fujioka et al, in 1979as a reliable method of expressing the size of adenoids and patency of nasopharyngeal airway.^[19] An ANR of greater than 0.7 is subjectively judged to have enlarged adenoids. Mean ANR was calculated by dividing adenoidal depth by nasopharyngeal depth.

The adenoidal measurement represents the distance from the point of maximal convexity of the adenoid shadow (A1-Figure 2) antero-inferiorly to the anterior margin of the basiocciput (A-Figure 2).

The nasopharyngeal measurement represents the distance between the posterior border of the hard palate and sphenobasiocciput synchondrosis (b1-b2 Figure 2)



Adenoidal measurements of x-ray nasopharynx: A represents distance from A1, point of maximal convexity, along inferior margin of adenoid shadow to line b1b2, drawn along straight part of anterior margin of basi-occiput.

RADIOLOGICAL GRADING OF ADENOID SIZE

- Grade 0 (0.0-0.25) - No Adenoid Enlargement
- Grade 1 (0.26-0.50) - Minimal Enlargement
- Grade 2 (0.51-0.75) - Moderate Enlargement
- Grade 3 (0.76-1.00) - Gross Enlargement.

Coming to comparison of steroid strength mometasone furoate is more potent than hydrocortisone, and less potent than dexamethasone.

MECHANISM OF ACTION:

Mometasone possesses anti-inflammatory, antipruritic, and vasoconstrictive properties. It is presumed to act by anti-inflammatory - efficacy mediated inhibition of production of inflammatory cytokines. Mometasone circulate in the blood easily, crossing cellular membranes and binding with cytoplasmic receptors, resulting in the transcription and synthesis of proteins. Mometasone also inhibits the actions of the enzyme cytochrome P450 2C8 which participates in the activity of monooxygenase.

THERAPEUTIC USES:

1. Seasonal allergic rhinitis
2. Adenoid hypertrophy
3. Atopic eczema
4. Psoriasis
5. Contact dermatitis

SIDE EFFECTS OF INHALED CORTICOSTEROIDS:

Local effects:

- Candidiasis of oral cavity
- Cough
- Ulceration of nasal septum
- Candidiasis of pharynx
- Disturbances of taste

- Nausea
- Headache
- Nasal discharge

Systemic side Effects:

- Hypothalamic pituitary-adrenal axis suppression
- Osteoporosis
- Bruising
- Cataracts
- Glaucoma
- Metabolic abnormalities (glucose, insulin, triglycerides)
- Psychiatric disturbances

DRUG INTERACTIONS: There are no hazardous drug interactions with mometasone furoate.

MATERIAL & METHOD

Study setting: Hospital Based study

Study design: Randomised Control Study

Method of randomization : Chit picking method 48 papers will be taken ,out of which upto 24th paper will given group A and rest group B, then fold them correctly into a chit, put them in a box and pick a chit everytime when a patient comes and divide them accordingly.

Study period: 1 YEAR

Study population : Subjects attending KLES DR Prabhakar Kore Hospital, Belagavi during January 2021 to December 2021. Subjects of age 2 to 14 years attending Otolaryngology department with complaints of chronic adenoid hypertrophy.

Selection Criteria :

INCLUSION CRITERIA: All patients with clinically confirmed diagnosis of adenoids with X-ray Nasopharynx (lateral view) and whose clinical symptom evaluation was done by eliciting response from parent/child in a pre-structured questionnaire which encompassed

- Nasal congestion
- Mouth breathing
- Nasal discharge
- Snoring
- Day time sleepiness

- Hyponasal voice
- Ear popping

EXCLUSION CRITERIA: Children with

- Postive history of allergy to any antibiotics
- Upper respiratory infection within last 2 weeks
- Nasal anatomical anomaly like nasal septum deviation
- Sinonasal disease such as nasal polyposis
- Craniofacial malformation including cleft lip, cleftpalate
- Genetic disorders like Down’s syndrome
- Neurologic disorders; cardiovascular disease;immunodeficiency
- Children with history of epistaxis or hypersensitivity tosteroids or any other drug allergy were excluded from the study

Sample size(n): 48

Formula- Sample size formula:

The minimum sample size formula based on mean and standard deviation is

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

where z_{α} is linked with the level of significance and z_{β} is linked with the power of the test. For 5% level of the significance z_{α}

=1.96 and $z_{\beta} = 0.84$ for 80% power of the test. Ref:

\bar{X}_1 is the mean of the first group (1.00) and \bar{X}_2 is the mean of the second group (3.53).

s_1 is the standard deviation of the first group (2.64) and s_2 is the standard deviation of the second group (3.55).

With these values the sample size obtained is 24

There will be two groups with minimum 24 cases in each group

METHODOLOGY: After obtaining ethical clearance from our institution, Informed consent will be obtained. Detailed evaluation of the patient including detailed history and complete clinical examination including anterior and posterior rhinoscopy will be done. Any other symptoms apart from nose complaints will be noted. After clinical diagnosis, randomised prospective study will be done in the department of ENT on 48 children who will meet the inclusion criteria.

Each of the symptoms, Nasal congestion, Mouth breathing, Nasal discharge, Snoring, Day time sleepiness, Hyponasal voice, Ear popping will be scored from 0 (absent) to 4 (severe) over visual analogue scale (VAS). Nasal obstruction index will be calculated by averaging the scores measured over point scale for mouth breathing and speech hyponasality symptoms.

Sampling Procedure : After randomized selection of subjects by using Chit picking methods, the subjects will be given standard medical management i.e amoxicillin/clavulanic acid and then divided into 2 groups

Group A - will be given standard antibiotic

(amoxicillin/clavulanic 40mg/kg/day) alone for 2 weeks. Group B -will be given standard antibiotic + intranasal steroid spray (mometasone 1 spray 50mcg in each nostril once daily) for 2 weeks.

Pre treatment and Post treatment scoring will be compared to assess the efficacy of intranasal corticosteroid spray.

STATISTICAL ANALYSIS

The study is focused on comparison of two groups and the software used is SPSS 20th version. For the continuous quantitative variables mean and standard deviation will be calculated.

The inter group continuous variables will be compared using suitable tools of statistics like unpaired student's t test. Two quantitative variables, within a group, will be compared using student's paired t test.

The categorical data will be expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics will be tested using Chi-square test or Fisher's exact test.

Discrete variables will be represented by median.

Nonparametric tests will be used for comparing discrete variables.

Suitable graphs will be used to depict the comparison.

For all the tests the value of p less than 5% (0.05) will be considered significant.

RESULTS

Total of 48 patients fulfilling inclusion criteria are included in present study after obtaining the informed consent. The patients were randomly allotted into two groups as cases (n=24) and controls (n=24).

Patients were grouped into two groups based on treatment group which was selected randomly by chit method. The patients were grouped as Group A (Control) with standard antibiotic treatment (amoxicillin/clavulanic 40mg/kg/day) alone for 2 weeks. Group B (Test) with standard antibiotic added with intranasal steroid spray (mometasone 1 spray 50mcg in each nostril once daily) for 2 weeks.

There was significant difference in the mean age between the groups. The mean age in cases was 6.83 ± 3.06 and in control it was 10.25 ± 2.47 . ($p < 0.05$) Among the cases, the age group of distribution was majority in 4-8yrs and among the controls it was age group of 8-12yrs.

Gender distribution was comparable between the groups. Among the cases 70.83% were male and 29.17% were female, similarly in control group 66.67% were male and 33.33% were female. Overall there is male preponderance (male to female ratio of 2.2:1) among the included study in the group with no significant difference in the distribution between the groups.

Table 1: Showing the mean age difference between the groups

Age in years	Test group				Control group				p-value	Inference
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
	6.83	3.06	2	13	10.25	2.47	4	14	0.001*	HS

Figure 1: Showing the mean age difference between the groups

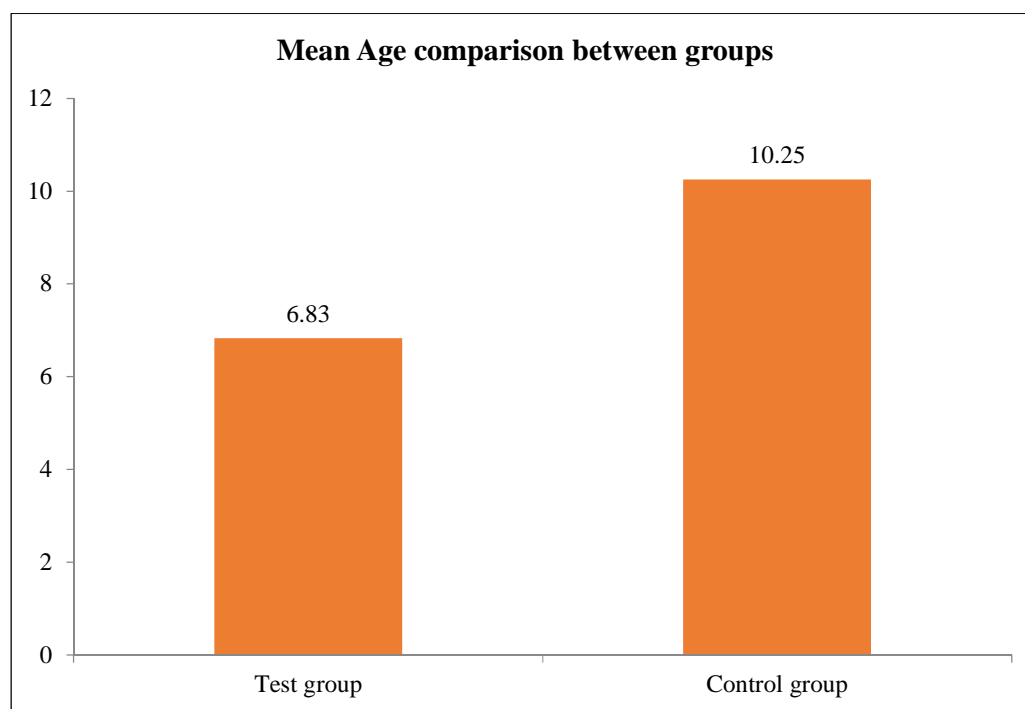


Table 2: Showing the age-wise distribution of patients between the groups

Age in years	Test group		Control group	
	NUMBER	%	NUMBER	%
2 - 4	3	12.50	0	0.00
4 - 6	6	25.00	1	4.17
6 - 8	7	29.17	1	4.17
8 - 10	2	8.33	5	20.83
10 - 12	4	16.67	7	29.17
12 - 14	2	8.33	8	33.33
14 - 16	0	0.00	2	8.33
TOTAL	24	100.00	24	100.00

Figure 2: Showing the age-wise distribution of patients between the groups

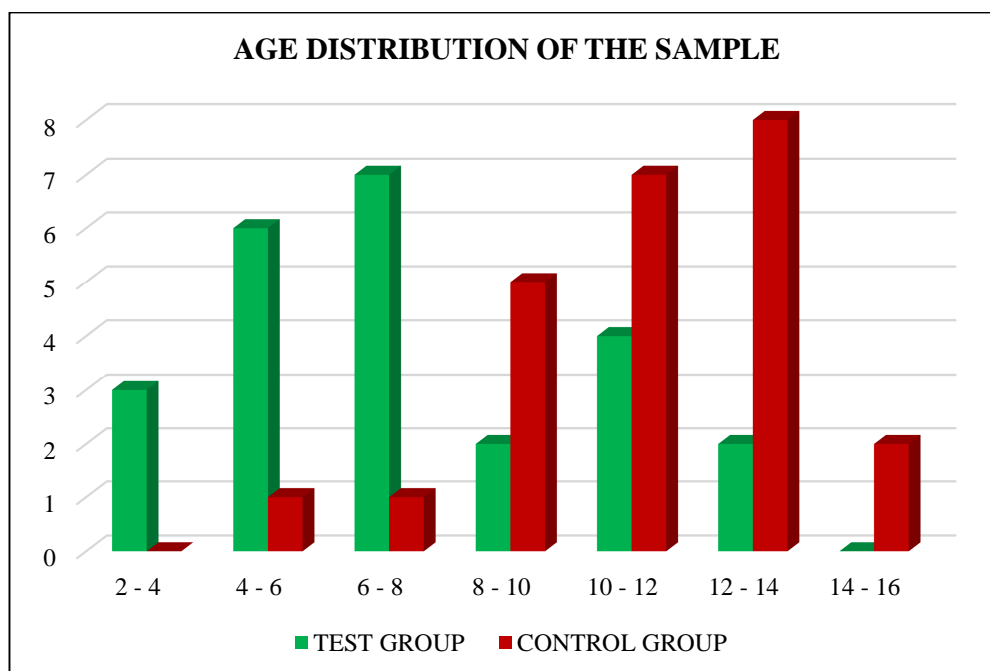


Table 3: Showing the gender wise distribution of patients between the groups

GENDER	Test group		Control group	
	Number	%	Number	%
FEMALE	7	29.17	8	33.33
MALE	17	70.83	16	66.67
TOTAL	24	100.00	24	100.00

Figure 3: Showing the gender wise distribution of patients between the groups

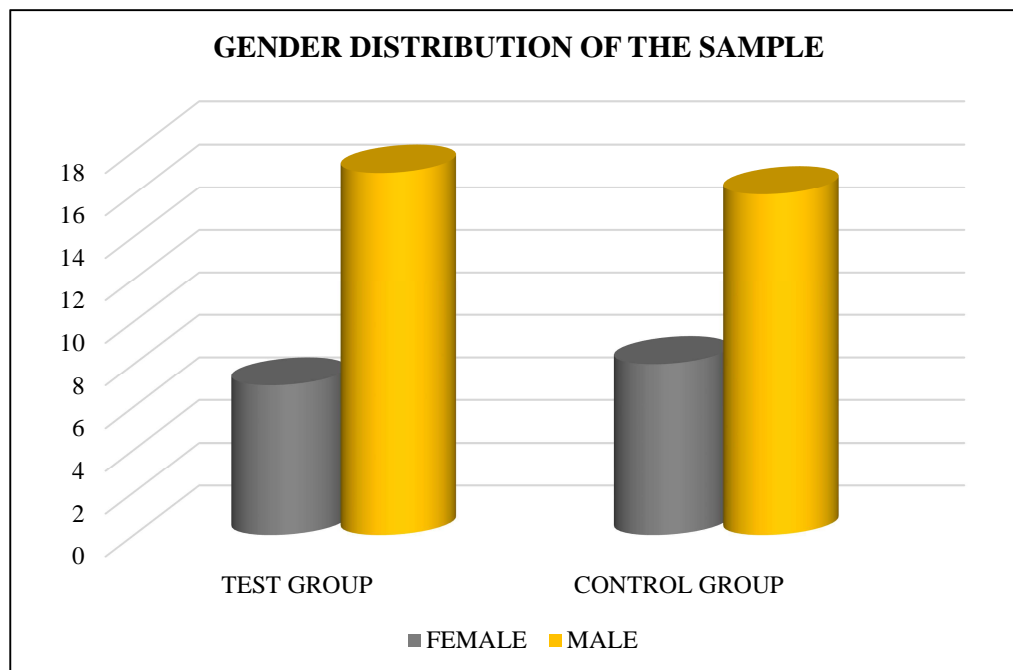


Table 4: Showing the mean VAS score of nasal obstruction between the groups

NASAL OBSTRUCTION	Test group				Control group				p-value	Inference
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BEFORE	2.17	0.70	1	3	2.83	0.64	2	4	0.0012	VS
AFTER	1.46	0.66	1	3	2.25	0.99	1	4	0.0021	VS

Figure 4: Showing the mean VAS score of nasal obstruction between the groups

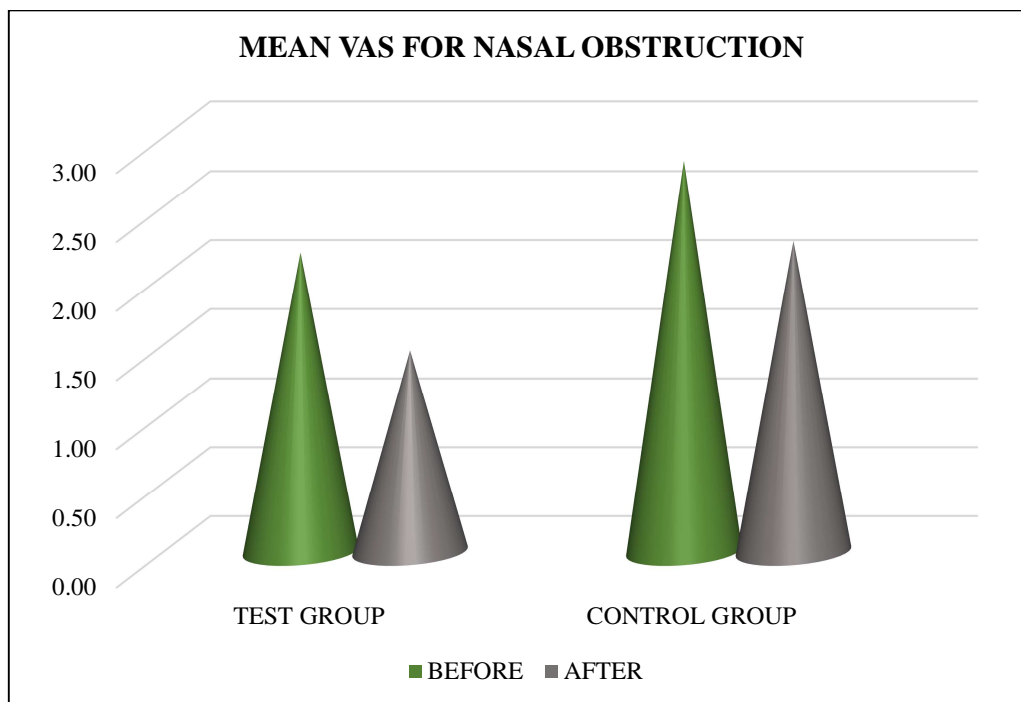


Table 5: Showing the mean VAS score of nasal obstruction within the test groups

Test group								p- value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
2.17	0.70	1	3	1.46	0.66	1	3	0.0004	HS

Table 6: Showing the mean VAS score of nasal obstruction within the control groups

Control group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
2.83	0.64	2	4	2.25	0.99	1	4	0.0096	VS

Figure 5: Nasal Obstruction mean VAS score changes before and after treatment within groups

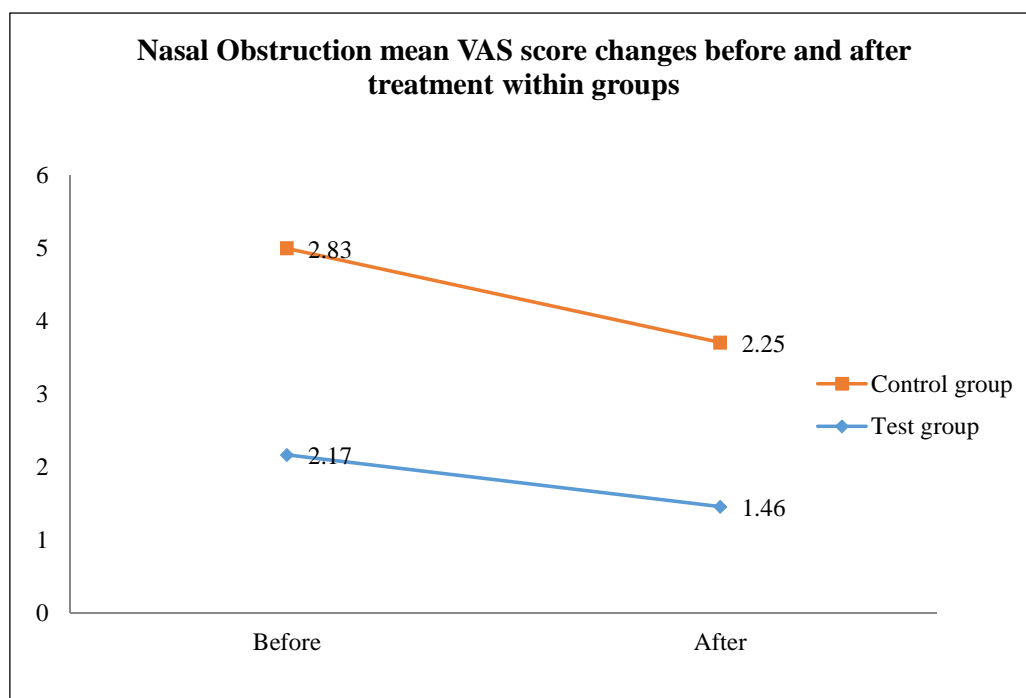


Table 7: Showing the mean VAS score of mouth breathing between the groups

MOUTH BREATHING	TEST GROUP				CONTROL GROUP				p-value	Inference
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BEFORE	1.96	0.62	1	3	2.25	0.74	1	3	0.1459	NS
AFTER	1.50	0.66	1	3	2.21	0.78	1	3	0.0014	VS

Figure 6: Showing the mean VAS score of mouth breathing between the groups

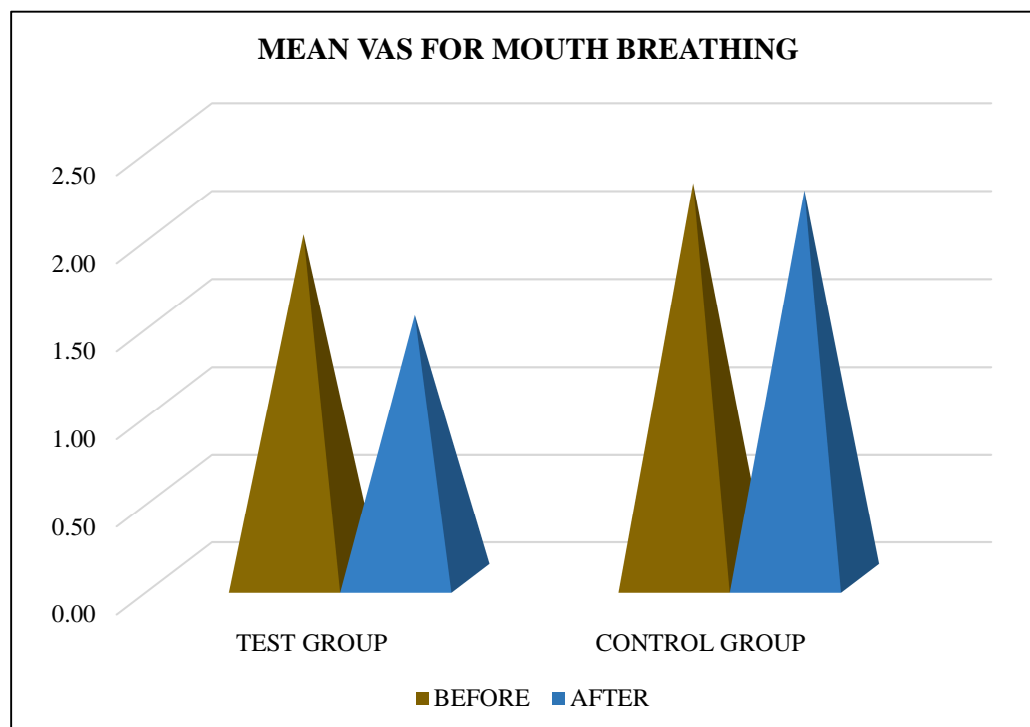


Table 8: Showing the mean VAS score of mouth breathing within the test groups

Test group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
1.96	0.62	1	3	1.50	0.66	1	3	0.0425	S

Table 9: Showing the mean VAS score of mouth breathing within the control groups

Control group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
2.25	0.74	1	3	2.21	0.78	1	3	0.6086	NS

Figure 7: Mouth breathing mean VAS score changes before and after treatment within groups

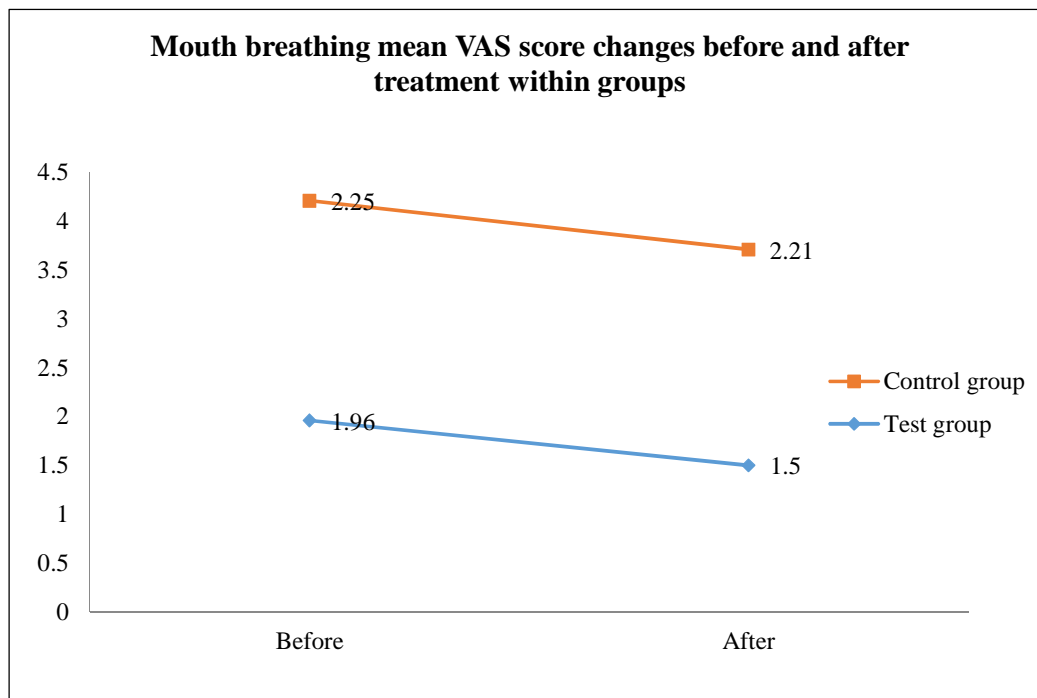
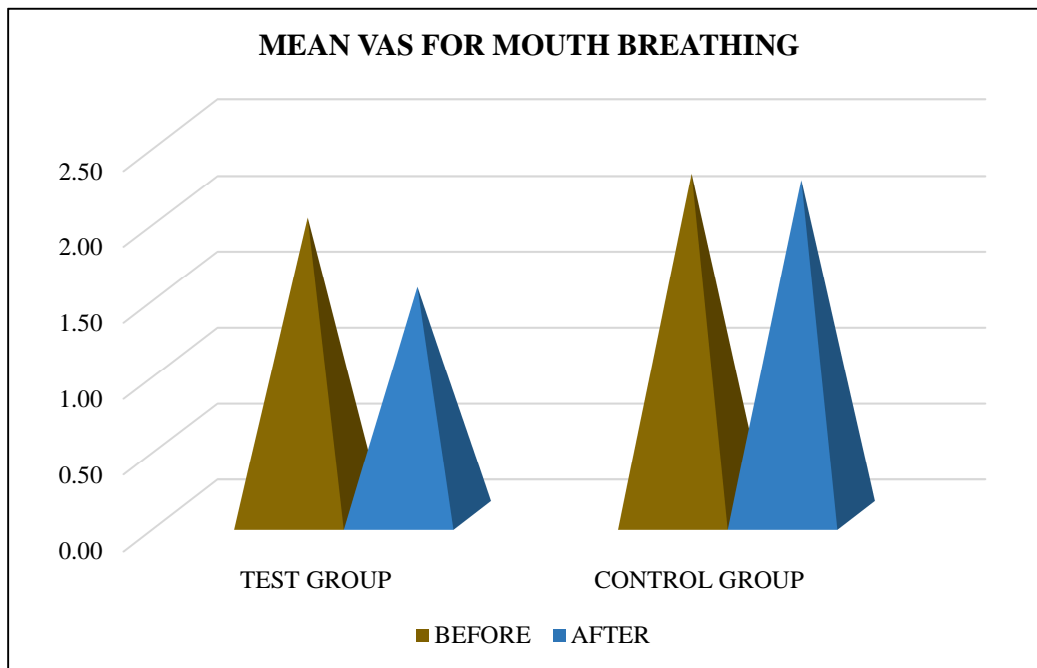


Table 10: Showing the mean VAS score of nasal discharge between the groups

NASAL DISCHARGE	Test group				Control group				p-value	Inference
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BEFORE	0.58	0.93	0	2	1.63	1.01	0	3	0.0006	HS
AFTER	0.33	0.56	0	2	1.17	0.82	0	2	0.0002	HS

Figure 8: Showing the mean VAS score of nasal discharge between the groups

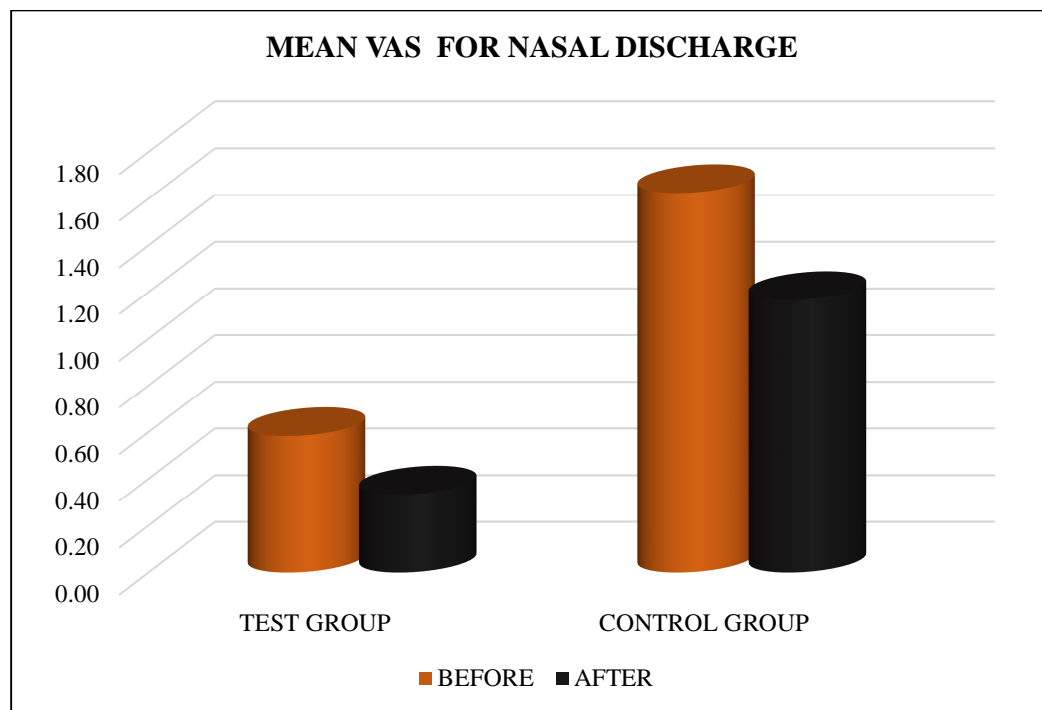


Table 11: Showing the mean VAS score of nasal discharge within the test groups

Test group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
0.58	0.93	0	2	0.33	0.56	0	2	0.0238	S

Table 12: Showing the mean VAS score of nasal discharge within the control groups

Control group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
1.63	1.01	0	3	1.17	0.82	0	2	0.0456	S

Figure 9: Nasal discharge mean VAS score changes before and after treatment within groups

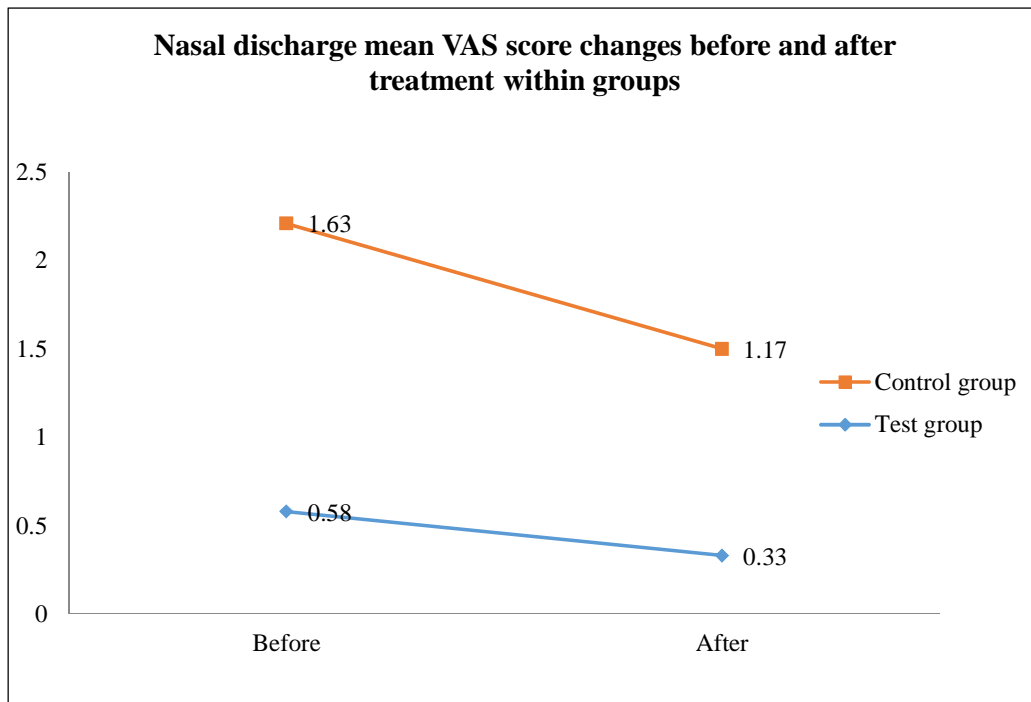
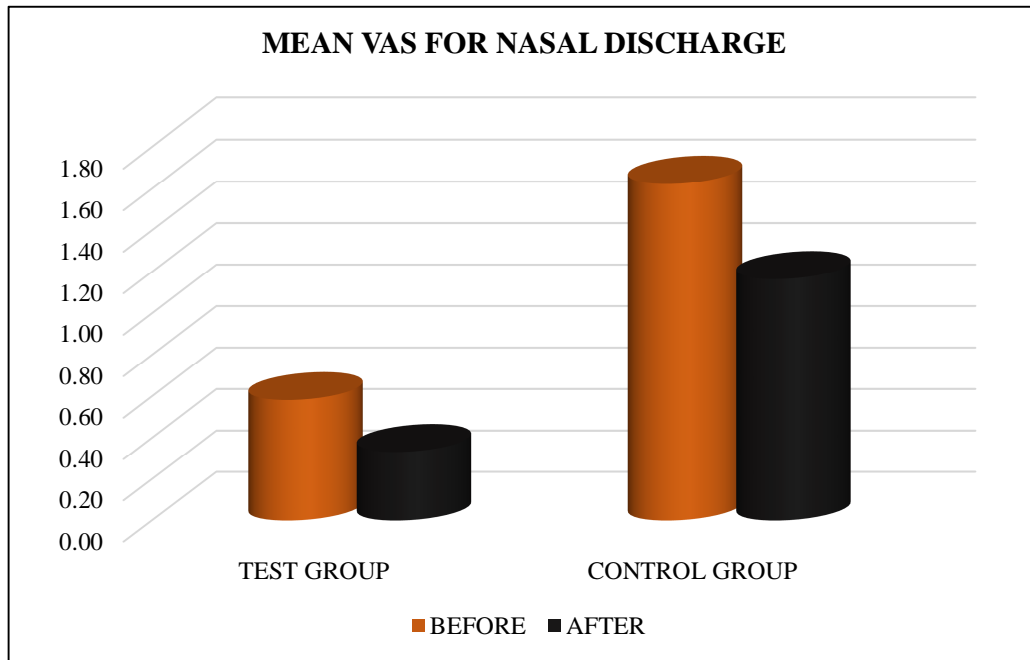


Table 13: Showing the mean VAS score of snoring between the groups.

SNORING	Test group				Control group				p-value	Inference
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BEFORE	1.71	0.69	0	3	2.29	0.55	1	3	0.0022	VS
AFTER	1.17	0.64	0	3	2.21	0.59	1	3	< 0.0001	HS

Figure 10: Showing the mean VAS score of snoring between the groups.

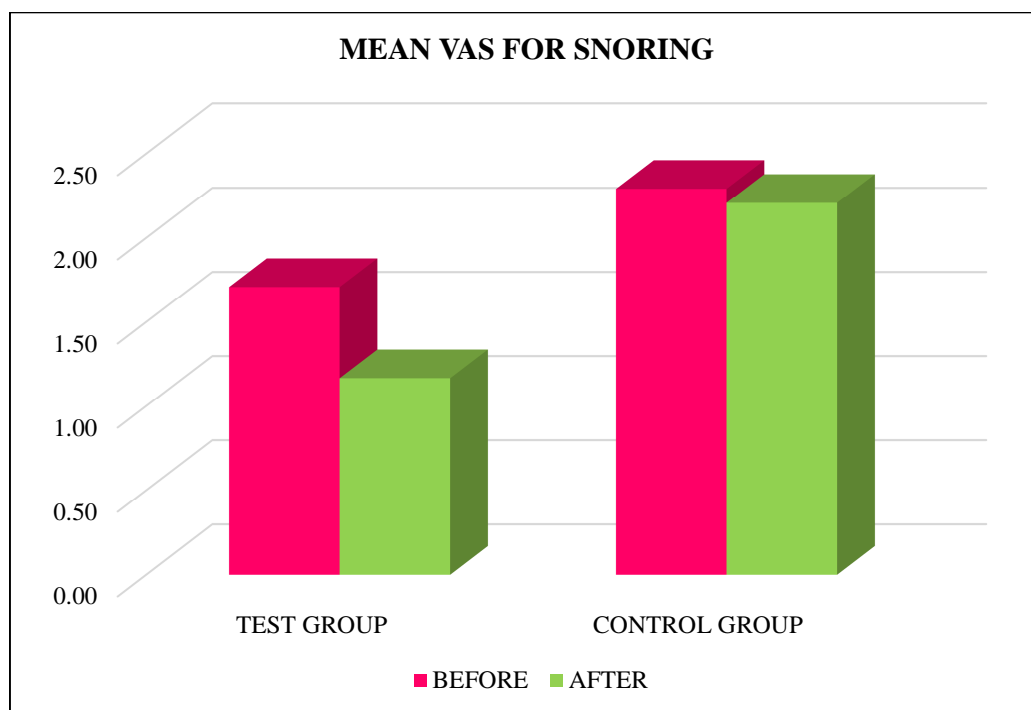


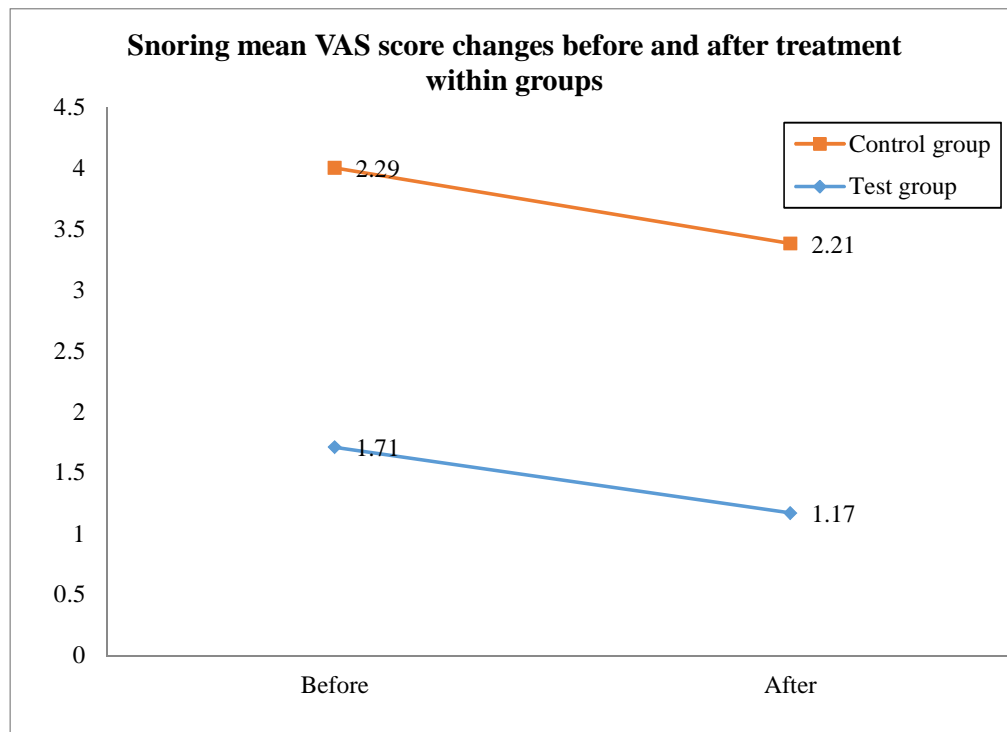
Table 14: Showing the mean VAS score of snoring within the test groups.

Test group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
1.71	0.69	0	3	1.17	0.64	0	3	0.0035	VS

Table 15: Showing the mean VAS score of snoring within the control groups.

Control group								p-value	Inference
Before				After					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
2.29	0.55	1	3	2.21	0.59	1	3	0.3073	NS

Figure 11: Snoring mean VAS score changes before and after treatment within groups



DISCUSSION

Adenoid hypertrophy is an obstructive condition caused by enlarged adenoids. Adenoid hypertrophy can be caused by infectious causes. Pathogens that cause adenoid hypertrophy include both viral and bacterial pathogens. Adenovirus, coronavirus, coxsackievirus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), herpes simplex virus, parainfluenza virus, and rhinovirus are among the viral pathogens linked to adenoid hypertrophy.^[20,21] Because the adenoids typically shrink and retract during puberty, adenoid hypertrophy is more frequent in children than in adults. In children, the prevalence has been estimated at 34.5%.^[22] Adenoid hypertrophy is responsible for some of the more common complications related to disease of the adenoids. As they enlarge the tissues can create a significant obstacle to the flow of air through the nasopharynx. This enlargement can cause mouth breathing, snoring, and OSA. OSA can be a life-threatening disease if left untreated. Removing the adenoids can increase the flow of air through the nasopharynx, decreasing obstructive episodes, and leading to better CPAP compliance or resolution of the condition altogether.^[23]

Enlarged adenoids may also obstruct the opening of the Eustachian tubes in the nasopharynx. Without proper function of the Eustachian tube, negative pressure can build in the middle ear. This negative pressure can lead to the formation of an effusion which can cause conductive hearing loss and speech problems, as well as serve as a nidus for bacterial infections.^[23]

Long-standing adenoiditis with subsequent adenoid hypertrophy can lead to the development of what is known as adenoid facies or long-face syndrome. Enlarged

adenoids can block the nasopharynx and result in obligate mouth breathing, which can lead to craniofacial abnormalities including a high-arched palate and retrognathic mandible.^[23]

The present randomised control study was conducted among all the patients fulfilling inclusion criteria with chronic adenoid hypertrophy presenting to ENT and HNS department of KLES DR Prabhakar Kore Hospital, Belagavi during the study period of 1 year. The present study is aimed to determine whether the additional of intranasal corticosteroids to the standard medical regimen has a better outcomes in reducing the size of adenoids so as to avoid adenoidectomy.

Patients were grouped into two groups based on treatment group which was selected randomly by chit method. The patients were grouped as Group A (Control) with standard antibiotic treatment (amoxicillin/clavulanic 40mg/kg/day) alone for 2 weeks. Group B (Cases/Test) with standard antibiotic added with intranasal steroid spray (mometasone 1 spray 50mcg in each nostril once daily) for 2 weeks.

Total of 48 patients fulfilling inclusion criteria are included in present study after obtaining the informed consent. The patients were randomly allotted into two groups as cases (n=24) and controls (n=24).

There was significant difference in the mean age between the groups. The mean age in cases was 6.83 ± 3.06 and in control it was 10.25 ± 2.47 . ($p < 0.05$) Among the cases, the age group of distribution was majority in 4-8yrs and among the controls it was age group of 8-12yrs. In a study by Venkatesha BK et al., documented the majority of patients in their study were in the age group of 6-10yrs of age.^[24]

Gender distribution was comparable between the groups. Among the cases 70.83% were male and 29.17% were female, similarly in control group 66.67% were male and 33.33% were female. Overall there is male preponderance (male to female ratio of 2.2:1) among the included study in the group with no significant difference in the distribution between the groups. In a study by Pai-Vishwas K et al., documented 48.3% male and 51.7% female with mean age group of 6.7 ± 1.84 in group A and 6.37 ± 2.10 in group B. There was slight female preponderance in their study with female to male ratio of 1.07:1.^[25]

Nasal obstruction score was found to be significantly different between the groups before and after. The mean score of nasal obstruction in cases before treatment (2.17 ± 0.7) and after treatment (1.46 ± 0.66) showing significant reduction. Similarly, in control group the mean score of nasal obstruction showing the significant reduction in mean score before (2.83 ± 0.64) and after (2.25 ± 0.99) treatment. However, the mean reduction in cases (1.46 ± 0.66) is more compared to the controls after (2.25 ± 0.99) treatment.

In study by Venkatesha BK et al. on use of mometasone nasal spray in adenoid hypertrophy, documented the nasal obstruction index in 35 patients had mean symptom score of 0.53 ± 0.11 on day of inclusion in the study. Mean score after intervention by using mometasone nasal spray (100 microgram/day) was 0.38 ± 0.11 , mean difference obtained was 0.15. P values obtained was <0.00 which was statistically significant.

In a study by Rabia Monga et al., documented that, the mean nasal obstructive symptom score after momtesone nasal spray treatment was significantly improved from 12 to 5.8 compared to treatment with saline nasal spray which improved from

12.06 to 11.1, but was not significant. By 8 weeks, the mean nasal obstruction symptom score and adenoid/choana ratio had decreased.^[26]

In another trial, Bhargava and Chakravarti discovered statistically significant decreases in nasal obstruction symptom ratings (2.67 to 0.23; $p=0.001$) after 24 weeks of using mometasone nasal spray.^[27]

In a study by Pai-Vishwas K et al., documented no significant difference in the nasal obstruction symptoms among the patients undergoing the adenoidectomy and patients opted for mometasone nasal spray.^[25]

Mouth breathing mean score was found to be significantly different between the groups after treatment in our study . The mean score of mouth breathing in cases before (1.96 ± 0.62) and after (1.50 ± 0.66) treatment showing reduction. Similarly, in control group the mean score of mouth breathing showing the significant reduction in mean score before (2.25 ± 0.74) and after (2.21 ± 0.78) treatment. However, the mean reduction in cases (1.50 ± 0.66) is more compared to the controls after (2.21 ± 0.78) treatment. Similar to present study Venkatesha BK et al., documented 35 patients had mean mouth breathing symptom score of 2.40 ± 0.50 on day of inclusion in the study. Mean score after using mometasone nasal spray was 1.51 ± 0.51 , mean difference obtained was 0.886.^[24]

In our study nasal discharge mean score was found to be significantly different between the groups. The mean score of nasal discharge in cases before (0.58 ± 0.93) and after (0.33 ± 0.56) treatment showing reduction. Similarly, in control group the mean score of mouth breathing showing the significant reduction in mean score before (1.63 ± 1.01) and after (1.17 ± 0.82) treatment. ($p<0.05$) In a study by Bhat et al.,

discovered that Mometasone furoate nasal spray is beneficial in managing concurrent nasal disorders like as allergic rhinitis and sinusitis, which also contribute to runny nose, particularly in youngsters.^[28]

In our study, snoring mean score was found to be significantly different between the groups before and after treatment.($p<0.05$) The mean score of snoring in cases before (1.71 ± 0.69) and after (1.17 ± 0.64) treatment showing reduction.($p<0.05$) In control group the mean score of snoring showing reduction in mean score before (2.29 ± 0.55) and after (2.21 ± 0.59) treatment however it was not statistical significant. ($p>0.05$).

In study by Venkatesha BK et al., documented 31 patients had mean snoring symptom score of 1.40 on day of inclusion in the study. Mean score after intervention was 0.71, mean difference obtained was 0.686.^[24]

Study by Gupta et al., on snoring caused by adenoids discovered a significant improvement after treatment with mometasone nasal spray in all aspects of obstructive sleep apnea caused by adenoid hypertrophy.^[29] Rezende et al., found that mometasone nasal spray significantly improved nasal blockage when compared to saline nasal spray in another research. There was also a considerable decrease in adenoid area as compared to saline nasal douching, which had no effect on adenoid size^[30]

There was no presence of the day time sleeping, hyponasality and ear popping among the patients included in our study. In study by Venkatesha BK et al., documented hyponasality of voice with 35 patients had mean symptom score of 2.0 ± 0.64 on day of inclusion in the study. Mean score after treatment with mometasone

furoate nasal spray was 1.40 ± 0.60 , mean difference obtained was 0.60. Ear popping was documented in 16 patients had mean symptom score of 1.56 on day of inclusion in the study. Mean score after intervention was 0.94, mean difference obtained was 0.16^[24]

Madiseti S et al., documented that symptom scores improved significantly in the steroid group (mometasone nasal spray) , while no significant improvements were observed in control patients treated with antibiotic (amoxicillin and potassium clavulanate/cefprozil/cefuroxime axetil) along with saline nasal drops and concluded that in children, nasal steroid spray (mometasone nasal spray) is safe and well tolerated. Intranasal steroid therapy may be explored as a therapeutic option in children with adenoid hypertrophy, as well as in individuals who are unwilling or unable to undergo surgery.^[31] In a study done by E J Schenkel et al on use of mometasone furoate nasal spray in children for a year concluded that no evidence of HPA-axis suppression in MFNS-treated subjects at any time point.^[32]

Venkatesha BK et al., documented that Mometasone furoate nasal spray caused improvements in outcomes of nasal obstruction, snoring, total nasal symptoms, ear symptoms and overall quality of life^[24]. Similar to present study, various studies concluded that the intranasal steroid therapy can be considered as a treatment option in children with adenoid hypertrophy and among the patients not willing to undergo or contraindicated for surgery.^{6,7,10,12-14}

CONCLUSION

In current study, there is a significant improvement of symptoms such as nasal obstruction, snoring, mouth breathing, nasal discharge was noticed and quality of life in chronic adenoiditis patients after the addition of corticosteroids to the standard medical regimen.

Mometasone has lower bioavailability and it undergoes extensive first-pass metabolism and there is no clinical evidence that mometasone furoate nasal spray suppresses the function of the hypothalamic–pituitary–adrenal axis when administered locally. Moreover the long term complications and sequelae of surgery such as alteration of immunological system, post operative bleeding, recurrence of adenoids and expenditure of surgery can be avoided.

Hence mometasone can be considered as an alternative to surgery in treating adenoid hypertrophy in chronic adenoiditis patients.

SUMMARY

The present randomised control study was conducted among all the patients fulfilling inclusion criteria with chronic adenoid hypertrophy presenting to ENT and HNS department of KLES DR Prabhakar Kore Hospital, Belagavi during the study period of 1 year. The present study aimed to determine the additional of intranasal corticosteroids to the standard medical regimen has a better efficacy in treating the patients with chronic adenoiditis to avoid the requirement of surgical procedure.

Patients were grouped into two groups based on treatment group which was selected randomly by chit method. The patients were grouped as

Group A (Control) with standard antibiotic treatment (amoxicillin/clavulanic 40mg/kg/day) alone for 2 weeks.

Group B (Cases) with standard antibiotic added with intranasal steroid spray (mometasone 1 spray 0mcg in each nostril once daily) for 2 weeks.

Total of 48 patients fulfilling inclusion criteria are included in present study after obtaining the informed consent. The patients were randomly allotted into two groups as cases (n=24) and controls (n=24).

- There was significant difference in the mean age between the groups. The mean age in cases was 6.83 ± 3.06 and in control it was 10.25 ± 2.47 . ($p < 0.05$)
- Among the cases, the age group of distribution was majority in 4-8yrs and among the controls it was age group of 8-12yrs.

- Gender distribution was comparable between the groups. Among the cases 70.83% were male and 29.17% were female, similarly in control group 66.67% were male and 33.33% were female.
- Overall there is male preponderance (male to female ratio of 2.2:1) among the included study in the group with no significant difference in the distribution between the groups.
- Nasal obstruction score was found to be significantly different between the groups before and after.
 - The mean score of nasal obstruction in cases before (2.17 ± 0.7) and after (1.46 ± 0.66) treatment showing significant reduction. Similarly, in control group the mean score of nasal obstruction showing the significant reduction in mean score before (2.83 ± 0.64) and after (2.25 ± 0.99) treatment. However, the mean reduction in cases (1.46 ± 0.66) is more compared to the controls after (2.25 ± 0.99) treatment.
- Mouth breathing mean score was found to be significantly different between the groups after.
 - The mean score of mouth breathing in cases before (1.96 ± 0.62) and after (1.50 ± 0.66) treatment showing reduction. Similarly, in control group the mean score of mouth breathing showing the significant reduction in mean score before (2.25 ± 0.74) and after (2.21 ± 0.78) treatment. However, the mean reduction in cases (1.50 ± 0.66) is more compared to the controls after (2.21 ± 0.78) treatment.
- Nasal discharge mean score was found to be significantly different between the groups.

- The mean score of nasal discharge in cases before (0.58 ± 0.93) and after (0.33 ± 0.56) treatment showing reduction. Similarly, in control group the mean score of mouth breathing showing the significant reduction in mean score before (1.63 ± 1.01) and after (1.17 ± 0.82) treatment. ($p < 0.05$)
- Snoring mean score was found to be significantly different between the groups before and after treatment. ($p < 0.05$)
 - The mean score of snoring in cases before (1.71 ± 0.69) and after (1.17 ± 0.64) treatment showing reduction. ($p < 0.05$) In control group the mean score of snoring showing reduction in mean score before (2.29 ± 0.55) and after (2.21 ± 0.59) treatment however it was not statistical significant. ($p > 0.05$) However, the mean reduction in cases (1.17 ± 0.64) is more compared to the controls after (2.21 ± 0.59) treatment.
- There was no presence of the day time sleeping, hyponasalality and ear popping among the patients included in the study.

LIMITATION

The limitation of the study is that, it is a single centric study conducted among small sample size with single intervening drug treatment. The study follow-up is for short period, the long term follow-up can be planned to study the efficacy and side effects of the drug. The study also can be extended to compare with the symptoms improvement between the adenoidectomy and the nasal steroid spray groups.

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ANNEXURES

ANNEXURE -1

INFORMED CONSENT

“TO COMPARE THE EFFICACY OF ADDITION OF MOMETASONE NASAL SPRAY TO THE STANDARD MEDICAL TREATMENT IN REDUCTION OF ADENOID HYPERTROPHY IN CHRONIC ADENOIDITIS: A ONE YEAR RANDOMISED CONTROL STUDY”

PRINCIPAL INVESTIGATOR : _____

CO-INVESTIGATOR : _____

INTRODUCTION AND PURPOSE:

The present study is conducted among patients who have adenoid hypertrophy in ENT & HNS department in KLES Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi for symptoms due to adenoid hypertrophy .I hereby request you to voluntarily participate for the same.

PROCEDURE:

If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed.

After getting inducted in the study, you will be evaluated with anterior rhinoscopy, posterior rhinoscopy, X-ray of nasopharynx lateral view and diagnosis will be made accordingly .Mometasone furoate nasal spray will be administered and its efficacy will be assessed .

BENEFITS:

Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS:

Methods applied to do the study are safe.

COST OF PARTICIPATION:

The cost of the routine investigations will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY:

The results of the study may be published in journals for scientific purposes. However your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However your identity will not be revealed.

QUERIES AND CONTACT:

If you have any query about rights as a research participant you can contact Dr.Roopam Bellad, Professor, Department of Paediatrics and Chairman, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects research.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness (Relative):

Signature of the guide:

Date:

ANNEXURE-II

PROFORMA

**“TO COMPARE THE EFFICACY OF ADDITION OF MOMETASONE NASAL
SPRAY TO THE STANDARD MEDICAL TREATMENT IN REDUCTION OF
ADENOID HYPERTROPHY IN CHRONIC ADENOIDITIS : A ONE YEAR
RANDOMISED CONTROL STUDY”**

Date:

O.P. No:

IP No:

Name:

Age:

Sex:

Occupation:

Address:

Phone No:

D.O.A D.O.D

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness

Past History:

Personal History:

Family History:

Physical Examination:

I) General Physical Examination -

Vital Pulse

Blood pressure- Respiratory Rate-

Pallor Icterus Clubbing Cyanosis

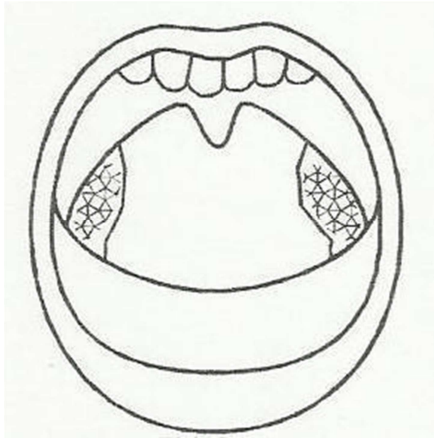
Lymphadenopathy Oedema

II) ENT Examination 1.NOSE EXAMINATION

External appearance

- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella Tip elevation test

2. ORAL CAVITY and OROPHARYNX:

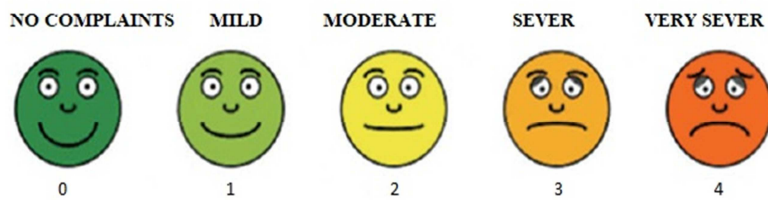


2. NECK EXAMINATION :

Diagnosis:

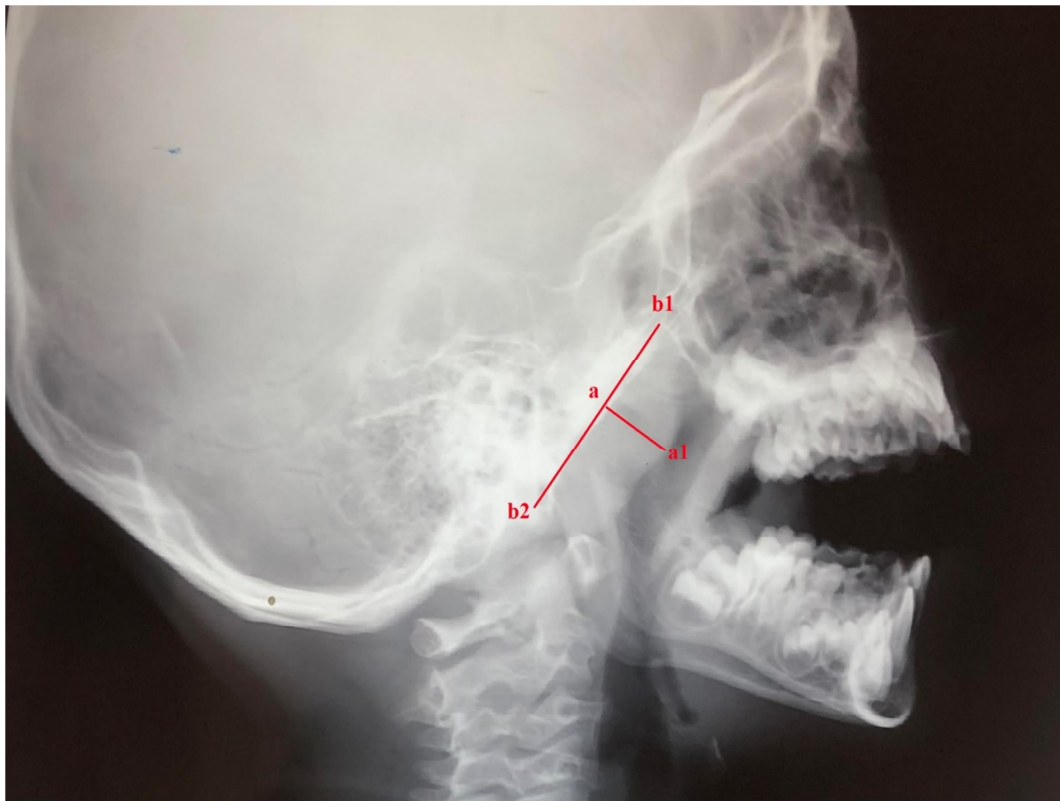
X-ray OF NASOPHARYNX LATERAL VIEW

SYMPTOMS SCORING - VISUAL ANALOGUE SCALE



ANNEXURE –III

PHOTOGRAPH



Photograph-1 X- Ray Nasopharynx lateral View

The adenoidal measurement represents the distance from the point of maximal convexity of the adenoid shadow (a1-Figure 3) antero-inferiorly to the anterior margin of the basiocciput (a-Figure 3).

The nasopharyngeal measurement represents the distance between the posterior border of the hard palate and sphenobasiocciput synchondrosis (b1-b2 Figure 3)

ANNEXURE - IV

KEY TO MASTER CHART

AGE- in years

SEX - Male & Female

GROUPS

- **Control** – Antibiotic (amoxicillin/clavulanic 40mg/kg/day) alone for 2 weeks.
- **Test** – Antibiotic plus intranasal steroid spray (mometasone 1 spray 50mcg in each nostril once daily) for 2 weeks

SYMPTOMS SCORING – Visual Analogue Scale

- 0- No sympoms
- 1- Mild symptoms
- 2- Moderate symptoms
- 3- Sever symptoms
- 4- Very sever symptoms

ANNEXURE -V

MASTER CHART

SL NO	Name	AGE	SEX	C/T	SYMPTOMS (vas scoring)													
					nasal obstruction		mouth breathing		nasal discharge		snoring		day time sleeping		hyponasality		ear popping	
					before	after	before	after	before	after	before	after	before	after	before	after	before	after
1	VIJAY KUMAR	14	M	C	3	2	2	2	2	1	2	2	0	0	0	0	0	0
2	ABISHEK	9	M	T	2	1	2	1	2	2	2	1	0	0	0	0	0	0
3	RACHANA	10	M	C	3	2	3	3	3	2	2	2	0	0	0	0	0	0
4	ALFMA	7	F	T	3	1	2	1	2	1	2	1	0	0	0	0	0	0
5	SOUJANYA	7	F	T	2	1	2	1	0	0	1	1	0	0	0	0	0	0
6	BASAVARAJ	2	M	T	1	1	2	1	2	1	1	1	0	0	0	0	0	0
7	KUSHI	6	F	C	2	1	2	2	2	1	2	2	0	0	0	0	0	0
8	MALLIKARJUN	4	M	C	2	2	1	1	2	1	2	2	0	0	0	0	0	0
9	SAMARTH	12	M	C	3	2	3	3	0	0	3	3	0	0	0	0	0	0
10	PRATIKSHA	11	F	C	3	3	3	3	2	2	3	3	0	0	0	0	0	0
11	KARIAPPA	10	M	T	2	1	2	1	0	0	2	1	0	0	0	0	0	0
12	KAMAL	13	M	C	3	3	2	2	2	1	2	2	0	0	0	0	0	0
13	ASHVITH	4	M	T	2	1	2	1	0	0	2	2	0	0	0	0	0	0
14	SAMARTH K	10	M	C	3	2	2	2	2	2	3	2	0	0	0	0	0	0
15	SANVI	4	F	T	1	1	1	1	2	1	1	1	0	0	0	0	0	0
16	MOHD KAIF	6	M	T	2	1	2	1	0	0	2	1	0	0	0	0	0	0
17	ABHIMANYU	9	M	T	3	2	2	2	0	0	2	1	0	0	0	0	0	0
18	SHARAN RAJ	8	M	C	4	4	3	3	2	2	2	2	0	0	0	0	0	0
19	ZEEYAN	8	M	C	3	2	2	1	0	0	1	1	0	0	0	0	0	0
20	SAHARSH	6	M	T	2	2	2	1	0	0	2	1	0	0	0	0	0	0

21	JANESH	12	M	C	3	3	2	2	2	1	2	2	0	0	0	0	0	0
22	AYAN C	12	M	C	4	4	3	3	2	2	3	3	0	0	0	0	0	0
23	NAUMAN T	10	M	T	3	2	3	2	0	0	2	1	0	0	0	0	0	0
24	GANESH	8	M	C	3	2	2	2	2	2	2	2	0	0	0	0	0	0
25	VAISHNAVI	7	F	T	2	1	2	1	0	0	2	1	0	0	0	0	0	0
26	KUSHI RAMESH	10	F	C	3	3	3	3	0	0	3	3	0	0	0	0	0	0
27	TEJASWANI	12	F	C	4	4	3	3	2	2	3	3	0	0	2	2	0	0
28	SAHARSH	6	M	T	3	2	3	2	0	0	2	1	0	0	0	0	0	0
29	ATHARVA	3	M	T	2	1	2	2	2	1	1	1	0	0	0	0	0	0
30	SHREYA M	11	F	T	3	2	2	2	0	0	2	1	0	0	0	0	0	0
31	MALLIKARJUN R	14	M	C	3	3	3	3	3	2	3	3	0	0	0	0	0	0
32	PHAJAL	12	M	C	2	1	2	2	0	0	2	1	0	0	0	0	0	0
33	ABHISHEK B	12	M	T	3	3	3	3	0	0	3	3	0	0	0	0	0	0
34	MANIKANT	13	M	T	1	1	1	1	2	1	1	1	0	0	0	0	0	0
35	ROHIT	10	M	T	2	1	2	2	0	0	2	1	0	0	0	0	0	0
36	MOHD ZEESHAN	3	M	T	3	2	2	2	0	0	2	1	0	0	0	0	0	0
37	NANDA DODDAMANI	12	F	C	2	1	1	1	2	1	2	2	0	0	0	0	0	0
38	RENUKA PATIL	7	F	T	3	3	3	3	0	0	3	3	0	0	0	0	0	0
39	SAJEED BUDIHAL	4	M	T	1	1	1	1	2	1	1	1	0	0	0	0	0	0
40	PREETAM	8	M	C	2	1	1	1	2	1	2	2	0	0	0	0	0	0
41	KRUTIKA	10	F	C	3	3	3	3	2	2	3	3	0	0	0	0	0	0
42	CHANDAN PRAKASH	4	M	T	2	1	2	2	0	0	2	1	0	0	0	0	0	0
43	VAISHALI	12	F	C	3	2	2	2	0	0	2	2	0	0	0	0	0	0
44	MANVITA	5	F	T	2	2	1	1	0	0	0	0	0	0	0	0	0	0
45	SURYAKANT	5	M	T	2	1	1	1	0	0	1	1	0	0	0	0	0	0
46	AMOGH	8	M	C	2	1	2	2	0	0	2	2	0	0	0	0	0	0
47	ASHWINI	10	F	C	2	1	1	1	2	1	2	2	0	0	0	0	0	0
48	URMAN	10	M	C	3	2	3	3	3	2	2	2	0	0	0	0	0	0