"ROLE OF NASAL CORTICOSTEROID SPRAY & IT'S EFFECTS IN ALLERGIC RHINITIS IN RELATION TO N.O.S.E SCORE & NASAL SMEAR EOSINOPHILIA IN KLES DR.PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTER BELGAUM: 1 YEAR OBSERVATIONAL STUDY"

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ROLE OF NASAL CORTICOSTEROID SPRAY & IT'S EFFECTS IN ALLERGIC RHINITIS IN RELATION TO N.O.S.E SCORE & NASAL SMEAR EOSINOPHILIA IN KLES DR. PRABHAKAR KORE CHARITABLE HOSPITAL BELGAUM: 1 YEAR OBSERVATIONAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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ABBREVIATIONS

AEC	ABSOLUTE EOSINOPHIL COUNT
AR	ALLERGIC RHINITIS
ECP	EOSINOPHIL CATIONIC PROTEIN
IG	IMMUNOGLOBULIN
IL	INTERLEUKINS
ISAAC	INTERNATIONAL STUDY OF ASTHMA AND ALLERGIES IN CHILDHOOD
LNP	LATERAL NASAL PROMINENCE
MNP	MEDIAL NASAL PROMINENCE
NOSE	NASAL OBSTRUCTION SYMPTOM EVALUATION
PGD	PROSTAGLANDIN D
TH	TYPE 2 HELPER
WHO	WORLD HEALTH ORGANISATION

ABSTRACT

Background: Nasal Obstruction Symptom Evaluation score is a simple method to assess the severity of the symptoms of Allergic Rhinitis. The Present study was done to know the effect of Nasal corticosteroid spray in Allergic Rhinitis in relation to N.O.S.E score & Nasal smear eosinophilia in KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre Belgaum.

Material & Method: This prospective observational study was conducted among the patients of Allergic Rhinitis visiting ENT & HNS Department, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgaum for 1 year. A total of 50 patients fulfilling inclusion criteria are included in study after obtaining the informed consent. All the nasal smears collected for nasal smear eosinophilia were co-related with AEC before & after treatment with intranasal corticosteroid spray & was followed up after 3 months.

Result: The mean age of patients is 32.48±12.77, with 40% female participants and 60% were male participants. The male to female ratio in 1.5:1, with male preponderance. The Nasal smear eosinophil before treatment was found to be significantly higher (5.023±2.01) compared to after treatment count (0.444±0.08), with $p<0.05$. The NOSE score was found to be significantly higher before treatment (47.1±1.56) compared to after treatment (16.40±0.85), with $p<0.05$. There is a moderate strength of association between the Nasal smear eosinophil count with AEC ($r=0.450$, $p<0.05$) and weak strength of positive correlation between the NOSE score with the AEC ($r=0.201$, $p<0.05$).

Conclusion: Nasal corticosteroid spray is effective in Allergic Rhinitis in relation to both NOSE score & NSE. NOSE score is better indicator of control of Allergic Rhinitis compared to NSE. The examination of NOSE score is simple, inexpensive, and non-invasive. As a result, it can be utilised as a replacement for AEC value in clinical settings.

Keywords: NOSE score, Rhinitis, AEC, Nasal Smear,

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INTRODUCTION

Allergic rhinitis is a common health issue world-wide affecting the life quality. Early recognition and diagnosis is important. Absolute Eosinophil Count is the fastest tool to recognise at the earliest.

The N.O.S.E score is simple, easier, and faster method used in various studies of nasal obstruction which can be followed up before and after treatment with intra-nasal corticosteroid spray.[3]

Etiology of allergic rhinitis is identified using a nasal smear for eosinophilia. Because of uncertainty in its reliability and validity, it is not frequently used in diagnosis of allergic rhinitis.[2]

As eosinophils play main role in Allergic Rhinitis, correlating AEC & Nasal smear eosinophilia would be very useful to see severity before & after treatment.

Need for study is to see how effective Intranasal corticosteroid spray Fluticasone Proprionate in this study will play in patients of Allergic Rhinitis.

As N.O.S.E scale is utilised to know the acerbity of symptoms after course of treatment, this can help determine up to what extent intranasal steroid spray would help patient on follow up basis after 3 months.

AIMS & OBJECTIVES

Aim: To know the effect of Nasal corticosteroid spray in Allergic Rhinitis in relation to N.O.S.E score & Nasal smear eosinophilia in KLEs Dr. Prabhakar Kore Hospital & Medical Research Center Belgaum.

Objective:

- To measure the N.O.S.E score in allergic rhinitis.
- To estimate Nasal Smear Eosinophilia (NSE) count in allergic rhinitis.
- Correlate N.O.S.E score with the Nasal Smear Eosinophilia count among the patients with allergic rhinitis.

REVIEW OF LITERATURE

Specific type of atopic disorder allergic rhinitis causes nasal blockage, rhinorrhoea, nasal itiching and sneezing. In immediate phase, there is IgE-mediated immunological response to inhaled antigens, followed by late phase mediated by leukotriene.

In India, cases of allergic rhinitis is 20% - 30%. According to studies, prevalence of allergic rhinitis is growing every year.[4]

Brief relevant anatomy:

Role of nasal cavity is humidification of air inspired. Muco-ciliary clearance of tiny particles in nasal mucosa is aided by mucus secreted by epithelial layer.[5]

Maxillary, frontal, sphenoid & ethmoid sinuses are air filled mucosal lined sinuses that surround nasal cavity.[5]

External nasal valve is 1st part noticed when approaching from anterior to posterior direction. Respiratory epithelium is lined by pseudostratified ciliated columnar epithelium.[6,7]Cribriform plate can be reached through tiny perforations in mucosa of nasal cavity's roof.

- Posteriorly: Body of sphenoid bone & Cribriform plate of ethmoid,
- Anteriorly: Nasal bone & Nasal spine of frontal bone,

Nasal cavity's floor is wider than its ceiling.[6]

- Anteriorly: Maxillary palatine process.
- Laterally: Palatine bone's horizontal plate.

Anterior part of septum contains Kiesselbach plexus.[8]

Attachments:

- Nasal bone superiorly.
- Maxillary nasal spine antero-inferiorly.
- Perpendicular plate a part of ethmoid bone, posteriorly & superiorly.
- Vomer and maxillary crest located posterior-inferior.

Nasal cavity sinuses:

Largest sinuses are maxillary sinuses, found in face. Floor of orbit fits roof of sinus. This wall is fragile. Centre portion of maxillary sinus roof houses infraorbital nerve. Maxillary sinus's floor is created by alveolar process of hard palate and maxilla. Maxillary bone's anterior surface creates sinus's anterior wall and divides sinus from cheek. Ostium also acts as an entrance point for majority of nerves and blood vessels. Accessory ostium can be seen in roughly 1/3rd population. Anterior and posterior fontanelles are names given to these ostia.[9]

Ethmoid sinus is complicated bone labyrinth of thin-walled cells in anterior base of skull. About 6-10 ethmoid cells are found in adults.[9] Orbital plate and lamina papyracea is made of labyrinth's lateral wall. Frontal bone forms roof's anterior portion, and sphenoid bone's body and palatine bone's orbital process constitute roof's posterior portion. Depending on where they are located within ethmoidal complex and where middle turbinate is attached, cells are categorised as posterior or anterior ethmoid cells. While posterior ethmoid cell drains into superior meatus, anterior ethmoid cell empties into middle meatus infundibulum.

Frontal sinuses are most variable and essentially unique. Up to 5% of people have agenesis of either one or both frontal sinuses. Posterior wall of frontal sinus corresponds to anterior wall of anterior cerebral fossa. Sinus can enter middle meatus' anterior region thanks to frontonasal duct.

Sphenoid sinus: Frontal sinuses have highest variation and are virtually as unique as fingerprints. Agenesis of one or both frontal sinuses affects up to 5% of the population. Posterior wall of the frontal sinus corresponds to the anterior wall of the anterior cerebral fossa. The sinus cavity's floor shapes the top portion of the orbits. They are roughly L-shaped, with horizontal and vertical compartment. The frontonasal duct allows the sinus to enter anterior section of the middle meatus.[9]

Functions of paranasal sinuses:

Cilia beats the mucus blanket toward the ostium. The functions of the sinuses are debatable. Promotes facial harmony and make cranium lighter. They can also be viewed as a brain protective. The air conditioning, voice resonance chambers, or sense of smell, are likely less.[10]

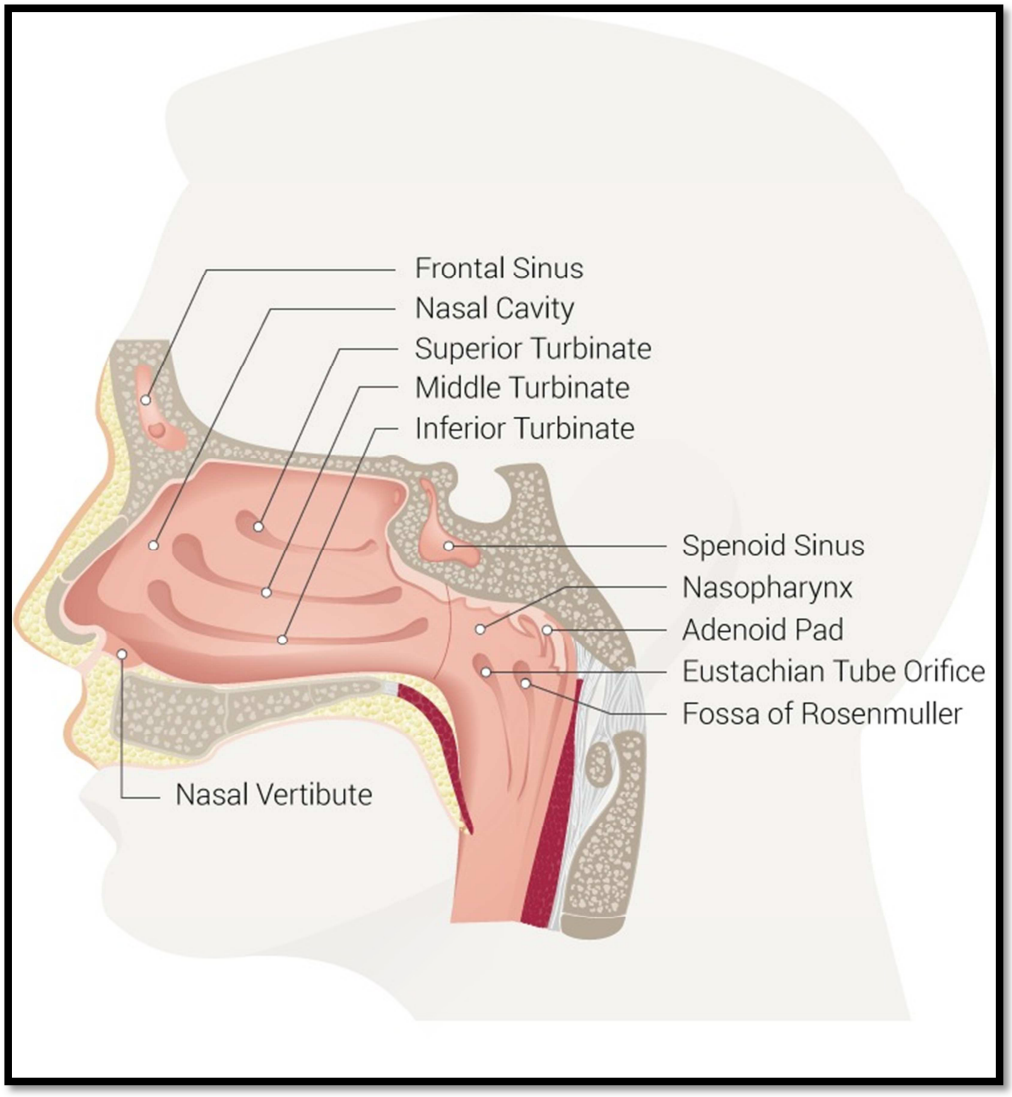

Figure 1: Nasal cavity, frontal sinus and superior turbinate[11]

Embryology:

After 4th week of intrauterine life, oval thickenings of surface ectoderm form inferior and lateral to frontonasal prominence. They have mesenchyme on outer borders, which starts to multiply and produce medial and lateral nasal. Nasal alae are formed by LNP. Septum, ethmoid, and cribriform plate are all formed by MNP.[14,15]

As maxillary prominences grow, nasal structures migrate medially. After 6th week, maxillary prominences start to merge at nasolacrimal groove with LNP. Between 6th and 8th week of pregnancy, choanae begin to fuse nasal and mouth cavities. 5 ethmoturbinals start to produce on nasal cavity's lateral wall at same moment .[14–16]

A) Agger nasi cells and uncinate process

B) Ethmoid bulla

C) Basal lamella of the middle turbinate

D) Superior turbinate

E) Supreme turbinate

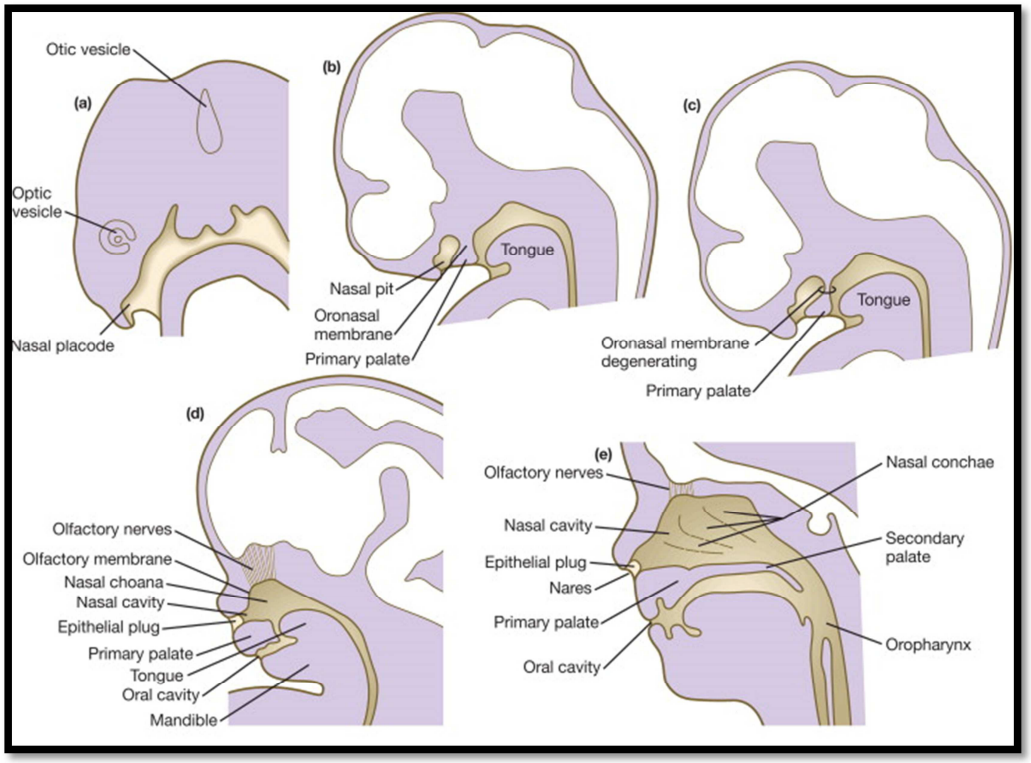

Figure 2: Development of nasal cavity[17]

Blood supply:

External & internal carotid, maxillary, facial artery, Kiesselbach's, and Woodruff's plexus, as well as other blood vessels, deliver blood to nasal septum.

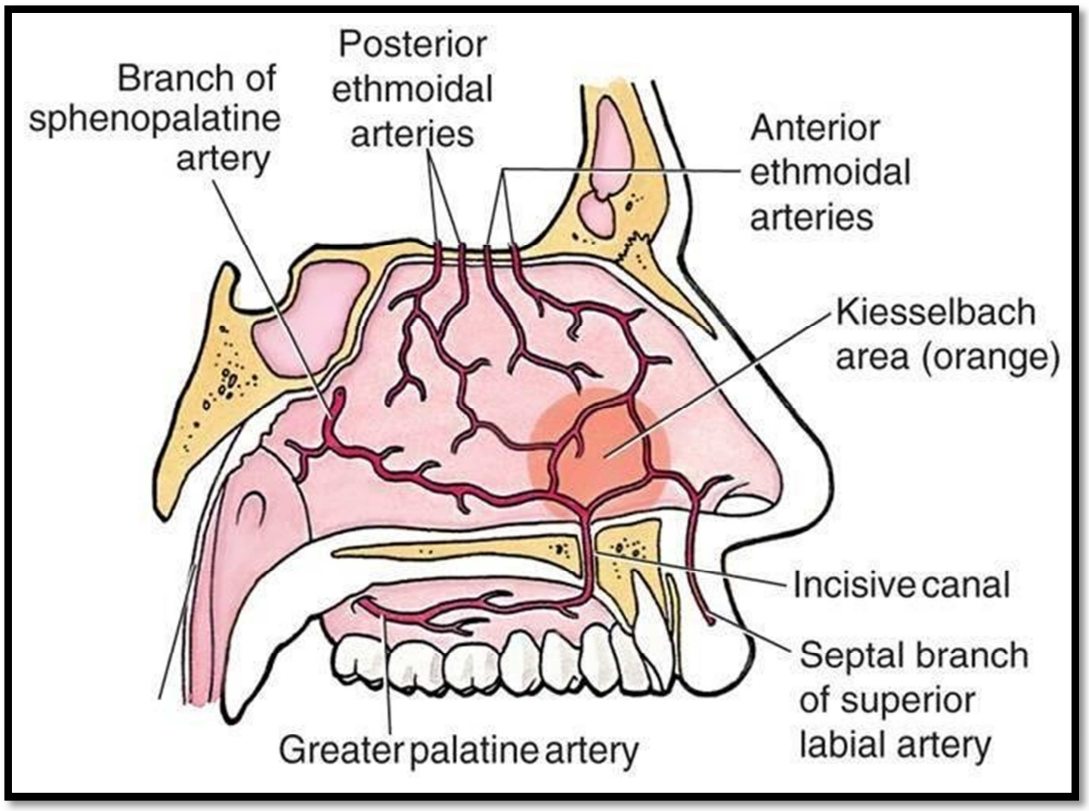

Figure 3: Blood supply of septum[17]

Lymphatics:

Level IB is where anterior nasal part drains. Retropharyngeal lymph nodes and posterior nasal part of sinuses drain into upper cervical group of lymph nodes.[18,19]

In addition to nasal blockage, postnasal drip, rhinorrhea, nares itching and sneezing, allergic rhinitis is an atopic condition.[20] It can be characterised as intermittent or chronic, with roughly 20% and 40% respectively.[21] It is curable once identified, intra-nasal glucocorticoids being 1st line treatment.

Epidemiology:

It affects 10 to 30% of childrens and adults in developed nations.[22,23] Age group of 6 to 7 years and 13 to 14 years, the overall prevalence of rhino-conjunctivitis was 8.5 and 14.6 percent, respectively. Intermittent type of allergic rhinitis appears to be more frequent in children, but chronic rhinitis is higher in adults.[26]

According to a 2018 systematic study, 3.6 percent of individuals missed work and 36 percent reported reduced job performance owing to allergic rhinitis. Economic analyses have revealed that the bulk of the financial burden for AR is accounted for by indirect expenses related with reduced job productivity.[27]

Risk factors:

- Atopy family history
- Male gender
- Birth at the season of pollen
- Firstborn status
- Use of early antibiotics
- Smoking exposure among mother during 1st year of life.
- High immunoglobulin E (IgE) levels >100IU/ml before the age of 6m.[28–30]

Breastfeeding's role in the development of AR is frequently contested, although it is still encouraged owing to its numerous other recognised advantages and lack of related hazards. There is no evidence that avoiding pets as a youngster reduces AR; nevertheless, early exposure may promote immunological resistance.[31,32]

Etiology:

Reaction starts on exposure to allergen within few minutes, culminating in degranulation of mast cells. This results in the release of a number freshly synthesised mediators.

Histamine causes sneeze by activating the trigeminal nerve and also contributes to rhinorrhea. Leukotrienes and prostaglandins are also responsible in causing nasal congestion by acting on blood vessels. Four to six hours after the initial reaction, mast cells begin to release cytokines including interleukin IL-4 and IL-13, establishing the late phase response. These cytokines promote eosinophil, T-lymphocyte, and basophil infiltration in the nasal mucosa, resulting in nasal edema and congestion.[32]

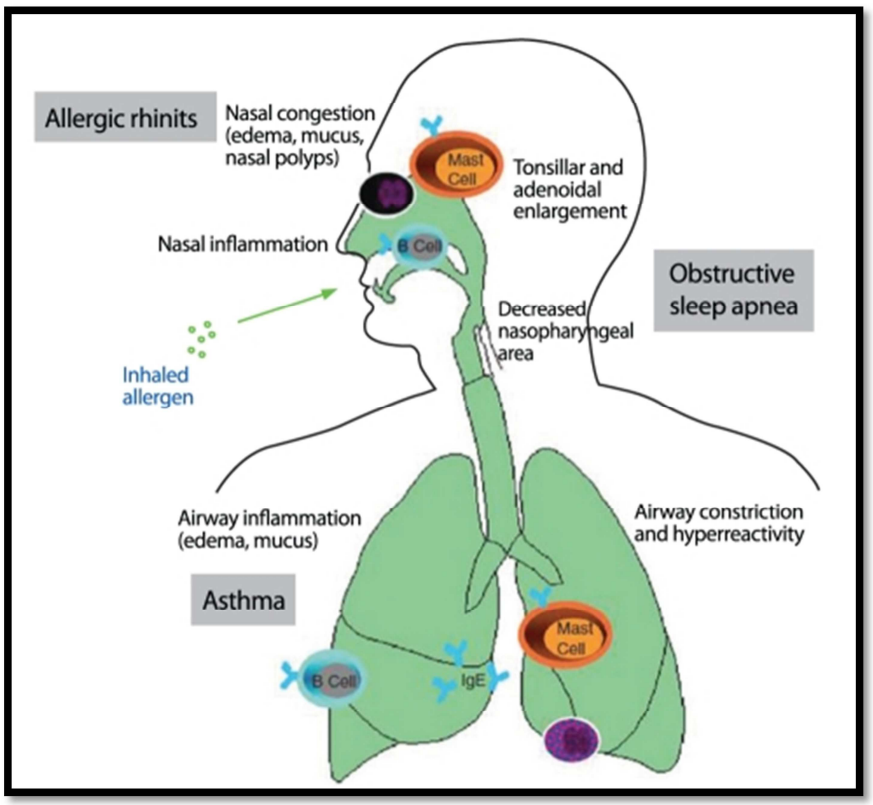

Figure 4: Chronic allergic respiratory syndrome[32]

Early and late phase:

Antigen presentation cells select antigens, prepare them, and then deliver them to helper T cells. Helper T cells that have been activated release IL-13 and IL-4 work with B cells to promote the synthesis of an allergen specific to IgE. The high affinity receptors on the surface of mast cells are then bound by it.

Early stage response:

Begins minutes after allergen exposure and lasts for 2-3 hours. Degranulation of mast cells is a crucial part of this stage. It is brought on by mast cells degranulating and releasing a variety of mediators. Sneezing is brought on by the primary mediator, histamine, which activates trigeminal nerve. Histamine, combined with prostaglandins and leukotrienes that act on blood vessels, activates mucous glands, causing mucus production (rhinorrhea), which causes nasal congestion.[32,33]

Late-phase reaction:

It occurs 4-6 hours after stimulation of antigen`, frequently follows early phase response. This phase is characterized by persistent features of sneezing and and continuous nasal congestion lasting 18-24 hours. It is inflammatory in nature, with an inflammatory cellular influx containing T-cells, basophils, and eosinophils.[32,33] Mediators in this phase include major basic protein (MBP), platelet activating factor, and eosinophil cationic protein (ECP).[34]

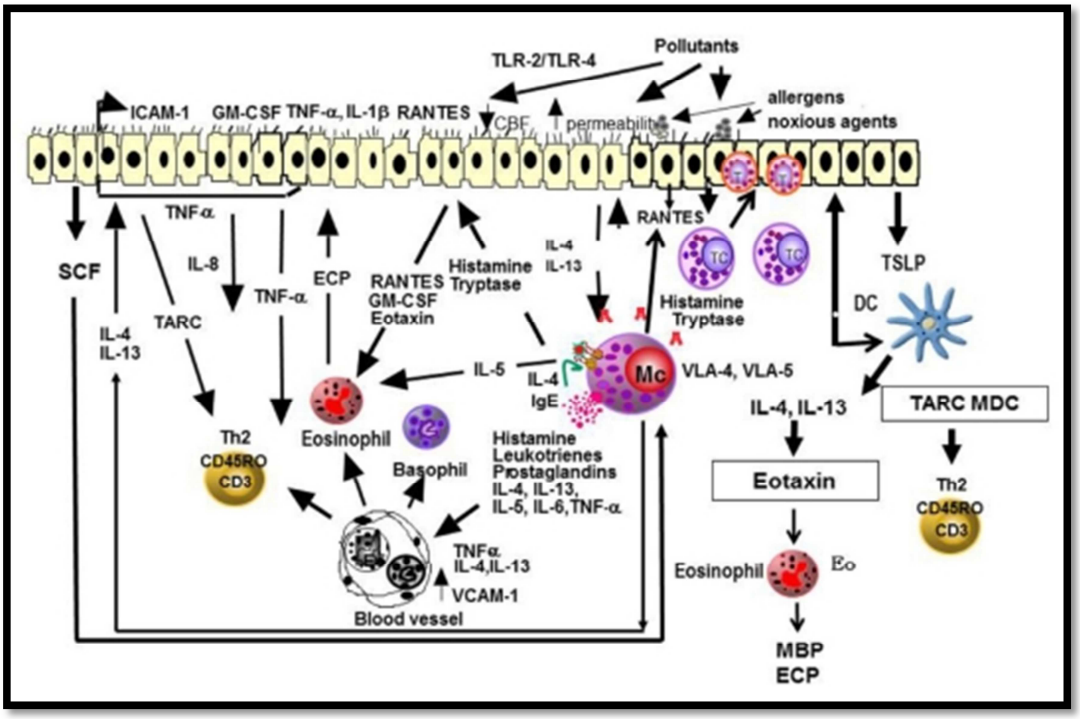

Figure 5: Ongoing inflammation in allergic rhinitis[33]

Basophil concentration in nasal discharge is inversely correlated with sickness severity. Basophils are mostly active in this phase and generate histamine, IL-4 and IL-13 in response to FcRI-dependent activation.

Due to their critical role in chronic allergy diseases, eosinophils are important targets for basic and clinical research.[35] Chemokines such RANTES and eotaxin36 also encourage eosinophil migration.

Cytokines like IL-5 and GM-SCF maintain eosinophils alive within the tissue lasting days or weeks, preventing apoptosis. MBP, ECP, EDN, and eosinophil peroxidase are found in mature eosinophils and function in immunological processes of allergic inflammation, particularly in alteration of the surface epithelium.[32,37]

Clinical manifestations

The allergic rhinitis presents with [21,38,39]

- Paroxysms of sneezing
- Nasal discharge
- Nasal congestion
- Nasal pruritis
- Irritability

Pattern of symptoms

Table 1: Classification:

Intermittent – taking place over the course of four weeks or four days per week.
Persistent- Lasting for more than four weeks or more than four days per week.
Mild indicates the absence of the following symptoms: Sleep disturbance Day-to-day activity impairment, impairment of work.
Moderate-severe: When one or more of the following symptoms are present, it is considered to be "moderate-severe": Sleep disruption. Deterioration of regular chores, leisure time, or athletics. Detriment to studies or employment.

An worldwide panel of 34 respiratory allergy specialists, with partnership of WHO, suggested this categorization scheme. The WHO addressed allergic rhinitis because of its influence on asthma, which is consistent with consensus asthma guidelines.

Physical findings[21]

In individuals with active allergic rhinitis, following physical signs may be present:

- Infraorbital edema and darkening caused by subcutaneous venodilation, sometimes known as "allergic shiners."
- Dennie-Morgan lines inferior to the eye lid suggestive of allergic conjunctivitis.
- A transverse nasal crease formed due to rubbing the tip of nose with palm repeatedly known as “allergic salute".
- "Allergic facies", common in children with early-onset of allergic rhinitis.

The patient should be examined for:

- Nasal mucosa – showing pale bluish hue or pallor.
- Clear rhinorrhea at anteriorly
- Hyperplastic lymphoid tissue – resemble cobblestones
- Tympanic membrane – may be retracted or serous fluid accumulation behind TM.

Symptoms associated:

- Allergic conjunctivitis
- Rhino-inusitis
- Bronchial Asthma
- Atopic dermatitis
- Oral allergy syndrome

Differential diagnosis:

- Vasomotor rhinitis
- Infectious rhinitis
- Cerebrospinal fluid leak
- Non-allergic rhinitis with eosinophilia syndrome
- Chemical rhino-sinusitis.
- Rhinitis in pregnancy
- Drug induced rhinitis
- Nasal polyposis
- Nasopharyngeal neoplasm

Clinical evaluation:

It is a clinical diagnosis based on history and physical examination. A favourable response to nasal steroid therapy can help confirm the diagnosis.

Skin testing is more sensitive than serum testing and to be less expensive. Patients with comorbidities are all contraindications to skin allergy testing.[41,42]

Uncommonly used testing include the nasal cytology and direct inhalation challenge with allergen.

Nasal cytology:

Although nasal cytology is very vague and insensitive, some scientists use it to assist identify allergic rhinitis from infection-related rhinitis. In situations of allergic rhinitis, the Wright stain of nasal secretions, presence of neutrophils indicates an infectious process in contrast.

Nasal eosinophilia can also be present in the conditions like;

- Bronchial Asthma
- Nasal polyp
- Non-allergic rhinitis with eosinophilia syndrome.

Treatment:

The management of AR include:

- Pharmacotherapy
- Allergen avoidance
- Allergen immunotherapy

Commonly used therapies include:

- Nasal saline spray or irrigation
- Glucocorticoids nasal sprays
- Dry aerosol formulations
- Decongestant sprays
- Oral antihistamines

Glucocorticoids nasal spray for treatment of rhinitis:

1) **Ciclesonide (50 mcg/spray):**

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)- 2years
- Usual pediatric dose per nostril- 2 to 11 years: One or two sprays once daily
- ≥12 years: Two sprays once daily.
- Type of preparation (alcohol content)- Aqueous suspension pump spray.

2) **Fluticasone Furoate (27.5 mcg/spray):**

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)- 2 years
- Usual pediatric dose per nostril- One / two sprays daily once for 2 to 11 years of age.
- Type of preparation- Aqueous suspension.

3) **Fluticasone Proprionate (50 mcg/spray):**

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)- 4 years
- Usual pediatric dose per nostril- 4 to 11 years One spray once daily. ≥12 years: Two sprays once daily.
- Type of preparation (alcohol content)- Aqueous suspension pump spray (0.25% alcohol).

4) **Mometasone (50 mcg/spray):**

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)- 2 years

- Usual pediatric dose per nostril-For 2 to 11 years of age group: One spray per day, ≥12 years: Two sprays once daily.
- Type of preparation (alcohol content)- Aqueous suspension pump spray.

5) <u>Budesonide (32 mcg/spray):</u>

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)-6years.
- Usual pediatric dose per nostril- For age group 6 to 11 years, one spray daily twice.
- Type of preparation (alcohol content)- Aqueous suspension pump spray.

6) <u>Flunisolide:</u>

- Usual adult dose per nostril: Two sprays once daily.
- Lower age limit when used in children (years)-6years.
- Usual adult dose per nostril: Two sprays two or three times daily (maximum two sprays four times daily).
- Usual pediatric dose per nostril-6 to 14 years: One spray three times daily or two sprays twice daily, ≥15 years: Two sprays two or three times daily.
- Type of preparation (alcohol content)- Aqueous suspension pump spray (contains propylene glycol, a possible irritant).

There was a significant association between the AEC and NOSE score among patients in a study by Dutta A et al., published in 2020, "to investigate role of N.O.S.E scale in management of allergic rhinitis. The study reported a mean NOSE scale of 64.07 +/- 16.71 and a mean AEC of 633.07 +/- 152.77. N.O.S.E scale can be employed in follow-up care with intranasal corticosteroid spray, according to the study's findings.[49]

Indranil Pal et alstudy .'s from 2017 "to examine the nasal smear eosinophil count connection with the allergic rhinitis and to set a cut-off value" discovered that an eosinophil count of > 0.3 per HPF in allergic rhinitis is highly specific diagnostic indicator. It has a 62% sensitivity. 100% was shown by nasal smear for eosinophilia of > 0.3 per HPF.

A study by Chandra RK et al. (2016) revealed that allergic polyp incidence, at 68%, was higher than inflammatory polyp incidence, at 32%. Serum IgE levels increased by two folds as much in allergic polyp group as they did in control group, and polyp fluid IgE levels were very significant (P 0.001) compared to IgE serum levels in allergic polyp group.[47]

According to a study conducted by Emily M. Ambizas et al., (2015) they have concluded that intranasal corticosteroids is more effective than leukotriene antagonists.[45]

Study conducted in 2015 by Mudunuri RK et al, “to assess prevalence of eosinophilia in patients with allergic rhinitis”, observed high correlation between nasal smear eosinophilia and allergic rhinitis. Specificity 87% and Sensitivity 61% in nasal smear for eosinophilia.[44]

Study done by Ashkarali et al., conducted in 2015 “to assess the association between absolute eosinophil count and nasal symptoms using nasal obstruction symptom evaluation (NOSE) scale in allergic rhinitis”, documented that higher AEC value was correlated with higher NOSE score among patients and concluded that N.O.S.E score is simple, non-invasive, very economical.[1]

According to Anand K. Patel et al., it was found in the study conducted in 2014 "to assess the NSM and blood AEC with severity of clinical score" that there was a strong correlation between nasal smear eosinophilia and the severity of the N.O.S.E score. The N.O.S.E score and the AEC did not correlate. There was shown to be a strong correlation between AEC and intensity of allergic rhinitis symptoms. [3]

Intervals to establish class of ranges were provided by a 2012 study by Michael J. Lipan et al., "to develop the categorization system of the nasal blockage using a subjective validated QoL instrument." Based on responses to the N.O.S.E score survey, it was classified as mild (5–25), moderate (30–50), severe (5–75), or extreme (80–100) nasal blockage. It was shown that N.O.S.E score is essential method for monitoring patients with nasal obstruction.[43]

Above studies are deficient regarding role of nasal corticosteroid spray before & after treatment in relation to N.O.S.E score & Nasal smear eosinophilia based on follow up.based on follow up.

MATERIAL & METHOD

An observational study among the patients of Allergic Rhinitis visiting ENT & HNS Department, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgaum for 1 year.

Study setting: Hospital Based study

Study design: Prospective Observational study

Study population: 50

Study period: 1year

Formula for sample size:

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

where P stands for the prevalence percentage and d for the likelihood of the prevalence difference in percentage terms. Z and significance level are related. Z = 1.96 at a 5% level of significance.

Reference:

"Profile of Patients with Allergic Rhinitis (AR): A Clinic Based Cross-Sectional Study from Kolkata, India". Study population - 568, Out of which 462 were diagnosed with Allergic Rhinitis. Study conducted by Deb A et al.[50]

With P = 84.31% and d =15% of P =12.65%, the sample size is 32.

To get confirmative result, the sample size will be taken as 50.

Inclusion criteria:

- All patients above 13years of age.
- All patients with anterior or posterior rhinorrhoea , sneezing, nasal blockage, and /or itching nares for consecutive days.

Exclusion criteria:

- Bronchiectasis
- Obstructive Airway Disease
- Recent Nasal surgeries
- Usage of oral or nasal decongestants before treatment.

Study method:

Informed consent was taken. Detailed evaluation of the patients including detailed history & complete Nasal examination were done. All patients were given N.O.S.E score questionnaire & Nasal smear for Eosinophilia was taken by taking swab from the mucous membrane of inferior meatus using sterile cotton & smeared over the glass slide, allowed it to air dry for 2minutes & Ethyl alcohol spray was used over the smear for fixation. Later stained with methenamine Giemsa stain 7 sent to pathology department for nasal smear eosinophil count & was correlated with NOSE score before & after treatment with Fluticasone Proprionate nasal spray & follow up was done after 3 months

Follow up: Yes

Follow up period: 3 months

STATISTICAL ANALYSIS

Since the study is of observational study, the planned analysis is as follows. Mean and standard deviation was calculated for the continuous quantitative variables. The summarized data were represented using tables, figures, bar diagram and pie charts. For the purpose of comparison if the data is divided into two groups i.e before & after treatment with correlation to N.O.S.E score & Nasal Smear Eosinophilia. The continuous variables were compared by student's paired t-test and for independent data unpaired t-test was used. Discrete variables were represented by median. The relation between the outcome, clinical and demographic characteristics were tested by Chi-square test, test of proportion or Fisher's exact test. For all the tests, p value less than 5% (0.05) was considered significant.

RESULTS

Mean age of patient is 32.48±12.77, with 40% female participants and 60% were male participants. Male to female ratio is 1.5:1, with male preponderance. The mean score of nasal smear eosinophil count per HPF before treatment was 5.023 & mean score after treatment was 0.444. The mean NOSE score before treatment was 47.1 & after treatment was 16.40. The NOSE score & NSE were correlating very well in patients with AR in our study & also to note is that it was directly proportional to each other.

In our study, the maximum N.O.S.E score was 14/16. Minimum was 1/16.

Also, the maximum Nasal Smear for Eosinophilia was 90 per HPF, & minimum was zero per HPF.

Mean N.O.S.E score before treatment was 47.1±1.56 & mean N.O.S.E score after treatment was 16.40±0.85.

Nasal smear eosinophil count per HPF before treatment was 5.023±2.01 & N.O.S.E score before treatment was 47.1±1.56, Nasal smear eosinophil count per HPF after treatment was 0.444±0.08 & N.O.S.E score after treatment 16.40±0.85. Both of the variables (N.O.S.E score & Nasal smear eosinophilia) among patients with allergic rhinitis correlate well with each other.

Table 1: Patient's mean age

	N	Minimum	Maximum	Mean	SD
Age	50	13.0	60.0	32.480	12.77

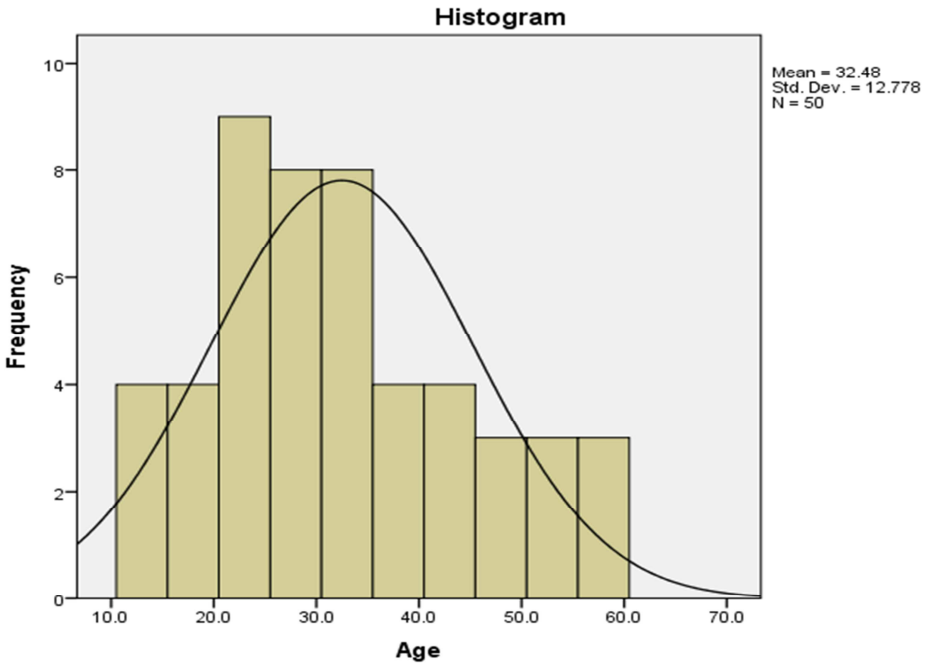

Figure 1: Histogram showing the age distribution

Table 2: Age wise distribution of participants		
Age	Frequency	Percent
13-20yrs	8	16
21-30yrs	17	34
31-40yrs	12	24
41-60yrs	13	26
Total	50	100

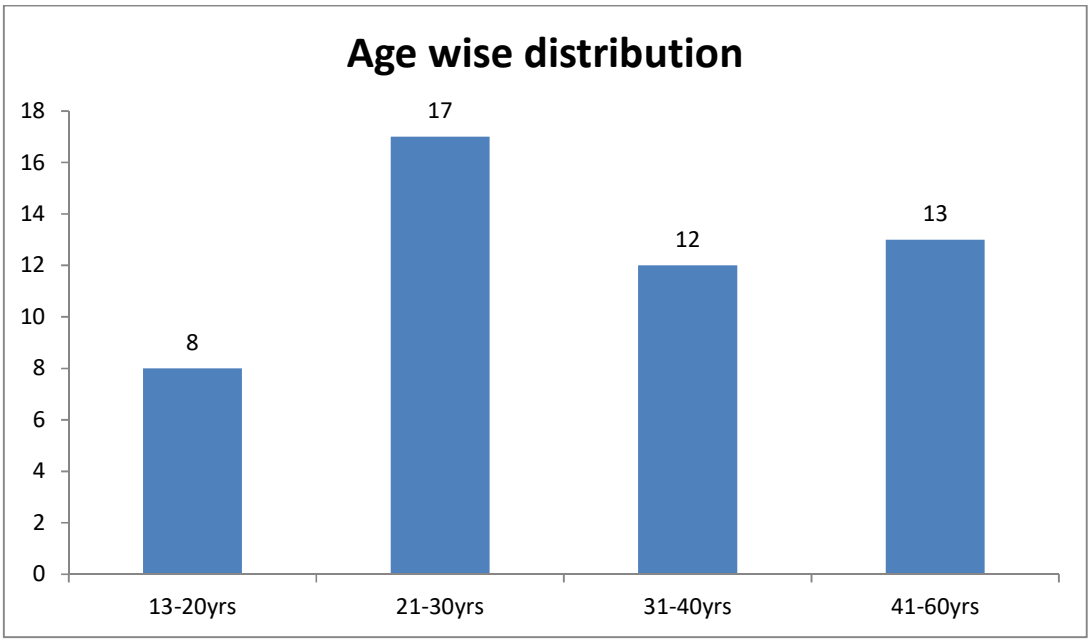

Figure 2: Age wise distribution of participants

Table 3: Gender distribution			
		Frequency	Percent
Gender	Female	20	40.0
	Male	30	60.0
	Total	50	100.0

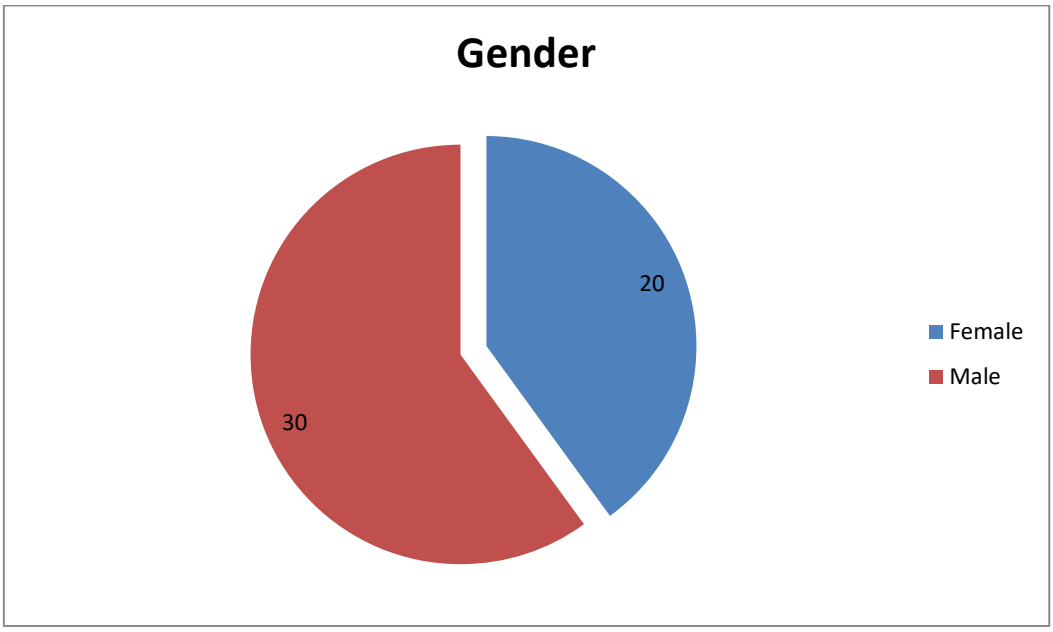

Figure 3: Gender distribution

Table 4: Comparison of mean level of nasal smear eosinophil count and NOSE score before and after treatment with paired t-test.

	Before treatment Mean ±SE	After treatment	Paired t-test (p-value)
Nasal smear eosinophil count per HPF	5.023±2.01	0.444±0.08	0.025*
NOSE score	47.1±1.56	16.40±0.85	0.001**

*p<0.05 was considered statistically significant and **p<0.001 was considered statistically highly significant.

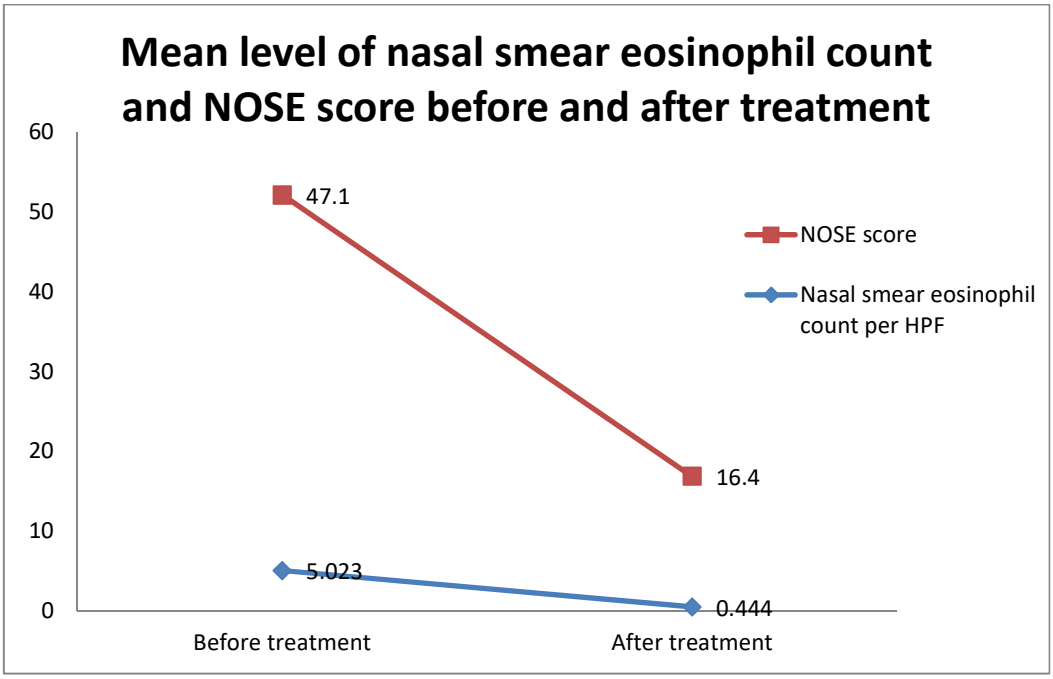

Figure 10: Comparison of mean level of nasal smear eosinophil count and NOSE score before and after treatment

Table 5: Pearson's correlation of nasal smear eosinophil count and NOSE score with absolute eosinophil count

Pearson's correlation		AEC
Nasal smear eosinophil count	R	.450**
	Sig	.001
NOSE score	R	.201**
	Sig	.05

*. Correlation is significant at the 0.05 level (2-tailed).

There is an association between the Nasal smear eosinophil count with AEC (r=0.450, p<0.05) & positive correlation between the NOSE score with the AEC (r=0.201, p<0.05).

DISCUSSION

Allergy rhinitis is the most common illness affecting the airways, and its progression is determined by the combination of genes, environment, and immunological variables. Symptoms such as nasal obstruction, pruritis, sneezing, and secretions are used in diagnosis of allergic rhinitis.[51,52]

When an allergen is breathed by patient with a sensitized immune system, the allergen causes IgE to be produced. According to research, eosinophils are involved in pathogenesis of allergic respiratory disorders. Thus, mast cells are stimulated to mediators, which serve as augmenting factors for eosinophilic infiltration in allergic illness.[3,53]

When exposed to an allergen, several inflammatory cells enter the nasal lining. T cells invading the nasal mucosa are mostly Th2 in type and produce cytokines that stimulate IgE plasma cell production. In turn, IgE synthesis causes the release of inflammatory mediators causing dilatation of arterioles, increased permeability of vascular system, pruritis, and contraction of smooth muscle.[54,55]

Our study aimed to assess the effect of Nasal corticosteroid spray in Allergic Rhinitis in relation to N.O.S.E score & Nasal smear eosinophilia in 50 patients. The mean age of patients in our study is 32.48 ± 12.77. The ratio between male and female is 1.5:1, with preponderance of male. Similarly in the study done by Kumar et al[56] in the year 2012 was 1:1.6. Our study correlated well with above study.

Nasal cytogram is simple, non- invasive economical procedure which can be used as an alternative to peripheral smear eosinophilia as both are equally helpful in diagnosing allergic disorders.

In our study the Nasal smear eosinophil before treatment was found to be significantly higher (5.023±2.01) compared to after treatment count (0.444±0.08), with $p<0.05$. Whereas study done by Pal I et al in 2017 documented 5.23+-9.076 before treatment. But did not relate N.O.S.E score to one another after treatment. [2]

An eosinophil count of 40-440 cells per microliter of blood is considered normal. AEC determines the amount of eosinophils, which are white blood cells. Several investigations have found a link between eosinophils and allergic illness. In participants who had a dual reaction to allergen challenge, there was a link between the severity of allergic rhinitis and peripheral blood eosinophilia.[56]

In our study, there is an association between the nasal smear eosinophil count with AEC ($r=0.450$, $p<0.05$), which is statistically significant.

Our findings imply that the N.O.S.E score can be utilised to determine the severity of symptoms. It can also be used to assess symptoms alleviation after a therapy course, also improvise patient care by understanding potential therapeutic effects.

In our study, a positive correlation between the N.O.S.E score with the AEC was noted ($r=0.201$, $p<0.05$).Whereas, in a study done by Patel AK et al in 2017, showed no association between AEC and N.O.S.E scores and no nasal smear eosinophilia.[3]

In our study correlation between N.O.S.E score and pre & post treatment, p value was 0.01. Whereas a study done by Harugop A. et al in 2020, the N.O.S.E score pre treatment had a p value of 0.02.[48] Both this & our study were statistically significant. Our study gave an added advantage of post treatment follow-up compared to the above study.

CONCLUSION

Nasal smear for eosinophilia is simple, economical, faster and a non-invasive technique for assessing the severity of allergic rhinitis. N.O.S.E score can be utilised to know the severity of allergic rhinitis before & after treatment with intra-nasal corticosteroid spray. Intra-nasal corticosteroid spray for a period of 3 months reduces the nasal smear for eosinophilia significantly.

In our study, the N.O.S.E score & Nasal Smear for Eosinophilia were correlated with each other in Allergic Rhinitis both pre-treatment & post treatment. We found that in our study, both NOSE score & NSE was directly proportional to each other in pre & post treatment of AR. The N.O.S.E score & Nasal Smear for Eosinophilia are very good indicators for diagnosis & prognosis of Allergic Rhinitis patients whereas AEC was not a good indicator for assessing pre & post treatment of AR.

Nasal Smear for Eosinophilia can be used as an adjuvant to the NOSE score. Hence, as per our study & results, the NOSE score can be utilised as an indicator for assessing pre & post treatment of AR. NOSE score is easier, cheaper & faster compared to NSE. AEC value in clinical settings. Both NOSE score and Nasal Smear for Eosinophilia is more reliable than AEC in Allergic Rhinitis.

SUMMARY

Our present study aimed to assess the effect of Nasal corticosteroid spray in Allergic Rhinitis in relation to N.O.S.E score & Nasal smear eosinophilia in KLEs Dr. Prabhakar Kore Hospital & Medical Research Center Belgaum. A total of 50 patients fulfilling inclusion criteria are included in the study after obtaining the informed consent.

The mean age of patients is 32.48±12.77, with 40% female participants and 60% were male participants.

The male female ratio is 1.5:1, with male preponderance.

On assessment of the nasal smear for eosinophilia and N.O.S.E score before and after treatment, we found a significant change in the mean scores between the groups. ($p<0.05$). The Nasal smear eosinophil before treatment was found to be significantly higher (5.023±2.01) compared to after treatment count (0.444±0.08), with $p<0.05$.

The NOSE score was found to be significantly higher before treatment (47.1±1.56) compared to after treatment (16.40±0.85), with $p<0.05$.

There is a moderate strength associated between the Nasal smear eosinophil count with AEC ($r=0.450$, $p<0.05$).

There is a weak strength of positive correlation between the NOSE score with the AEC ($r=0.201$, $p<0.05$).

AEC didn't correlate with Nasal Smear for Eosinophilia & N.O.S.E score in pre & post treatment in Allergic Rhinitis.

N.O.S,E & NSE can be utilised in any small set ups or rural areas where IgE, AEC estimation, other allergic testing facilities are difficult to access or not available.

N.O.S.E score is directly proportional to Nasal Smear for Eosinophilia.

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ANNEXURE - I

PROFORMA

Date:

O.P. No:

Name: Age:

Sex: Occupation:

Address: Phone No:

CLINICAL PROFILE:

Chief Complaint :

History of Present Illness :

Past History :

Personal History :

Family History :

General Physical Examination -

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Oedema

1) NOSE EXAMINATION

External appearance

- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test :

Anterior Rhinoscopy :

Posterior Rhinoscopy :

Paranasal Sinus Examination :

2. EAR EXAMINATION:

	Right	**Left**
Pinna		
Pre auricular area		
Post auricular area		
External auditory canal Tympanic membrane		

TUNING FORK TESTS:

Rinne's test 256 Hz

512 Hz

1024 Hz

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION:

3 THROAT EXAMINATION :

4. NECK EXAMINATION :

Diagnosis:

ANNEXURE - II

INFORMED CONSENT

"ROLE OF NASAL CORTICOSTEROID SPRAY & ITS EFFECTS IN ALLERGIC

RHINITIS IN RELATION TO N.O.S.E SCALE & NASAL SMEAR EOSINOPHILIA : 1 YEAR OBSERVATIONAL STUDY"

PRINCIPAL INVESTIGATOR: DR.

Post Graduate student

Department of Otorhinolaryngology.

CO-INVESTIGATOR : DR.

Professor, Department of Otorhinolaryngology and Head and Neck Surgery.

INTRODUCTION AND PURPOSE: The purpose of the study is to observe the effectiveness of Nasal corticosteroid spray in relation to N.O.S.E scale & Nasal smear eosinophilia before & after treatment.

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 for Allergic Rhinitis on the basis of symptoms & clinical evaluation. The subject will then have to undergo Nasal smear for eosinophilia before starting the treatment.

BENEFITS: The subject will not be eligible for any kind of monetary benefits or any free services.

RISKS: Methods applied to do the study are safe.

COST OF PARTICIPATION: The cost of the Investigation 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 queries regarding the study, you can contact Dr Harsha Hegde, Chairperson, JNMC, IEC, & Scientist D, ICMR, National nstitute of Traditional Medicine, Belagavi - 9480422500.

STATEMENT OF CONSENT :

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.

Signature of the Participant :

Date :

Name :

Signature of witness :

Date :

Name :

Signature of the investigator:

Date :

Name :

ASSENT <18years

I have read the information in this form. After understanding all details about the study I agree to give assent to be included as a volunteer in the study titled " Role of Nasal corticosteroid spray & iys effects in Allergic Rhinits in relation to N.O.S.E score & Nasal Smear Eosinophilia in KLEs Dr. Prabhakar Kore Hospital & Research Centre Belgaum - A Prospective Observational stud".

Name of the Participant : Signature / Left thumb impression

Name of the Parent : Signature of the parent :

Name of the investigator : Signature of the investigator :

Name of witness : Signature of witness :

Date :

Place :

TIME PLAN

INVESTIGATORS: Dr.

Dr.

PHASE	TIME PERIOD	OUTLINE OF PLAN
1)	JULY 2020 to OCTOBER 2020	1. Identification of research question. 2. Review of literature. 3. Development of. proforma. 4. Submission of synopsis.
2)	JANUARY 2021 to DECEMBER 2021	1. Data collection
3)	JANUARY 2022 to AUGUST 2022	1. Analysis of the collected data. 2. Discussion and write up work.
4)	SEPTEMBER 2022	1. Submission of dissertation to KLE University, Belgaum.

BUDGET ANALYSIS

"ROLE OF NASAL CORTICOSTEROID SPRAY & ITS EFFECTS IN ALLERGIC RHINITIS IN RELATION TO N.O.S.E SCALE & NASAL SMEAR EOSINOPHILIA : 1 YEAR OBSERVATIONAL STUDY"

Study Investigator:

Dr. P.G. (M.S. E.N.T. & H.N.S.), JNMC, Belgaum

A. Direct :

Personnel : Nil

Equipments : Nil

Investigations : Nasal smear eosinophilia

Rs.

B. Indirect Cost :

Printing and copying supplies :Rs 7000

Data Collection and Transport : Nil

Meeting and Other Expenses : Nil

Total Cost =

Normal Range of NOSE score:

- Mild: 5-25
- Moderate: 30-50
- Severe: 55-75
- Extreme: 80-100

ANNEXURE - III

QUESTIONNAIRE

MODIFIED N.O.S.E SCALE

Name :
Age :
I.P/O.P No :

How much of a problem is/are the following condition for you at present (before treatment) ?

	NOT A PROBLEM	VERY MILD PROBLEM	MODERATE PROBLEM	FAIRLY BAD PROBLEM	SEVERE PROBLEM
a. Nasal stuffiness or obstruction.	0	1	2	3	4
b. Trouble breathing through my nose.	0	1	2	3	4
c. Trouble sleeping.	0	1	2	3	4
d. Unable to get enough air through my nose during exertion.	0	1	2	3	4

PLEASE ENCIRCLE THE SEVERITY ABOVE FOR FURTHER EVALUATION

MODIFIED N.O.S.E SCALE

Name :
Age :
I.P/O.P No :

How much of a problem is/are the following condition for you at present (after treatment) ?

	NOT A PROBLEM	VERY MILD PROBLEM	MODERATE PROBLEM	FAIRLY BAD PROBLEM	SEVERE PROBLEM
a. Nasal stuffiness or obstruction.	0	1	2	3	4
b. Trouble breathing through my nose.	0	1	2	3	4
c. Trouble sleeping.	0	1	2	3	4
d. Unable to get enough air through my nose during exertion.	0	1	2	3	4

PLEASE ENCIRCLE THE SEVERITY ABOVE FOR FURTHER EVALUATION

ANNEXURE – IV

MASTER CHART

SL.NO.	NAME	AGE	SEX	IP /OP number	Nasal smear eosinophil count before treatment (per HPF)	Nasal smear eosinophil count after treatment (per HPF)	Random Blood Sugar level	NOSE score before treatment	NOSE score after treatment	AEC (10x3 uL)
1	AMAR SINGH	23Y	M	6387472	0.5	0.3	97mg/dl	12/16-60	3/16-15	0.1
2	BRAHMANANDA	45Y	M	1087851	11	0.3	106mg/dl	9/16-45	2/16-10	0.25
3	RENUKA SANJAY	38Y	F	1067997	0.4	0.3	104mg/dl	12/16-60	3/16-15	0.15
4	SANTOSH DATTA	42Y	M	1091616	5	0.2	95mg/dl	7/16-35	3/16-15	0.3
5	MUSKAAN MEHBOOB	21Y	F	5124274	2	0.3	89mg/dl	8/16-40	5/16-25	0.15
6	KAVERI PATIL	21Y	F	1091148	0.3	0.2	117mg/dl	11/16-55	4/16-20	0.5
7	**PRAVEEN**	**45Y**	**M**	**1090144**	**0.1**	**0.1**	**112mg/dl**	**12/16-60**	**3/16-15**	**0.5**
8	SHOBHA	46Y	F	6336504	1	0.4	98mg/dl	10/16-50	4/16-20	0.25
9	PRAJWAL	17Y	M	1089914	0.6	0.2	87mg/dl	6/16-30	3/16-15	0.2
10	YALLALING	15Y	M	1088368	6	0.1	86mg/dl	6/16-30	2/16-10	0.18
11	NAVID ASLAM	15Y	M	6002460	0.8	0.4	97mg/dl	8/16-40	3/16-15	0.66
12	RAMESH	13Y	M	1087836	1	0.5	98mg/dl	7/16-35	2/16-10	0.25
13	BHIMAVVA	32Y	M	1087851	4	0.3	109mg/dl	11/16-55	6/16-30	0.35
14	VAMAN	34Y	M	1087821	8	0.6	127mg/dl	12/16-60	4/16-20	0.15
15	SUWARNA	34Y	F	1086483	4	0.2	122mg/dl	11/16-55	4/16-20	0.31
16	SANDEEP	26Y	M	1086979	2	0.3	116mg/dl	8/16-40	1/16-5	-
17	MAHANTESH	24Y	M	1084805	5	0.2	101mg/dl	9/16-45	5/16-25	0.31
18	SHIVANYA SANTOSH	27Y	F	1084687	3	0.3	103mg/dl	7/16-35	3/16-15	0.l
19	SADASHIV	25Y	M	1084357	0.8	0.3	109mg/dl	7/16-35	3/16-15	0.3

20	SAKKUBAI	26Y	F	1085292	0.4	0.1	122mg/dl	11/16-55	5/16-25	0.12
21	CHANDRAKANTH	60Y	M	1083591	2	0.7	135mg/dl	10/16-50	4/16-20	0.21
22	VITTHAL R	22Y	M	1080855	2	0.3	98mg/dl	7/16-35	1/16-5	1.0
23	NILAVAR	58Y	M	1036045	0.5	0.2	99mg/dl	12/16-60	3/16-15	0.3
24	**IRRAVVA**	**55Y**	**F**	**1036209**	**0.2**	**0**	**105mg/dl**	**13/16-65**	**5/16-25**	**0.15**
25	KAVITHA	21Y	F	1080441	0.2	0	112mg/dl	12/16-60	3/16-15	0.15
26	**JANAPPA**	**49Y**	**M**	**1036471**	**0.1**	**0.1**	**88mg/dl**	**6/16-30**	**2/16-10**	**0.18**
27	VINOD S	19Y	M	1036916	7	1	98mg/dl	6/16-30	2/16-10	0.8
28	RUDRAPPA	35Y	M	1037559	1	0.1	109mg/dl	11/16-55	3/16-15	0.15
29	MEENAZ	32Y	F	1038051	2	0.3	110mg/dl	10/16-55	2/16-10	0.25
30	SANJU RAMAPPA	30Y	M	1075636	1	0.4	112mg/dl	11/16-55	3/16-15	0.1
31	VISHAL	20Y	M	1038065	2	0.2	94mg/dl	8/16-40	2/16-10	0.13
32	HALAPPA	35Y	M	1038206	0.6	0.2	96mg/dl	10/16-50	3/16-15	0.18
33	RAPHIK	34Y	M	1040313	0.4	0.2	102mg/dl	6/16-30	2/16-10	0.76
34	DEEPALI SHANKAR	28Y	F	5980097	8	2	110mg/dl	10/16-50	5/16-25	0.28
35	RISHIKESH	22Y	M	1040750	0.6	0.1	104mg/dl	9/16-45	3/16-15	0.55
36	NAGAVVA	53Y	F	1041258	4	0.3	111mg/dl	11/16-55	5/16-25	0.7
37	BASAVARAJ	26Y	M	1041303	0.6	0.1	97mg/dl	11/16-55	5/16-25	0.5
38	***SOMAVVA***	***42Y***	***F***	***1044830***	***40***	***3***	***91mg/dl***	***12/16-60***	***5/16-25***	***0.44***
39	MALA	38Y	F	1044916	6	2	106mg/dl	10/16-50	3/16-15	0.08
40	SACHIN ISHWARAPPA	36Y	M	1073140	4	1.3	108mg/dl	12/16-60	4/16-20	0.5
41	AISHWARYA	14Y	F	1026524	Nil	0.2	98mg/dl	8/16-40	2/16-10	0.13
42	***MALLAVA***	***46Y***	***F***	***1026662***	***90***	***0.6***	***114mg/dl***	***14/16-70***	***4/16-20***	***1.1***
43	SANGEETA	26Y	F	1035539	4	Degenerated	117mg/dl	11/16-55	3/16-15	0.58
44	BABU JOTIBA	60Y	M	1090514	3	0	121mg/dl	8/16-40	3/16-15	0.1

45	NINGAPPA	38Y	M	1038565	1	0.4	103mg/dl	12/16-60	2/16-10	0.1
46	PRAJWAL	24Y	M	1098146	2	0.1	98mg/dl	4/16-20	2/16-10	0.08
47	**KAVERI**	**26Y**	**F**	**1097450**	**1**	**1**	**97mg/dl**	**7/16-35**	**5/16-25**	**0.58**
48	***SUSHILA***	***52Y***	***F***	***1097559***	***3***	***0.2***	***118mg/dl***	***9/16-45***	***5/16-25***	***0.05***
49	ASHRANI	35Y	F	4836384	1	0.1	111mg/dl	10/16-50	3/16-15	0.08
50	BHIMANNA	19Y	M	6023353	2	0.8	89mg/dl	6/16-30	2/16-10	0.3