"ASSESSMENT OF CHANGES IN INTRANASAL MOISTURE AS AN EFFECT OF A DEVIATED NASAL SEPTUM USING INTRANASAL SCHIRMER TEST "- A ONE YEAR HOSPITAL-BASED OBSERVATIONAL STUDY

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ABBREVIATIONS

CBF	Ciliary beat frequency
DNS	Deviated nasal septum
E. coli	Escherichia coli
ET	Eustachian tube
GSPN	Greater superficial petrosal nerve
Ie	That is
IgA	Immunoglobulin A
IgE	Immunoglobulin E
IgG	Immunoglobulin G
IgM	Immunoglobulin M
MALT	Mucosa-associated lymphoid tissue
MCC	Mucociliary clearance
P. aeruginosa	Pseudomonas aeruginosa
PAMPs	Pathogen-associated molecular patterns
PPG	Pterygopalatine ganglion
Strep. pneumoniae	Streptococcus pneumoniae
ULC	Upper lateral cartilage
URTI	Upper respiratory tract infection

ABSTRACT

BACKGROUND

The mucosa of the nose acts as a guardian that protects the epithelium. An anatomical change in the structure of the nose, like deviation of the nasal septum can lead to an alteration in nasal resistance and the airflow patterns of the nose. These changes in physiology adversely affect the nasal mucosal lining, causing drying up and crusting of secretions, and also thinning of epithelium and epistaxis. Therefore, assessment of the status of moisture levels in the nasal cavity is an indirect measurement of the effect of deviation of septum on the nasal mucosa. Schirmers strips are filter paper strips that are conventionally used to assess the amount of tear production in the eye. In our study, we used the Schirmers strips intranasally in patients with a deviated nasal septum in an attempt to quantify the status of the nasal moisture in an easy manner.

OBJECTIVE

To study the effects of deviated nasal septum on nasal moisture status using intranasal Schirmer test.

MATERIALS AND METHODS

Our study was an observation study that included 60 patients with nasal septum deviation and 60 subjects without any deviated nasal septum. Intranasal Schirmer test was performed to all patients and normal population in both nasal cavities.

RESULT

We found that on convex (deviated) side of septum, the Schirmers values were lesser (4.78 ± 2.82mm), as compared to the concave side (10.70 ± 4.97mm). This was of statistical significance (p-value < 0.0001). The mean difference between the two sides in the case group was 5.72 ± 2.78 and the in the control group it was 1.65 ± 0.66 this disparity was again found to be statistically significant. It was also noted that the mean value on the concave side (10.70 ± 4.97mm) was closer to (and greater than) that of the control group (9.18 ± 2.32), as compared to the mean value on the convex side (4.78 ± 2.82mm).

CONCLUSION

The moisture levels were found to be less on the deviated (convex) side of the septum. This finding highlights the negative effects to the nasal mucosa as an effect of septal deviation. Mean difference in Schirmer value between the two sides was also found to be significant. It was also noted that the Schirmer value was greater than the mean value of the control group, as well as the value of Schirmer on the convex side of deviated septum.

KEYWORDS

Intranasal Schirmer test, nasal septal deviation, nasal secretions, nasal moisture.

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INTRODUCTION

The mucosa of the nasal cavity functions as a guardian that protects the epithelium under it against organisms like bacteria, viruses, and inhaled particles. It has many functions like airway hydration and catching foreign bodies, thereby enabling clearance by mucociliary movement.[1]

Mucous blanket has two layers:

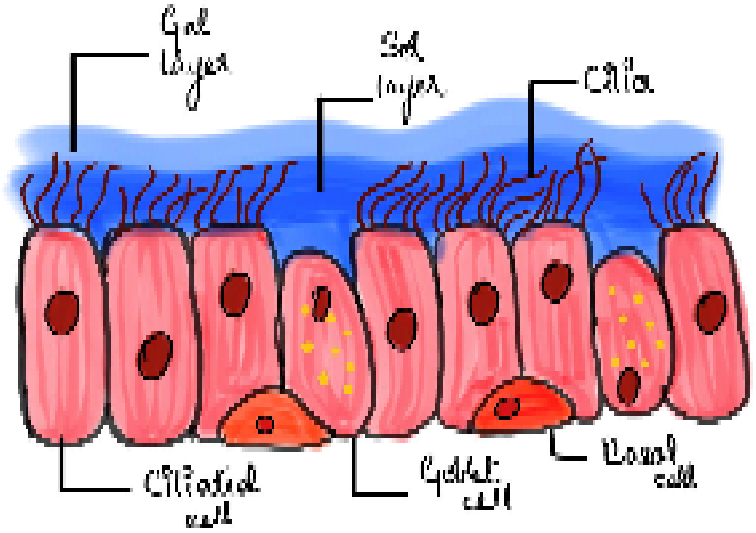


Fig 1.The two layers of mucous blanket

Outer mucous layer is a gel type of layer. The goblet cells and glands of submucosa produce this layer.

Periciliary fluid is also known as the 'sol' layer, it lies engulfing the cilia of the epithelial cells.

The epithelium produces this layer by the transport of ions across it. In simpler words, the respiratory fuction of the nose is to heat up, moisten & cleanse the air that is inspired. The anatomy of the nasal cavity, structures within it, it's mucosal surface and the relation between them are intricate, this intricacy is essential to accomplish it's functions.

Nasal septum lies in the midline, diving the cavum nasi into two cavities. These cavities are not divided equally. As a result of this unequal division, the nasal turbinates change their size in an attempt to create a constant, but dynamic slit space for flow of air. Functions of the nasal cavity are achieved optimally only if the structural alignment of the septum and the turbinates and their relationship with eachother result in an adequate slit space all through the "working phase" along with the slenderest slit like space during duration of the "resting phase".[2] Zuckerkandl conducted a study in 1882 on a large assortment of skulls that the septum of the nose is not usually straight, but in fact displays something he described as "physiological deviations." Hanif et al also concluded that not all deviations of the septum triggers the sensation of nasal obstruction. [3]

Gogniashvili et al. mentions that 90% of the normal population exhibits nasal septal deviation.4] Narrowing of the airflow path results in increase in airway resistance. The relationship of resistance provided, and area of cross section of a constricted area of cavum nasi is not linear, it is exponential. [2] Turbulence produced withing the nasal cavity, not only improves interaction of air with mucosal lining of nasal cavity. A constant turbulent form of air that flows can triggers drying up of the lining mucosa of nose and an augmented resistance to the movement of air. [5][6] Dehydration of nasal mucosa in this manner leads to drying up and thickening of nasal mucous, which further leads to the formation of crusts.
The increased airway resistance occurs due to the fact that the turbulent flowing particles strike against one another and against the walls of the cavum nasi, and this preceeds energy loss. However, it has also been mentioned that turbulence is blamable for a trifling increase in resistance, as opposed to the escalation due to areas of narrowing, as with patients with deviated nasal septum. According to G.H. Mlynski,

the perception of that nasal "stuffiness" complained from patients is not an end result of heightened resistance to airflow. In reality, it is an entirely subjective complaint, perceived as a result of turbulence in the nose, as well as the drying up of the nasal mucosa.[2] Dryness of the nasal cavity results in drying up of nasal secretions which can lead to the formation of crusts in the nose. These crusts further enhance the symptom of nasal obstruction in these patients.

Thermoreceptors that are present in nasal lining epithelium also play a part during interpretation of free airflow by a patient as a lack of nasal obstruction. TRPM8 "menthol" thermoreceptors, are receptors present at the ends of Trigeminal afferent nerves. these are set off when high velocity airflow moves through the nasal cavity on inhalation and causes the water content of the fluid over the epithelial lining to evaporate, leading to a sensation of 'cooling'. The "cool" stimulus over the epithelium is then perceived as patency nasal cavity & unobstructed airway tract. This leads to a reduction in the work of breathing, which is done by intercostal muscle groups mainly, and accessory muscles. Pathologies, like deviated nasal septum, that generate nasal mucosal thickening or the production of unwarranted amounts of mucus will partially clog up the airway and restrict evaporation, a process that is imperative for proper cooling of the epithelial lining, and thus reduce the sensation of free and unobstructed flow of air, and thereby lead to a subjective sensation of nasal obstruction.[7] These excessive mucosal secretions, when exposed to the increased turbulence; causes dehydration of the secretions and increased crust formation, as mentioned before.

A study by Bailie N et al. using nasal airflow simulations proved that within Little's area of the septum there is high amount of shear stress, which may be able to justify the tendency of spontaneous bleed to occur at this location. The

conformational alignment in relation to structures contained by the cavum nasi is what determines the amount, and the subsequent distribution of shear stress over the nasal walls. In their study, maximum amount of shear stress was seen to occur over deviated aspect of deviated septum ie; convex side. This may clarify why a specified set of patients seem liable to repeated episodes of epistaxis when there is existence of a deviation. [8]

Conclusion of one study conducted under Kumar L et al. suggests deviated nasal septum as the root microscopic histopathological type of nasal mucosal alteration, which was depicted by permeation of lymphocytic cells, even metaplastic changes of the normal epithelium to a squamous type of epithelium. These changes affect both of the sides (of the septum), but it was noted to be of less significance on convex side. These type of changes may predispose some patients to chronic rhinitis & chronic rhino-sinusitis.[9]

Hence assessing status of nasal moisture in patients with septal deviation is an indirect method to know the effect on the nasal mucosa. Objective tests to assess the status of intranasal moisture are cumbersome and inconvenient to the patient.

Schirmer strips are filter paper strips that are conventionally used to assess the amount of tear production in the eye. In our study, we used the Schirmers strips intranasally in patients who are seen to have a deviation of their nasal septum in an attempt to quantify status of the nasal moisture in an easy manner. Such a study has never been conducted in the Indian population before.

OBJECTIVE

To study the effects of deviated nasal septum on nasal moisture status using intranasal Schirmer test.

REVIEW OF LITERATURE

NASAL MUCOSA

The nose has several important functions, including warming the moistening the inspired air. It also reabsorbs moisture from the air that is expired out.[10] The adult human nose acts as a passage way for about 12,000 litres of air per day.[11]

The mucosa of the nasal cavity acts as a natural defence against infection. It has a role to play in both non specific type of immunity and acquired immunity. Therefore, drying out of this protective nasal mucosa due to any cause can affect this defence mechanism, by disrupting its integrity and can also affect the mucociliary transport.[12] Particles of size greater than 0.5, to 1 micro meter (μm) are trapped by the very efficient mucosa of the nose, and further cleared out from the nasal cavity by mucociliary clearance.[13] Particles encountered in the air during the inspiratory phase that are bigger than 3 μm mostly settle during the earlier point of respiration, like at valve area. Particles with size < 3 micro m, but greater than 0.5 μm are filtered and transported using ciliary propulsion towards direction of nasopharynx.[14]

Mucociliary clearance (MCC) is a physiological mechanism which consists of mucus production and mucus transport within the airway. It aids in removal of nasal secretions and debris. MCC is always the major fashion in security of the respiratory lining, and particularly for sinuses of the nose.[13]

NASAL MUCOSA

MICROSCOPIC ANATOMY

The vestibule region of the nose has stratified and squamous epithelium as it's lining epithelium. This squamous epithelium converts slowly to the columnar type of epithelium, which is ciliated and pseudo stratified type around the area of the valves

of nose. This transition zone is between 1 to 2 millimetres in thickness and present over a dense area of anastomoses formed by arteries. Confluence of these vessels results in the formation of a plexus is known as the "Kiesselbach" plexus / the "Little's area", and has been found to be the reason for 80% of cases of bleed from the nose. This is attributable to its heavy underlying blood vessels and a location placed anteriorly that makes it more prone for epistaxis. [15]

The most anteroinferior columnar epithelium is the part that is most under stress from airflow, especially of the inspired air. It may undertake squamous metaplasia as an adaptive mechanism.

The respiratory mucosa consists 80% of columnar type of epithelium, 20% are goblet cells, and only less than 5% are formed by basal cells. The columnar part of the epithelium is mainly pseudostratified, it includes both ciliated type of cells as well as nonciliated ones.

Whereas, the epithelium within the sinus cavities are also columnar epithelium but here it is mainly consisting of simple columnar cells with cilia.[16]

Microvilli are present on the surface of the cells. Microvilli are tiny and slender projections, best describes as 'hair-like. These are formed by actin protein and are 1 to 2μ m in length. These microvilli help to increase substantially, the overall surface area covered by the columnar type of cells.[17]

The mucosal layer is made up of superficial layer with inconstant number of goblet cells over a basement layer or membrane, below which a lamina propria consisting of vascular layers and glandular type of layers is present and lastly, periosteum (as seen in Fig. 2)[13]

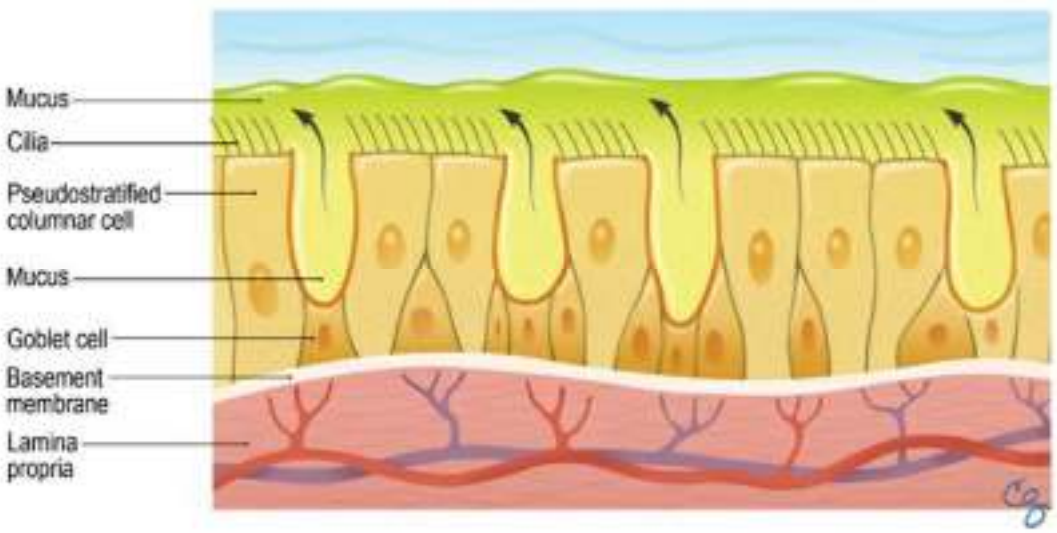


Fig 2. The sinonasal mucosa [13]

Pseudostratified and ciliated, columnar type of epithelium is seen, with a substantial quantity of goblet cells, that are placed over a highly vascular stroma containing small amounts of infiltrate.

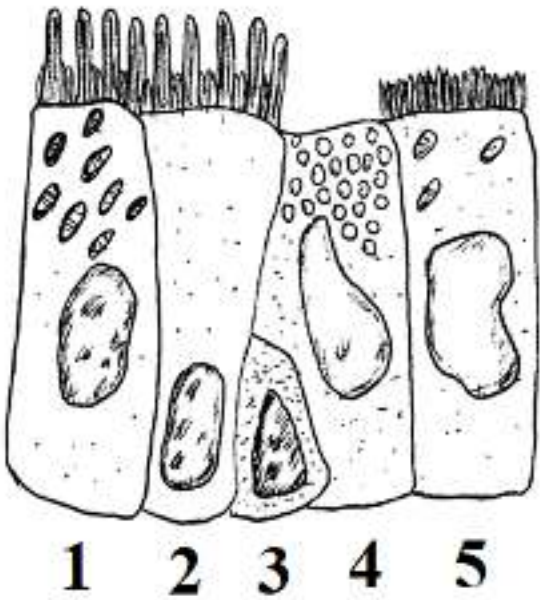


Fig 3. Illustration of respiratory epithelium.[14] Depicted are : Ciliated columnar cells (1&2), Basal cells (3), Goblet cells (4), Nonciliated columnar cells (5).

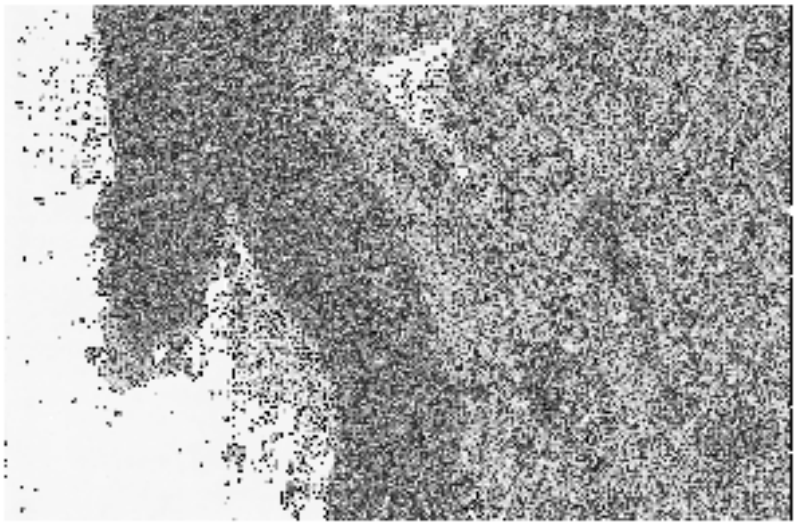


Fig 4. Normal nasal mucosa depicted under the microscope using hematoxylin-eosin stain. [14]

The goblet cells: These cells are interspersed between the columnar cells, they produce mucus—Mucus contains a glycoprotein crucial for to the viscous nature and the elastic property, called mucin. The apical end of specialized cells called goblet cells are swathed by microvilli and there is present a tiny ductal opening via which the cell discharges its secretions, which then line the nasal cavity (as seen in Fig 5)

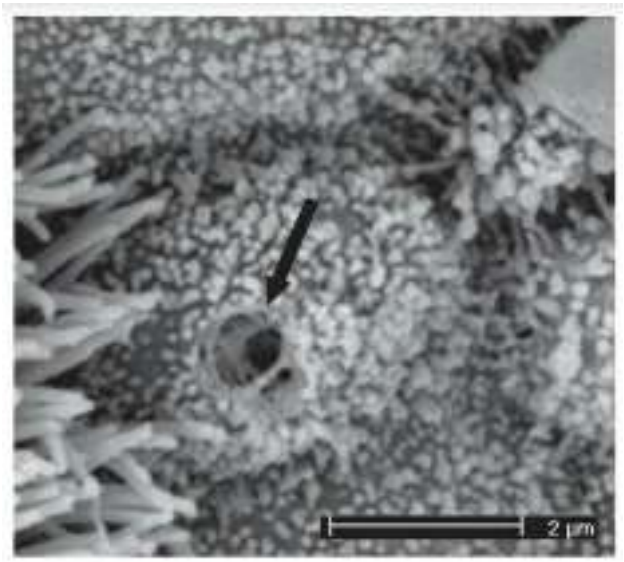


Fig 5. Electron microscopy image of a single goblet cell. Arrow: Microvilli over surface and duct of the gland.

Basal cells remain anchored to basement layer by hemidesmosomes. They operate as progenitors by dividing to form goblet cells or columnar cells in the future by the process of differentiation and help securing the ciliated cells on top of it to the basement layer.[18]

Epithelial lining has three varieties of intercellular connections:

Zonula adherens anchor epithelial cells onto their basement layer with protein structures like hemidesmosomes. Desmososmes (also known as macula adherens) connect one cell to another adjacent cell. It also has actin-like filaments. (Fig. 6).[13]

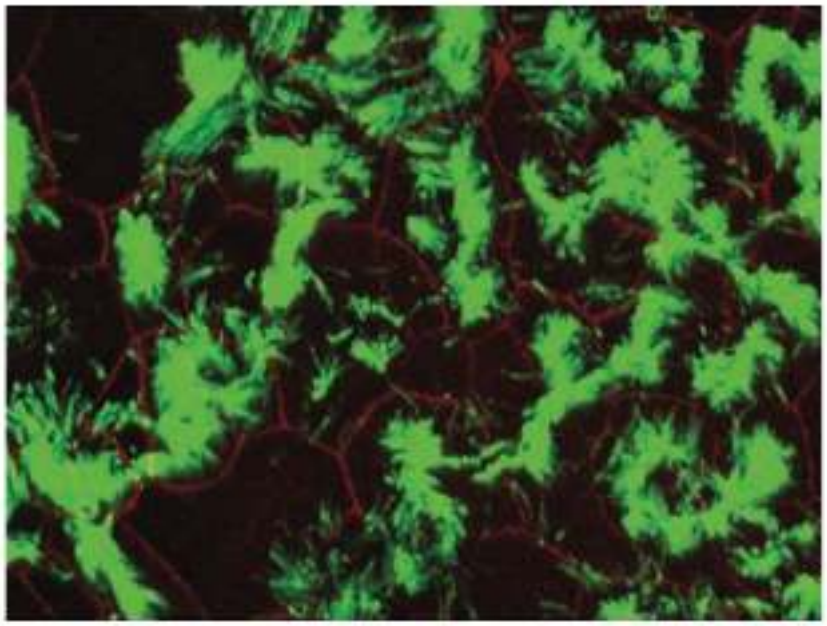


Fig 6. Immunofluorescence stained sinonasal mucosa. Zona occludens (Seen in red) & type IV β-tubulin ie; cilia of the cell. (Seen in Green)[13]

Each epithelial cell is surrounded by tight junctions, this makes the epithelium impermeable to pathogens, and even water. Gap junctions connect the cytoplasm of nearby cells of the epithelial lining to one another. They permit certain charged particles to lead through them and hence play an imperative role in transfer of charges and therefore aid in coordinated movement of cilia overlying the nasal mucosa. [19]

Lamina propria- Contains the glandular, nervous and vascular structures supplying the mucosal lining of the sinonasal structures. This layer is differentiated into -superficial gland layer, -middle vasculature, -deep gland layer. There are different type of glands- Serous type of glands produce a predominantly watery-type of secretion are present on the anterior parts of septal mucosa and over the lateral parts of wall of cavum. This watery secretion promotes to the moisture of the mucosa. Seromucinous type of secretory glands are observed all through the nasal cavity, their secretions are a mixture of serous-type and mucinous-type.

Numerous goblet cells arranged around a common lumen form the "intraepithelial glands", but these provide only minimal amounts of mucus to nasal secretions.

Parasympathetic fibres exit brainstem (specifically, superior salivatory nucleus). These fibres are then transported by the nervus intermedius. Nervus intermedius arises from 7^{th} cranial nerve (facial nerve). Through nervus intermedius, these fibres reach the GSPN- greater superficial petrosal nerve that course all through lamina propria layer of the epithelium of nose.

Sympathetic fibers arise from the gangliated cord, at the superior cervical ganglion they synapse. Then conducted by the deep petrosal nerve. Through the vidian nerve (after it arises by the joining up of the GSPN & deep petrosal nerve), these sympathetic fibres enter ganglion called PPG-pterygopalatine ganglion. At the PPG there is synapsis of parasympathetic fibres, and the trigeminal nerve then carries these fibres to the nasal mucosa, especially to the underlying vessels.

Secretions of the glands are produced as a result of parasympathetic stimulation of lamina propria directly. This effect can be blocked by anticholinergic

drugs like atropine. Sympathetic type of nerve fibres provide a more substantial function in vasoconstriction & decongestion. [18]

THE MŪCUS

A blanket of nasal secretion lines the cavum nasi. This mucus blanket has two separate layers, the outer one called the 'gel' and the inner layer is called the 'sol'. The gel layer is viscous and elastic, both these properties are due to the presence of mucin proteins.

The sol layer has lesser viscosity as compared to the gel layer and it is made of water and electrolytes like sodium, potassium, calcium and chloride.

Mucus is made up if water mainly (around 95%), the other components are proteins and peptides (2-3%), salts (1%). The normal pH of the mucus blanket is 5.5 to 6.5 ie; it is slightly acidic. Per day, 600-1,800mL of secretions are generated by the mucosa of the cavum nasi. [20]

MUCIN PROTEINS: These large glycoproteins are secreted by goblet cells. The carbohydrate side chains of these proteins help adhesins on microorganisms to get tethered, and have recognition sites for adhesins of organisms like influenza virus, and bacteria like Mycoplasma pneumoniae, P. aeruginosa, Strep. pneumoniae and E. coli.[21]

Proteins like glycoproteins have a crucial role in dehydrated portions of mucus.The foremost objective of these proteins are to lock in foreign and unfamiliar particles, and thus, aid in their clearance. [14] Hence these proteins play an essential part in defence.

The gel layer has the mucous glycoproteins and proteins from the serum collect in the sol.

Mucin proteins can also connect to endogenous particles of protein in mucus layer, enzymes like lysozyme and other proteins like lactoferrin, this can safeguard and structurally strengthen these proteins, helping them to perform their functions of host defence.[22] Mucins recognize and bind to proteins on the surface of microorganisms called adhesins. Once this microorganism-mucin binding is complete, clearance of these organisms is promoted.[23]

Mucus layer contains several proteins that assist in immune defence function in the local region. Proteins like lysozyme, lactoferrin, antitrypsin, and surfactants help in innate immunity.

Lysozyme is an enzyme that catalyzes bacterial cell wall hydrolysis. It is more efficient against mostly Gram stain-positive bacteria. Antimicrobial and immunomodulatory activities are also seen as actions of lactoferrin. Both bacteria and fungi require iron for survival. When lactoferrin binds iron, it deprives the organisms of this nutrient. Direct damage to the lipopolysaccharides of outer wall, especially bacteria with Gram stain-negative type wall can also be done by lactoferrin.

Proteins with a surfactant property are collectin (collagen-lectin) proteins, that have antimicrobial properties against bacteria like Staphylococcus species, Streptococcus species, Klebsiella pneumoniae, P. aeruginosa, E. coli etc.[24]

Collect in proteins can attach to PAMPs on the outer membranes of microorganisms via “calcium dependent carbohydrate” binding domains, this promotes clearance of these organisms from the system.[25,26,27]

MALT

Mucosa-associated lymphoid tissue (MALT) produces IgA & IgG, these are formed mostly from within mucosa lining the the inferior and middle turbinates. IgE

performs a starring role in allergy and IgM are at lower concentrations in secretions of nasal cavity.

IgA

IgA helps opsonizing pathogens and expedite phagocytosis of cells like macrophages and the neutrophilic cells. Along with lysozyme function, the activated complement system, IgA has a more particular effects that are bactericidal against particular organisms for example, Strep. pneumoniae.[28]

Dendritic cells are also present in MALT, these cells help in handling antigens and present to the T-cells. These T-cells go ahead and activate B cells.[29]

Disorders like cystic fibrosis, where a genetic defect in CFTR gene results in alteration of sodium chloride transport which inturn affects the osmotic propogation of water molecules- endothelium to mucus. This results in abnormally thick and viscous mucus. These patients tend to have impaired sinonasal mucociliary mechanism, thereby affecting clearance, and they thus, commonly end up with recurrent and severe infections of the respiratory tract.[30]

THE CILIARY STRUCTURE AND FUNCTION

Each epithelial cell has 50-200 cilia. Cilia are organelles that are cylindrical in shape, length = 5 to 7 micro m., diameter = 0.2 to 0.3 micro m., that are present on apical surface & affixed to the epithelial cell via centriole- derived basal bodies and these lie within the cell.[20]

The ultrastructure of the cilia consists of microtubules that are interconnected.

Three bonds form the crux of this structural interconnection:

1.Nexin links-They are doublets with an elastic property. These help to stabilize the cells by acting as a bridging structure.

2.Dyneins- These assist 9 doublets to glide together.

3.Spokes- These keep the cilia from falling apart. [14]

Alpha-and beta-tubulin dimers form protofilaments, which in turn form the microtubules. Membrane overlying the cilia is component of plasma membrane that covers the cell.

Axoneme is formed by two singlet microtubules in the centre, these are encircled by 9 pairs of micro-tubules, each having an alpha and a beta tubule (Fig. 7). Alpha-tubules have a whole ring of 13 proto-filaments, and β-tubules have an incomplete ring that consists of ten proto-filaments. [13]

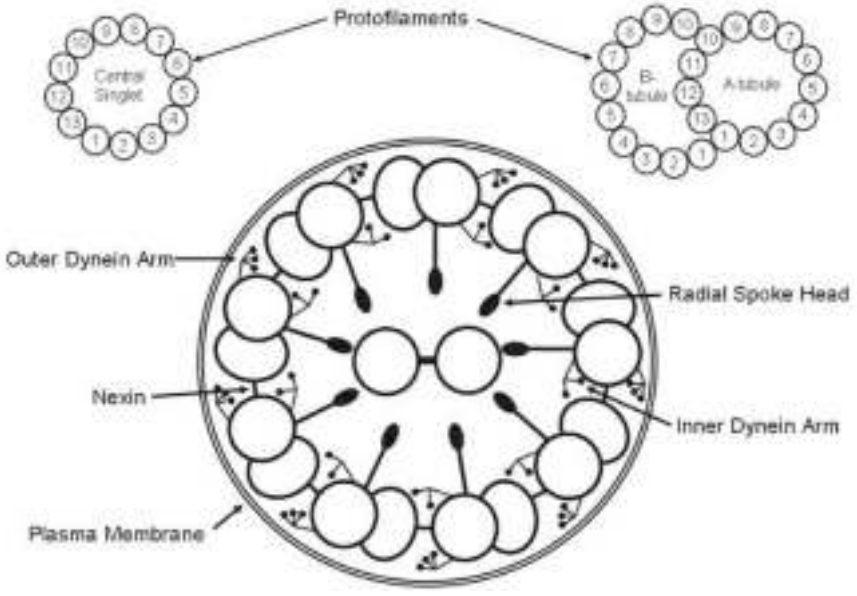


Fig. 7. Ultrastructure of the axoneme. [13]

Movement of the cilia involve two strokes a‘power’ one which is forward and a ‘recovery’ one. For the duration of the power-stroke, which is an arc like movement of the extended cilium, and on highest point of the motion, the tip portion of the cilium makes communication with the outer layer of the mucus or the ‘gel’ phase, this

transmits energy to the mucus which is a force that is directional in nature. At the "recovery-stroke" , the cilium now curves 90° & is swept back towards the initial location. This recovery stroke occurs within the runnier fluid layer that lies around the cilia or the 'sol'.

This whole motion is ATP-dependent.

The anchoring part of the axoneme is the basal body. This structure and it's orientation is most important determinant of the orientation of the stroke. (Fig. 8)

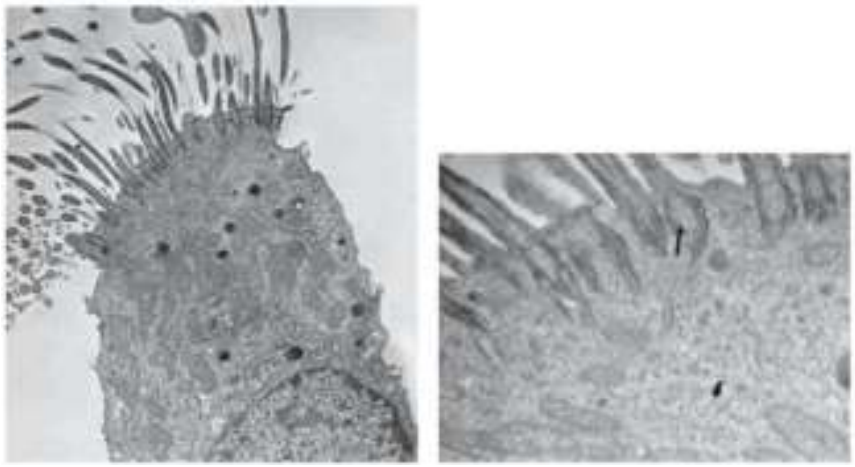


Fig 8 Ciliated epithelial cell, as seen under the electron microscope showing the (arrow) basal body. [13]

Fig. 9. Electron microscopy of cilia. [14] (From Anand VJ, Pange WR. Practical Endoscopic Sinus Surgery. New York: McGraw-Hill; 1993.

The coordinated movement of the cilia are described as a meta-chronous wave. A concept explains this organized movements of cilia is a directional transmission of intracellular calcium waves occur via gap junctions that connect adjacent epithelial cells. [31]

One of the theories proposed is the 'hydrodynamic wave theory', it proposes that only a few cilia, if moving in a coordinated manner, is imperative to create a proper hydro-dynamic type of wave in their partly liquid surrounding environment. This hydrodynamic wave can then induce the cilia to beat in a well coordinated and timely manner. [32]

Spontaneous ciliary beat frequency (CBF) can vary from around 9 to 15 hertz in humans, and the tip of the cilia peaks a velocity upto 600 to 1000 μm/s. And the consequential mucus velocity lies in the range of 3 - 25 mm per minute. This powerful and quick beating of cilia consequences in a clearing process that is very efficient and can eradicate the entire mucus blanket of nasal cavity, and even mucus blanket within a sinus in a span of 10 minutes. [33]

The beat frequency of the cilia are affected by both extracellular as well as intracellular pH. Upsurge in the pH levels within the cell leads to an intensification in beat frequency, similarly, a reduction in pH generates a diminution in the beat frequency.

Frequency of beating of ciliary structures has also been shown to fluctuate according temperature, idyllic temperature for proper CBF lying between 32° - 37° Celcius.[34]

Additionally, any stimulation directly to the cilia also causes an upsurge in CBF, is due to an intensification in Ca2+ ions within the cell. Mechanical type of stimulation is then circulated to the adjoining cells via gap junctions, this process

further galvanizes the extrusion of calcium from calcium reserve bunches present within the cell. This finally results in an intensification in CBF over total area around the site of a mechanical type of stimulation.[35]

On mechanical or osmotic stimuli locally, the nasal mucosa secretes adenosine and uridine, which are nucleotides. They act on the nasal mucosa itself in a paracrine fashion and stimulate mucociliary clearance.[36]

Several aspects affect competent ciliary kinesis. Lack of body hydration as may be seen in case of use of systemic diuretics or decongestant medication, can affect the ciliary motility negatively. It also may be noted in patients with nasal septum that is deviated, where movement of air in the forward-facing part of the nose parches the ciliated mucosa covering septum as well as anterior parts of the turbinates.[37]

Smoking is detrimental to nasal mucosa. It shows a change in the viscosity of the mucus as well as a smaller number of cilia. The chemical toxins present in tobacco can act as an irritant, which provokes an intensification in amount of secretions. And the diminishing of MCC can cause a stillness of nasal secretions as well as congestion of the nasal mucosa.

This effect is more marked in heavier smokers and is seen 8 hours after exposure to tobacco.[38]

The Sinonasal Mucociliary Clearance Patterns [13]

The cilia of the nasal mucosa are able to propel mucus from the sinuses, to the nasal cavity. From here they are further propelled towards the nasopharynx. The mucus is then moved to the gastrointestinal tract which is active immunologically and helps in removal of organic and inorganic debris.

This nasal mucosal clearance has certain natural patterns and is directional in nature. Knowledge of these patterns and direction is important during surgical interventions.

In the maxillary sinus, mucus flows against gravitational force, superomedially, from the most inferior portion of the maxillary antrum, upwards. This movement, as mentioned before is boosted by the ciliary action. So the coating of mucus is moved skyward along the medial wall and horizontally across the root of antrum of Highmore towards the natural opening that's situated at supero-medial wall. In case of anterior group of ethmoidal cells, the mucus is directed towards their individual, separate ostia and from there towards the infundibulum in the cavum nasi. Mucus layer from the posterior group of ethmoidal cells gets propelled in an upward direction towards the superior meatus of the nasal cavity and from there it eventually drains out into spheno-ethmoidal region. Sphenoid sinus drains via a natural opening into the spheno-ethmoidal region.

Frontal sinus has a unique mucus flow pattern in both a retrograde and an anterograde manner. Medial portion, the mucus travels superiorly, and then laterally along it's roof. Whereas, mucus along the floor, as well as the ventral & dorsal wall, then carried medially, towards ostium. From ostium mucus drains into "frontal recess" and the infundibulum.

Osteomeatal complex- region where the mucus flow from the frontal, the anterior ethmoid air cells and maxillary sinus, all converge. From ostiomeatal complex, the secretions are propelled in the direction of uncinate process, inferior nasal concha towards posterior surface of the nasopharyngeal mucosa. The mucus flow passes in front of, & below the eustachian tube opening (Fig. 10)

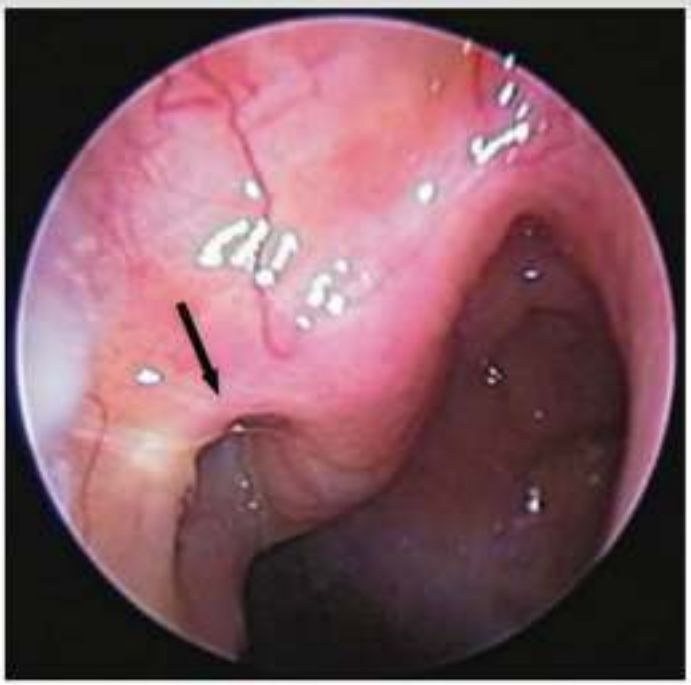


Fig 10. 0 degree endoscopy showing secretions (arrow) moving from the middle meatus & spreading over the ET opening. [13]

On the other hand, the mucociliary flow from the posterior half of ethmoid sinus and sphenoid air cells travels posterior and superior in relation to ET orifice, flowing in the direction the posterior part of the nasopharyngeal mucosa. [13]

NASAL AIRFLOW

The nasal passage and mouth act as a conduit for about 10000 liters of airflow every single day. From here, air moves into the lower part of respiratory system.[14] Mucosa of the cavity contains several arterioles, venous sinusoids and arterio venous anastomoses. The cumulative area of the mucosa of nose is around 150 cm^2. [39]

The nasal cavity and the structures within in provide significant resistance to the inspired air. During normal respiration, this nasal component of resistance justifies about 50% part from the total resistance of airway against airflow. This resistance plays significant role in respirational function of nose. [40]

Crusade of air flow via the nasal cavity is aided by combined movements by lungs and the muscles of the diaphragm, which creates the positive and negative prossure required to cause nasal airflow. The air from the environment is humidified, warmed and filtered out as it passes through the nose. This provides a protective function for the lungs. These functions are done mainly by the mucosa and mucus layer over the nasal epithelium.

The normal respiratory airflow ranges between 5L/min to 12L/min, and a pressure change of 50kPa between the nose and the nasopharynx.[43]

Once particles are entrapped in mucus blanket, they are sweeped away by movement of the cilia and also the microorganisms that get trapped are exposed to the immune system interactions and suppressed. [42]

Air is also exposed to the olfactory area, which aids in the sensation of smell as well as taste.

There are several methods to assess the machineries of different nasal functions like heating, humidify, olfaction, MCC etc. [43]

Rhinomanometry assesses the effect due to dimensions of cavum nasi on air flow. Different areas of the nose present resistance to the nasal airflow, and the presentation of this resistance is different when the air is inspired and when it is expired.

The airstream is dynamic within the nasal cavity and changes from laminar to turbulent as it moves in the nose. Air enters nose at vestibule at a lower velocity and it this portion has a laminar flow. As it passes further posteriorly, it meets areas of resistance, like the valve region. As air passes through this narrow space, the velocity of the air increases. The airflow here on shows a swirling pattern, also known as a turbulent flow. This turbulence is vital for the proper activity of the nose as it allows for velocity of the airflow to fall and prolonged exposure to mucosal blanket. This has been discussed more in detail further on.

Anatomic changes like septal deviation and turbinate hypertrophy affect the resistance offered by the nose to inspired air, apart from causing a reduction in area of mucosa, thereby affecting the proper nasal function. [44]

NASAL RESISTANCE [45]

Nasal resistance, as mentioned before, is very important for the functioning of the nose. It also prevents the collapse of the lower respiratory tract. Resistance is provided by three important anatomical structures: vestibule, valve area, turbinals. When the resistance provided by the nose in increased, there is corresponding increase in the negative intrathoracic pressure, which enhances the ventilation of the lung.

Nasal airflow is said to have two components or phases. Initially, during inspiration, the nasal airflow first passes through the nasal vestibule and curves superiorly, following which, it encounters the nasal valve area.

Nasal vestibule collapse is prevented by contraction of the ala nasi muscles during inspiration. During deep inspiration the vestibule may collapse due to the negative pressure. The ala nasi muscle is contracted during times of increased

inspiration like exercise. This results in a variation in the shape and radius of that vestibule, which prevents the surge in resistance occurring due to vestibule fall.[45]

Internal valve

The internal valve is an area beneath the caudal border of the ULC of the nose located 2cm posterior to nares this area is slenderest area in system of airway, having total sectional area ranging between 55 to 83 mm^2, providing significant proportion of the nasal resistance.

The limits of the nasal valve are: Superiorly: lower end of ULC along with septum medially. Inferiorly: nasal floor. Laterally: pyriform aperture with the nearby fibrous and fatty tissues. Posteriorly: head of inferior turbinate.

Therefore, any change in the size of the turbinate, or the position of the nasal septum can result in a change in the dimension of the nasal valve region, resulting int a change in resistance offered by it. The nasal valve produces the most turbulent airflow.[46]

The clinical importance of the nasal valve lies in the fact that, treatment of the components of the nasal valve can alter patients complaints of obstructed nose by altering the resistance.

As air stream exits this nasal valve area posteriorly, its directs the airflow in a caudal and posterior direction across anterior tip of inferior turbinate. It is dispersed through a wider distribution, this enhanced distribution provides contact of the air with more mucosal surface area, such as those of the turbinates. If the airflow was to pass without any resistance, this enhanced mucosal contact would have been lost. This air-mucosal contact is essential for the nasal mucosa to perform its functions adequately.

The nasal turbinates, their anatomically curved surfaces enable them to provide increased surface areas on which the airflow can have contact, and functions like warming of air, humidification and filtering can occur. After the contact with the turbinates, the air stream passes further posteriorly, towards the choana. At the choana, the direction of the air stream in now changed, directed inferiorly, towards the larynx and the lower respiratory tract.

The uncinate is a bony structure that structurally resembles a sickle, in middle meatal region of the cavum nasi. As an airstream passes this structure, the opening of maxillary sinus is protected from the airstream.

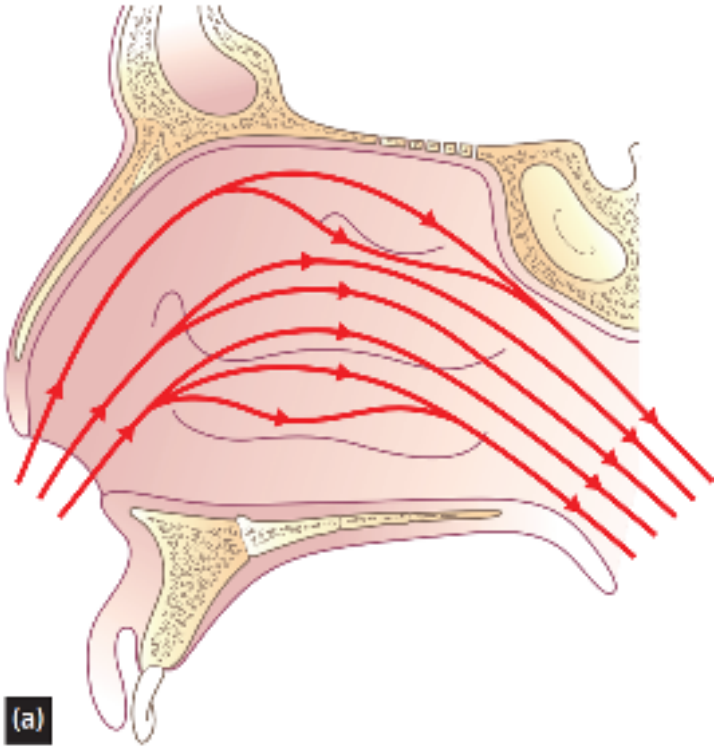


Fig. 11. Direction of inspiratory airflow[45]

The anatomy of the nasal cavity also presents similar baffles to the airstream to protect the frontal cell opening, and opening of ethmoidal air cells (Anterior and posterior).

Computational fluid dynamic studies have suggested that maxillary sinus openings do not have a significant effect on the nasal airstream, whereas an accessory ostium can provide a path for some amount of airflow into the maxillary sinus. [47, 48]

NASAL VALVE

Anatomically, the valve area is constituted of four components. [49] Each of these components act as a resistor to airflow.

The four components are:

1. Area formed in the middle of septum and lower end of ULC
2. Bony entrance of cavum nasi
3. Inferior turbinate
4. Septal nasal wall

Pathologies of the nose, like deviated nasal septum lead to a dysfunctional nasal mucosa. The area that lies between internal valve & anterior end of middle concha has a major role in humidification & heating air that enters via the nares. [50]

A more severe type of DNS is linked to sinus pathologies and turbinate abnormalities. [51]

Airflow in a nose with a deviated nasal septum has been compared with that of a normal one using functional models. The stream of airflow was found to be compressed at the site of deviation. The stream ran along concavity on the contralateral side. Formation of dead spaces, turbulence and eddy currents were also noted at sites posterior to the deviation.

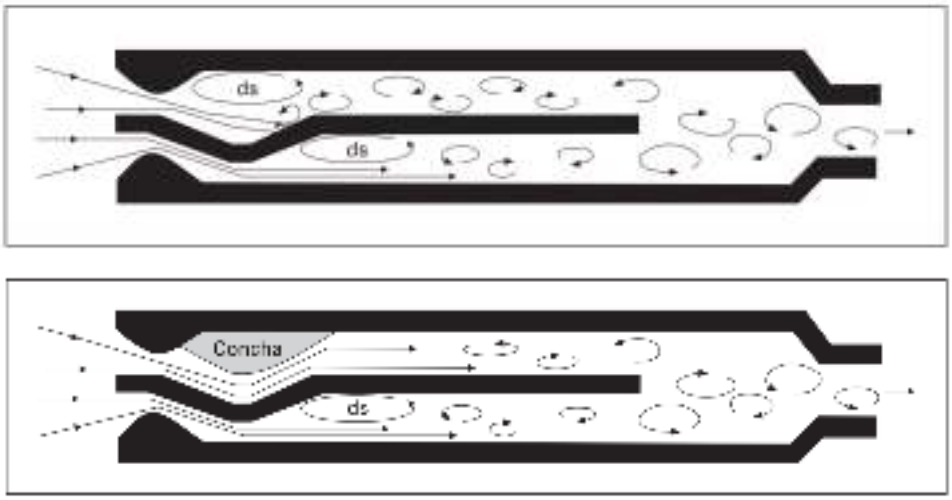


Fig. 12 Flow in models with deviated nasal septum (A) and with concha bullosa (B). Straight arrows depict laminar flow of air ; circling or curved arrows depict turbulent flow; ds: dead space.

An increase in resistance to airflow occurs at sites of narrowing due to increased friction in these regions. Turbulent airflow also leads to an increase in resistance to airflow.

As opposed to previous studies, more recent studies suggest that airflow resistance is not the mechanism by which a person perceives the sensation of airflow. Rather, it has been suggested that cooling of nasal mucosa by the inspired air, which the mechanism by which inspired air is warmed assists in discerning ventilation in nose. Therefore, any dysfunction of nasal mucosa which hampers its function can lead to the individual perception of an obstructed nose.[7]

This can be further substantiated by a study showing that topical nasal anaesthesia using 4 % lignocaine decreases the subjective sensation of nasal airflow. [52] Symptomatic complaints of a dry nose like formation of crusts, post nasal drip and the feeling of obstruction of airway is told to be a direct consequence of changes in nasal mucosal histology like alteration in goblet cell number and elastic fiber content.[53] Turbulence leads to greater changes in temperature as compared to laminar

airflow. Changes in nasal cavity anatomy will lead to greater degree of turbulent airflow.[54] Normally, turbulence of airflow provides certain advantages such as helping particulate matter in air that is inhaled to come to strike mucosa, get trapped and be swallowed.[55] Therefore turbulence indeed helps in filtering. The goal of treatment of nasal obstruction should therefore be to restore adequate mucosal cooling.[56]

Histological changes like increased inflammatory cells, lymphocytic infiltrates and decreased mucosal glands were also seen on the non deviated side of the septum. Other changes like squamous metaplasia were also observed on the same side as deviation.[57, 58] Another significant component of a patient with deviated nasal septum is the shear stress which is found to be increased in regions of narrowing within the nasal cavity. The highest value of shear stress was found to be at the same side as the deviation. And this correlates with the fact that it is the same side as deviation (convex side) that patients with epistaxis have propensity to bleed. [8]

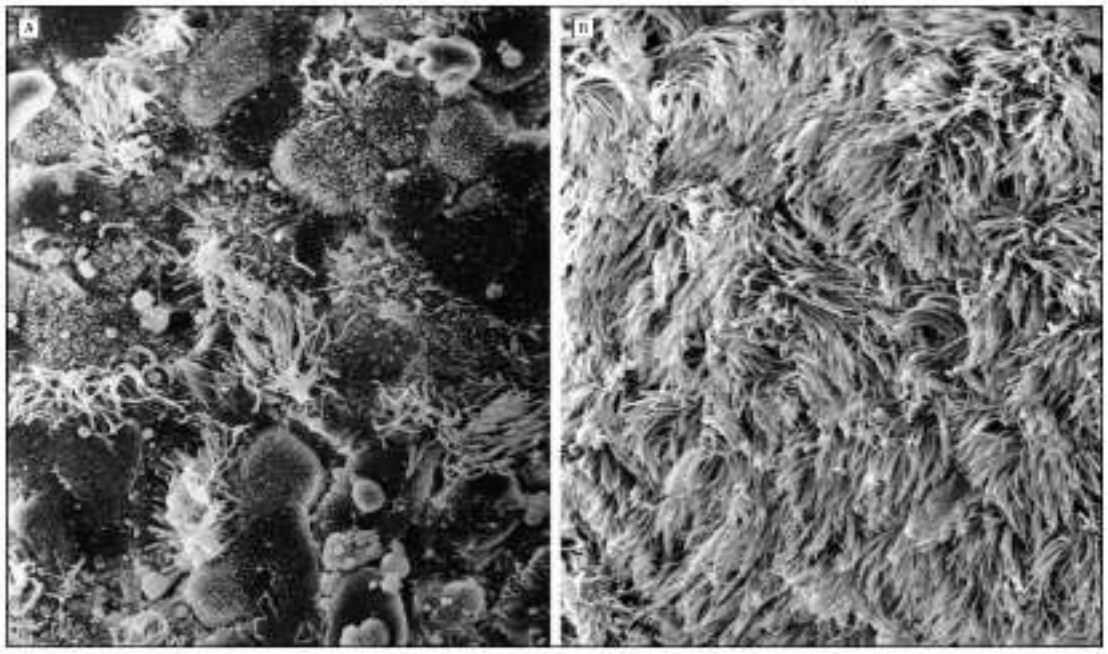


Fig 13. Electron microscopy image (A) Less density of distribution of cilia on the concave portion (B)Comparitively larger density on convex portion

On electron microscopy, concave part was seen to have a less dense distribution of cilia than deviated side. This indicates a more terrible absence of cilia over concave side in deviated nasal septum.

Same study also found an increased mucociliary clearance time on the concave part of the deviated septum, and was also most likely as a result of the loss of cilia on the concave side. Mucociliary clearance is affected by any pathology that affects the activity of the cilia. [59] The cause of loss of cilia over the concave part of the septal deviation was attributed to increased airflow.[57]

EPISTAXIS & SHEAR STRESS

Constant flow to air in the nasal cavity exerts a continuous wall shear stress (WSS) on the nasal epithelium.[60] Shear stress over the walls of the nasal septum can overwhelm the warming and moistening properties of the nasal vasculature and predispose the patient to nasal bleeding. Overall, anterior nasal bleeds are responsible for 80% of cases of epistaxis. These anterior nasal bleeds occur at a confluence of vessels named the “Kiesselbach” plexus. This plexus is seen on the caudal region of the ventral half of septum, known as “Little’s area”. [61] Kiesselbach’s plexus is an arterial anastomosis formed by the internal carotid artery via it’s terminal branches, along with external carotid artery. Kiesselbach’s plexus has protective warming and moistening properties, and shear stress leading to dryness and trauma can exceed these properties and thus lead to epistaxis.

Another effect of shear stress and the subsequent development of dryness which promotes drying up and crusting of secretions, these dried up secretions, apart from imparting a sensation of nasal obstruction, can also lead to nose picking and hence epistaxis.[8]

This is also substantiated by the finding that antiseptic creams are an effective treatment for anterior epistaxis as the cream acts as a protective layer, thus preventing the damage of the underlying mucosa by shear stress, thus allowing the underlying mucosa to heal effectively.[62]

Epistaxis rates are found to higher when the climate is dry, substantiating the fact that a dry nasal mucosa is more prone to bleeding.[63]

QUANTIFICATION OF NASAL AIRFLOW

Some tests that are used to quantify airflow withing nasal cavity in in objective manner are: 1.Rhinomanometry- a method that calculates resistance to airflow. 2.Acoustic type of rhinometry measures volume of the cavity and the sectional area it. As mentioned before, these measured values do not have a direct, significant impact on the individual sensation of nasal flow of air and the complaints of obstructed nose.

Hence, there is a lack of objective clinical tests to diagnose and treat nasal congestion. Treatment based on subjective opinion can lead to inconsistent outcomes of treatment.[56]

Broadly, there are two ways[64] of objectively assessing obstruction:

(i) Assessing anatomy of nasal airway radilogically

(ii) Airflow assessment

The following are methods that can objectively measure and assess the respiratory pathway:

(a) Assessment of measurements of cavity and associated structures

(b) Calculation of nasal airflow

(c) Rhinomanometry

These tests are also cumbersome as they demand custom made aapparatus and can result in patient being uncomfortable. [65]

Imaging of nasal cavity using modalities such as computed tomography provides a clear view of the cross sectional anatomy. These images can then be used to estimate the dimensions of the nasal cavity. Acoustic rhinometry can be used for assessment of these nasal dimensions, as it is a less expensive method. [64]

Rhinomanometry involves the synchronized assessment of the quantity of the pressure and air movement via the nasal cavity. Compiling both flow and pressure concurrently allows the estimation of nasal airflow resistance. [66]

Acoustic type of rhinometry has been used to evaluate the dimensions of the cavity and airway. These measurements are made by reflected waves of sound, caused by structures within the nose. The method entails touching an incident sound wave to medium and then detecting the reflected wave and making calculations based on these findings. The anatomy of the structure can be determined by calculating the difference between the times taken by incident sound and the reflected sound waves, and their amplitudes. Acoustic rhinomanometry, however does not measure the airflow through the nose.[67]

Computational fluid dynamics, on the other hand is used to develop a model that has 3 dimensions using radiological imaging like Computed Tomography.

In these 3 dimensional models, different pressures of airflow, which represent the distinct pressures across the nasal cavity during the cycle of respiration are used. The computerized software then calculates the velocity of flow in different anatomic sites within the cavity of nose at certain point of time during respiration. Calculations like these hep to study the impact of various anatomic variations or pathologies in the respiratory air stream. [68]

SCHIRMERS

Schirmers strips are made of Whatman No. 41 filter paper. Whatman filter papers are made of high quality cellulose. It is used routinely in ophthalmology to measure the rate of tear production, it works by the principle of capillary action. It is calibrated from 0-35 mm such that the wetting distance can be measured in millimeters. (Fig 13)

It is used as an indirect measure of tear production, thus acting as a simple apparatus to evaluate the status of ocular surface.[69]

Even though the strip end is usually rounded, its presence in the fornices of the eyes induces reflexed tear secretion via a trigeminal nerve stimulation. The strip absorbs these secretions and the length of strip that gets wetted points towards the amount of secretions.[70]

In ophthalmologic setting it has been performed bilaterally. When performed without local anesthetic it is called Schirmer type I and when done along with a locally acting anesthetic drug Schirmer type II. The strip is placed at confluence of middle & lateral 1/3rd of the lower lid.[71] The subject is asked to close his/her eye-lids gently, and the length of strip that is soaked is read after 5 minutes from the standardized Schirmers strip. Wetting distance that is less than <5 mm in both Schirmer-I and Schirmer-II tests or a variation above 30% between the two sides in Schirmer-I-test is considered pathologic.[72]

A modified version of this test has been used intraorally to diagnose salivary gland hypofunction in patients who complain of dry mouth. In this modified schirmers test, Schirmers strip is positioned on the floor of the oral cavity and distance of strip wetted after a full 5 minutes was noted.[73,74]

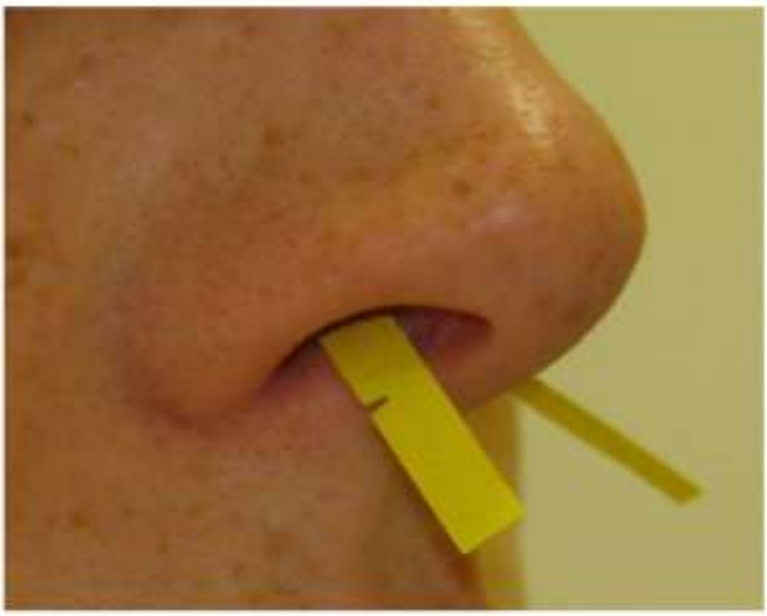


Fig 14. Placement of intranasal Schirmers strips on the anterior part of nasal septum.[75]

Use of these strips to measure intranasal moisture has been evaluated in a few other studies.

Lindermann et al. attempted to quantify a standard value for adult nasal secretion. Their study included 159 non smokers and 30 healthy smoking volunteers. In their study, majority of the values fell between the ranges of 6-18mm, which showed that there is wide range of variability in nasal moisture even in normal individuals.[75] This was attributed to the different patterns of nasal cycles in different individuals.[76,77] However, this study also noted a decrease in Schirmer value in volunteers who were smokers, as opposed to non-smokers ($p < 0.05$). This difference was hence statistically significant, showing that habits like smoking do affect the intranasal moisture.[75]

Intranasal Schirmer test was also done in patients with deviation of septum to assess effect caused by deviated septum on the mucosa and the moisture status of the nasal mucosa.[78]

This study had the following conclusions:

- The Schirmer test values were:
    - Convex sides → 20.71±7.29
    - Concave side → 23.35±6.47
- There was no statistical significance of the above difference (p=0.054).
- Comparison of intranasal wetting distance values of the normal population group with subjects having deviations of septum showed no statistical significance in the concave part of DNS (p = 0.101) or the convex part (p = 0.584).
- On deviated part (convex) of septum, values were less than values of the contralateral or concave part, however, there was no statistical significance in this difference.

The decreased values on the deviated side was told to be due to decreased humidity on the deviated side of the septum as a result of the altered airflow. Local turbulent vortices are formed, and the high velocity of airflow anterior to the septal deviation, causes an increase in airway resistance, this can lead to damage to deviated portion mucosa as well as dryness.[79]

The lack of a significant difference in the values maybe due to the fact that a compensatory inferior turbinate hypertrophy develops. This is alleged to have a protective role in preventing excess dryness of nasal mucosa on the non deviated side.[80]

Also, 34 patients in their study had greater wetting distances on using Schirmer strip over non-deviated portion, highlighting humidification of the inferior conchal mucosa on opposite side of deviation.

MATERIALS AND METHODS

Source of data

For our study, we collected data from patients who attended the E.N.T & HNS outpatient department in Dr Prabhakar Kore Charitable Hospital from January 2020 to December 2020.

Method of data collection

This study in an observational type of study was performed between the months of January and December in the year 2020.

INCLUSION CRITERIA:

We included patients who have a deviated nasal septum, who were advised septoplasty, and subjects without deviated nasal septum who are attending the ENT & HNS department in KLE Dr. Prabhakar Kore charitable hospital, after excluding certain patients mentioned under exclusion criteria by history, clinical examination and relevant investigations.

EXCLUSION CRITERIA:

- Patients with any other nasal pathology other than a deviation of septum.
- Those who do not wish to be included in our study
- Patients over 60 years of age
- Smokers
- Patients giving any history of URTI in the last two months
- Patients with allergic rhinitis (on history and clinical examination)
- History of any nasal surgeries
- Patients using intranasal medications that affect nasal moisture such as steroid sprays.

METHODOLOGY:

- After taking informed consent from the patient, their demographic details, a clinical history was taken. This included any history of allergic symptoms and history of smoking.
- All patients will be clinically examined, including a general physical examination, examination of the ear, nose and throat, & endoscopic nasal examination, followed by administration of the intranasal schirmers test.

PROCEDURE

Instruments used in the administration of intranasal Schirmer test were: Tilley's forceps, Thudicum's nasal speculum, Sterile Schirmer strip. (Photograph 1 and 2)

Intranasal schirmers test will be performed as follows:

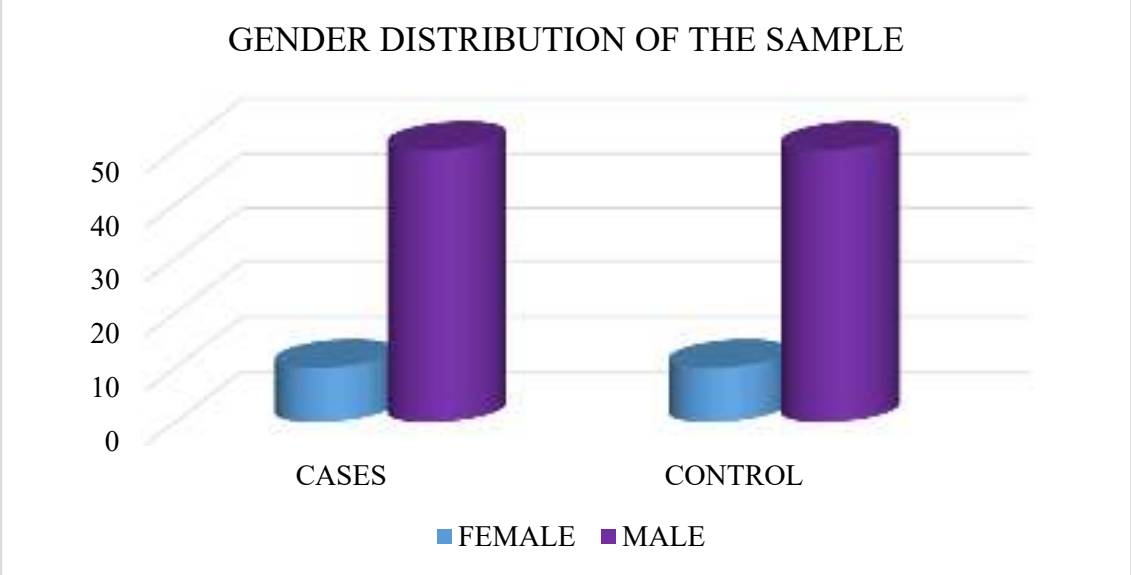
- All tests were untaken in both nasal cavities by the same investigator.
- Tests were done between 10AM and 2PM under standardized conditions of humidity.
- Test strip was creased at 5 mm distance from the curved end at an angle of 45 degrees. (Photograph 3 and 4)
- Schirmers strips were placed in both the nasal cavities; on the mucosa, on the anterior part of septum, 5 mm behind the mucocutaneous junction while performing anterior rhinoscopy. (Photograph 5 and 6)
- After 10 min, forceps were used to remove the wetted strips and measure distance.
- Wetting distance is measured as per the markings on schirmers test strip and recorded. (Photograph 7)

RESULTS

TABLE 1

GENDER	CASE	CONTROL
FEMALE	10	10
MALE	50	50
TOTAL	60	60

GRAPH 1

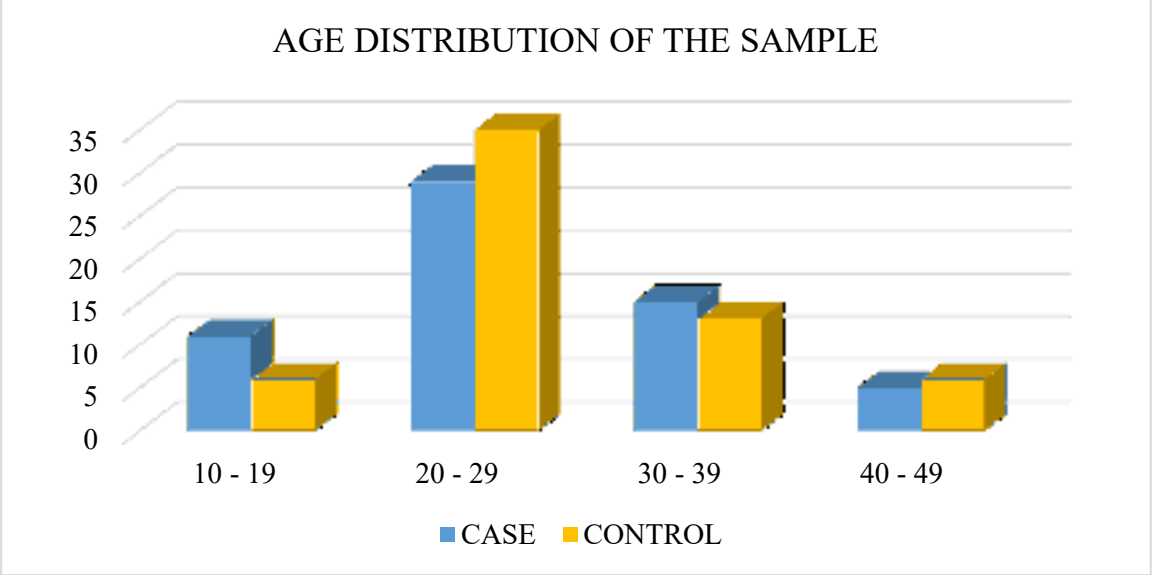


As shown in Table 1 and graph 1, the gender distribution in this study is equal between cases and controls, there were 10 females and 50 males each, in the case and control group.

TABLE 2

AGE	CASE	CONTROL
10 - 19	11	6
20 - 29	29	35
30 - 39	15	13
40 - 49	5	6
TOTAL	60	60

GRAPH 2



There were 11 cases and 6 controls in the 10 – 19 years age group; 29 cases and 35 controls in 20 – 29 years group; 15 cases, & 13 controls in 30 – 39 years age group, and 5 cases and 6 controls in the 40 – 49 year group, as shown in table 2 and graph 2.

In the following tables p value is calculated using student's unpaired t test using SPSS 20 software:

Abbreviations:

NS -NOT SIGNIFICANT

S – SIGNIFICANT

VS - VERY SIGNIFICANT

HS - HIGHLY SIGNIFICANT

TABLE 3

	CASES				CONTROL					
	MEAN	S.D.	MINIMUM	MAXIMUM	MEAN	S.D.	MINIMUM	MAXIMUM	p VALUE	INFERENCE
AGE	26.07	8.07	16	44	26.53	7.84	16	45	0.7486	NS

The mean age was 26.07 years in case group, and 26.53 in control group. (Table 3)

TABLE 4

FOR CASES

ANTERIOR RHINOSCOPY SIDE OF DEVIATED SEPTUM	NUMBER
LEFT	26
RIGHT	34
TOTAL	60

As shown in table 4, amongst the 60 cases, there were 26 cases deviation of septum (convex side) to right, whereas 34 patients had a deviation to the left.

SCHIRMER VALUES (CASES)

TABLE 5

SCHIRMERS VALUES (MM)	(DEVIATED) CONVEX SIDE	CONCAVE SIDE
<6mm	38	10
6-18mm	22	48
>18 mm	0	2
TOTAL	60	60

As seen in table 5, in the case group, majority of the shirmers values were <6mm over convex part (deviated side) of septum. On concave side, the values ranged from 1mm-25mm, with majority falling in the 6-18mm range.

TABLE 6

	(DEVIATED) CONVEX SIDE (MM)				CONCAVE SIDE (MM)					
	MEAN	S.D.	MINIMUM	MAXIMUM	MEAN	S.D.	MINIMUM	MAXIMUM	p VALUE	INFERENCE
SCHIRMERS VALUES	4.78	2.82	1.000	17	10.07	4.97	1.000	25	< 0.0001	HS

GRAPH 3

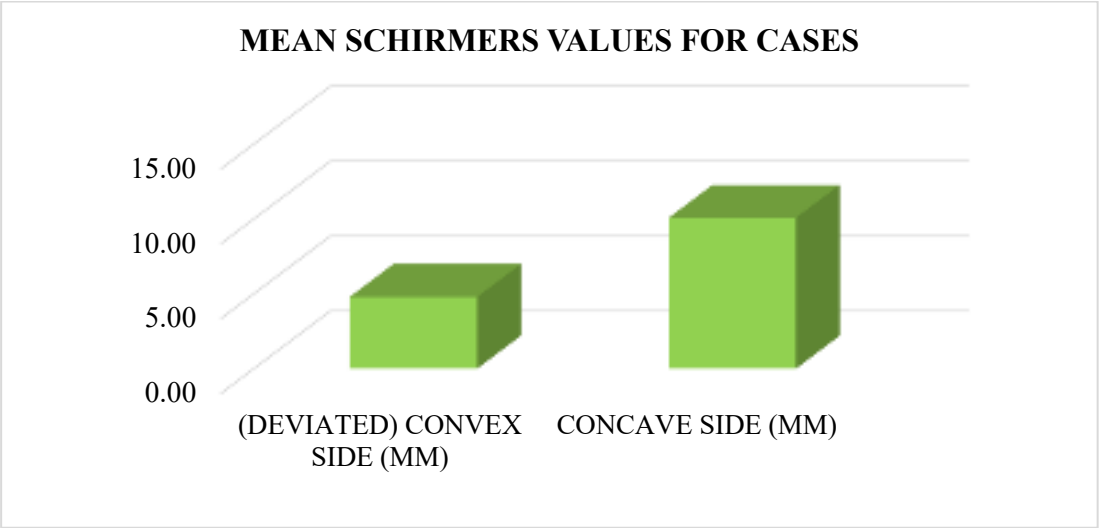


Table 6 and graph 3 show that the mean Schirmer value on the convex side was 4.78mm, whereas on the concave side the mean value was 10.70mm.

SCHIRMER VALUES (CONTROLS)

TABLE 7

SCHIRMERS VALUES (MM)	RIGHT	LEFT
<6mm	6	2
6-18mm	54	58
>18mm	0	0
TOTAL	60	60

Table 7: Schirmer values in the control group were taken from either side of the septum, the values ranged from 4mm to 15mm, with majority of the values falling in the 6-18mm range on both sides.

TABLE 8

	RIGHT				LEFT					
	MEAN	S.D.	MINIMUM	MAXIMUM	MEAN	S.D.	MINIMUM	MAXIMUM	p VALUE	INFERENCE
SCHIRMERS VALUES	8.97	2.56	4	14	9.38	2.38	5	15	0.3581	NS

GRAPH 4

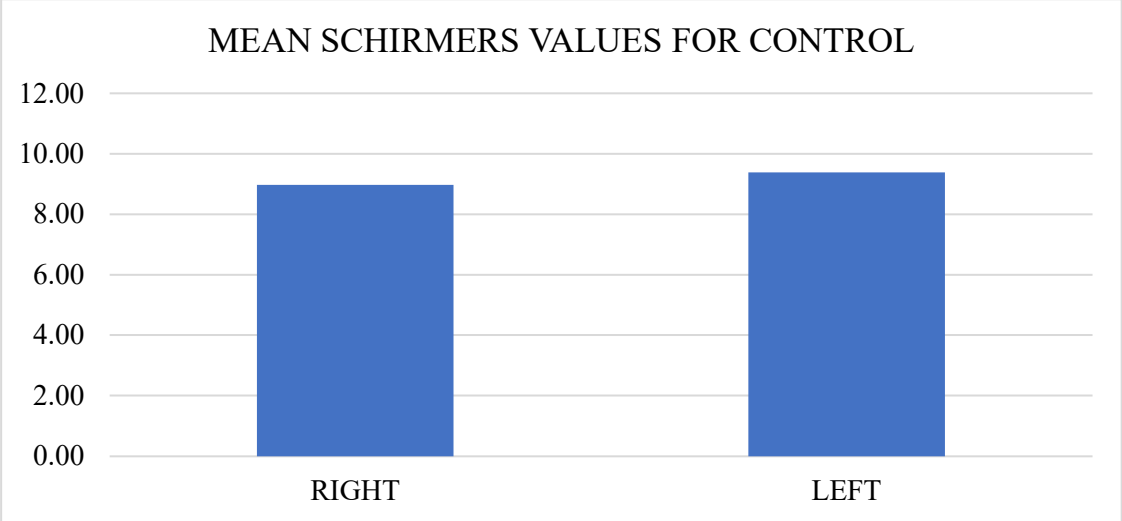


Table 8 and graph 4: The values of Schirmer were compared between the right and the left sides of normal septum of control group. Mean value on right was 8.97mm and that on the left was 9.38mm.

COMPARISON BETWEEN CASES AND CONTROLS

TABLE 9

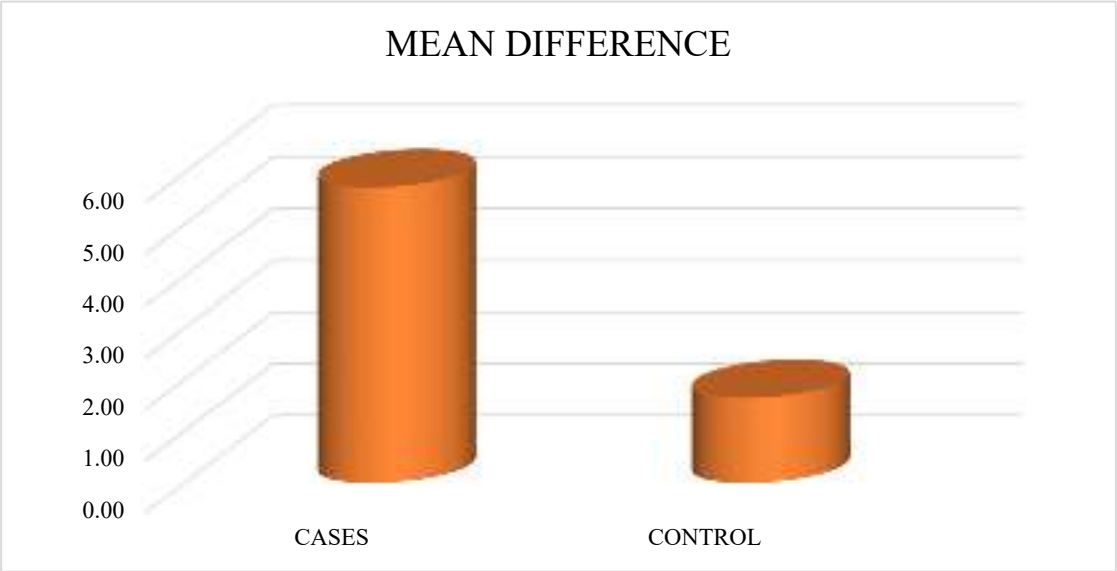
DIFFERENCE (between two sides of septum)	CASE	CONTROL
0	0	1
1	3	24
2	4	30
3	9	5
4	4	0
5	7	0
6	13	0
7	8	0
8	2	0
9	8	0
10	1	0
13	1	0
TOTAL	60	60

The difference in schirmers values between the two sides of the septum were <3mm in all the controls, whereas it ranged from 1mm-13mm difference between the two sides in cases, with majority of the values falling between 3mm-9mm.

TABLE 10

	CASES				CONTROL					
	MEAN	S.D.	MINIMUM	MAXIMUM	MEAN	S.D.	MINIMUM	MAXIMUM	p VALUE	INFERENCE
DIFFERENCE	5.72	2.78	1	13	1.65	0.66	0	3	< 0.0001	HS

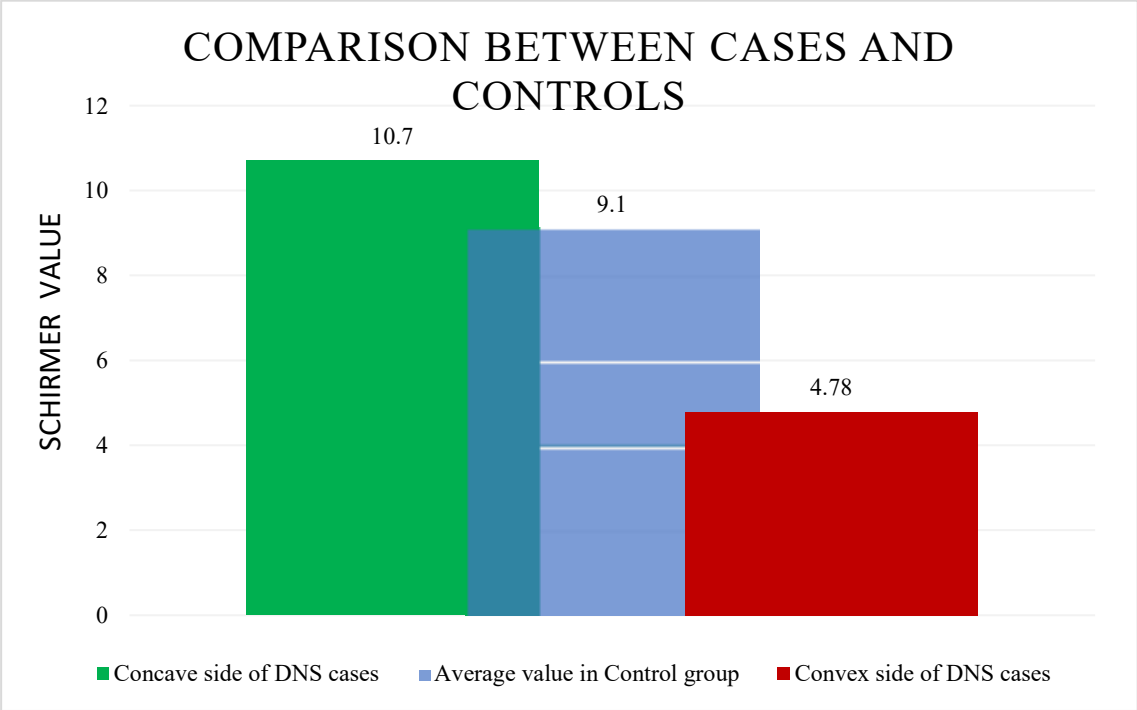
GRAPH 5



As seen in table 10, the mean difference in schirmers values between the two sides of the septum in cases was 5.720 mm, and in controls the mean difference between the sides was 1.65mm.

This is also depicted in graph 5.

GRAPH 6



As seen in graph 6:

Control group, showed an average of the mean schirmers value of the right & left side of septum was 9.1mm, this value was closer to the mean value of schirmers in the concave side of the septum in the case group, which was 10.7 mm.

DISCUSSION

The complaint of a dry nose is commonly encountered in ENT. Few studies have even shown a rise in these complaints and this rise has been attributed to changes in our environment, like pollution and the use of air-conditioning.

Deviation of the nasal septum can lead to an alteration in nasal resistance and the airflow patterns of the nose. These changes in physiology adversely affect the nasal mucosal lining, causing drying up and crusting of secretions, and also thinning of epithelium and epistaxis. These complications of the deviated septum can be avoided if the dryness of nasal mucosa is detected early.

Objective tests to assess nasal airflow like rhinomanometry are cumbersome to perform and can be uncomfortable for the patient.

The Schirmer test has previously been evaluated as a simple, non-invasive test to assess the status of the nasal mucosa. In a previous study by Lindermann et al in 2014, use of Schirmer strips intranasally was found to be well tolerated by patients.[75] Another study undertaken by Özlem Önerci et al in 2018, 52 patients having deviated nasal septum and noted that the mean Schirmer value was greater on the concave portion of septal deviation. [78]

The test was done bilaterally, values between 6-18mm are considered normal, as was suggested by Lindermann et al, where 80% of people with a healthy mucosa had values that fell within these limits. [75] This normal range was reflected in our controls, where majority of the values fell in the 6-18mm range on both sides. Where the mean value on right was 8.97mm± 2.56mm and that on the left was 9.38mm± 2.38mm.

Through our study, our goal is to assess the effects a deviation in nasal septum can have on intranasal moisture, by measuring objectively, the amount of nasal secretions on either side of the septum. The values were then compared between deviated and non-deviated side of the septum. Intranasal schirmers values of patients with deviated nasal septum were also compared with those of the normal population.

For the purpose of our study, we excluded patients above the age of 60 years, as age is known to alter the nasal moisture status significantly. [81]

Similarly, cigarette smoking was also found to affect the nasal secretions and moisture within the nasal cavity and hence we also excluded patients and volunteers who were smokers. [75]

Subjects with a history of allergic symptoms were not included in our study, as this affects the intranasal moisture due to the increased amount of nasal secretions in these patients.

Our study includes 60 patients who were found to have a septal deviation, and in this group 10 subjects are female and 50 are male. The mean age was 26.07 years (case group). No statistical significance was noted in the variation amongst subjects in either group in terms of age or gender distribution (p value for this was greater than 0.05). Thus there was no gender or age bias in our study.

There were 26 patients (43.3%) with a deviated septum (convex side) to the right, whereas 34 patients (56.6%) had a deviation to the left.

It was found that over convex (deviated) side of septum, the Schirmers values were lesser, as compared to the concave side. The mean Schirmer value on the convex side was 4.78 ± 2.82mm, whereas on the concave side the mean value was 10.70 ±

4.97mm. The difference between these two values was found to be of statistical significance, with a p-value of < 0.0001. This finding was similar to that of Özlem Önerci et al, who conducted a similar study in 2018 on 52 deviated nasal septum subjects and noted- mean Schirmer value was greater on the concave portion of septum. However, the difference wasn't statistically significant as per their study. [78]

This difference in moisture can be attributed to two reasons:

1) The increase in velocity of airflow at the site of narrowing due nasal deviation can lead to the formation of a turbulent pattern of airflow, this turbulence leads to drying up nasal secretions, apart from mechanical damage to the nasal mucosa. These lead to decreased moisture of epithelium over deviated side and hence, lower wetting distance on performing intranasal Schirmers. [68,69]

2) Epithelium over non-deviated side showed presence of a compensatory hypertrophy of the inferior concha. Hypertrophy is presumed to occur as a protective mechanism against excessive drying and crusting in the larger nasal cavity due to higher amount of airflow.[80,82]

In our study, 57 out of 60 patients were found to have a higher Schirmer value on the non deviated side, and on clinical examination, 49 of these patients were noted to have a compensatory turbinate hypertrophy on non deviated portion.

In control group, majority of Schirmer values, both over the right as well as left side of the "normal" septum fell in the 6-18mm range, proving that both the nasal cavities have comparable and good moisture status in the absence of a septal deviation.

The mean wetting distance for controls on the right side was 8.9 ± 2.56 and left side was 9.38 ± 2.38 and this difference was found to be statistically insignificant. This shows that the Schirmer values were comparable between the two sides in controls, thereby solidifying the concept that a deviated nasal septum affects intranasal moisture adversely. These values also fell within the normal range as describes in a previous study. [75]

We also found it worthwhile to compare the difference in the Schirmers values between the two sides of the septum in case of cases and controls, as even if the absolute value of Schirmers values ranged from 1-25mm on either side, the difference between the concave, & convex side in patients having a deviated nasal septum was striking. The mean difference in the case group was 5.72 ± 2.78 and the in the control group it was 1.65 ± 0.66 this disparity was again found to be statistically significant. These findings were in contrast to that of Özlem Önerci et al, as the difference was not statistically significant in their study. [78]

On comparing the concave and convex sides separately to the mean of Schirmers value in control group, it was noted that the mean value on the concave side (10.70 ± 4.97mm) was closer to (and greater than) that of the control group (9.18 ± 2.32), as compared to the mean value on the convex side (4.78 ± 2.82mm). This signifies that although the nasal cavity is widened on the concave side, which could potentially lead to excessive drying of the mucosa due to increased airflow, the nasal moisture is maintained at a normal level. This can be attributed to the compensatory enlargement occurring in inferior turbinate mucosa on concave part, which instigates a greater secretion of protective mucus. Thus preventing drying up of the nasal cavity.

To our knowledge, this is a comparison that has not been done in any previous similar study.

One of the points to be noted is that, Lindermann et al. concluded in one of their studies done in 2014, that there is no statistical correlation when comparing the results of objective assessment such as rhinomanometry or acoustic rhinomanometry and intranasal Schirmer test values. [75] These tests were not used in our study.

We recommend that correction of anatomical abnormalities like deviation of nasal septum, in an attempt to correct the nasal physiology would be worthwhile. This will help to prevent the complications of dryness, and improve the quality of life of patients.

CONCLUSION

This is the first study of it's kind done in the Indian population. There is only one other study, done in Turkey in 2018 by Özlem Önerci et al that studied the effect of nasal septal deviation on intranasal moisture.[78] Using the strips to assess nasal moisture in population having a deviation of nasal septum, our study found that, the moisture levels are less over the deviated (convex) side of deviation. This finding is in line with the widely known negative aspects of septal deviation on airflow patterns within patient's nose as well as it's negative effects on the nasal mucosa itself.

Additionally, we also found a statistically significant difference when comparing the Schirmers values between the two sides of the septum in deviated nasal septum and controls. It was also noted that the Schirmer value on the concave portion of cases was greater than the mean value of the control group, as well as the value of Schirmer on the convex portion in cases. This is an observation that was not noted in previous studies.

We recommend performing corrective surgery in patients with deviated septum, to correct and restore the nasal physiology. This can prevent complications of dryness of nasal mucosa and improve the quality of life of patients

More studies, preferably on a larger population should be done to further strengthen these finding as well as to assess how other nasal pathologies can affect the nasal mucosa and intranasal moisture levels. Further studies can also be done to assess the post operative difference in Schirmer values in patients after corrective surgery.

SUMMARY

Assessment of the status of moisture levels in the nasal cavity is an indirect measurement of how the deviation in septum can affect the nasal mucosa. Objective methods to assess the same are cumbersome, requiring equipment, expertise and patient cooperation. Schirmers strips are filter paper strips that are conventionally used to assess the amount of tear production in the eye. Therefore, in our study, we used the Schirmers strips intranasally in those who were found to have a deviated septum, in an attempt to quantify the status of the nasal moisture in an easy manner.

We conducted this study in an effort to quantify objectively, the effects of deviated nasal septum on nasal moisture status using intranasal Schirmer test as our tool.

Our study was an observation study that included 60 subject with nasal septum that had a deviation and 60 subjects without any deviated nasal septum.

We performed intranasal Schirmer test to all patients and normal population. The test was done bilaterally.

After analysis of our findings, we found that on convex (deviated) side of septum, the Schirmers values were lesser (4.78 ± 2.82mm), as compared to the concave side (10.70 ± 4.97mm). This was of statistical significance (p-value < 0.0001). The mean difference of the two sides in the case group was 5.72 ± 2.78 mm and the in the control group it was 1.65 ± 0.66 mm this disparity was again found to be statistically significant. It was also noted that the mean value on the concave side

(10.70 ± 4.97mm) was closer to (and greater than) that of the control group (9.18 ± 2.32), as compared to the mean value on the convex side (4.78 ± 2.82mm).

The findings of our study highlight the negative sequelae of a septal deviation on the airflow in the nose, as well as the nasal mucosa itself. Giving an objective finding of lesser wetting distances on the convex portion of septal deviation.

We would like to conclude that, using the Schirmers strips intranasally was found to be a simple and quick method to objectively analyze the moisture status of the nose. Subjects did not complain of discomfort and there were no complications. We recommend performing corrective surgery in patients with deviated septum, to correct and restore the nasal physiology. This can prevent complications of dryness of nasal mucosa and improve the quality of life of patients.

Further studies can also be performed to compare the preoperative and postoperative Schirmers wetting distances in patients with deviated nasal septum, after corrective surgery. We also recommend that more studies be done, to analyze the effects of other nasal pathologies on the nasal mucosa.

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ANNEXURE I. ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 306 **Date: 24/12/2019**

To.

REG. NO: BE0119009

PG student in Otorhinolaryngology and Head & Neck Surgery,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ASSESSMENT OF CHANGES IN INTRANASAL MOISTURE AS AN EFFECT OF A DEVIATED NASAL SEPTUM USING INTRANASAL SCHIRMER TEST – A ONE YEAR HOSPITAL –BASED OBSERVATIONAL STUDY KLES DR. PRABHKAR KORE HOSPITAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II

INFORMED CONSENT

"ASSESSMENT OF CHANGES IN INTRANASAL MOISTURE AS AN EFFECT OF A DEVIATED NASAL SEPTUM USING SCHIRMER TEST"- A ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY.

PRINCIPAL INVESTIGATOR: REG. NO: BE0119009

Post Graduate student

Department of Otorhinolaryngology.

CO-INVESTIGATOR : DR. _____

Professor, Department of Otorhinolaryngology

J.N. Medical College

INTRODUCTION AND PURPOSE:

The present study is conducted among patients with deviated nasal septum and normal population attending the out-patient department of ENT & HNS in KLE's Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, Belgaum. You are requested to participate in the study and your participation is completely voluntary.

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 intranasal moisture status by using a simple 10 minute test using intranasal Schirmer strips.

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 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. Reshma Ramanan without any hesitation on Mobile no: 9916198348 and the guide Dr. N. R. Ankle, Mobile No: . If you have any questions about rights as a research participant you can contact Dr Roopa M Bellad, Professor, department of Paediatrics, 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:**

माहितीपूर्ण संमती

"स्कीमर्स चाचणी वापरत असणा ना□ सेष्टमच्या परिणामस्वरूप आंतरि□ मॉइस्चरमध्ये होणा-□ा बदलांचे आ□ लन" - ए□ वर्षाच्या हॉस्पिटल बेस्ड ऑब्सरव्हिएशनल स्टडी.

प्रिन्सिपल इन्व्हेस्टिगेटर: Dr. REG. NO: BE0119009

पदव्युत्तर विद्यार्थी

Otorhinolaryngology विभाग.

□□कारी अन्वेषक: Dr. _____

Otorhinolaryngology विभाग

जे.एन. मेडिकल कॉलेज

परिचय आणि उद्देश: केएलईच्या डॉ.प्रभाकर कोरे चरिटेबल □ॉस्पिटल आणि मेडिकल रि□र्च □ेंटर, बेळगाव येथील ईएनटी आणि एचएनए□च्या बाह्य रुग्ण विभागात विचलित नाकातील □ेष्टम आणि □ामान्य लोक□ंख्या अ□लेल्या रूग्णांमध्ये □ा अभ्या□ केला जातो. आपल्याला अभ्या□ामध्ये □□भागी □ोण्याची विनंती आ□े आणि आपला □□भाग पूर्णपणे ऐच्छिक आ□े.

प्रक्रिया: आपण या अभ्या□ामध्ये भाग घेण्या□ □□मती दर्शविल्या□, □ंबंधित आकडेवारी प्रोफार्मा नु□ार गोळा केली जाईल आणि अंतिम निदानाची पुष्टी □ोईल. अभ्या□ामध्ये □ामील झाल्यानंतर, इंट्रानें□ल शिर्मर पट्ट्यांचा वापर करून 10 मिनिटांची □ाधी चाचणी वापरुन आपले इंट्रानें□ल ओलावा स्थितीचे मूल्यांकन केले जाईल.

फायदे: अभ्या□ामध्ये आपल्या □□भागाच्या आधारे रुग्ण कोणत्या□ी प्रकारच्या आर्थिक लाभां□ाठी किंवा विनामूल्य □ेवे□ाठी पात्र ठरणार ना□ी.

जोखीम: अभ्या□ा□ाठी लागू केलेल्या पद्धती □ुरक्षित आ□ेत.

□□भागाचा खर्चः अन्वेषणाचा खर्च अभ्या□ विषयाद्वारे व□न केला जाईल. अन्य अप्रत्यक्ष खर्च अन्वेषक तपा□ेल.

गोपनीयता आणि गोपनीयता: अभ्या□ाचे निकाल वैज्ञानिक उद्देशाने नियतकालिकांमध्ये प्रकाशित केले जाऊ शकतात. तथापि, आपली ओळख उघड केली जाणार ना□ी. □ंकलित केलेली □र्व मा□िती कोडित केली जाईल जेणेकरून अन्वेषक व्यतिरिक्त इतर कोणाला□ी आपली ओळख कळू शकणार ना□ी.

अभ्या□ानु□ार आपली इच्छा अ□ल्या□ आपण कधी□ी अभ्या□ामधून माघार घेऊ शकता.
परिणाम प्रकाशित करण्या□ाठी प्रमाणीकरण: □ंशोधक या अभ्या□ामधून गोळा केलेल्या मा□ितीचा उपयोग वैज्ञानिक बैठकींमध्ये □ादरीकरणा□ाठी करू शकतात. तथापि, आपली ओळख उघड केली जाणार ना□ी.

प्रश्न आणि □ंपर्क: अभ्या□ा□ंदर्भात का□ी शंका अ□ल्या□ मोबाईल क्रमांक: 9916198348 आणि कोणत्या□ी मार्गदर्शकाबद्दल डॉ. रेश्मा रामानन यांच्याशी □ंपर्क □ाधू शकता आणि मार्गदर्शक डॉ. एन. आर. अंकले, मोबाइल नंबर: □ंशोधन □□भागी म्हणून आपल्याला □क्कांबद्दल का□ी प्रश्न अ□ल्या□ आपण डॉ. रूपा एम. बेलाड, प्रोफे□र, बाल रोगशास्त्र विभाग, जवा□रलाल ने□रू मेडिकल कॉलेज मानवी विषयांच्या □ंशोधनावरील □ंस्थागत नीतिशास्त्र □मितीशी □ंपर्क □ाधू शकता.

□ंक्षिप्त □ारांश: मला या □ंमती फॉर्मची □र्व □ामग्री माझ्या स्थानिक भाषेत स्पष्ट केली गेली आ□े आणि अभ्या□ाबद्दल माझ्या □र्व प्रश्नांना माझ्या मा□ितीनु□ार □मजून घेतल्यावर आणि त्या स्पष्ट केल्यावर, मी

अभ्या□ात □□भागा□ाठी माझी स्वेच्छा □ंमती देतो. मी ज्यांना मी ओळखतो त्या प्रत्यक्षदर्शी□मोर माि□ती □ंमती फॉर्मवर □□ी करतो.

□□भागीचे नाव व स्वाक्षरी / डाव्या अंगठ्याचा ठ□ा:

मुलाखतदाराचे नाव व स्वाक्षरीः

नाव आणि स्वाक्षरी / प्रत्यक्षदर्शीच्या डाव्या अंगठ्याचा ठ□ा (□ंबंधित):

मार्गदर्शकाची □□ी: तारीख:

ಮಾಹಿತಿ ಕನ್ಸೆಂಟ್

"ಸ್ಕಿರ್ಮರ್ ಟೆಸ್ಟ್ ಅನ್ನು ಬಳಸುತ್ತಿರುವ ವಿಕೃತ ನಾಸಲ್ ಸೆಪ್ಟಮ್ನ ಪರಿಣಾಮವಾಗಿ ಇಂಟ್ರಾನಾಸಲ್ ಮೊಯಿಶ್ಚರ್ನಲ್ಲಿ ಬದಲಾವಣೆಗಳ ಮೌಲ್ಯಮಾಪನ" - ಒಂದು ವರ್ಷದ ಹಾಸ್ಪಿಟಲ್ ಆಧಾರಿತ ಅಬ್ಸರ್ವೇಷನಲ್ ಸ್ಟಡಿ.

ಪ್ರಿನ್ಸಿಪಾಲ್ ಇನ್ವೆಸ್ಟಿಗೇಟರ್: REG. NO: BE0119009

ಸ್ನಾತಕೊತ್ತರ ವಿದ್ಯಾರ್ಥಿ

ಒಟೊರಿನೋಲರಿಂಗೋಲಜಿ ಇಲಾಖೆ.

ಸಹ-ಸಂಶೋಧಕ: ಡಿ.ಆರ್._____

ಪ್ರೊಫೆಸರ್, ಒಟೊರಿನೋಲರಿಂಗೋಲಜಿ ವಿಭಾಗ

ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಕಾಲೇಜು

ಪರಿಚಯ ಮತ್ತು ಉದ್ದೇಶ:

ಪ್ರಸ್ತುತ ಅಧ್ಯಯನವನ್ನು ಬೆಲ್ಗಾಮ್ನ ಕೆಎಲ್ಇನ ಡಾ.ಪ್ರಭಾಕರ್ ಕೋರೆ ಚಾರಿಟೇಬಲ್ ಆಸ್ಪತ್ರೆ ಮತ್ತು ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರದಲ್ಲಿ ಇಎನ್ಟಿ ಮತ್ತು ಎಚ್ಎನ್ಎಸ್ನ ಹೊರ ರೋಗಿಗಳ ವಿಭಾಗಕ್ಕೆ ಹಾಜರಾಗುವ ಮೂಗಿನ ಸೆಪ್ಟಮ್ ಮತ್ತು ಸಾಮಾನ್ಯ ಜನಸಂಖ್ಯೆಯ ರೋಗಿಗಳಲ್ಲಿ ನಡೆಸಲಾಗುತ್ತದೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸಲಾಗಿದೆ ಮತ್ತು ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ.

ವಿಧಾನ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಒಪ್ಪಿದರೆ, ಪ್ರೊಫಾರ್ಮಾದ ಪ್ರಕಾರ ಸಂಬಂಧಿತ ಡೇಟಾವನ್ನು ಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಅಂತಿಮ ರೋಗನಿರ್ಣಯವನ್ನು ದೃ will ೀಕರಿಸಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರ್ಪಡೆಗೊಂಡ ನಂತರ, ಇಂಟ್ರಾನಾಸಲ್ ಸ್ಕಿರ್ಮರ್ ಸ್ಟ್ರಿಪ್ಗಳನ್ನು ಬಳಸಿಕೊಂಡು ಸರಳವಾದ

10 ನಿಮಿಷಗಳ ಪರೀಕ್ಷೆಯನ್ನು ಬಳಸುವ ಮೂಲಕ ನಿಮ್ಮನ್ನು ಇಂಟ್ರಾನಾಸಲ್ ತೇವಾಂಶದ ಸ್ಥಿತಿಗೆ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ.

ಪ್ರಯೋಜನಗಳು:

ನಿಮ್ಮ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯಿಂದಾಗಿ ರೋಗಿಯು ಯಾವುದೇ ರೀತಿಯ ವಿತ್ತೀಯ ಪ್ರಯೋಜನಗಳು ಅಥವಾ ಉಚಿತ ಸೇವೆಗಳಿಗೆ ಅರ್ಹನಾಗಿರುವುದಿಲ್ಲ.

ಅಪಾಯಗಳು:

ಅಧ್ಯಯನ ಮಾಡಲು ಅನ್ವಯಿಸಲಾದ ವಿಧಾನಗಳು ಸುರಕ್ಷಿತವಾಗಿವೆ.

ಭಾಗವಹಿಸುವಿಕೆಯ ವೆಚ್ಚ:

ತನಿಖೆಯ ವೆಚ್ಚವನ್ನು ಅಧ್ಯಯನ ವಿಷಯವು ಭರಿಸುತ್ತದೆ. ಇತರ ಪರೋಕ್ಷ ವೆಚ್ಚಗಳನ್ನು ತನಿಖಾಧಿಕಾರಿ ಭರಿಸುತ್ತಾರೆ.

ಗೌಪ್ಯತೆ ಮತ್ತು ಗೌಪ್ಯತೆ:

ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ನಿಯತಕಾಲಿಕಗಳಲ್ಲಿ ಪ್ರಕಟಿಸಬಹುದು. ಆದಾಗ್ಯೂ, ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ. ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಕೋಡ್ ಮಾಡಲಾಗುವುದು ಇದರಿಂದ ತನಿಖಾಧಿಕಾರಿಯನ್ನು ಹೊರತುಪಡಿಸಿ ಬೇರೆ ಯಾರಿಗೂ ನಿಮ್ಮ ಗುರುತು ತಿಳಿಯುವುದಿಲ್ಲ.

ಅಧ್ಯಯನದಿಂದ:

ನೀವು ಬಯಸಿದರೆ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು.

ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಲು ಅಧಿಕಾರ:

ಸಂಶೋಧಕರು ಈ ಅಧ್ಯಯನದಿಂದ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ವೈಜ್ಞಾನಿಕ ಸಭೆಗಳಲ್ಲಿ ಪ್ರಸ್ತುತಪಡಿಸಲು ಬಳಸಬಹುದು. ಆದಾಗ್ಯೂ, ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ.

ಪ್ರಶ್ನೆಗಳು ಮತ್ತು ಸಂಪರ್ಕ:

ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನೀವು ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9916198348 ಮತ್ತು ಮಾರ್ಗದರ್ಶಿ ಡಾ. _____, ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: ನಲ್ಲಿ ಯಾವುದೇ ಹಿಂಜರಿಕೆಯಿಲ್ಲದೆ ಡಾ. REG. NO: BE0119009 ಅವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು. ಸಂಶೋಧನಾ ಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿ ನೀವು ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕ ಡಾ.ರೂಪಾ ಎಂ ಬೆಲ್ಲಾಡ್ ಅವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು, ಜವಾಹರಲಾಲ್ ನೆಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸಮಿತಿಯ ಮಾನವ ವಿಷಯಗಳ ಸಂಶೋಧನೆ.

ಕನ್ಸೆಂಟ್ ಸಾರಾಂಶ:

ಈ ಒಪ್ಪಿಗೆಯ ರೂಪದ ಎಲ್ಲಾ ವಿಷಯಗಳನ್ನು ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನ್ನ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಸ್ಪಷ್ಟಪಡಿಸಿದ್ದೇನೆ, ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನನ್ನ ಸ್ವಯಂಪ್ರೇರಿತ ಒಪ್ಪಿಗೆಯನ್ನು ನಾನು ಈ ಮೂಲಕ ನೀಡುತ್ತೇನೆ. ನಾನು ಗುರುತಿಸಿದ ಪ್ರತ್ಯಕ್ಷದರ್ಶಿಯ ಮುಂದೆ ಮಾಹಿತಿಯುಕ್ತ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು ಮತ್ತು ಸಹಿ / ಎಡ ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ:

ಸಂದರ್ಶಕರ ಹೆಸರು ಮತ್ತು ಸಹಿ:

ಪ್ರತ್ಯಕ್ಷದರ್ಶಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ / ಎಡ ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ (ಸಾಪೇಕ್ಷ):

ಮಾರ್ಗದರ್ಶಿಯ ಸಹಿ: ದಿನಾಂಕ:

सूचित सहमति

"एक अलग नासात्मक समतुल्य योजना बनाने के परीक्षण में निहित विभिन्न प्रकार के परिवर्तन के रूप में परिवर्तन" - एक वर्ष की अवधि के दौरान एक व्यक्ति का अध्ययन किया जाता है।

प्रिंसिपल इन्वेस्टिगेटर: REG. NO: BE0119009

स्नातकोत्तर छात्र

प्राध्यापक, ओटोरहिनोलारिंजियोलॉजी विभाग।

सह-निवेशक: DR._____

प्राध्यापक, ओटोरहिनोलारिंजियोलॉजी विभाग

जे.एन. चिकित्सा महाविद्यालय

परिचय और भविष्य:

वर्तमान अध्ययन KLE के डॉ। प्रभाकर कोरे चैरिटेबल हॉस्पिटल एंड मेडिकल रिसर्च सेंटर, बेलगाम में ईएनटी एंड एचएनएस के उट-पेशेंट विभाग में भाग लेने वाले नाक सेप्टम और सामान्य बादी वाले रोगियों के बीच योजित किया जाता है। पसे अनुरोध है कि अध्ययन में भाग लें और पकी भागीदारी पूरी तरह से स्वैच्छिक हो।

प्रक्रिया:

यदि प इस अध्ययन में भाग लेने के लिए सहमत हैं, तो प्रासंगिक डेटा प्रोफार्मा के अनुसार एकत्र किया जाएगा और अंतिम निदान की पुष्टि की जाएगी।

अध्ययन में शामिल होने के बाद, पको इंट्रानैसल शिमर स्ट्रिप्स का उपयोग करके सरल 10 मिनट के परीक्षण का उपयोग करके इंट्रानैसल नमी की स्थिति का मूल्यांकन किया जाएगा।

लाभ:

रोगी अध्ययन में अपनी भागीदारी के धार पर किसी भी तरह के मौद्रिक लाभ या मुफ्त सेवाओं के लिए पात्र नहीं होंगे।

जोखिम:

अध्ययन करने के लिए लागू तरीके सुरक्षित हैं।

साझेदारी का हिस्सा:

जांच की लागत अध्ययन विषय द्वारा वहन की जाएगी। अन्य अप्रत्यक्ष खर्चों को अन्वेषक द्वारा वहन किया जाएगा।

गोपनीयता और गोपनीयता:

अध्ययन के परिणाम वैज्ञानिक उद्देश्यों के लिए पत्रिकाओं में प्रकाशित हो सकते हैं। हालांकि, पकी पहचान उजागर नहीं की जाएगी। एकत्रित की गई सभी सूचनाओं को कोडित किया जाएगा ताकि जांचकर्ता के अलावा किसी को भी पकी पहचान का पता न चले।

अध्ययन से विदधावल:

 प चाहें तो किसी भी समय अध्ययन से पीछे हट सकते हैं।

परिणामों को प्रकाशित करने के लिए धन्यवाद:

शोधकर्ता वैज्ञानिक अध्ययनों में प्रस्तुतिकरण के लिए इस अध्ययन से प्राप्त जानकारी का उपयोग कर सकते हैं। हालांकि, पकी पहचान उजागर नहीं की जाएगी।

प्रश्न और संपर्क:

यदि पके पास अध्ययन के बारे में कोई प्रश्न हैं, तो प डॉ। REG. NO: BE0119009 से

मोबाइल नंबर: 9916198348 और डॉ। _____, मोबाइल नंबर: पर बिना किसी संकोच के संपर्क कर सकते हैं। यदि प एक अनुसंधान भागीदार के रूप में अधिकारों के बारे में कोई प्रश्न पूछना चाहते हैं, तो प डॉ। रूपा एम बेलाड, प्रोफेसर, बाल रोग विभाग, जवाहरलाल नेहरू मेडिकल कॉलेज संस्थागत चार समिति के मानव विषयों के शोध से संपर्क कर सकते हैं।

सहमति सारांश:

मुझे अपनी स्थानीय भाषा में इस सहमति फॉर्म की सभी सामग्री समझाई गई है और अध्ययन के बारे में अपने सभी प्रश्नों को मेरे सर्वोत्तम ज्ञान के लिए स्पष्ट किया है, मैं इस अध्ययन में भागीदारी के लिए अपनी स्वैच्छिक सहमति देता हूं। मैं एक प्रत्यक्षदर्शी के सामने सूचित सहमति पत्र पर हस्ताक्षर करता हूं जिसे मैं पहचानता हूं।

प्रतिभागी का नाम और हस्ताक्षर / बाएं अंगूठे का निशान:

साक्षात्कारकर्ता का नाम और हस्ताक्षर:

नाम और हस्ताक्षर / प्रत्यक्षदर्शी के बाएं अंगूठे का निशान (सापेक्ष):

गाइड का हस्ताक्षर: दिनांक

ANNEXURE III

PROFORMA

"ASSESSMENT OF CHANGES IN INTRANASAL MOISTURE AS AN EFFECT OF A DEVIATED NASAL SEPTUM USING SCHIRMER TEST" – A ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY IN KLES Dr. PRABHAKAR KORE CHARITABLE HOSPITAL.

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:

I) General Physical Examination -

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Oedema

II) ENT Examination

1. **NOSE EXAMINATION**

External appearance

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

Cold spatula test

Cottle's test

Anterior Rhinoscopy

Posterior Rhinoscopy

Paranasal Sinus Examination

2. EAR EXAMINATION:

Right

Left

Pinna

Pre auricular area

Right

Left

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. **ORAL CAVITY AND OROPHARYNX EXAMINATION:**
4. **NECK EXAMINATION:**

Diagnosis:

Routine tests: CBC: **GRBS:**

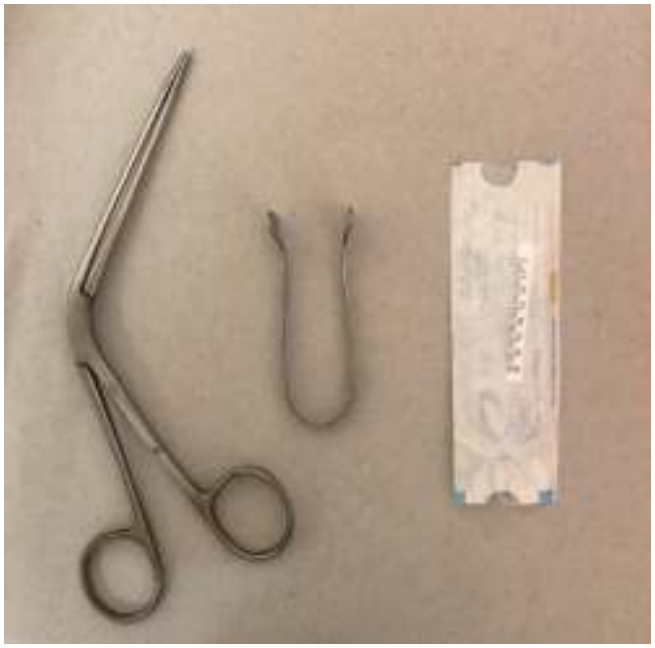
LFT: **MR**

INS- Intranasal Schirmer

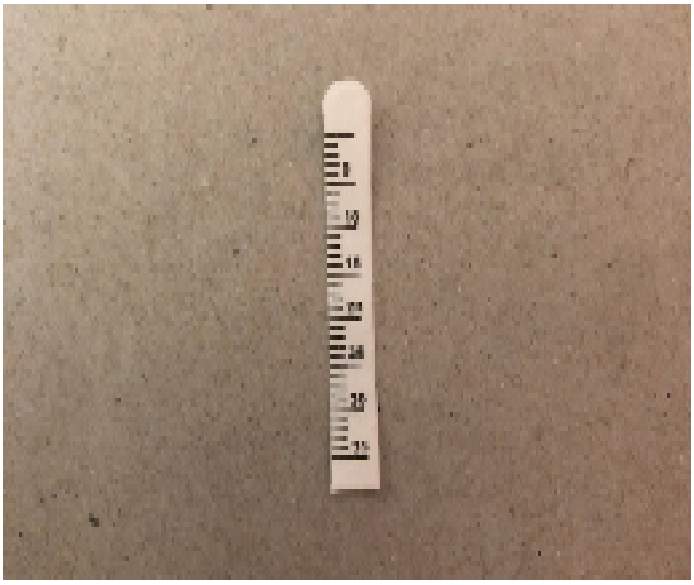
INS* value on the convex (deviated) side	INS* value on the concave (non-deviated) side

ANNEXURE IV

PHOTOGRAPHS



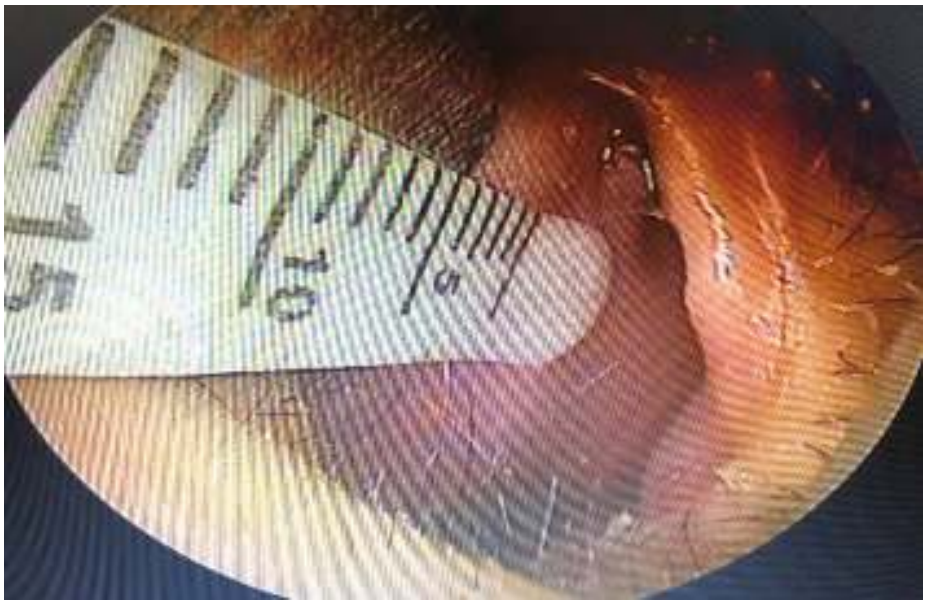
PHOTOGRAPH 1. Instruments used in administration of intranasal Schirmer test (From left to right) Tilley's forceps, Thudicum's nasal speculum, Sterile Schirmer strip.



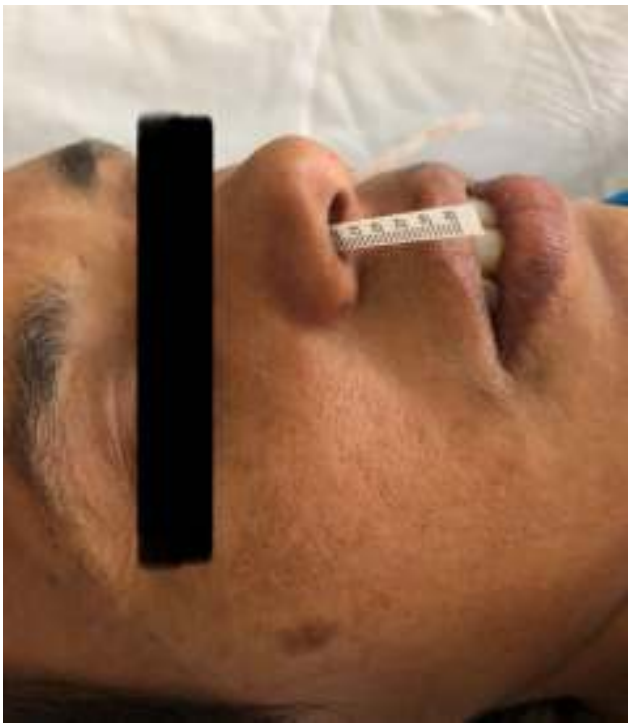
PHOTOGRAPH 2. Schirmer strip with calibration from 0-35 mm

PHOTOGRAPH 3. Schirmer strip folded to 45 degrees at 5mm mark and held using Tilleys forceps

PHOTOGRAPH 4. Schirmer strip folded at 5mm mark and held using Tilleys forceps



PHOTOGRAPH 5. Schirmer strip placed over anterior part of septum, 5mm behind the mucocutaneous junction



PHOTOGRAPH 6. Schirmer strips placed in both nasal cavities for a duration of 10 minutes

PHOTOGRAPH 7. Wetting distance of 15mm noted on this Schirmer strip

ANNEXURE V - KEY TO MASTERCHART

IP NUMBER	IN PATIENT NUMBER
OP NUMBER	OUT PATIENT NUMBER
MM	MILLIMETER
L	LEFT
R	RIGHT

CASES						
Serial number	Age/Sex	Op/Ip Number	Anterior Rhinoscopy- Side of deviated septum	Schirmers Values		
				(Deviated) Convex side (mm)	Concave side (mm)	Difference
1	30/Male	996741	L	5	15	10
2	16/Female	996512	R	4	9	5
3	32/Female	996556	L	4	10	6
4	16/Male	996442	L	7	17	10
5	22/Male	997261	R	5	15	10
6	34/Male	997929	R	12	25	13
7	23/Male	998845	R	2	8	6
8	23/Male	998878	R	2	5	3
9	22/Male	998729	L	1	6	5
10	26/Male	998681	R	5	15	10
11	23/Male	1001148	R	5	7	2
12	21/Male	5621150	R	17	25	8
13	21/Male	5621167	L	9	2	7
14	39/Male	5625277	L	1	4	3
15	21/Male	1001711	L	7	8	1
16	22/Male	5627445	R	1	4	3
17	43/Female	5617330	R	6	3	3
18	22/Male	561329	L	5	6	1
19	25/Male	5631325	L	1	6	5
20	30/Female	5617285	R	4	6	2
21	36/Female	1003221	R	4	9	5
22	19/Male	1004185	L	4	1	3
23	19/Female	993181	L	2	3	1
24	21/Male	993044	L	2	4	2
25	23/Male	997934	R	3	6	3
26	19/Male	997958	R	8	15	7
27	26/Male	1000576	R	1	8	7
28	21/Male	994087	R	2	6	4
29	20/Male	100125	L	3	10	7
30	21/Male	1001762	L	5	11	6
31	25/Male	1022829	R	1	4	3
32	22/Male	1022926	L	2	5	3
33	21/Male	1020753	R	4	10	6
34	16/Male	1023649	L	7	14	7
35	44/Male	1027060	L	7	17	10

36	24/Male	1023318	R	7	11	4
37	21/Female	1024253	L	6	12	6
38	38/Male	1024737	R	6	12	6
39	30/Male	1028404	L	7	18	11
40	20/Male	1028348	R	3	10	7
41	37/Male	1028921	R	6	13	7
42	17/Male	1024470	R	7	17	10
43	33/Female	1029618	L	4	14	10
44	18/Male	1029935	R	7	15	8
45	17/Male	1030109	R	6	12	6
46	17/Male	1030901	R	5	11	6
47	40/Male	1031253	L	4	10	6
48	21/Male	1031219	L	4	14	10
49	36/Female	1031303	R	4	10	6
50	40/Male	1032667	L	8	14	6
51	35/Male	1036049	R	2	8	6
52	20/Male	1035969	L	6	10	4
53	32/Male	1035979	R	5	10	5
54	21/Male	1079845	L	3	9	6
55	16/Male	1033267	R	7	10	3
56	44/Male	1036051	R	6	11	5
57	24/Male	1037049	R	3	8	5
58	26/Female	1025630	L	7	11	4
59	38/Male	997914	R	4	6	2
60	35/Male	997964	R	2	9	7

CONTROLS					
Serial number	Age/Sex	Anterior Rhinoscopy	Schirmers Values		Difference
			Right side	Left side	
1	32/Male	No deviated nasal septum	7	10	3
2	20/Female	No deviated nasal septum	12	14	2
3	32/Female	No deviated nasal septum	5	6	1
4	16/Male	No deviated nasal septum	8	10	2
5	22/Male	No deviated nasal septum	7	7	0
6	30/Male	No deviated nasal septum	4	6	2
7	23/Male	No deviated nasal septum	8	6	2
8	23/Male	No deviated nasal septum	10	8	2
9	23/Male	No deviated nasal septum	8	7	1
10	28/Male	No deviated nasal septum	12	11	1
11	23/Male	No deviated nasal septum	14	15	1
12	25/Male	No deviated nasal septum	4	5	1
13	25/Male	No deviated nasal septum	10	9	1
14	40/Male	No deviated nasal septum	6	7	1
15	21/Male	No deviated nasal septum	12	10	2
16	22/Male	No deviated nasal septum	10	11	1
17	43/Female	No deviated nasal septum	13	12	1
18	22/Male	No deviated nasal septum	7	8	1
19	25/Male	No deviated nasal septum	8	11	3
20	33/Female	No deviated nasal septum	9	10	1
21	38/Female	No deviated nasal septum	12	11	1
22	21/Male	No deviated nasal septum	7	9	2
23	20/Female	No deviated nasal septum	9	11	2
24	21/Male	No deviated nasal septum	6	7	1
25	23/Male	No deviated nasal septum	12	14	2
26	20/Male	No deviated nasal septum	10	8	2
27	26/Male	No deviated nasal septum	7	10	3
28	21/Male	No deviated nasal septum	9	11	2
29	20/Male	No deviated nasal septum	7	8	1
30	21/Male	No deviated nasal septum	12	13	1
31	23/Male	No deviated nasal septum	9	7	2
32	22/Male	No deviated nasal septum	8	10	2
33	21/Male	No deviated nasal septum	13	12	1
34	21/Male	No deviated nasal septum	7	10	3
35	45/Male	No deviated nasal septum	4	5	1
36	24/Male	No deviated nasal septum	10	8	2

37	29/Female	No deviated nasal septum	7	9	2
38	38/Male	No deviated nasal septum	10	8	2
39	35/Male	No deviated nasal septum	13	12	1
40	20/Male	No deviated nasal septum	8	10	2
41	27/Male	No deviated nasal septum	9	11	2
42	17/Male	No deviated nasal septum	5	7	2
43	30/Female	No deviated nasal septum	11	9	2
44	18/Male	No deviated nasal septum	11	12	1
45	17/Male	No deviated nasal septum	9	11	2
46	17/Male	No deviated nasal septum	7	8	1
47	41/Male	No deviated nasal septum	12	14	2
48	21/Male	No deviated nasal septum	11	9	2
49	36/Female	No deviated nasal septum	7	8	1
50	40/Male	No deviated nasal septum	10	12	2
51	35/Male	No deviated nasal septum	8	6	2
52	20/Male	No deviated nasal septum	9	7	2
53	32/Male	No deviated nasal septum	4	7	3
54	21/Male	No deviated nasal septum	11	9	2
55	16/Male	No deviated nasal septum	12	10	2
56	44/Male	No deviated nasal septum	12	11	1
57	24/Male	No deviated nasal septum	7	8	1
58	26/Female	No deviated nasal septum	12	11	1
59	38/Male	No deviated nasal septum	8	6	2
60	35/Male	No deviated nasal septum	9	11	2