"A RANDOMISED COMPARATIVE STUDY OF 3% HYPERTONIC SALINE VERSUS 0.5% DILUTED BETADINE NASAL IRRIGATION IN THE POST OPERATIVE CASES OF FUNCTIONAL ENDOSCOPIC SINUS SURGERY"

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

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Sub: Institutional Ethical Clearance for the study.

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ABSTRACT

TITLE –

A Randomised Comparative study of 3% Hypertonic Saline versus 0.5% Diluted Betadine nasal irrigation in the post operative cases of Functional Endoscopic Sinus Surgery.

OBJECTIVE -

1. To compare 3% hypertonic saline and 0.5% povidine iodine "nasal douching in post-operative cases of endoscopic sinus surgery.
2. To see the tolerability and effectiveness of 0.5% betadine solution in post-operative cases of sinus surgery
3. To assess the impact of 3% hypertonic saline and 0.5% betadine solution nasal irrigation" on the "QUALITY OF LIFE" using the sinonasal outcome (SNOT 22) questionnaire.

METHOD-

A one year study with a sample size of 68 (34 in each group) to assess the impact of 3% hypertonic saline and 0.5% betadine solution nasal irrigation" on the "QUALITY OF LIFE" at 1st week, 1st month and 3rd month.

RESULTS-

The study showed significant difference at the end of 1st week and 1st month in both groups proving betadine solution to be slightly better whereas in the 3rd month the hypertonic saline showed better results.

CONCLUSION-

This study proves that that both 0.5 % betadine solution and 3 % hypertonic saline" are equally significant with 3% hypertonic saline having slightly better results, where 0.5 % diluted betadine solution has proven to be slightly better in the short-term treatment up to 1 month, and 3 % hypertonic saline proved to be better in a long-term treatment upto 3 months.

KEYWORDS-

Chronic rhinosinusitis, nasal polyp, betadine solution, hypertonic saline

LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
CRS	Chronic rhinosinusitis
FESS	Functional Endoscopic Sinus Surgery
CRSwNP	Chronic rhinosinusitis with nasal polyposis
CRSsNP	Chronic rhinosinusitis without nasal polyposis
BS	Betadine solution
HS	Hypertonic saline
AR	Allergic rhinitis
QOL	Quality of life
SNOT - 22	Sinonasal outcome score

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INTRODUCTION

Chronic Rhinosinusitis (CRS) is a disease characterized by persistent inflammation of the nasal and paranasal sinuses. It can be diagnosed radiologically through a CT scan or endoscopically, both indicating mucosal changes within the osteomeatal complex and/or sinuses[1.] Typically, CRS is an antegrade process in which the host immune system and foreign substances absorbed through the nose interact abnormally to cause mucosal inflammation[2]. Both conventional and current treatment plans frequently include nasal irrigation. There have been suggestions for improved mucus clearance, increased ciliary beat activity, elimination of biofilm, inflammatory mediators, or antigens, as well as a protective function for the sinonasal mucosa[3]. It appears that iodine's microbicidal activity involves blocking vital bacterial cellular structures and processes. Additionally, it oxidizes nucleotides, fatty/amino acids, and cytosolic enzymes involved in the respiratory chain, denaturing and deactivating them in bacterial cell membranes[4]. It is well known that using hypertonic saline, diluted betadine saline, and normal saline improves mucociliary clearance. Following Functional Endoscopic Sinus Surgery (FESS), the nasal cavity exhibits oedema, crusting, clot accumulation, and discharge in the first few days following surgery. This causes severe nasal blockage, infection, bleeding, and the development of nasal synechiae. Povidone-iodine (PVP-I) has a broad range of microbicidal effects, even after brief start durations. No resistance forms, in contrast to local antibiotics and other antiseptic materials[5]. The studies done have not yet concluded which nasal irrigation is better and more significant in the postoperative period. Therefore, nasal douching is advised for patients in order to prevent these issues and improve their quality of life (QoL) during the early post-operative phase.

This study aimed to compare efficacy of hypertonic saline nasal irrigation against diluted betadine saline nasal irrigation in the postoperative period after functional endoscopic sinus surgery for therapy of chronic sinusitis.

OBJECTIVES

1. To compare 3% hypertonic saline and 0.5% povidine iodine “nasal douching in post-operative cases of endoscopic sinus surgery.

2. To see the tolerability and effectiveness of 0.5% betadine solution in post-operative cases of sinus surgery

3. To assess the impact of 3% hypertonic saline and 0.5% betadine solution nasal irrigation” on the “QUALITY OF LIFE” using the sinonasal outcome (SNOT 22) questionnaire.

REVIEW OF LITERATURE

A) DEVELOPMENT OF THE NOSE AND PARANASAL SINUSES (PNS)-

About fourth week of pregnancy, nose begins to form. It is developed from several mesenchymal processes. The **ectoderm** above the **stomatodium** creates the olfactory placode, which dips inward to form an olfactory pit, nestled between folds of mesoderm on the frontonasal process. By the fifth week of gestation, this pit deepens into a sac called the **nasal sac**.

The philtrum and the columella are the result of the medial nasal mechanisms merging with the maxillary mechanisms during the development of the facial features. Additionally, “they fuse with the frontal prominence to form the hard palate, ethmoid bones, nasal bones, forehead bones, and cartilaginous section of the nose. The nasal bone, upper lateral cartilage, and lower lateral cartilage's lateral crus are formed by lateral” nasal folds. A bucconasal membrane initially divides the primitive mouth and nasal chamber.

The nasofrontal process and the combined medial nasal processes give rise to the nasal septum, which grows downwards. By the ninth and twelfth weeks of pregnancy, the nasal septum and palatine processes merge anteriorly and posteriorly, respectively[2]. The olfactory epithelium is composed of olfactory placodes.

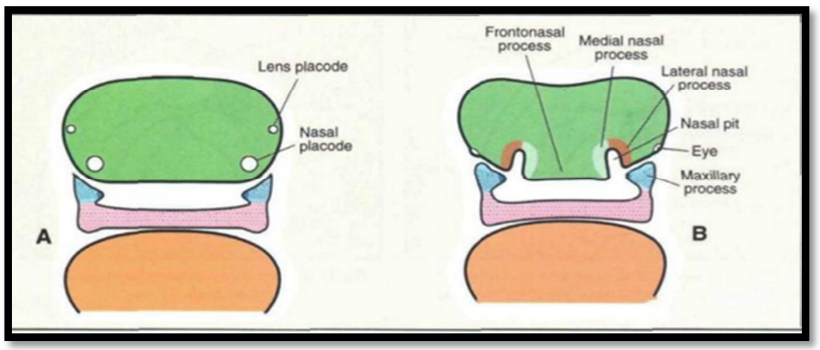


Figure 1- Development of nose

Maxilla: The maxilla starts forming around the sixth and seventh week of gestation, with five separate ossification centres. By the 4th month of pregnancy, these centres fuse to form several facial structures, like the alveolar, frontal, palatine, zygomatic process, including orbital floor.

Ethmoid Bone - Ethmoid bone develops with three ossification centres – one for the perpendicular plate that appears after birth, and one each for the labyrinth that begins forming approximately the fourth or fifth month of pregnancy and is partially completed at birth. These centres eventually fuse around the 2nd year of life, all contributing to the formation of the sieve-like plate (cribriform plate) that allows passages of olfactory nerves.

Frontal Bone- Unlike most skull bones that start from cartilage, the frontal bone begins to ossify directly from a membrane present in each superciliary ridge around week eight of pregnancy. Metopic suture divides the frontal bone's two halves during birth[6]. The procedure typically begins in the 2nd year of life and is finished by the 8th year.

The sphenoid bone is split into two halves, which finally fuse together. These two segments, the presphenoid and postsphenoid, combine to create the sphenoid bone's main body by the eighth month of pregnancy.[6]

The turbinates, begin taking shape around week sixth of gestation and arise on the lateral aspect of the nose from a sequence of elevations. The inferior most elevation, known as the **maxilloturbinal**, develops into the largest turbinate – **The inferior turbinate.**

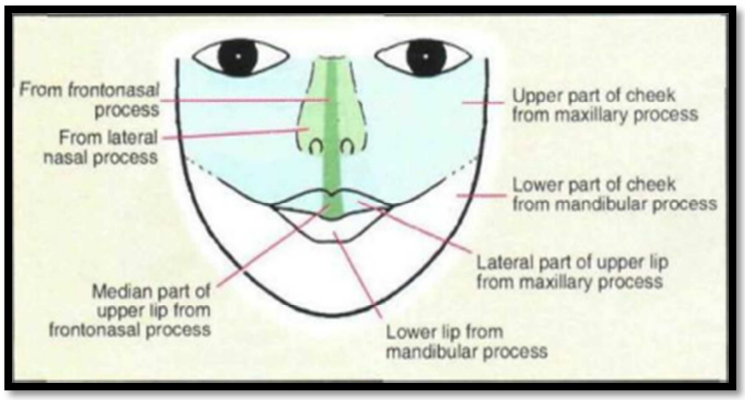


Figure 2- Development of nose and paranasal sinuses

The maxillary sinus is the earliest developing sinus in the human foetus. It starts forming around the tenth week of gestation. This sinus originates as a little pouch from the ethmoid region, nestled in the infundibulum and nasal capsule, and developing right behind the uncinate process.[7,8]

The mid part of the face continues to develop, and when the permanent teeth erupt, the sinus floor gradually descends, reaching a level 0.5 to 10 millimetres lower than the floor of the nasal cavity. As a result, sinus has more room to grow and reach adult size[9]. Ethmoid sinus starts taking shape around the fourth month of pregnancy and has a multicentric origin. Primitive ethmoid cells make up the majority of ethmoid sinus cells that start in the middle meatus.

The ethmoid sinus is fully formed at birth. By the time an individual reaches the age of 12, the ethmoid has nearly grown to adult size. Early maturity may bring about some further enlargements[9]. The sphenoid bone undergoes pneumatization which expands the sphenoid sinus significantly. By the time a child reaches seven years old, they frequently arrive at the floor of the sella turcica, the saddle-shaped pituitary gland depression in the sphenoid bone. According to some estimates,

pneumatization advances at a 0.25 mm annual pace starting at age four, though this is not always the case[10].

At birth, the frontal sinus is still quite small. Around the fifth year of life, the sinus starts expanding superiorly[1]**.** The frontal sinus reaches adult size by the time a person is twelve years old. Although the frontal recess is often a tiny hourglass section, nearby anterior ethmoidal cells may encroach over a longer, more tortuous course. Since the sinus is the last anatomical structure to fully mature in early adulthood, these variances are directly related to its embryological development.[1,3]

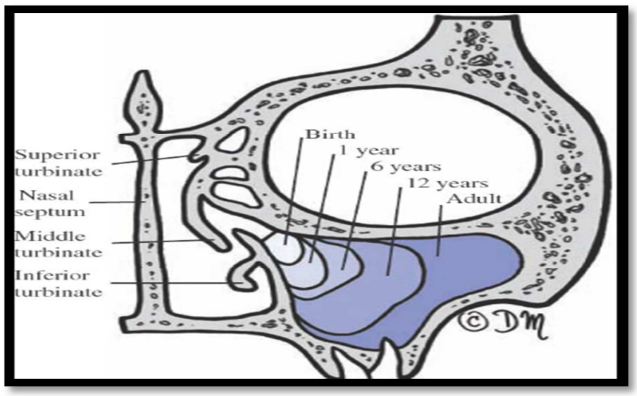


Figure 3 – Development of paranasal sinuses

B) <u>ANATOMY OF NOSE AND PARANASAL SINUSES-</u>

NASAL CAVITY - The "nasal cavity serves as an airway that extends from the external nares or nostrils in the front to the choanae in the back, where it joins the nasopharynx. It connects the palate to the cribiform plate, a bone that forms part of the skull's base, vertically.

The nasal cavity consists of a floor, roof, lateral wall, and medial wall" on each side. There is a divide in the nasal cavity.

NASAL SEPTUM –

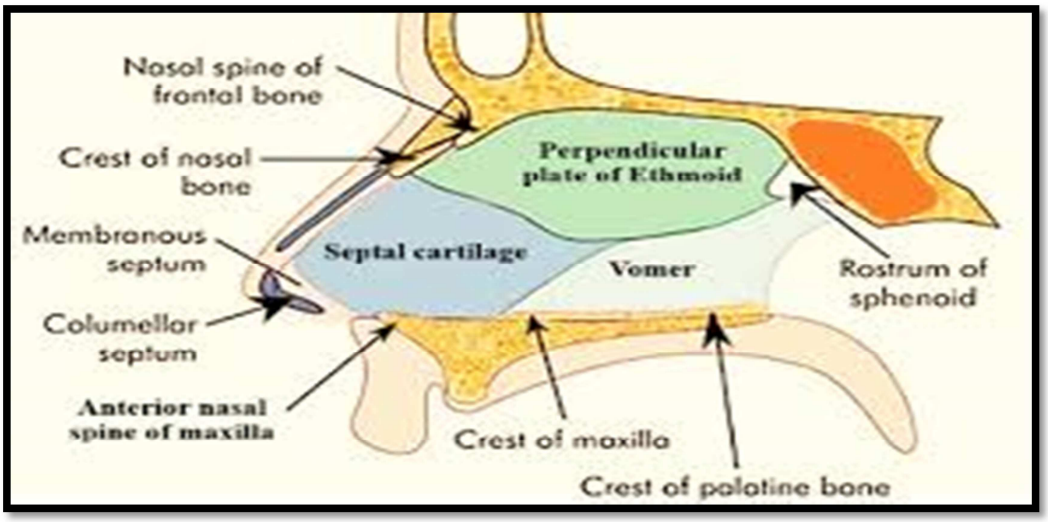


Figure 4 – Nasal septum

The "nasal septum is a wall that separates the two parts of the nasal cavity.

The lower and upper lateral alar cartilages, together with the quadrilateral cartilage that constitutes the cartilaginous section, make up the anterior portion of the nasal" septum.

The "perpendicular plate of the ethmoid, which is adjacent to the cribriform plate, forms the superior and anterior sections of the septum.

The maxilla and palatine bones form a bony ridge that the vomer's inferior border joins to, while the anterior border articulates with the quadrilateral cartilage inferiorly and the perpendicular plate above. The nasal" septum's free rear border is formed by the vomer's posterior edge[1].

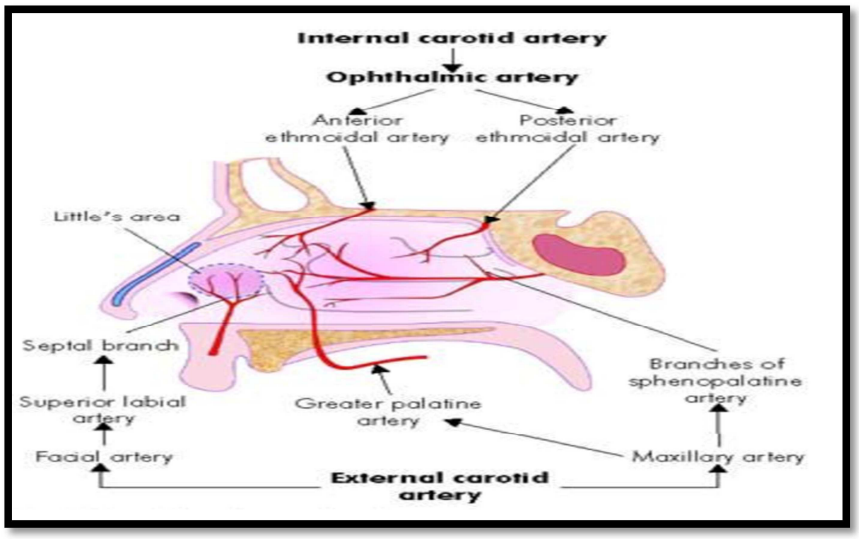


Figure 5 – Arterial supply of nasal septum

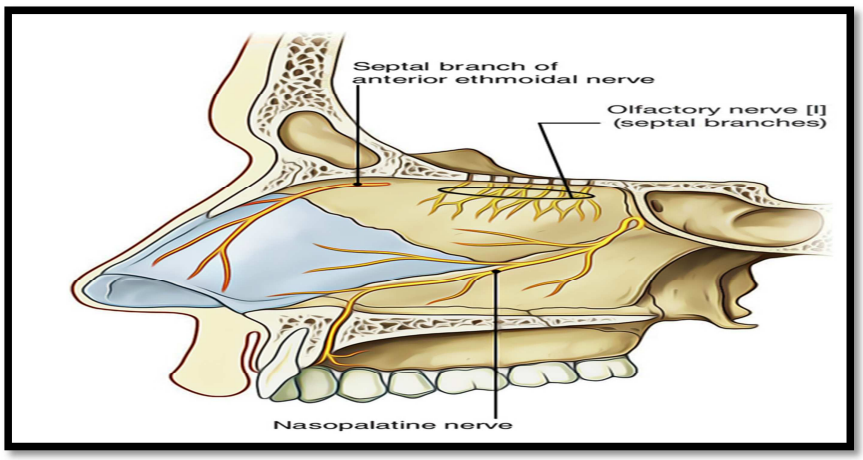


Figure 6 – Nerve supply of nasal septum

LATERAL WALL OF THE NOSE-

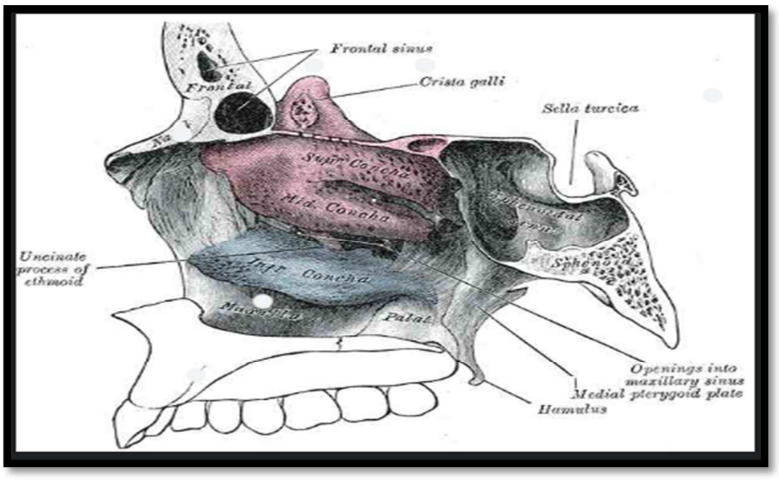


Figure 7 – Lateral wall of the nose

The "lateral wall of the nasal cavity is divided into three sections: The maxilla, inferior turbinate, and the frontal process of the maxilla comprise the anterior portion of the lateral nasal wall; the ethmoid labyrinth, the maxilla, and the posterior portion of the lateral nasal wall are represented by the medial pterygoid plate of the sphenoid bone and the perpendicular plate of the palatine" bone[11].

INFERIOR MEATUS- It extends "the majority of the nasal cavity's length and is lateral to the inferior turbinate bone. In" adults, its height typically ranges from 1.6 to 2.3 centimetres, with an average of 1.9 centimetres.[1]

INFERIOR TURBINATE- The inferior concha, also known as inferior turbinate bone, is the only separate bone in the group of turbinates, with an irregular texture. The respiratory epithelium covering the turbinate has many goblet cells (about 8/mm2) that become less dense at the posterior end.[13,2]

MIDDLE MEATUS - It acts as a drainage point for several sinuses. This middle meatus receives mucus and air from the maxillary sinus, frontal sinus, and anterior

ethmoid cells. The maxillary hiatus, a sizable aperture in the maxilla bone's medial wall, aids in this drainage.

UNCINATE PROCESS- Because of its form, the uncinate process takes its name from the Latin word "**uncinatus**," which means hooked. This thin, curved piece of bone arises from the roof of ethmoid bone and runs anteroposteriorly and posterosuperiorly, and attaches to several other bony structures. The inferior turbinate bone's ethmoid process and the palatine bone's perpendicular plate[11].

ETHMOIDAL INFUNDIBULUM- Within the nasal cavity, there is a three-dimensional area called the ethmoid infundibulum. This area is shaped like a cleft. "The anterior side of the ethmoidal bulla serves as the posterior limit of the ethmoidal infundibulum. Through the inferior hiatus semilunaris, the infundibulum enters into the middle meatus from this side. Superiorly, the uncinate process has a major influence on the structure of the ethmoidal infundibulum[11].

AGGER NASI- The supreme concha is a small bony elevation or ridge found on the lateral wall of the nasal cavity, near the front. It's a remnant structure from the nasoturbinal bone present in some lower mammals. It is the anterior portion of the ethmoid bone in humans and resembles a little crest that sits just in front of the attachment point of the middle" turbinate bone.[1]

THE FRONTAL RECESS- The "frontal sinus has a natural drainage opening called the ostium. This opening is narrow in the middle, resembling an hourglass shape, and leads directly into a space called the frontal recess.

THE ETHMOIDAL BULLA- The ethmoid bulla is the largest cell in the anterior ethmoid sinuses. There may occasionally be an aperture or split in the basal lamella

that makes up the posterior wall of the bulla and the base of the middle" turbinate. This region is called the retrobullar recess.

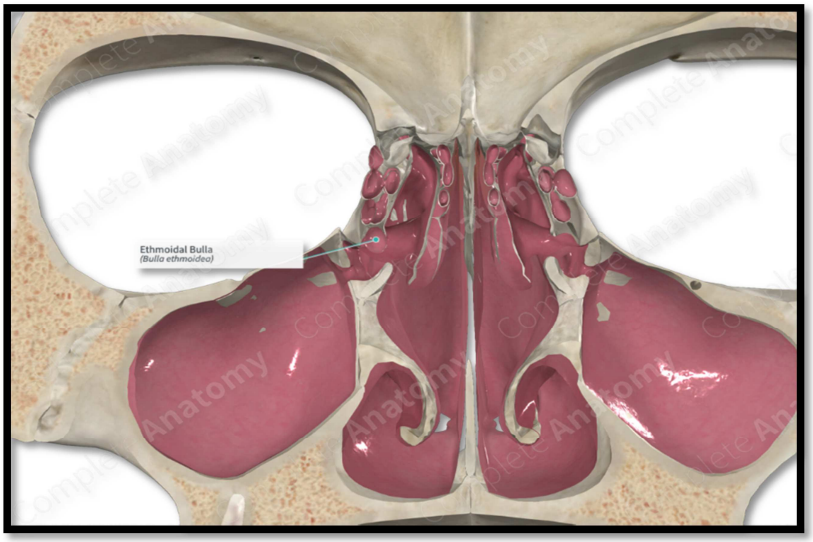


Figure 8 – Ethmoid bulla

There's another space located above the ethmoid bulla and the retrobullar recess, called the suprabullar recess.

SUPERIOR MEATUS-The superior turbinate serves as another defining characteristic of this meatus. This area receives the posterior ethmoidal cells' opening.[1]

SPHENOETHMOIDAL RECESS- The "ostium of the sphenoid sinus is located in the sphenoethmoidal recess, which is medial to the superior turbinate.[1]

PARANASAL SINUSES –

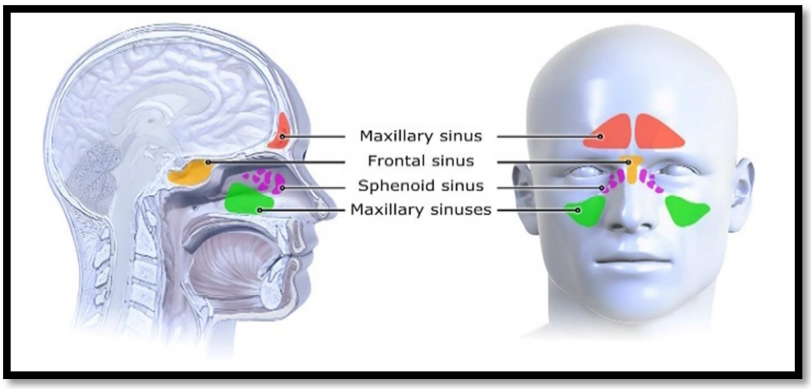


Figure 9 – Paranasal sinuses

The skull has a network of air-filled cavities" called paranasal sinuses(PNS). These spaces surround the nasal cavity and are located near important structures like orbits, the brain, blood vessels, and nerves. There are 4 main "paranasal sinuses:

- **Maxillary sinuses**
- **Ethmoid sinuses**
- **Frontal sinuses**
- **Sphenoid sinus**

These sinuses" play a role in several functions, including:

- **Lightening the head**
- **Humidifying inhaled air**
- **Warming inhaled air**
- **Resonance for speech**
- **Protection around the brain and other vital structures.** [11,14]

Maxillary Sinus - Inside the maxillary bone lies an air chamber shaped like a pyramid called the maxillary sinus. The main body resembles a four-sided pyramid. They are formed by four processes: **The frontal process, the Zygomatic process, the Alveolar process, Palatine process.** The normal measurements of an adult maxillary sinus are 32 to 45 millimeters in width, 38 to 45 millimeters in length, and 36 to 45 millimeters in height. The average maxillary sinus has a volume of around 14.25 cubic centimeters.[11] The inner lining "of the maxillary sinus is made of ciliated columnar epithelium, with tiny hair-like structures called cilia. The maxillary sinus has the highest concentration of goblet cells in this lining tissue when compared to the other paranasal sinuses (median: 9700 per" square millimeter). This goblet cell mucus-producing unit.

Although they are less common than goblet cells, seromucinous glands can also be found in the maxillary sinus. Nonetheless, compared to other sinuses, the maxillary sinus has a higher density of these glands, which are usually centered around the ostium, or entrance, that joins the sinus to the nasal cavity.[1]

Ethmoid Sinus- The ethmoid sinus is a multi-layered structure with air chambers. Measuring an average of 3.3 cm by 2.7 cm by 1.4 cm, the ethmoid sinus is a very small bone. The number of air cavities within the ethmoid sinus can vary from person to person, ranging from 3 to 15 cells.

Sphenoid Sinus- It's wedge-shaped (sphenoid means wedge-like in Greek) and positioned in the middle, separating the anterior cranial fossa from the middle cranial fossa. It consists of 2 inferior plates (lateral and medial pterygoid plates), two wings (greater and smaller), and a body. On either side of the sphenoid sinus are the openings (ostia) -These openings are relatively large on a macerated skull, measuring around 5-8 millimetres in diameter.

The sphenoethmoidal recess is the area into which the sphenoid sinuses drain. The position of this recess is medial and superior to the supreme and superior turbinates. Individual differences exist in the dimensions and configuration of the sphenoid sinuses.

Epithelium of the sphenoid sinuses is comparable to the lining of the ethmoid sinuses in terms of goblet cell density. These goblet cells, which produce mucus, are found at an average concentration of 6200 per square millimetre (mm2). However, the sphenoid sinuses have the lowest number of seromucinous glands compared to other paranasal sinuses. The density of these glands is only about 0.06 per square millimetre (mm2).[13]

Frontal Sinus- Though they are absent at birth, they grow as children. They normally have a vertical and a horizontal compartment and when fully developed, they resemble the letter "L".

The frontal sinuses drain into the frontal recess. The lining of the frontal sinuses contains:

- **Goblet cells:** These cells produce mucus, but at a lower density (5900 per square millimetre) in contrast to other sinuses.
- **Seromucinous glands:** These glands are even less frequent (0.08 per square millimetre) than goblet cells.

  The frontal sinuses are supplied by the anterior ethmoidal along with supraorbital arteries.[1]

NASAL MUCOSA-

The lining of the nasal cavity can be classified into:

- **Anterior and vestibule:** It's made of a tough, layered tissue called keratinized stratified squamous epithelium, which sits on a layer of connective tissue called lamina propria. The presence of keratin makes this part waterproof. The vibrissae are present in the lower part of this region, near the nares. These hairs curve inwards and help filter large particles from the air we breathe.
- **Posterior:** The limen nasi is the lining that transitions to a moist tissue called the mucosa. This mucosa is initially lined with non-keratinizing stratified squamous epithelium, a type of tissue without the waterproof keratin layer. Posteriorly, the lining changes to pseudostratified ciliated columnar epithelium, which is rich in goblet cells.
- **Pseudostratified ciliated columnar epithelium with goblet cells:** This is dominant lining throughout most of the nasal cavity. It's a specialized tissue with several key features:
    - **Pseudostratified:** Multiple cell layers appear present, but actually only one layer directly touches the surface.
    - **Ciliated:** Tiny hair-like structures called cilia project from the surface and help move mucus and trapped particles posteriorly.
    - **Goblet cells:** These cells produce mucus, which helps moisten the air you breathe and traps dust and other debris.

Goblet cells and pseudostratified ciliated columnar epithelium make up the majority of the nasal cavity's lining. However, there can be variations:

- **Olfactory Epithelium:** In the olfactory cleft, the cells may be low columnar or cuboidal, specialized for smell detection.

- **Cilia:** The proportion of cells with tiny hair-like projections (cilia) can vary across the lining. Cilia help move mucus and trapped particles.[16]

Within the lamina propria, seromucinous glands secrete secretions into the nose. At a pace of 6 mm per minute, ciliary activity (mucociliary escalator or rejection current) continuously moves the mucus film posteriorly into the nasopharynx. IgA, lactoferrin, beta-defensin, and lysozymes are all present in the secretions.[3,16]

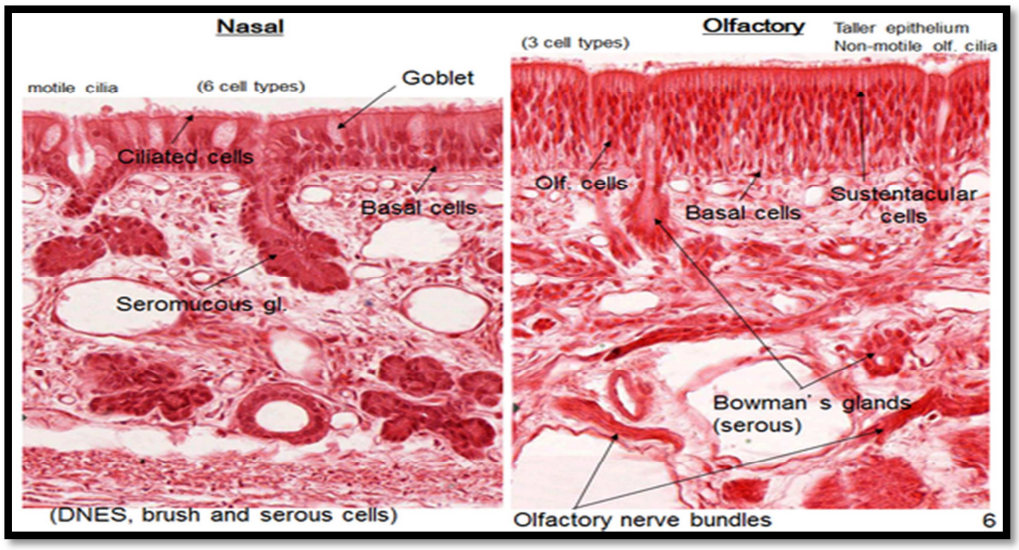


Figure 10 – Nasal and Olfactory epithelium

C) PHYSIOLOGY-

Ultrastructure of Cilia- Tiny hair-like structures called cilia play a vital role in keeping the nasal cavity clean. Their primary function here is to propel mucus, a sticky film that traps dust, germs, and other unwanted particles, backward toward the nasopharynx.

The coordinated beating of these numerous cilia creates a wave-like motion, propelling the mucus film backward at a steady pace. This movement is often referred to as the mucociliary escalator or rejection current.

There are two layers to the nasal mucus film: a lower, more fluid layer where cilia can move easily and an upper, more viscous one. To move the viscous layer, tiny hooks on the tips of the cilia penetrate it.[2]

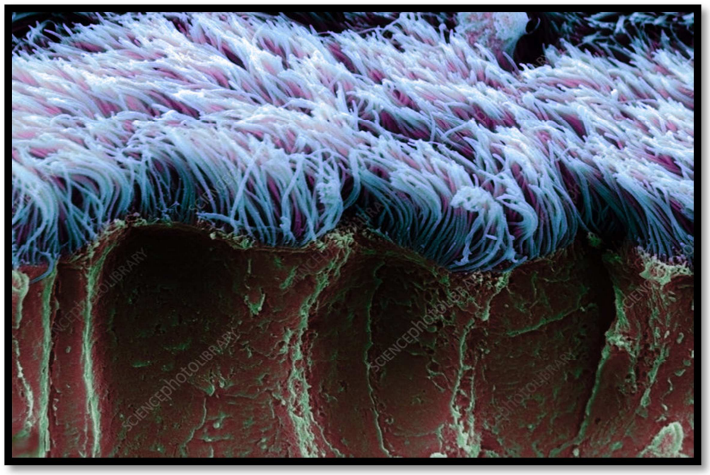


Figure 11– Cilia

Ciliary action- The beating of cilia is crucial for propelling mucus in the nose. The frequency of this beating is measured in Hertz (Hz) and is between 7 and 16 at normal body temperature (around 37°C). The frequency remains fairly constant within a specific temperature range, from 32°C to 40°C.

Each beat cycle consists of two distinct phases:

1. **Propulsive Stroke**
2. **Recovery Phase**

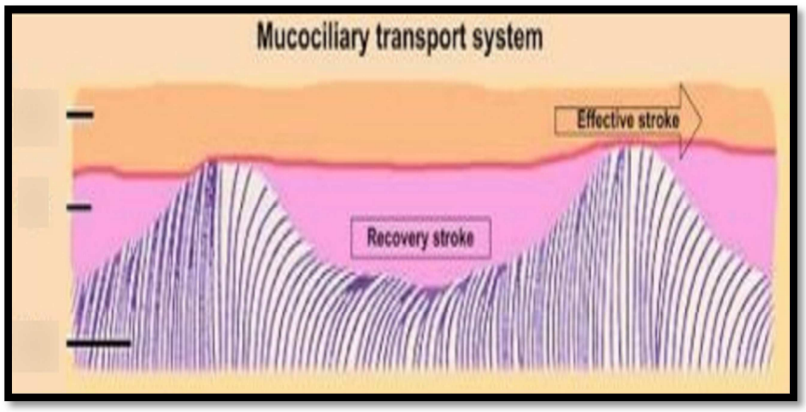


Figure 12 – Mucociliary transport system

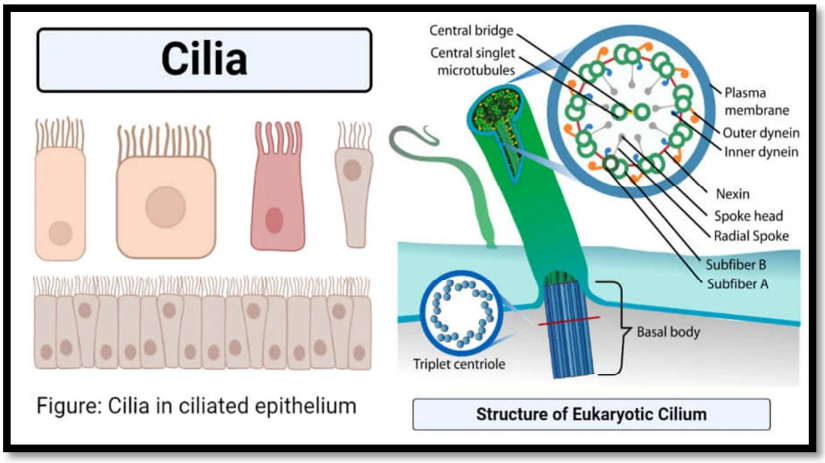


Figure 13– Structure of cilium

Nasal secretions-There are two components to nasal secretions: mucus and water. Mucus glands generate glycoproteins, while serous glands are the primary source of water and ion production, with capillary network transudation acting as an indirect source. The two cell types that create the glycoproteins present in mucus are the glandular mucus cells and the goblet cells found inside the epithelium. Serous glands are located exclusively in the vestibular region of the anterior section of the nose. When aroused, these secrete enormous amounts of water. Goblet cells and mixed glands are less common in sinuses. Glycoproteins are responsible for mucus's two most commonly measured properties, viscosity and elasticity.[1,3]

Pathways of secretion transport-

Drainage Paths in the Maxillary Sinus- Mucus production takes place at the floor of the maxillary sinus, where drainage starts. The stellate pattern refers to the star-shaped way that mucus disperses throughout the sinus floor. Subsequently, the mucus moves along the sinus walls, gradually coming together at an ostium—a normal opening. The ostium itself is located within a funnel-shaped cavity called an infundibulum. The mucus passes through this funnel and exits "the maxillary sinus through the infundibulum and ostium, emptying into the middle meatus of the nasal cavity.

The frontal sinus has a distinct drainage channel. The inferior walls and floor of the sinus, as well as the interfrontal septum, are responsible for moving the mucus laterally along the roof and back medially. Once out of the sinus, the secretions pass through the frontal recess and the sinus several times before combining with the maxillary sinus secretions through the ostium. The secretions encounter an inwardly directed path and a whorl-like ciliary arrangement above the ostium. The ethmoidal cells will drain to a dependent ostium" or toward the ostium via a spiral transport pattern.[6]

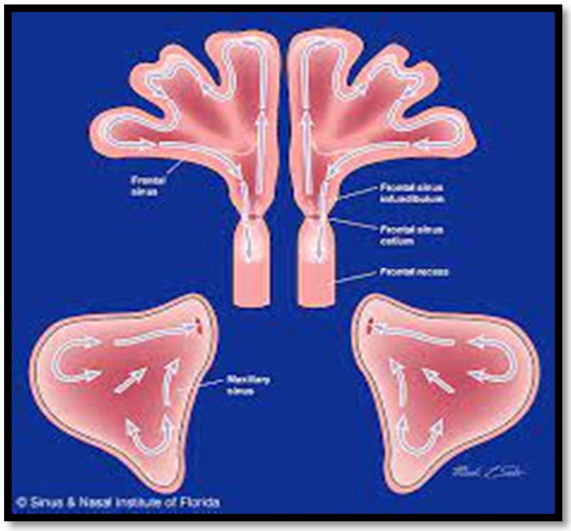


Figure 14 – Mucociliary drainage of sinuses

RHINOSINUSITIS-

It is recommended to refer to "the inflammation of the nose and paranasal sinuses as rhinosinusitis.

CLASSIFICATION OF RHINOSINUSITIS

1. Acute (ARS):7 days to less than 4 weeks
2. Subacute – four to twelve weeks
3. Recurrent acute - ≥four episodes of ARS per year
4. Chronic - ≥twelve weeks
5. Acute exacerbation of chronic" pain refers to an abrupt worsening of CRS followed by a return to baseline.[6]

PATHOPHYSIOLOGY-

Several factors can increase the chances of developing rhinosinusitis. Here's a breakdown of some key categories:

Host-Related Factors: These factors are specific to the individual characteristics and health conditions.

Genetic factors: Diseases like cystic fibrosis or immotile cilia syndrome can cause the tiny hair-like structures called cilia, which help clear mucus from the sinuses, becoming dysfunctional.

Anatomic abnormalities: Structural variations in the nasal cavity can affect drainage and airflow. Examples include a concha bullosa or a paradoxical turbinate (a turbinate that touches the septum and obstructs airflow).

Medical conditions: A weakened immune system can lead to infections, such as rhinosinusitis, and is a side effect of several systemic disorders and medical therapies.

Neoplasms: In rare cases, tumors or growths in the nose or sinuses can obstruct drainage contributing to sinus infections.

Allergic or immune disorders: Rhinosinusitis can also arise as a result of immune system issues and allergies.

Rhinosinusitis can also arise due to external sources such as fungal, bacterial, or viral infections, or inflammation resulting from "fungal or bacterial colonization.[1, 17, 18,] trauma; exposure to tobacco smoke, either primary or secondary; [2, 19,] noxious chemicals or chronic or acute irritants; or iatrogenic causes, such as nasal packing, medication, surgery, or the placement of a nasogastric tube. There is increasing evidence that those who suffer from allergies and asthma are more likely to suffer from rhinosinusitis, both acute and chronic.[1]

Scientists are actively investigating the role of various cells and proteins involved in the inflammatory response, particularly in Chronic Rhinosinusitis (CRS). This complex inflammatory process likely involves a multitude of factors, including:

- **Immune Cells:** Many white blood cells are being studied for their potential involvement in sinus inflammation, including T cells, B cells, mast cells, eosinophils, neutrophils, and" T lymphocytes.

Signalling Molecules: Proteins like immunoglobulins (antibodies), interleukins, tumor necrosis factor (TNF-alpha), and major basic proteins are being explored for their role in communicating and amplifying the inflammatory response. [1,17,20,21]Other

elements, like as biofilms, superantigens, and osteitis, have also been found to be potentially important in the onset or maintenance of CRS.[1,17,20]

In cases of chronic rhinosinusitis, lymphocytes, plasma cells, and eosinophils proliferate. Eosinophilic infiltrates by themselves are typically visible in the sinus cavities or mucosa. In cases of chronic rhinosinusitis, lymphocytes, plasma cells, and eosinophils proliferate. Eosinophilic infiltrates by themselves are typically visible in the sinus cavities or mucosa. Fibrosis of the lamina propria is evident. There could be bacteria and fungi.[1,22,17,20,18,21]

Chronic rhinosinusitis (CRS) is increasingly recognized as a primary inflammatory condition, with or without the involvement of infectious microbes.

Consequently, certain cases may involve bacteria, fungi, or viruses, but other cases might not involve any discernible pathogenic organism. Staphylococcus species (a total "of 55 percent) and Staphylococcus aureus twenty percent are the most common bacteria in individuals with CRS who do contain possibly harmful germs.[1, 22, 23] According to certain research, Enterobacteriaceae, organisms,[1,23] Gram-negative bacteria, anaerobes, and fungi are highly prevalent.[2,21]

DIAGNOSIS OF CRS-

Definitive techniques for diagnosing CRS are still pending. For CRS, a duration longer than 12 weeks is advised. The term rhinosinusitis, which includes nasal polyps, refers to sinus and nasal inflammation that manifests as two or more of the following symptoms:

Blockage/congestion;

Discharge: anterior/posterior (discolored); facial pressure /pain; loss or reduction of smell Plus, either: endoscopic symptoms of:

- polyps;
- mucopurulent discharge from middle meatus;
- or oedema/mucosal obstruction primarily in middle meatus; and or
- Mucosal alterations in the osteomeatal complex and/or sinuses" are seen on computed tomography (CT).[1,3]

MEDICAL APPROACH TO RHINOSINUSITIS -

Initial Steps in Managing Rhinosinusitis

When dealing with rhinosinusitis, the initial approach often focuses on two key areas:

1. **Reducing Predisposing Factors:**
    - Identifying and addressing any underlying factors that might be contributing to the sinus problems is crucial. This could involve managing allergies, addressing anatomical abnormalities in the nasal cavity through medications or minimally invasive procedures, or stopping medications that might be weakening the immune system.
2. **Improving Sinus Drainage:**
    - Medications help in improving drainage from sinuses, particularly the osteomeatal complex (OMC). The OMC is a narrow passageway that connects the sinuses to the nasal cavity. Medications like nasal steroids or saline irrigation can help reduce inflammation and swelling in the lining of the nose and sinuses, allowing for better drainage of mucus.

3. **Decongestants.**
4. **Nasal douching.**
5. **Antibiotics for infective rhinosinusitis**
6. **Follow up after six weeks;**

If nothing changes A CT scan is performed to exclude the underlying condition and to serve as a guide in the event that surgery is necessary.

Consider in cases

- -Topical/oral corticosteroids (for a few days) in addition to non-absorbed drops (elongated)
- Trial of anti leukotriene, antihistaminic.
- Immunotherapy and gammaglobulin replacement therapy for severe immunological deficiencies.
- In cases when there is no improvement after three to six months, surgical surgery may be considered for CRS.[1]

FUNCTIONAL ENDOSCOPIC SINUS SURGERY- The principal aim of 'Messerklinger' method, supported by Stammberger [1,24,25,26] is to eliminate pathology in the osteomeatal complex to the extent necessary to accomplish ventilation and drainage. This conservative approach addresses the underlying pathophysiology, which is why Kennedy supports the term 'functional.[27]

Saline Nasal Irrigation for Upper Respiratory Conditions- Saline nasal irrigation, also known as sinus rinsing, is a technique that involves using a saltwater solution to wash out mucus and debris from the nasal cavity. It can be a helpful addition (adjunctive therapy) to the treatment plan for various upper respiratory conditions.

- **Chronic Rhinosinusitis (CRS):** Saline irrigation shows clear benefits in managing symptoms associated with CRS. It can help thin mucus, clear congestion, and promote drainage from the sinuses, leading to overall symptom relief.

- **Allergic Rhinitis (AR):** The evidence for using saline nasal irrigation for allergic rhinitis is less conclusive, particularly for mild to moderate cases. While it may provide some symptomatic relief, more research is needed to determine its definitive role in managing allergies.

- **Acute Upper Respiratory Tract Infections (Common Cold):** Similar to allergic rhinitis, the evidence for saline irrigation in acute upper respiratory infections is not as strong. It may offer some symptomatic relief, but more studies are needed to confirm its effectiveness.

For the majority of people, "saline nasal irrigation is a safe and typically well-tolerated procedure. By adjusting the salinity and method, minor negative effects can be prevented. Acute and chronic rhinosinusitis, viral upper respiratory tract infections (URTIs), and allergic rhinitis are frequent upper respiratory illnesses that have a detrimental effect on patients' quality of life. Saline nasal irrigation is an adjuvant treatment for upper respiratory conditions that most likely originated in" Ayurveda.

The practice of rinsing the nose with salt water has been around for centuries. While its roots can be traced back to ancient medical traditions, detailed descriptions of its use in modern medical journals appeared in the early 1900s. Many sinus and nasal issues can now be effectively treated with saline nasal irrigation, which is safe and effective. In fact, a survey found that a large majority (87%) of family doctors recommend it to their patients for different conditions.[28]

The Irrigation Process: Saline nasal irrigation involves gently flushing the nasal cavity with a saltwater solution. There are two main methods for doing this-

Low-pressure spray or squirt bottle: This method delivers the saline solution with a gentle force.

Gravity-based device (neti pot): This method uses a container with a spout designed to fit comfortably in the nostril. The saline solution flows through the nasal cavity due to gravity.

In both methods, the saline solution goes into one nostril and drains out the other, cleansing the nasal passage as it flows.

Mechanism of Action- It is unclear how precisely saline nasal irrigation works. One theory is that upper respiratory disorders are caused by a breakdown in the nasal mucosa's protective capacity. Saline nasal irrigation has a number of physiological advantages that may improve the function of the nasal mucosa, consisting direct cleansing, the removal of inflammatory mediators, and increased mucociliary function as demonstrated by a rise in ciliary beat frequency.[28]

CHRONIC RHINOSINUSITIS- The most frequent reason for saline nasal irrigation is CRS, or rhinosinusitis that lasts longer than 12 weeks. A Cochrane study determined that saline nasal irrigation is an effective supplementary treatment for the signs of CRS on basis of favourable clinical as well as functional results.

Povidone-iodine (Betadine)- Clinicians have a variety of tools at their disposal to prevent and combat infections in wounds. One common approach involves using topical antiseptics applied directly to the wound site. These antiseptics aim to kill bacteria or halt their growth.

Among these topical antiseptics, povidone-iodine (Betadine) is a widely used option. It combines iodine, which acts as the germ-killing ingredient (bactericidal), with a synthetic polymer called povidone. The most widely utilized form is a 10% water solution with one percent of the iodine readily available. Other formulations of povidone-iodine are also available; these include a surgical scrub and a skin cleanser with a detergent base that contains 0.75% accessible iodine.[3,29]

QUALITY OF LIFE (QOL)-

Assessing Quality of Life After Sinus Surgery: The SNOT 22 Questionnaire

In the field of ENT surgery, evaluating a patient's quality of life QoL after procedures is crucial. One tool used for this purpose was the Nasal Obstructive Symptoms Evaluation questionnaire. However, this questionnaire was limited in scope, focusing solely on nasal symptoms and offering a brief assessment.[30]

The **SNOT 22 questionnaire** emerged as a more comprehensive alternative. Developed specifically for rhinosinusitis (sinus inflammation), it goes beyond nasal symptoms and encompasses how sinus issues affect a patient's overall well-being. This broader approach, combined with a wider range of questions compared to the Nasal Obstructive Symptoms Evaluation questionnaire, has made the SNOT a valuable tool. Several studies have confirmed its effectiveness in assessing quality of life after surgeries like septoplasty (correction of a deviated septum).

An investigation by Rabago et al.,[32] examined the potential benefits of hypertonic saline nasal irrigation (HSNI) for a broader range of sinonasal conditions. Twenty-eight individuals from an earlier qualitative study on nasal irrigation—all of whom were already using HSNI on a daily basis—were the participants in in-depth interviews.

12 out of the twenty-one participants with allergic rhinitis mentioned that HSNI helped improve their symptoms. This suggests a potential benefit for this specific condition.

Limited Evidence for Other Conditions: While two participants with asthma and one with nasal polyposis reported some positive effects on their respective conditions, the overall evidence for HSNI's effectiveness in these areas was less conclusive.

The present research emphasizes the need for more investigation into the possible advantages of HSNI for a range of sinonasal disorders, in addition to allergic rhinitis.[32]

Nasal Douching for Chronic Rhinosinusitis: A Promising Adjunct Therapy

The possible advantages of nasal douching for chronic rhinosinusitis (CRS) were examined in this study by Taccariello M et al.[33]. Forty CRS patients were split into three groups by researchers at the Royal National Throat, Nose, and Ear Hospital in London:

- Group 1 (19 patients): Received a traditional alkaline nasal douche alongside their regular treatment.
- Group 2 (21 patients): Used a sterile seawater spray in addition to standard CRS therapy.
- Group 3 (control group, 22 patients): Received only standard CRS treatment without nasal douching.

The results suggest that nasal douching, regardless of the solution used, led to significant improvements in both groups. The investigation also revealed variations between both douching techniques:

- The alkaline solution enhanced the endoscopic appearance of the nasal cavity but did not significantly impact the quality of life.
- The sterile seawater spray, on the other hand, led to better quality of life scores without a significant effect on the endoscopic findings.

The control group, which did not receive any nasal douching, did not experience any changes in either endoscopic appearance or quality of life scores. These findings suggest that nasal douching can be a valuable adjunct therapy for chronic rhinosinusitis, offering potential benefits for both the physical condition of the nasal cavity and patient well-being. However, the choice between an alkaline douche or a sterile seawater spray may influence the specific outcomes.[33]

Hypertonic Saline vs. Normal Saline for Chronic Sinusitis

In this investigation, conducted by "Ramabhadraiah et al.,[34] the efficacy of normal saline (0.9%) and hypertonic saline (3.5%) nasal drops in treating chronic sinusitis was evaluated.

A double-blind randomized controlled experiment was carried out by the researchers on fifty patients between the ages of 18 and 45 who had been diagnosed with chronic sinusitis. Two groups were randomly selected from among the participants:

- **Group A:** Received normal saline (0.9 percent) nasal drops for 4 weeks.
- **Group B:** Received hypertonic saline (3.5 percent) nasal drops" for 4 weeks.

This study, concludes that hypertonic saline (3.5% concentration) is a more effective treatment for chronic sinusitis compared to normal saline (0.9%). This research adds to the evidence that hypertonic saline nasal drops can be a valuable tool

in managing chronic sinusitis, offering relief from symptoms and improving quality of life.[34]

Betadine Disrupts Ciliary Function in Respiratory Cells -

This study by Kim et al.,[35] researched effects of Betadine on ciliated human respiratory cells, which are essential for clearing mucus and debris from the airways.

Betadine, at both 5% and 10% concentrations (including the clinical dose), significantly impaired the function of cilia in cultured respiratory cells.

These findings suggest that Betadine can have a adverse impact on the respiratory system's natural cleansing processes. The study by Kim et al. highlights potential negative impact of Betadine on respiratory health. Caution should be exercised when considering topical Betadine solutions for the respiratory mucosa, as it may disrupt the essential function of cilia.[35]

Povidone-Iodine Irrigation for Wounds-

The study "Povidone-iodine wound irrigation and wound sepsis" by Rogers DM et al.,[36] examined the effectiveness of povidone-iodine (Betadine) solution for wound irrigation in preventing surgical site infections. Researchers compared wound irrigation with povidone-iodine solution to normal saline solution in 187 patients undergoing various general surgeries. There was not a significant difference in the two groups' rates of wound infections. It's crucial to remember that no one study can offer conclusive answers. To definitively demonstrate the efficacy of povidone-iodine wound irrigation, more investigation is required. While this study suggests povidone-iodine might not be superior to saline for preventing infections, it may still have some antiseptic properties. However, the Kim et al. study mentioned earlier highlights a

potential concern: Betadine can have a negative impact on the function of cilia, which are important for wound healing.

The use of povidone-iodine for wound irrigation remains a topic of debate. Obtaining advice from a healthcare professional regarding the best wound care techniques for a specific situation is imperative.[36]

Daily Isotonic Nasal Irrigation for Allergic Rhinitis

Research investigation that examined "the efficacy of saline nasal irrigation (SNI) for allergic rhinitis (AR) was conducted by Kristina E. Hermelingmeier et al.[28] A thorough review of papers on SNI and AR published between 1994 and 2010 was carried out by the researchers. They focused on prospective randomized controlled trials, considered the gold standard for clinical investigation. This investigation contributes to the increasing amount of research that shows regular saline nasal irrigation is a safe and efficient adjunctive treatment for AR. It can improve symptoms, potentially reduce medication needs, and enhance overall well-being without causing unwanted side effects.[28]

Tap Water Nasal Irrigation for Seasonal Allergies

The effectiveness of tap water nasal irrigation for seasonal allergic rhinitis was examined in this Xiong et al.[38] experiment. There were 64 individuals in the investigation who had been diagnosed with seasonal allergic rhinitis". Two groups were randomly selected from among the participants:

- **Tap Water Nasal Irrigation Group:** Used tap water for nasal irrigation.

- **Non-Tap Water Nasal Irrigation Group:** Used a non-tap water solution (likely distilled or sterile water).

- Both groups received the medication desloratadine (common allergy medication) as part of the treatment.

Researchers measured the participants' quality of life (QoL) related to allergic rhinitis before and after three weeks of treatment. When comparing the tap water nasal irrigation group's QoL scores to those of the non-tap water group, the study discovered statistically significant improvements. This suggests tap water nasal irrigation offered additional benefits beyond just medication. It may help improve the overall well-being of patients alongside their regular allergy medication.[38]

Povidone-Iodine Irrigation Effective in Reducing Surgical Site Infections

The study by Sindelar WF et al.,[39] investigated the effectiveness of povidone-iodine (PVP-I) solution for wound irrigation in preventing surgical site infections (SSIs). The study involved 500 patients undergoing various general surgeries. One of two groups was randomly allocated to the participants:

Treatment Group: Wounds were irrigated with PVP-I solution before skin closure.

Control Group: Prior to skin closure, saline solution was used to irrigate the wounds.

Based on the degree of bacterial contamination, the researchers classified wounds as clean, potentially infected, contaminated, or unclean. When utilizing PVP-I irrigation as opposed to saline irrigation, the researchers discovered a significant decrease in wound infections in all wound categories.[39]

MATERIALS AND METHODS

The current investigation was carried out at KLE Hospital and MRC, Belagavi, at the Department of Otorhinolaryngology and Head & Neck Surgery. The Institutional Ethics Committee for Human Subjects Research at Jawaharlal Nehru Medical College, KAHER, gave its approval to the project.

STUDY DESIGN: Prospective Randomized Comparative Study.

SELECTION OF PARTICIPANTS- The participants in the current investigation are all patients with chronic rhinosinusitis, both with and without polyposis, who visited all units of the Department of Otorhinolaryngology and Head and Neck Surgery at Jawaharlal Nehru Medical College, Belagavi, between October 1, 2022, and September 30, 2023.

Our sample size consists of all the patients who responded to a follow-up and who met the inclusion and exclusion criteria. Patients between the ages of 18 to 50 who had been diagnosed with chronic rhinosinusitis were chosen throughout this time. Two groups were randomly assigned to them. The patients getting operated on Monday, Tuesday and Wednesday will be **GROUP A** where they will be given 0.5 % betadine solution nasal wash postoperatively, and patients getting operated on Thursday, Friday, and Saturday will be **GROUP B** where they will be given 3% hypertonic solution nasal wash post operatively.

Patients will be assessed at the first week, first month, and third month postoperatively using the SNOT 22 questionnaire.

INCLUSION CRITERIA –

1. Candidate of FESS according to EPOS (2012) criteria
2. Age 18 - 60 years
3. Hb > 10 gm/dl

EXCLUSION CRITERIA –

1. All patients less than18 years and adults > 60 years
2. Patient who underwent revision FESS
3. Patients with mucociliary clearance diseases
4. Patients who didn't give consent for the study

Study Period: 27th September 2022 to 26th August 2023

Sample Size: 68 (34 in each group)

Study protocol: Patients presenting to ENT OPD, diagnosed with CRS, and counselled for FESS and postoperatively divided into two groups according to the method of randomization.

Data collection procedure:

- The patients visiting the ENT and HNS OPD with complaints suggestive of chronic rhinosinusitis will be examined, and a detailed history will be taken.
- The patient will be examined thoroughly.
- After the clinical diagnosis of chronic rhinosinusitis is made, the patient will be explained in their own vernacular language about the condition and will be counselled for FUNCTIONAL ENDOSCOPIC SINUS SURGERY and consent will be taken.

- Postoperatively, the patients will be divided into two groups, GROUP A receiving 3% hypertonic saline nasal wash and GROUP B receiving 0.5 % diluted betadine nasal wash.
- Patients will be assessed at the first week, first month, and third month postoperatively using SNOT 22 questionnaire.

Sample size formula: Using the mean and standard deviation as a basis, the minimum sample size formula is

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

where z_α is linked with the level of significance and z_β is linked with the power of the test. For 5% level of the significance z_α =1.96 and z_β =0.84 for 80% power of the test.

The parameter considered :

$\bar{X}_1$ is the mean of systolic blood pressure of the first group (21.83) and $\bar{X}_2$ is for the second group (26.03).

s_1 is the standard deviation of the first group (6.044) & s_2 is the standard deviation of the second group (6.29).

The sample size that results from these values is 34.

Each of the two groups will have a size of 34.

METHODS USED TO ASSESS THE OUTCOME- A patient intake process conducted, by gathering demographic information (occupation, name, age, address, sex) and carrying out a thorough physical examination and history. Consent was obtained with information.

The Sino-Nasal Outcome Test-22 (SNOT-22) assessed patient's experience of 22 symptoms over the months. These symptoms included nasal issues like congestion, discharge, and sneezing, as well as related problems like facial pain, sleep disturbance, fatigue, and emotional impacts.

Using a 0–5 category rating system, the patient selects the degree of their disease on each of the twenty- two items:

0=Not present/no problem

1=Very mild problem

2=Mild or slight problem

3=Moderate problem

4=Severe problem

5=Problem as “bad as it can be”

STUDY PROCEDURE –

Once Institutional Ethics Committee Board gave its approval, patients were assigned according to the study's inclusion and exclusion criteria to make sure they were suitable participants. Written informed consent was given to each participant following a comprehensive evaluation of the document and an explanation of its contents. After that, a thorough assessment was carried out, which included a general physical examination, a systemic examination of every bodily system, and a targeted examination of the throat, nose, and ears.

All participants completed the Sino-Nasal Outcome Test-22 (SNOT-22) to self-report severity of their symptoms over the three months. Each patient received a comprehensive instructional session on performing nasal irrigation.

STEP 1: GATHER THE SUPPLIES

1. Everyone received a 10-cc plastic syringe.
2. Plastic cannula
3. A container
4. commercially accessible hypertonic saline (three percent), appropriate for Group A.
5. To prepare 0.5 percent diluted betadine saline, mix 500ml of normal saline (for Group B) with 25ml of 10% betadine solution.
6. Applying the equation (Final conc.) * (Final volume) = (Initial conc.)

STEP 2: PROCEDURE OF NASAL IRRIGATION

1. Bend forward at the sink and incline the head to one side.
2. Place the cannula into the nose which is located at the highest point.
3. Inhale via your mouth.
4. In order to inject the fluid into the upper nose, push the syringe's handle.
5. In a few moments, the solution will begin to drain from the lower nostril.
6. After the syringe is empty, proceed further and softly release both nostrils.
7. Gently blow the nose
8. Once the syringe is full, rotate the head to the other side and repeat the process with the second nostril.
9. To do regularly three times for twelve weeks.

STEP 3: CLEAN THE EQUIPMENT

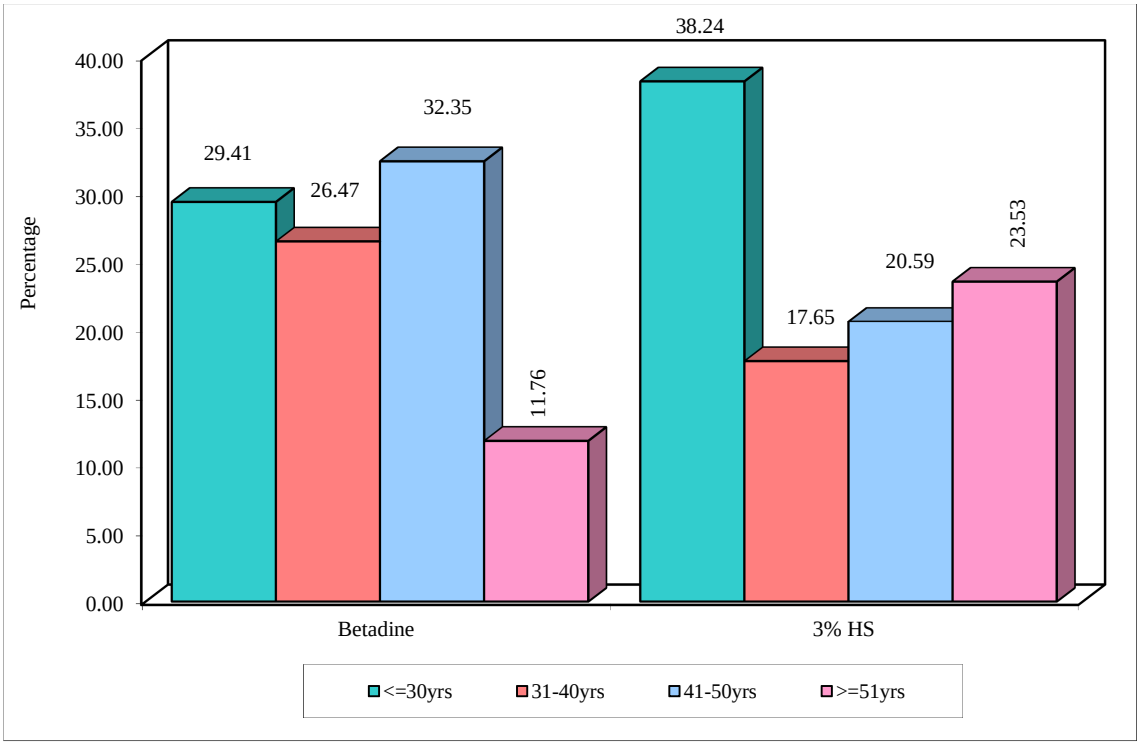
1. Every day, properly rinse and wash the cannula and syringe with warm water
2. Unused saline solution should be stored in a sealed container and kept at room temperature for up to five days.
3. To assess quality of life, the same SNOT-22 questionnaire was given at the conclusion of the four weeks. The gathered information was statistically analyzed.

RESULTS

DIVISION OF PATIENTS IN GROUP A AND GROUP B BY AGE

Table 1: Comparison of Betadine And 3% Hypertonic saline with age

Age groups	Betadine	%	3% HS	%	Total	%	Chi-square	p-value
<=30yrs	10	29.41	13	38.24	23	33.82	3.2140	0.3600
31-40yrs	9	26.47	6	17.65	15	22.06		
41-50yrs	11	32.35	7	20.59	18	26.47		
>=51yrs	4	11.76	8	23.53	12	17.65		
Mean	38.56		38.06		38.31			
SD	12.26		15.07		13.64			
Total	34	100.00	34	100.00	68	100.00		



Graph 1 : Comparison of Betadine And 3% Hypertonic saline with age

In Group A 10 (29.41%) were in the age group between < 30 years,

9(26.47%) were between 31-40yrs, 11(32.35%) were in between 41-50yrs and

4(11.76%) were in the age group of >51 yrs.

In Group B 13 (38.24%) were in the age group between < 30 years,

6(17.65%) were between 31-40yrs, 7(20.59%) were in between 41-50yrs and

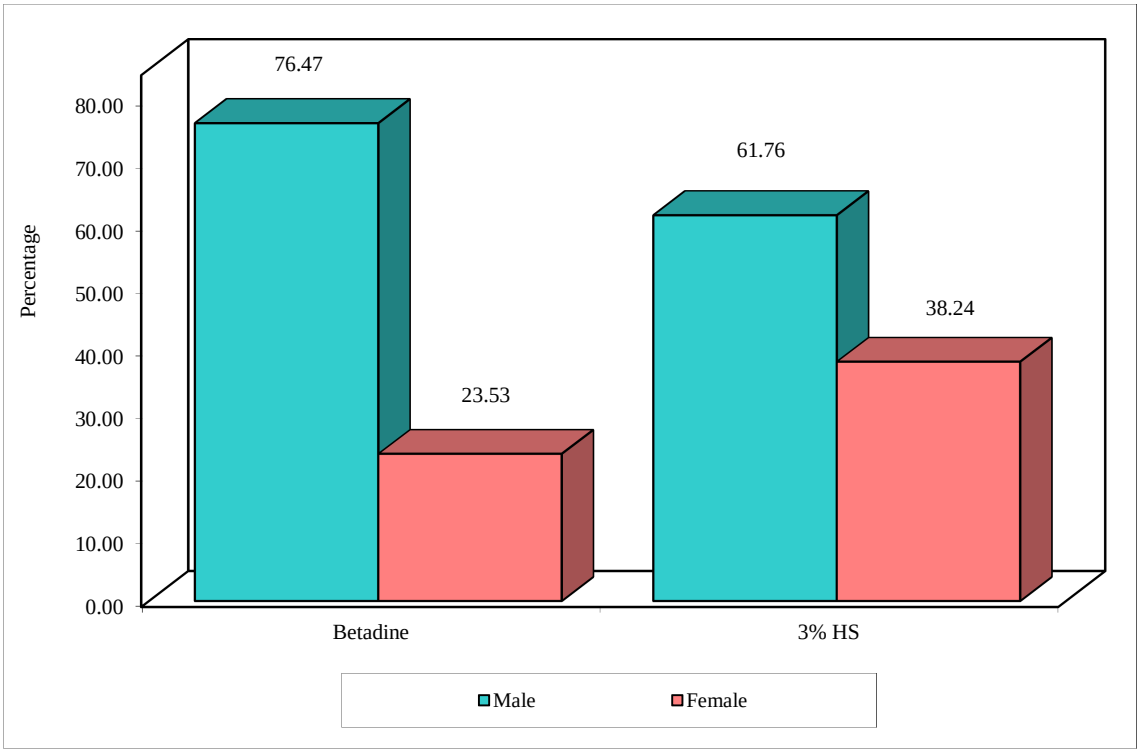
8(23.53%) were in the age group of >51 yrs.

Regarding the distribution of ages, there is no difference between the two groups. (Graph 1 & Table 1)

GENDER DISTRIBUTION

Table 2: Comparison of Betadine And 3% Hypertonic saline with gender

Gender	Betadine	%	3% HS	%	Total	%	Chi-square	p-value
Male	26	76.47	21	61.76	47	69.12	1.7220	0.1890
Female	8	23.53	13	38.24	21	30.88		
Total	34	100.00	34	100.00	68	100.00		



Graph 2: Comparison of Betadine And 3% Hypertonic saline with gender

There were a total of 68 patients out of which 47 (69.12 %) were males and 21(30.88%) were females. Among the distribution 26 (76.47%) males were given betadine solution as a part of treatment and 61.76% (21) males were given 3% hypertonic saline. Group A had 8 (23.53%) women who were prescribed betadine solution, while group B included 38.24% (13) females who were administered 3% hypertonic saline.

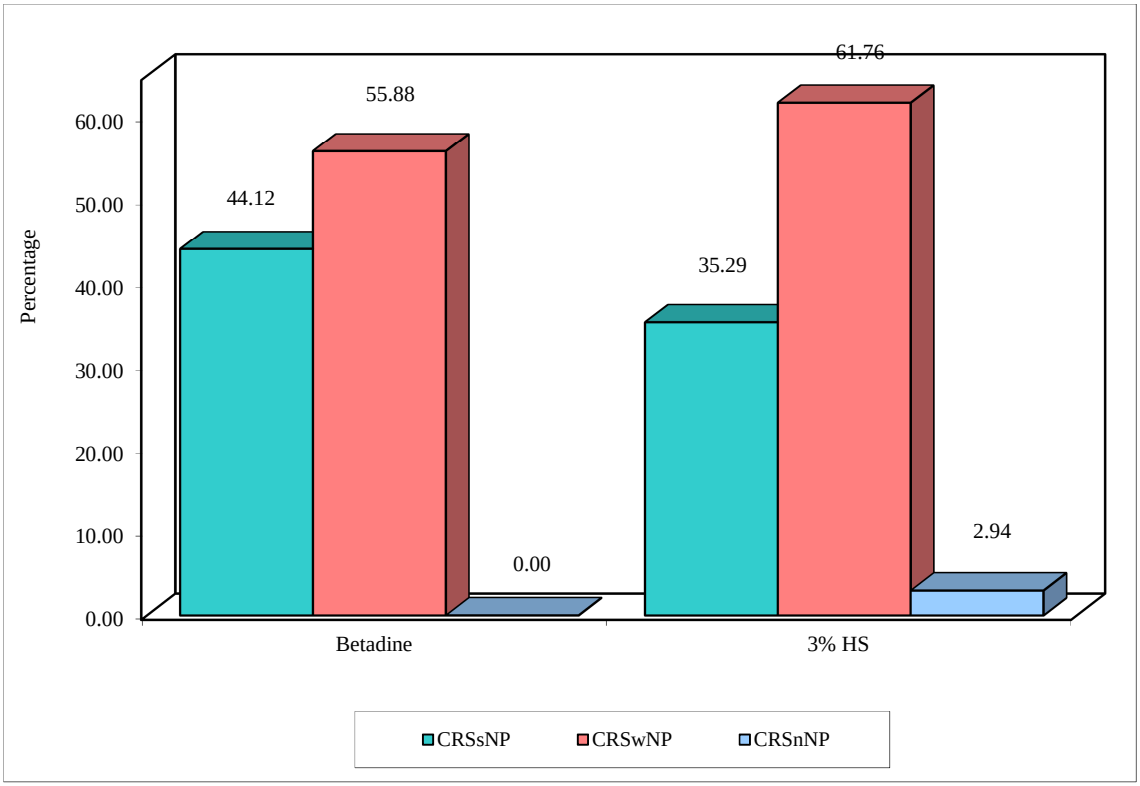
The gender distribution did not significantly differ between the two groups.

(Table 2 & Graph 2)

DIAGNOSIS

Table 3: Comparison of Betadine And 3% Hypertonic saline with diagnosis

Diagnosis	Betadine	%	3% HS	%	Total	%	Chi-square	p-value
CRSsNP	15	44.12	13	38.23	28	41.18	1.4330	0.4880
CRSwNP	19	55.88	21	61.76	40	58.82		
Total	34	100.00	34	100.00	68	100.00		



Graph 3: Comparison of Betadine And 3% Hypertonic saline groups with a diagnosis

There was a total of 28 patients diagnosed with CRS without nasal polyposis, of which 15 patients were allotted to Group A (patients were given betadine solution as nasal wash postoperatively) and 13 patients were allotted to Group B (patients were given hypertonic saline solution as nasal wash postoperatively).

A total of 40 patients were diagnosed with CRS with nasal polyposis, of which 19 patients were allotted to Group A (patients were given betadine solution as nasal wash postoperatively) and 21 patients were allotted to Group B (patients were given hypertonic saline solution as nasal wash postoperatively). (Table 3, Graph 3)

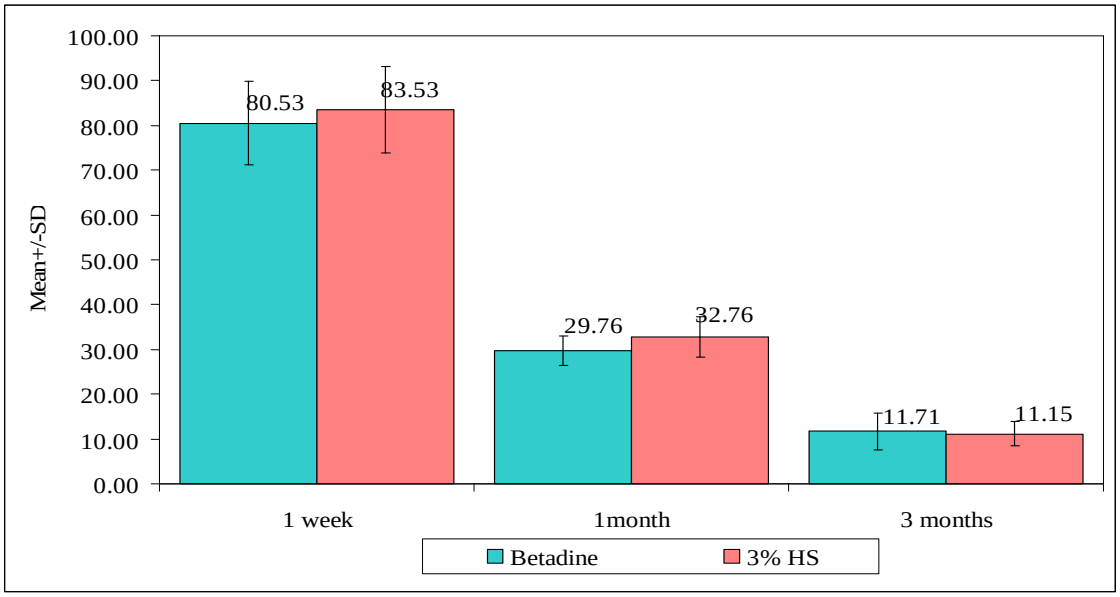
Considering diagnosis, there is not a significant distinction between the two groups. (Table 3, Graph 3).

COMPARISON OF BETADINE AND 3% HYPERTONIC SALINE WITH SNOT -22 SCORES AT DIFFERENT TREATMENT TIMES

Table 4: Comparison of Betadine And 3% Hypertonic saline with SNOT -22 scores at different treatment times by Mann-Whitney U test

Times	Betadine			3% HS			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
1 week	80.53	9.40	31.71	83.53	9.69	37.29	483.00	-1.1591	0.2464
1month	29.76	3.26	27.72	32.76	4.51	41.28	347.50	-2.8211	0.0048*
3 months	11.71	4.20	34.84	11.15	2.76	34.16	566.50	0.1349	0.8927
1W-1M	50.76	10.42	35.00	50.76	11.58	34.00	561.00	0.2024	0.8396
1W-3M	68.82	11.75	31.85	72.38	9.43	37.15	488.00	-1.0978	0.2723
1M-3M	18.06	5.16	28.43	21.62	5.35	40.57	371.50	-2.5267	0.0115*

*p<0.05



Graph 4: Comparison of Betadine And 3% Hypertonic saline with SNOT -22 scores at different treatment times

Using the Mann- Whitney U test and comparing betadine and 3 % hypertonic saline with SNOT-22 scores at different treatment times and following conclusions were derived in the groups. In the betadine group, at one week the mean was 80.53, the standard deviation was 9.40 with a mean rank of 31.71, at one month mean was 29.76, the standard deviation was 3.26 and the mean rank was 27.72, at the third-month mean was 11.71, standard deviation was 4.20 and standard deviation was 34.84.

In the 3% hypertonic saline group, at one week the mean was 83.53, the standard deviation was 9.69 with a mean rank of 37.29, at one month mean was 32.76, the standard deviation was 4.51 and the mean rank was 41.28, at the third-month mean was 11.15, the standard deviation was 2.76 and standard deviation was 34.00.

The U value on comparing 1 week with 1 month for both the groups was 561.00, the Z value was 0.2024 and the P value was 0.8396 proving it to be nonsignificant.

The U value on comparing 1 week with 3 months for both the groups was 488.00, the Z value was -1.0978 and the P value was 0.2723 proving it to be a significant difference.

The U value on comparing 1 month with 3 months was 371.50, the Z value was -2.5267, and the P value was 0.0115 proving it to be significant.

On comparing Betadine solution (BS) irrigation with Hypertonic saline solution (HS) irrigation at the end of 1st week, both solutions gave an equal improvement in patient symptoms and were found to be equally effective which was proved by p-value 0.2464.

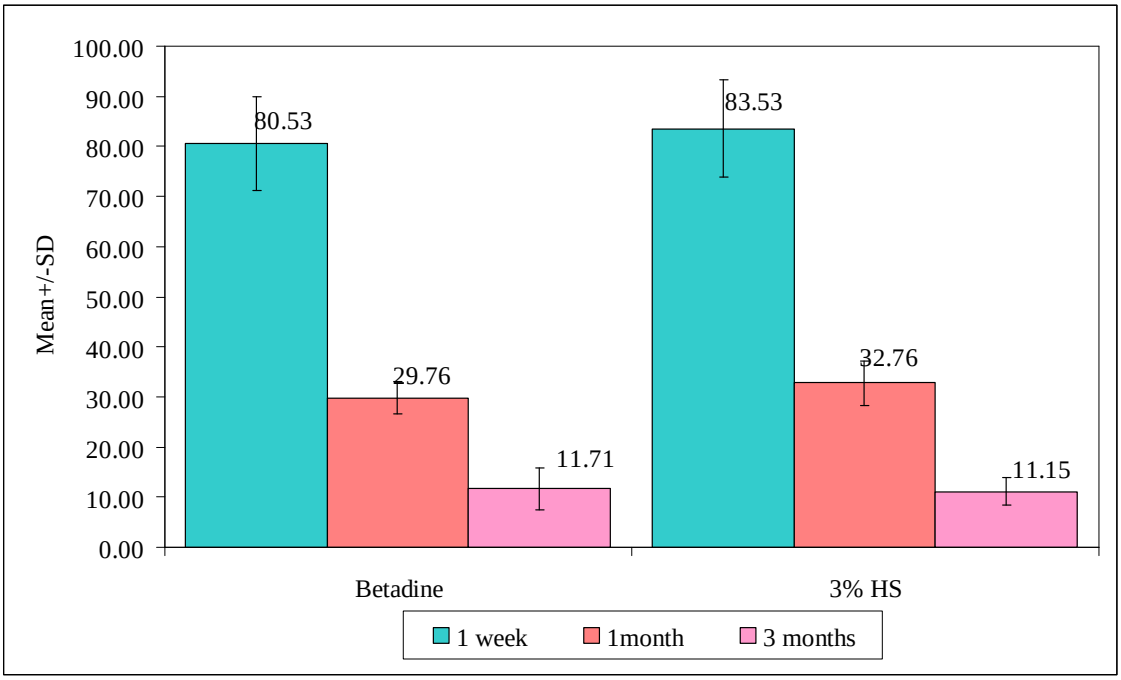
On comparing both the solutions at the end of 1st month, again both the solutions proved to be equally effective with no significant change in the post-operative status of patients demonstrated with a p-value of 0.048.

On comparing Betadine solution (BS) solution with Hypertonic saline solution (HS) irrigation at the end of 3rd month, the HS solution showed better results in post-operative conditions which were proved with a p-value of 0.8927 which is not significant. hence proving HS solution is better for long-term use. (Table 4, Graph 4).

COMPARISON OF DIFFERENT TREATMENT TIMES WITH SNOT -22 SCORES IN BETADINE AND 3% HYPERTONIC SALINE BY WILCOXON MATCHED PAIRS TEST

Table 5: Comparison of different treatment times with SNOT -22 scores in Betadine And 3% Hypertonic saline by Wilcoxon matched pairs test

Group	Times	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value	Friedman test	p-value
Betadine	1 week	80.53	9.40							
	1 month	29.76	3.26	50.76	10.42	63.04	5.0862	0.0001*	68.000	0.0001*
	1 week	80.53	9.40							
	3 months	11.71	4.20	68.82	11.75	85.46	5.0865	0.0001*		
	1 month	29.76	3.26							
	3 months	11.71	4.20	18.06	5.16	60.67	5.0862	0.0001*		
3% HS	1 week	83.53	9.69						68.001	0.0001*
	1 month	32.76	4.51	50.76	11.58	60.77	5.0862	0.0001*		
	1 week	83.53	9.69							
	3 months	11.15	2.76	72.38	9.43	86.65	5.0863	0.0001*		
	1 month	32.76	4.51							
	3 months	11.15	2.76	21.62	5.35	65.98	5.0863	0.0001*		



Graph 5: Comparison of different treatment times with SNOT -22 scores in Betadine And 3% Hypertonic saline

On comparing the two groups using the Wilcoxon matched pairs test at different times the following percentage of change was noted:

In the betadine group on comparing 1 week with 1 month % of change was 63.04, on comparing 1 week with 3 months % of change was 85.46 and on comparing 1 month with 3 months % of change was 60.67. The Z values are 5.0862, 5.0865, and 5.0862 accordingly. The P value was 0.0001 in all 3 categories proving it to be significant.

In the 3% hypertonic saline group on comparing 1 week with 1 month % of change was 60.77, on comparing 1 week with 3 months % of change was 86.65 and on comparing 1 month with 3 months % of change was 65.98. The Z values are 5.0862, 5.0863, and 5.0863 accordingly. The P value was 0.0001 in all 3 categories proving it to be significant.

In group A (BS), the significant percentage of change after using BS solution from the 1-week time to 1 month time was 63.04 whereas on comparing 1 week with 3 months the percentage of change was 85.46, and on comparing 1 month with 3 months' time period the significant percentage of change was 60.67.

In group B (HS), the significant percentage of change after using HS solution from the 1-week time to 1 month time was 60.77 whereas on comparing 1 week with 3 months the percentage of change was 86.65, and on comparing 1 month with 3 months' time period the significant percentage of change was 65.98. Hence this proves that hypertonic saline irrigation showed significant change when used up to 3 months. (Table 5, Graph 5).

DISCUSSION

CRS refers to any inflammation of the nose and paranasal sinuses that lasts for 12 weeks or longer.[17] It is believed that twenty percent of the global population is afflicted by CRS at any given moment.[42] One of the most common conditions, adults seek medical attention for is adult CRS, which raises the cost of direct medical care. According to estimates, CRS affects quality of life even more than chronic, incapacitating disorders like diabetes mellitus and congestive heart failure. It is more common than both hypertension and arthritis. Moreover, CRS results in significant emotional and functional damage in addition to major physical symptoms.[43]

The practice of rinsing the nasal passages with salt water i.e., nasal irrigations a feature of both modern medical treatments and older, traditional healing methods. Researchers have proposed several ways nasal irrigation with saline solution might benefit the body. Povidone-iodine (PVP-I) is a powerful antiseptic that kills a wide range of germs. Unlike some antibiotics and other antiseptics, bacteria don't seem to develop resistance to it. This makes PVP-I valuable beyond its traditional uses like skin and hand disinfection, wound treatment, and cleaning mucous membranes. It can also be beneficial for rinsing body cavities in certain conditions.

In order to evaluate the effectiveness “of 3% hypertonic saline and 0.5% diluted betadine saline irrigation in the treatment of chronic rhinosinusitis, this investigation was carried out at KLE Hospital and MRC, Belagavi. Following surgery, sixty-eight patients with diagnoses of chronic rhinosinusitis with polyps and CRS without nasal polyposis were split into two groups, treated appropriately, and subjectively evaluated employing the SNOT 22 Questionnaire. Following irrigation,

these parameters were evaluated at the one-week, one-month, and three-month follow-ups.

Of the 68 patients, twenty-eight were diagnosed with CRwNP (chronic rhinosinusitis with nasal polyposis) and forty with CRsNP (chronic rhinosinusitis without nasal polyposis). 41 (69.12%) were males and 27 (30.88%) were females. Out of 68 patients, headache was the most common symptom followed by nasal obstruction" and recurrent sneezing simultaneously.

The SNOT-22 measure is utilized to evaluate the therapy outcome for patients in both groups. Group A received 0.5% diluted betadine saline (BS) treatment; Group B received 3% hypertonic saline (HS) treatment; both groups displayed z values of 5.0863 and 5.0862, respectively, and both groups had a statistically highly significant "p" value of 0.001. Both groups underwent the Shapiro-Wilk test, and the results were compared in the first week. In group A (BS), the value was determined to be 0.9180, and in group B (HS), it was 0.9520.

At the end of 1st month, the value in group A(BS) was 0.9270, where as in group B(HS) was 0.9600.

At the end of 3rd month, the value in group A(BS) was noted to be 0.8990 and in group B(HS) was 0.9080, proving it to be a significant study.

The research done by Hermelingmeier et al.,[28] investigated the effectiveness of SNI as an additional treatment for allergic rhinitis (AR). The researchers conducted a systematic search for studies published between 1994 and 2010. According to the investigation's findings, saline nasal irrigation (SNI) with an isotonic saline solution can be an effective adjunctive treatment for patients with AR. [28]

In a publication done by Taccariello M et al.,[33] researchers investigated use of nasal douching in alleviating CRS symptoms. The study involved 40 CRS patients divided into three groups. Two groups received nasal douching alongside standard CRS treatment, with one group using a traditional alkaline solution and the other using a sterile seawater spray. The third group received only standard treatment.

The investigation discovered that when compared to the control group, nasal douching significantly improved endoscopic appearance ($p = .009$) and quality of life scores ($p = .008$), regardless of the type of solution used. Interestingly, the two douching solutions yielded different results. The seawater spray demonstrated the opposite impact from the alkaline douche, which enhanced endoscopic appearance but did not increase the quality of life scores.

These findings suggest that nasal douching may be a beneficial addition to standard CRS treatment for improving both objective (endoscopic) and subjective (quality of life) outcomes. However, the study also highlights that the type of douching solution might influence the specific benefits experienced. [33]

In the comparison of our study with Taccariello M et al.,[33] both the solutions hypertonic saline and betadine showed to improve the symptoms post-operatively with hypertonic saline proving slightly better in the long run.

The effects of betadine on ciliated human respiratory epithelial cells were examined in the study conducted by Kim et al., [35]. These cells, borders the airways, have cilia, which resemble hairs and aid in sweeping the respiratory system of mucus and debris.

The researchers then analyzed the rate at which the cilia beat (ciliary beat frequency).

- Within a minute, the percentage of cilia that were actively beating was considerably decreased by both five percent and ten percent betadine.
- In comparison to the control group, the cells exposed to betadine had a significant decrease in ciliary beat frequency.
- The effects of 10% and 5% betadine were not significantly different. [35]

In a comparison of our study with the study done by Kim et al.,[35] both the studies showed significant enhancement in the SNOT 22 score in the patients quickly over the period of 1 month whereas its efficacy reduced in the long usage period and didn't show much improvement on using up till 3 months.

Research by Ural et al.,[44] on the effectiveness of nasal irrigation for different nasal conditions and mucociliary clearance time, described how long it takes for mucus to be cleared from the nose.

Researchers recruited 132 adults and divided them into groups based on their nasal condition:

Control group (45 participants), AR (21 participants), Acute sinusitis (24 participants), Chronic sinusitis (42 participants)

The saccharine clearance test was used to determine mucociliary clearance time both before and after 10 days of nasal irrigation.

Consistent with the results, this study implies that nasal irrigation with isotonic or hypertonic saline can help improve mucociliary clearance in a variety of

nasal conditions. Even so, the choice of solution might be most effective depending on the specific condition.[44]

In the comparison of our studies with that of Ural et al.,[44] both the studies proved that rinsing the nasal cavity with salt water (saline solution) helps clear mucus. This works by keeping the inside of your nose moist and washing away any dried mucus.

Rinsing your sinuses (nasal irrigation) is an easy and affordable way to manage sinus and nasal problems. It can help people feel better without needing as many medications or doctor visits, which could also reduce the use of antibiotics.

Future studies on this hypothesis can be planned with more participants, multiple centres, and longer follow-up periods with objective evaluation in the form of endoscopic pictures to get stronger, more validated results and conclusions.

CONCLUSION

This investigation compares the effects of 0.5% povidine iodine and 3% hypertonic “saline nasal douching in post-operative endoscopic sinus surgery cases. It also evaluates the influence of 0.5 percent betadine solution nasal irrigation and three percent hypertonic saline nasal irrigation on the "QUALITY OF LIFE" using the Sinonasal Outcome (SNOT 22) questionnaire. This study's findings demonstrate a positive association between nasal irrigation and improvements in chronic sinusitis symptoms.

This study proves that that both 0.5 % betadine solution and 3 % hypertonic saline” are equally significant with 3% hypertonic saline having slightly better results, where 0.5 % diluted betadine solution has proven to be slightly better in the short-term treatment up to 1 month, and 3 % hypertonic saline proved to be better in a long-term treatment upto 3 months. This study suggests that nasal irrigation with any of these solutions may be helpful for improving mucociliary clearance and relieving symptoms of chronic sinusitis and also povidone-iodine irrigation might help with post-operative crusts prevention and infection but, more research is needed. Specifically, larger, double-blind randomized controlled trials are crucial to identify the effective percentage of povidone-iodine solution and pinpoint any potential risks associated with its use and its advantages over hypertonic saline. To ascertain which method is the most successful, further research is necessary.

SUMMARY

This study was conducted at KLE Hospital and MRC, between the time period of September 2022 to August 2023.

The goal of this research was to investigate the impacts of nasal irrigation with three percent hypertonic saline and 0.5 percent betadine solution on the "QUALITY OF LIFE" utilizing the sinonasal outcome (SNOT 22) questionnaire.

The investigation involved 68 individuals (aged 18 to 50 years), of whom 40 had CRS without nasal polyposis and 28 had CRS with polyposis; these patients were categorized into groups A and B based on the inclusion criteria. The SNOT-22 rating system is used for a preoperative subjective assessment following patient education and informed consent. The parameters were reviewed in each participant at the one-week, one-month, and three-month follow-ups after nasal irrigation. The Wilcoxon matched pairs test employed to examine data that was gathered.

The outcomes of the investigation showed a positive relationship between the parameters, indicating that nasal irrigation is a viable therapy option for polyposis- or chronic rhinosinusitis. It also demonstrated that both a dilute betadine solution and a hypertonic saline irrigation solution improved post-operative symptoms, with the hypertonic saline solution working slightly better over time.

LIMITATIONS

The limitations of our study include a smaller sample size, shorter follow-up period, single centre study.

BIBLIOGRAPHY

1. Gleeson M, Browning GG, Busssrton MJ, Clarke R, Hibbert J, Jones NS, Lund J,editors. Scott-Brown's otorhinolaryngology, head and neck surgery. 7th ed. London:Hodder Arnold. 2008

2. Cummings CW, Flint PW, Harker LA, Haughey BH, Richardson MA, RobbinsKT, Lund VJ, Niparko JK editors. Cummings otolaryngology, head and neck surgery. 5th ed. Philadelphia: Mosby, Inc.; 2010.

3. PP Devan, Kumar K, K Rubeena, Comparative study of 3% hypertonic saline, Normal saline and 0.5% diluted betadine saline in the treatment of allergic rhinitis. J Otorhinolaryngol and Allied Sci 2019;2(1):1-7

4. Bigliardi, P., Alsagoff, S., El-Kafrawi, H., Pyon, J., Wa, C. and Villa, M., 2022. Povidone iodine in wound healing: A review of current concepts and practices.

5. Tripathy, S. and Panda, R., 2019. Comparative study of hypertonic saline nasal douching versus normal saline nasal douching in post operative endoscopic sinus surgery patients. International Journal of Otorhinolaryngology and Head and Neck Surgery.

6. VJ Lund. Anatomy of the Nose and Paranasal sinuses. In:Alan G Kerr, Gleeson, editors. Scott-Brown's otorhinolaryngology, head and neck surgery.6th ed. London: Hodder Arnold. 1997 p: 1/5/1-1/5/28

7. Donald PJ, Gluckman JL, Rice DH. The Sinuses. New York: Raven;1995:15– 48.

8. Libersa C, Laude M, Libersa JC. The pneumatization of the accessory cavities of the nasal fossae during growth. Anat Clin 1981;2:265–273.

9. McGowan DA, Baxter PW, James J. The Maxillar Sinus. Oxford: Wright; 1993:1–25.

10. Hinck VC, Hopkins CEO Concerning growth of the sphenoid sinus. Archives of Otolaryngology. 1965; 82 : 62-6.

11. M Pias Clemente, Surgical anatomy of the paranasal sinuses. Sinus Surgery Endoscopic and Microscopic approaches. p:1-13, 50-55

12. Lund VJ. Inferior meatal antrostomy. Fundamental considerations of design and function. Journal of Laryngology and Otology, Suppl. 1988b; 15 : 1 - 18.

13. Tos M, Morgensen C. Mucus production in the nasal sinuses. Acta Otolaryngologica. Supplementum. 1979 ; 360: 131-4.

14. Netter FH. Atlas of Human Anatomy. Basle, Switzerland: Ciba-Geigy; 1989: 32–44.

15. Elwany S, Yacout YM, Talaat M, EI-Nahaas M, Gunied A Surgical anatomy of the sphenoid sinus. Journal of Laryngology. 1 983; 97 : 227-41 .

16. Susan Standring. Nose, Nasal cavity and Paranasal Sinuses. Gray's anatomy. The Anatomical Basis of Clinical Practice 40th edition. UK 2008. 32:983

17. Benninger M5, Ferguson BJ, Hadley JA, Hamilos DJ, Jacobs M, Kennedy DW. Adult chronic rhinosinusitis: Definitions, diagnosis, epidemiology and pathophysiology. Otolaryngology and Head and Neck Surgery. 2003; 129: S1-32.

18. Meltzer EO, Hamilos OJ, Hadley JA, Lanza DC, Marple BF, Nicklas RA et al. Rhinosinusitis: Establishing definitions for clinical -research and patient care. Otolaryngology and Head and Neck Surgery. 2 004; 114: 51-62.

19. Benninger MS. The impact of cigarette smoking and environmental tobacco smoke on nasal and sinus disease. American Journal of Rhinology. 1999; 13: 435-8.

20. Benninger M5, Anon J, Mabry RL. The medical management of rhinosinusitis. Otolaryngology and Head and Neck Surgery. 1997; 117: 541-9.

21. Ponikau JU, Sherris DA, Kern EB, Homburger HA, Frigas E, 'Gaffey TA et al. The diagnosis and incidence of allergic fungal sinusitis. Mayo Clinic Proceedings. 1999; 74: 877-84.

22. Lanza DC, Kennedy DW. Adult rhinosinusitis defined.Otolaryngology and Head and Neck Surgery. 1997; 117: 51-7.

23. Benninger MS, Appelbaum PC, Denneny JC, Osguthorpe DJ, Stankiewicz JA. Maxillary sinus puncture and culture in the diagnosis of acute rhinosinusitis: The case for pursuing alternative culture methods. Otolaryngology and Head And Neck Surgery. 2002; 127: 7-12.

24. Stammberger H. Endoscopic surgery for mycotic and chronic recurringsinusitis. Annals of Otology, Rhinology and Laryngology. 1985a; 119 : l - l l .

25. Stammberger H. Endoscopic endonasal surgery – New concepts in the treatment of recurring sinusitis. Part I. Anatomical and pathophysiological considerations. Otolaryngology, Head and Neck Surgery. 1985b; 94: 143-7.

26. Stammberger H. Endoscopic endonasal surgery – New concepts in the treatment of recurring sinusitis. Part II. Surgical technique. Otolaryngology, Head and NeckSurgery. 1985c; 94: 143-7.

27. Kennedy DW. Functional endoscopic sinus surgery: Technique. Archives of Oto-Rhino-Laryngology. 1985; 111: 6439.

28. Kristina E. Hermelingmeier, M.D. Rainer K. Weber, Ph.D., Martin Hellmich, Ph.D.,Christine P. Heubach, M.D.,2 and Ralph Mösges, Ph.D.2Nasal irrigation as an adjunctive treatment in allergic rhinitis: A systematic review and meta-analysis. Am J Rhinol Allergy. 2012 Sep-Oct; 26(5): e119–e125.

29. Burks RI1.Povidone-iodine solution in wound treatment. Phys Ther. 1998 Feb; 78(2):212-8.

30. Naraghi M, Amirzargar B, Meysamie A. Quality Of Life Comparison In Common Rhinologic Surgeries. Allergy Rhinol (Providence). 2012; 3(1): e1- e7. Published online 2012 Jun 21. doi: 10.2500/ar.2012.3.0020

31. Rabago D, Barrett B, Marchand L, Maberry R, Mundt M. Qualitative aspects of nasal irrigation use by patients with chronic sinus disease in a Multi method study. Ann Fam Med 2006 July-August; 4(4): 295-301.

32. Rabago D1, Guerard E, Bukstein D. Nasal irrigation for chronic sinus symptoms in patients with allergic rhinitis, asthma, and nasal polyposis: a hypothesis generating study. WMJ. 2008 Apr;107(2):69-75.

33. Taccariello M1, Parikh A, Darby Y, Scadding G. Nasal douching as a valuable adjunct in the management of chronic rhinosinusitis. Rhinology. 1999 Mar; 37(1):29-32

34. Ramabhadraiah Anil Kumar, Borlingegowda Viswanatha, Nisha Krishna, Niveditha Jayanna, Disha Ramesh Shetty. Efficacy of Hypertonic Saline and Normal Saline in the Treatment of Chronic Sinusitis in International Journal of

Otolaryngology and Head & Neck Surgery, 2013, 2, 90-96

35. J H Kim, J Rimmer, N Mrad, S Ahmadzada, R J Harvey. Betadine has a ciliotoxic effect on ciliated human respiratory cells. The Journal of Laryngology & Otology / Volume 129 / Supplement S1 / January 2015, pp S45-S50

36. Rogers DM, Blouin GS, O'Leary JP. Povidone-iodine wound irrigation and wound sepsis. SurgGynecol Obstet. 1983 Nov; 157(5):426-30.

37. Reimer K1, Wichelhaus TA, Schäfer V, Rudolph P, Kramer A, Wutzler P, Ganzer D, Fleischer W. Antimicrobial effectiveness of povidone-iodine and consequences for new application areas. Dermatology. 2002; 204 Suppl 1:114-20.

38. Xiong M1, Fu X, Deng W, Lai H, Yang C.Tap water nasal irrigation in adults with seasonal allergic rhinitis: a randomized double-blind study. Eur Arch Otorhinolaryngol. 2014 Jun; 271(6):1549-52.

39. Sindelar WF, Mason GR.Irrigation of subcutaneous tissue with povidoneiodine solution for prevention of surgical wound infections. Surg Gynecol Obstet. 1979 Feb; 148(2):227-31.

40. Keiji Fujihara, Akihiro Sakai, Muneki Hotomi, Noboru Yamanaka, The Effectiveness of Nasal Nebulizer Therapy with Cefmenoxime Hydrochloride Nasal Drops of Povidone Iodine for Acute Rhinosinusitis in Children. Practica Oto-Rhino-Laryngologica, Vol. 97 (2004) No. 7 P 599-604.

41. Anderson MJ, David ML, Scholz M, Bull SJ, Morse D, Hulse-Stevens M, Peterson ML. 2015. Efficacy of skin and nasal povidone-iodine preparation against mupirocin-resistant methicillin-resistant Staphylococcus aureus and S. aureus within the anterior nares. Antimicrob Agents Chemother 59:27652773.

42. Mazumdar A, Das S, Saha R, Ramachandran VG, Gupta N, Sharma S, Dar S. Correlation of Nucleic Acid Amplification Based Detection and Conventional Methods of Identification of Aspergillus Flavus Species in Chronic Rhinosinusitis. RRJMB. 2013 Jul-Sep; 2(3): 61-66.

43. Shivakumar T, Sambandan AP. Retrospective Analysis of the Effectiveness of Functional Endoscopic Sinus Surgery in the Treatment of Adult Chronic Rhinisinusitis Refractory to Medical Treatment. Indian J Otolaryngol Head Neck Surg. 2011 October; 63(4): 321–324.

44. Ural A1, Oktemer TK, Kizil Y, Ileri F, Uslu S.Impact of isotonic and hypertonic saline solutions on mucociliary activity in various nasal pathologies: clinical study. J Laryngol Otol. 2009 May; 123(5):517-21

ANNEXURE – I– INFORMED CONSENT FORM

A RANDOMISED COMPARITIVE STUDY OF 3% HYPERTONIC SALINE VERSUS 0.5% DILUTED BETADINE NASAL IRRIGATION IN THE POST OPERATIVE CASES OF FUNCTIONAL ENDOSCOPIC SINUS SURGERY

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective:

1. To compare 3% hypertonic saline and 0.5% povidine iodine nasal douching in post operative cases of chronic rhinosinusitis.
2. To see the tolerability and effectiveness of 0.5% betadine solution in post operative cases of sinus surgery .
3. To assess the impact of 3% hypertonic saline and 0.5% betadine solution nasal irrigation on the "QUALITY OF LIFE " using sinonasal outcome (SNOT 22) questionnaire .

Introduction:

Explanation of procedure:

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **"A RANDOMISED COMPARATIVE STUDY OF 3% HYPERTONIC SALINE VERSUS 0.5% DILUTED BETADINE NASAL IRRIGATION IN THE POST OPERATIVE CASES OF FUNTIONAL ENDOSCOPIC SINUS SURGERY".** My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE – II – PROFORMA

"A RANDOMISED COMPARATIVE STUDY OF 3% HYPERTONIC SALINE VERSUS 0.5% DILUTED BETADINE NASAL IRRIGATION IN THE POST OPERATIVE CASES OF FUNTIONAL ENDOSCOPIC SINUS SURGERY"

Date: I.P. No:

Name: Occupation:

Age: Phone No:

Sex:

Address:

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. **EAR EXAMINATION:**

	Right	Left
Pinna		
Pre auricular area		
Post auricular area		
Tragal Tenderness		
Mastoid Tenderness		
External auditory canal		
Tympanic membrane		

TUNING FORK TESTS:

Rinne's test: 256 Hz

512 Hz

1024 Hz

Weber's test:

Absolute Bone Conduction test

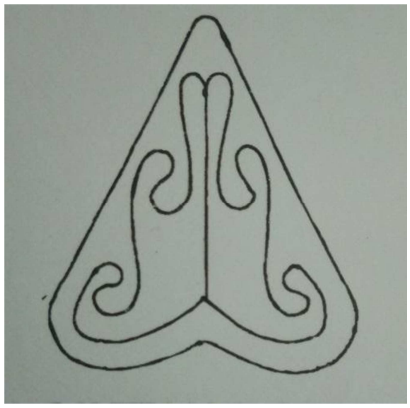
2. NOSE EXAMINATION:

External appearance

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

Cold spatula test

Anterior Rhinoscopy



Posterior Rhinoscopy

Paranasal Sinus Examination

	Right	Left
Frontal Sinus		
Ethmoidal Sinuses		
Maxillary Sinus		

3. THROAT EXAMINATION:

Oral cavity:

- Lips
- Labial and buccal mucosa
- Gingivolabial and gingivobuccal sulci
- Gingiva
- Teeth
- Hard palate

- Floor of mouth
- Anterior 2/3rd of tongue
- Retromolar trigone

Oropharynx:

- Soft palate
- Uvula
- Anterior pillar
- Tonsills
- Posterior pillar
- Posterior and lateral pharyngeal wall

Indirect Laryngoscopy

4. **NECK EXAMINATION:**

5. **CT PARANASAL SINUSES:**

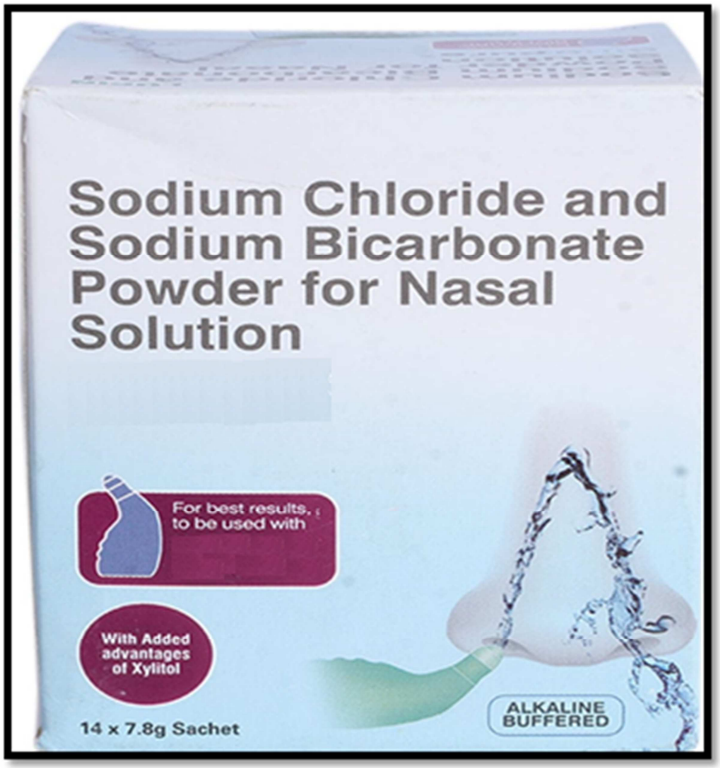
6. **DIAGNOSIS-**

ANNEXURE – III – PHOTOGRAPHS

Photographs 1 : 10% Povidine Iodine

Photographs 2: Preparation of Povidone iodine nasal douche

Photographs 3: 0.5% Diluted Betadine Solution



Photographs 4: Commercially available hypertonic nasal saline douche

ANNEXURE – IV – MATSRECHART

S No.	AGE	SEX	IP NOI.	DIAGNOSIS	BETADINE Vs 3% HYPERTONIC SALINE	SINONASAL OUTCOME SCORE 22		
						1 WEEK	1 MONTH	3 MONTH
1	37	M	1162093	CRSsNP	BETADINE	86	30	10
2	60	M	1155867	CRSwNP	BETADINE	80	30	9
3	48	M	1167169	CRSsNP	BETADINE	84	26	14
4	48	M	1161146	CRSwNP	BETADINE	86	26	15
5	62	F	1165116	CRSsNP	BETADINE	88	26	8
6	37	M	1165244	CRSsNP	BETADINE	84	30	8
7	48	F	1155811	CRSwNP	BETADINE	80	36	8
8	39	M	1160205	CRSsNP	BETADINE	78	36	9
9	20	M	1194883	CRSwNP	BETADINE	76	30	6
10	34	M	1170406	CRSwNP	BETADINE	60	30	20
11	28	M	1171634	CRSwNP	BETADINE	66	36	23
	27	M	1177920		BETADINE	64	32	18
13	47	M	1193673	CRSsNP	BETADINE	62	32	16
14	41	M	1171710	CRSsNP	BETADINE	66	32	8
15	47	F	1177227	CRSwNP	BETADINE	68	28	9
16	42	F	1180829	CRSsNP	BETADINE	84	28	9
17	65	M	1197064	CRSwNP	BETADINE	90	28	6
18	41	M	1188233	CRSwNP	BETADINE	94	24	10
19	31	F	1156675	CRSsNP	BETADINE	68	24	14
20	35	F	1186934	CRSwNP	BETADINE	78	24	16
21	39	M	1196706	CRSwNP	BETADINE	78	26	16
22	48	M	1193840	CRSwNP	BETADINE	84	32	8
23	30	M	1181691	CRSsNP	BETADINE	80	30	10
24	40	M	1205825	CRSsNP	BETADINE	86	32	10
25	21	M	1173776	CRSwNP	BETADINE	88	32	10
26	29	M	1178175	CRSwNP	BETADINE	84	32	15
27	46	M	1183328	CRSwNP	BETADINE	78	30	13
28	33	M	1162351	CRSsNP	BETADINE	80	26	8
29	19	M	1153595	CRSsNP	BETADINE	84	30	8
30	57	M	1159394	CRSsNP	BETADINE	88	30	16
31	19	M	1157517	CRSsNP	BETADINE	90	32	11
32	42	F	1155014	CRSwNP	BETADINE	94	32	17
33	22	F	1161944	CRSwNP	BETADINE	92	32	10
34	29	M	1204865	CRSwNP	BETADINE	90	28	10
35	25	F	1205850	CRSwNP	3% HS	94	26	10
36	44	M	1204291	CRSsNP	3% HS	94	24	14
37	36	F	1179522	CRSwNP	3% HS	80	32	16

38	18	M	1188603	CRSsNP	3% HS	80	32	8
39	33	M	1195437	CRSwNP	3% HS	86	32	8
40	23	F	1196989	CRSwNP	3% HS	88	28	8
41	20	M	1199406	CRSwNP	3% HS	90	36	8
42	22	M	1201693	CRSwNP	3% HS	94	28	10
43	41	M	1200864	CRSsNP	3% HS	98	40	13
44	48	F	1203323	CRSsNP	3% HS	96	42	12
45	61	M	1193819	CRSsNP	3% HS	98	32	14
46	33	F	1194963	CRSwNP	3% HS	88	32	15
47	27	M	1196810	CRSwNP	3% HS	98	28	16
48	18	F	1206161	CRSsNP	3% HS	80	26	11
49	50	F	1208945	CRSsNP	3% HS	78	28	10
50	55	F	10000776	CRSsNp	3% HS	86	32	11
51	54	M	10001692	CRSwNp	3% HS	88	34	8
52	55	M	1206578	CRSwNP	3% HS	88	32	8
53	49	M	10005807	CRSwNP	3% HS	78	34	13
54	32	M	1192613	CRSsNP	3% HS	90	36	14
55	65	F	1204561	CRSwNP	3% HS	66	38	12
56	20	M	1194883	CRSwNP	3% HS	68	38	12
57	60	M	10004357	CRSwNP	3% HS	90	32	18
58	30	M	10001926	CRSsNP	3% HS	84	34	12
59	21	M	10001179	CRSwNP	3% HS	76	36	10
60	28	F	10000100	CRSsNP	3% HS	76	40	8
61	40	F	1208945	CRSwNP	3% HS	76	36	8
62	18	M	10005982	CRSwNP	3% HS	80	32	8
63	47	M	10007042	CRSnNP	3% HS	80	32	8
64	41	M	10007612	CRSwNP	3% HS	80	30	10
65	26	M	10008915	CRSwNP	3% HS	66	28	10
66	64	F	10008846	CRSsNP	3% HS	60	36	12
67	58	M	10010475	CRSwNP	3% HS	88	28	12
68	32	F	10012250	CRSwNP	3% HS	78	40	12