DISSERTATION ON

"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR"

Dissertation submitted in partial fulfillment of the regulations for the award of the degree of

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BONAFIDE CERTIFICATE

This is to certify that, Dr.Amalu Thomas, postgraduate student (2019 - 2022) in the Upgraded Institute of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai, has done this dissertation titled **"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR**" under direct guidance and supervision in partial fulfillment of the regulations laid down by the Tamil Nadu Dr. MGR Medical University, Chennai for M.S. Branch–IV Otorhinolaryngology Degree Examination.

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DECLARATION

I, Dr.Amalu Thomas, solemnly declare that the dissertation titled **"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR**" is a bonafide work done by me at, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai under the guidance and supervision of **Prof.Dr.M.N.SHANKAR, MS., DLO.,** Professor of Department of Otorhinolaryngology, Madras Medical College. This dissertation is submitted to the Tamil Nadu Dr.MGR Medical University towards the partial fulfilment of the requirements for the M.S. Branch – IV, Otorhinolaryngology degree examination.

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CERTIFICATE – II

This is to certify that this dissertation work titled **"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR**" of the candidate **Dr.Amalu Thomas** with registration number 221914005 for the award of M.S.Degree in the branch of Otorhinolaryngology. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from the introduction to conclusion pages and result shows 1% percentage of plagiarism in the dissertation.

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LIST OF ABBREVIATIONS

- **CSF-CEREBROSPINAL FLUID**
- **ICP-INTRACRANIAL PRESSURE**
- **CT-COMPUTED TOMOGRAPHY**
- **NSF-NASOSEPTAL FLAP**
- **ELD- EXTERNAL LUMBAR DRAIN**
- **ITF-INFERIOR TURBINATE FLAP**
- **MTF-MIDDLE TURBINATE FLAP**
- **FE- FOVEA ETHMOIDALIS**
- **CP-CRIBRIFORM PLATE**
- **LL-LATERAL LAMELLA**
- **FS-FRONTAL SINUS**
- **TFL-TENSOR FASCIA LATA**
- **MT-MIDDLE TURBINATE**
- **MEC-MENINGOENCEPHALOCELE**

TABLE OF CONTENTS

INTRODUCTION

Cerebrospinal fluid (CSF) rhinorrhea occurs from breakdown of physiological barriers that separate subarachnoid space from nasal cavity. It results in direct communication between subarachnoid space and nasal cavity. It paves the way for spread of bacterial pathogens leading to significant morbidity (ascending meningitis). It may result from traumatic, iatrogenic, neoplastic, congenital, inflammatory causes. The diagnosis and localization may be problematic, but newer strategies has helped in making diagnosis easier.

The main principle of skull base reconstruction is to create a watertight seal, thus separating cranium and sinonasal cavity thus reconstructing the barrier for infections. Elimination of dead space, preservation of ocular and neurological functions and promote wound healing are main aims of leak repair. Surgical management is indicated when medical management fails. CSF rhinorrhea was traditionally treated with open surgical approaches, invention of endoscopes have brought a revolutionary change in its management. Walter Dandy first described successful intracranial repair through bifrontal craniotomy in 1926. Wigand later described transnasal endoscopic repair using fibrin glue to seal skull base defect.

Endoscopic approach allows for a better field of vision and magnification with enhanced illumination and angled visualization for the exact localization of leak. It also enables to precisely clean the mucosa from the bony defect

without significantly increasing the size of the defect, and to accurately position the graft material over the defect [3]. Smaller skull base defects less than 1cm, multi-layered grafts may be used. Larger defects more than 3cm requires closure with local or regional vascularised flaps, the postoperative leak rate was reduced to less than 4% [1].

Hadad-Bassagasteguy flaps has emerged as a major workforce in the skull base reconstruction especially after endoscopic expanded endonasal approaches. Various types of grafts and flaps used are temporalis fascia, fascia lata, septal, tragal cartilage, inferior, middle turbinate flaps, posterior nasoseptal flap, palatal flap, pericranial flap; and less frequently used include pedicled facial buccinator flap, occipito galeopericranial flap. In this study different types of free grafts and pedicled flaps, various types of grafting techniques used in endoscopic CSF leak repair will be assessed along with their efficacy and success rates.

REVIEW OF LITERATURE

Roman physician of antiquity Galen first described cerebrospinal fluid (CSF) rhinorrhea in 200 AD. He described it as CSF leak into the nose through pituitary and ethmoid regions. Willis in 1682, gave the first recorded description of CSF rhinorrhea. Charles Miller in 1862 confirmed it by autopsy. In 1899, St. Clair Thompson introduced the term 'rhinorrhoea' and the first series of patients with spontaneous CSF leaks. Also gave the differentiation between cerebrospinal rhinorrhoea and nasal rhinorrhoea. **Dandy** in 1926 reported the first CSF repair by bifrontal craniotomy using fascia lata graft. It provided direct access to repair, but recurrence rates were high (27%), in one study series only 60% of leaks were only successfully repaired.

In 1948, Gusta Dohlman used standard nasoorbital incision for external ethmoidectomy and was the first to describe the extracranial approach of leak repair. Vrabec and Hallberg described cribriform defect repair via endonasal route in 1964. Wigand and Stankiewicz closed endoscopically the minor CSF leaks that occurred during endoscopic sinus surgery (ethmoidectomy). In 1989 Papay et al. [4] , introduced rigid transnasal endoscopy for endonasal CSF leak repair.

Combination of intrathecal fluorescein and nasal endoscopes was introduced by Messerklinger, Reck and Wissen-Siegert, to diagnose anterior cranial fossa CSF leak. Fluorescein dye was first introduced in the field of ophthalmology in 1882 for diagnostic purposes. In 1960, Kirchner and Proud

demonstrated the use of intrathecal fluorescein which helped to localise the site of CSF fistulae which has gained popularity now

Cairns, a British neurosurgeon in 1937, first classified CSF leak into acute traumatic, postoperative, delayed traumatic and spontaneous. Ommaya; then Vrabec and Hallberg later modified this classification. In 1990, Mattox and Kennedy [5] presented a case series of CSF rhinorrhea which was addressed under endoscopic visualization.

Wigand et al. were the first to study the use of free grafts in endoscopic CSF leak repair. In 1952, **Oscar Hirsch** described the vascularised rotational flap, pedicle nasoseptal flap for endoscopic closure of CSF leak. In 2006 it was later reintroduced as Hadad Bassagasteguy flap for large skull base repairs.

Zeitouni et al. [35] in 1994, prefered free grafts in endoscopic CSF repair due to less interference with the nasal function. **Lanza et al.** [30] in 1996, analysed factors that are related to surgical outcome of the patient with CSF leaks. These are etiological factors, defect location, number of previous repair attempts, type of graft (s) used, lumbar drain placement and duration of CSF leakage prior to repair.

Wormald and McDonogh[32] in 1997 described an innovative technique for repairing CSF leaks called Bath-plug technique. Lumbar drain was inserted for all patients and intrathecal fluorescin was used for five patients to detect location of the leak. No intraop or postop complications were found.

Gassner et al. (1999) [26] studied in 95 patients and various methods were adopted like transeptal approach, transfacial, transcranial and endoscopic approach (8.6%). Among the different approaches endoscopic approach had the lowest recurrence rate. Local osteo-mucoperiosteal or chondro-mucoperichondrial flaps had more recurrence rates (22.2%) than free grafts (15.6%).

Zweig et al. [29] (2000) conducted a study series on 48 patients with 53 CSF fistulas, various graft materials were used for repair of skull base defects. Most surgeons chose to use free grafts (83%) like turbinate bone or mucosa abdominal fat and mucoperichondrium. Pedicled flap most commonly used were based on septum. Overlay technique was adopted in 46% of cases, for others underlay and obliteration techniques. Successful repair was achieved in 95% of cases. It was concluded that location and size of defect, method of closure or type of graft material do not influence the surgical outcome.

Hegazy et al.[33] in 2000, conducted a meta-analysis found no significant statistical difference between various grafting techniques and methods. They found a success rate of 90% after first attempt at repair. **Carrau et al.** (2002) [27] in their study developed a protocol to reduce the risk of recurrence in those with suspecting high pressure leaks; this included endoscopic repair, temporary CSF diversion methods, measurement of CSF pressure after the repair, ventriculoperitoneal shunting immediately if necessary. 25 cases of CSF leaks were selected out of them six cases (31%) were suspected to have high pressure hydrocephalus. Endoscopic repair done

for all of them, postoperatively ventriculoperitoneal shunt was placed for the six patients. No recurrence was noted in follow up period of 24-84 months.

Woodworth et al. [31] in 2008 conducted a retrospective study on 56 patients who underwent endoscopic repair.82% of them were obese; 96% had associated encephaloceles. 95% of the cases were successfully repaired endoscopically. Bone grafts derived from septum, mastoid or turbinate bone were used as underlay. Patients were treated with acetazolamide and lumbar drain was kept for cases with severe intracranial hypertension. Hence success rates depends on lowering underlying intracranial hypertension in cases of spontaneous leaks.

Horiguchi et al. (2010) [25] conducted study on 32 cases of large dural defects. 11 patients underwent repair with free grafts and 21 underwent repair with pedicled flaps. 27.3% cases presented with recurrence in non flap group and 9.5% in the flap group. Rate of insertion of ELD was 81.8% in the non-flap group and 4.8% in the flap group.

Virk JS et al. [24] (2013) conducted study on 54 patients in which 36 were spontaneous and 18 were traumatic CSF leaks. Most of the cases with spontaneous leaks were middle aged females with higher BMI thus re-establishing the association with benign intracranial hypertension. Success rates among first and second time surgery was found to be 93% and 100% respectively. In large skull base defects use of vascularised tissue grafts was found to have lower success.

Saafan et al. [17] in 2013 conducted a study on 40 cases of CSF rhinorrhea of which 22 cases were spontaneous, 12 following head injury and 6 cases following endoscopic sinus surgery. Defect size ranged from 3-17mm. Lateral lamella of cribriform was found to be the commonest site of leak. Endoscopic endonasal sandwiching technique was done using fascia lata. 95% (38) of cases had successful repair and 2 cases required second surgery in the follow up period of 12-24 months.

Mohindra et al. [34] (2015) reported a novel minimally invasive endoscopic technique in the obliteration of persistent craniopharyngeal canal; its attachment is first resected from inter-sphenoid floor and then from sphenoid walls and defect was obliterated with triple layer reconstruction with muscle, fat and fascia.

In a study conducted by **Natalie et al.** (2019) [23], locations of skull base defects were found as cribriform plate (44%), ethmoid (32%), lateral sphenoid (12%), and planum sphenoidale (12%). 92% of the leak sites were primarily repaired successfully. There were no postoperative neurological complications or cases of meningitis reported. In their study endoscopic repair of spontaneous CSF leaks with composite autograft of fascia and nasoseptal flap demonstrated high success rates.

In a comparative study done by **Chavan et al**. [36] (2021), done on 127 patients; success rate with free nasoseptal flap with septal cartilage was 97.3% when compared to fascia lata with fat which was 96.3%.

ANATOMY OF NOSE, PARANASAL SINUSES AND SKULL BASE

EMBRYOLOGY

Facial development takes place between 4th and 8th weeks of intrauterine life. It develops from five facial swellings that surround stomatodeum around the end of 4th week. In 5th week ectodermal thickenings develop on the frontonasal process called nasal placodes. The centre of which invaginates to form nasal pit, edges get raised to form lateral and median nasal process. Maxillary process present on either side, around 6-7 weeks grows medially and they fuse with the lateral nasal process and then with the median nasal process. This separates nasal pits from stomatodeum. Intermaxillary process grows backwards and forms the nasal septum. Lateral nasal process forms the ala and lateral nasal wall.

MAXILLARY SINUS: is the first to appear by 7th -10th week of gestation. They appear as a shallow groove expanding from primitive ethmoidal infundibulum into the mass of maxilla. Rapid growth occurs until age of seven and then gradual enlargement and completes development by 17-18yrs.

ETHMOID SINUS: develops in 9th -10th week of gestation. Develops by enchondral ossification. It develops from a cartilaginous olfactory capsule or paleosinus, other sinuses will develop from ethmoid into membranous bone via epithelial diverticula extrusions [9]. Series of folds called ethmoturbinals which are separated by grooves over lateral wall of nasal capsule. Around six to seven

folds are present initially, but only three to four persists by regression and fusion.

- First ethmoturbinal: rudimentary and incomplete in humans. Its ascending portion becomes agger nasi and descending portion forms uncinate process
- Second ethmoturbinal: forms middle turbinate
- Third ethmoturbinal: forms superior turbinate
- Fourth and fifth ethmoturbinals: fuse and form superior turbinate.

SPHENOID SINUS: develops by 12th week of gestation by evagination from sphenoethmoidal recess. At birth its small and gradual enlargement occurs starting at age of three during pneumatisation of sphenoid bone. Three types of pneumatisation patterns for sphenoid are noted 1) sellar (90%) 2) pre-sellar (9%) 3) conchal (1%).

In sellar type pneumatisation occurs posterior to sella turcica. Presellar type, pneumatisation upto anterior sella and conchal type has a shallow bowl with minimal pneumatisation. If pneumatisation occurs laterally to pterygoid root, it leads to formation of lateral sphenoid recess, resulting in exposure of neurovascular structures around sphenoid.

FRONTAL SINUS: development begins during 16th week. It originates from anterior ethmoidal complex. At birth they appear as a blind pocket. They are seen radiologically by 8yrs of age. Pneumatisation continues until 18yrs of age.

OSTEOLOGY

ETHMOID BONE:

Term derived from a Greek word which means “sieve”. It is a small bone with a cuboidal structure, it is relatively light and has a spongy texture. It forms the middle area of neurocranium. It forms part of medial wall of orbits, part of nasal septum, part of roof of orbit, lateral walls of nasal cavity, also the floor of anterior cranial fossa. It is a highly fragile bone. It is divided into 3 parts:

1. Cribriform plate
2. Perpendicular plate
3. Pair of labyrinth

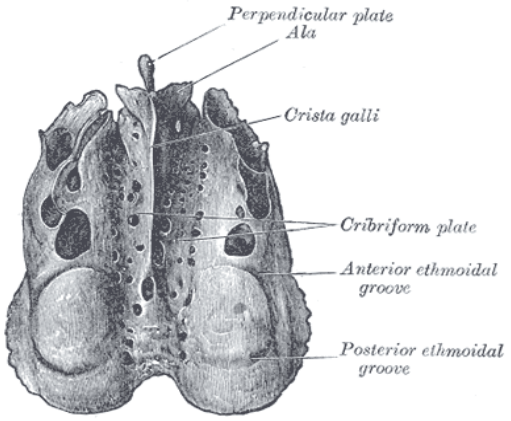


Fig 1: Ethmoid bone

→ CRIBRIFORM PLATE:

It is a horizontal perforated bony lamina, containing foramina for olfactory rootlets. It fills the notch between two orbital plates of the frontal bone. It also separates nasal cavity from anterior cranial fossa. On its upper aspect there is a projection called crista galli, it is occasionally pneumatised. It resembles the crest on head of Gallus domesticus. It gives attachment to falx cerebri. Ethmoid articulates with 13 bones: frontal, sphenoid, nasal bone, maxilla, lacrimal bone, palatine, inferior nasal concha and vomer. Cribriform plate has a lateral and

medial lamella. The oblique or vertical lateral lamella articulates with frontal bone and skull base is thinnest in this region of articulation called ethmoid fovea. Lateral lamella of cribriform plate is the thinnest (0.05-0.2mm) and vulnerable bone of anterior skull base it is the most common site for traumatic injuries. Pulsations of anterior ethmoidal artery can also lead to thinning of the part of bone where it emerges.

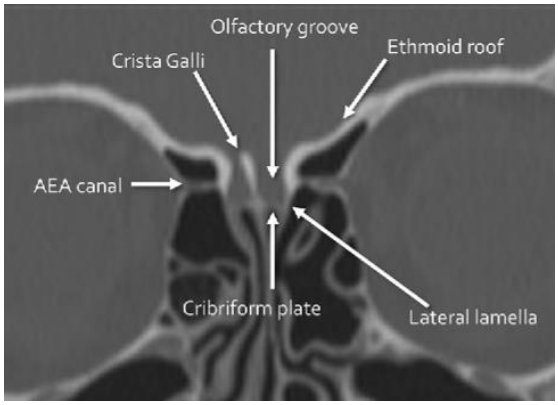


Fig 2: CT showing lateral lamella and cribriform plate

Keros has classified olfactory fossa depth based on the length of lateral lamella

- Type I: 1-3mm
- Type II: 4-7mm
- Type III: 8-17mm

Another classification is Gera classification based on angle formed between the lateral lamina of cribriform plate and lateral extension of a horizontal plane passing through the cribriform plate: Class I >80 degrees, low risk; class II 45-80 degrees, medium risk; class III less than 45 degrees [43].

PERPENDICULAR PLATE:

Quadrilateral plate arising from inferior aspect of cribriform plate. Forms the superior part of septum

LABYRINTH:

Otherwise called as lateral masses are composed of cuboidal boxes of air filled cells. Lateral part forms medial wall of orbit, medial surface forms lateral part of nasal cavity. Two shelf like projections arise from medial surface they form the superior and inferior conchae. It is internally divided to anterior and posterior parts by basal lamella, which is a part of middle turbinate. The largest and constant anterior ethmoidal air cell is bulla ethmoidalis.

Middle turbinate has three parts based on the attachments and orientation: anterior one third is in the sagittal plane it is attached to cribriform plate; middle one third lies in coronal plane and attached to lamina papyracea, it forms the basal or ground lamella; posterior one third lies in the horizontal plane attached to lamina papyracea and perpendicular plate of palatine bone.

Ethmoidal infundibulum is a cleft like three dimensional space on the lateral nasal wall of nose. Medial wall is formed by entire extent of uncinated process and its mucosal covering and lateral wall by lamina papyracea of orbit and frontal process of maxilla and by lacrimal bone anterosuperiorly. Anterior border of uncinated process fuses with these bones at sharp angle inferiorly and provides a bony communication with inferior turbinate.

FRONTAL BONE:

Frontal bone arises from neural crest cells. It undergoes membranous ossification. Two primary center arises, one for each half in the region of frontal tuberosity. At birth, frontal bone is made up of two halves separated by a median frontal suture. Frontal bone primordium develops at the supraciliary ridge region and later expands to top of the head. The union begins at second year and completes by eighth year. Parts of frontal sinus are squamous part, nasal part, two orbital plates, and two zygomatic process. Anterior wall of frontal sinus begins at nasofrontal suture line and ends below frontal bone protuberance. The posterior wall forms anteroinferior boundary of anterior cranial fossa in close contact with frontal lobes.

Anatomy of frontal sinus outflow tract depends on pneumatisation in that area. Frontal infundibulum, frontal ostium and frontal recess forms an hour glass configuration. Frontal sinus lies anterior to frontal recess endoscopically. Relations of frontal recess are anteriorly by agger nasi, posteriorly by bulla ethmoidalis, laterally by lamina papyracea, medial by middle turbinate. Roof is formed by fovea ethmoidalis. Upper end of uncinate process lies within frontal recess.

In 80% cases uncinate process gets attached to the lamina papyracea, recess enclosed within the dome is called recessus terminalis. Anterior wall of frontal recess is formed by a thick bone of frontal process of maxilla called frontal “beak”, size of which varies according to the pneumatisation of agger nasi.

Common cause of failure of endoscopic sinus surgery is the inadequate removal of cells obstructing frontal outflow tract.

- **SPHENOID BONE**:

Embryologic origin of sphenoid bone is complicated it develops from joining of two different primordia whose embryological origins are different. Cephalic mesoderm forms basi-post-sphenoid and orbitosphenoid, whereas basi-pre-sphenoid and alisphenoid have neural crest cell origin. First ossification centers appear by eighth week of fetal life.

Central portion is the body of sphenoid, which contains sphenoid sinuses. Anteriorly in the midline is a strong triangular process called rostrum; it articulates with vomer. Extending laterally are the greater and lesser wings. Retort shaped superior orbital fissure lies in between the wings. Lesser wing is attached to the body by two roots forming optic canal, transmits optic nerve and ophthalmic artery. Pterygoid process projects from the junction of greater wing and body of sphenoid, anterior surface forms posterior boundary of pterygopalatine fossa. Foramina lies in relation to pterygoid process are vidian canal inferomedially and foramen rotundum superolaterally.

Sphenoid sinuses are asymmetrical with right or left “sphenoid dominance”. Onodi cell is a posterior ethmoidal cell it is pneumatised superior and posterior to rostrum of sphenoid sinus. Configuration of intersphenoid septum is variable; in some cases septum is absent, some is centrally located others get inserted laterally to carotid canal. Hence care must be taken while

removing intersphenoid septum. 10 percent of CSF leaks are reported to be from sphenoid out of which 7% are spontaneous[11]. During sphenoid ossification which progresses from anterior to posterior, a small canal is formed that connects middle cranial fossa with nasopharynx. This was first described by Cruveilhier and later by Sternberg known as **Sternberg canal** or **lateral craniopharyngeal canal**. It is considered to be a potential source of leak from middle cranial fossa.

PHYSIOLOGY OF CEREBROSPINAL FLUID

Cerebrospinal fluid is an ultra-filtrate of plasma. It is circulated in intracranial and spinal compartments. It is clear and colourless fluid. It occupies ventricle, cisterns and the subarachnoid space of brain and spinal cord. Cushing in 1925, described CSF as "third circulation" and as a "nourishing liquor" (Stern and Gautier). The main function is to provide buoyancy to the brain tissue. Other functions include providing nourishment and removal of substances like neurotransmitters, metabolic by products [1]. CSF presents many exogenous products to choroid plexus thus cleaning extracellular surface of brain.

Secretion of CSF:

Produced by choroid plexus, is a cauliflower like growth of blood vessels, covered by a thin layer of epithelium. Secretion of CSF from choroid plexus into ventricles is dependent on active transport of sodium ions. Sodium ions pulls large amount of chloride due to its positive charge. There is simultaneous

efflux of potassium and bicarbonate. Diffusion of proteins by active or passive transport and active transport of glucose also occurs[3].Total volume of CSF is around 140mL, with around 20 mL in the ventricles , 50mL in the intracranial subarachnoid space and 70mL in paraspinal subarachnoid space[4]. CSF is produced at the rate of **0.2-0.7mL per minute or 500-700 mL per day**; being replaced in every 6-8 hours. Composition and pressure of CSF is maintained constant by various mechanisms.

Characteristics of normal spinal fluid are:

- Total volume -140 mL
- Colour: colourless, clear
- Opening pressure: 10-15cm H_2O (with patient lying in lateral position) in adults and ~4cm H2O in infants
- Osmolarity at 37^0C: 281mOsm/L
- Specific gravity: 1.006-1.008
- Acid –base balance: pH- 7.28-7.32
- Sodium: 135-150mmol/L
- Potassium: 2.7-3.9 mmol/L
- Chloride: 116-127 mmol/L
- Lactate dehydrogenase: Approx. 10% of serum value.
- Glucose: 45-80 mg/ld. (2/3rd of blood glucose value)
- Proteins: 20-40mg/dL
- Erythrocyte count: 0-10/mm^3
- Leucocyte count: 0-10/mm^3

- Culture: negative

80% of CSF is secreted by choroid plexus into ventricular cavity. Rest 20% contributed by ependyma and brain parenchyma. CSF produced from lateral ventricle flows to the third ventricle through interventricular foramen of Munro. Third and fourth ventricle are connected by aqueduct of Sylvius (cerebral aqueduct).CSF then flows into subarachnoid space through foramen of Lushka (into subarachnoid space around cerebral hemispheres and cerebellum) and foramen of Magendie (into spinal canal). CSF pressure fluctuates with respiration, arterial pulsations and with changes in head position. CSF secretion occurs in a steady state, hence it's the CSF absorption that plays a major role in maintaining CSF pressure. Any process that hinders CSF resorption increases the pressure.

CLASSIFICATION FOR CSF RHINORRHEA:

Proposed by **Ommaya et al**:

TRAUMATIC

- Accidental → Acute
- Iatrogenic → Delayed

NON-TRAUMATIC

- **High pressure leaks**

❖ Tumors : →Direct

→ Indirect

- Hydrocephalus →Obstructive

  →Communicating

  - **Normal pressure leaks**
- Congenital abnormalities
- Focal atrophy

  →Olfactory

  →Intrasellar
- Osteomyelitic erosion

CAUSES FOR CSF RHINORRHEA

- **SPONTANEOUS:**

Occurs in patients with no antecedent causes. They constitute around 3-4% of the cases. Elevated intracranial pressure is found to be the cause (idiopathic intracranial hypertension). It manifests in the form of benign intracranial hypertension otherwise called pseudotumor cerebri. This concept was first introduced by Dandy 1937.Clinical features include vision disturbances, pulsatile tinnitus, balance problems, headache. Commonly seen among obese middle aged women. **Modified Dandy's criteria** is related to benign intracranial hypertension:

1) Symptoms and signs of raised intracranial hypertension (headache, nausea, vomiting or papilledema)

2) No localizing signs in the neurological examination (except abducens nerve palsy)

3) Normal neuroimaging (except empty sella- "**delta sign**")

4) Opening pressure of lumbar puncture greater than 250mm H_2O

5) Alert and awake patient

6) No other causes of raised intracranial pressure

Various theories postulated regarding relationship of obesity and elevated ICP.

- Excess weight in the central compartment of the body leads to **high intra-abdominal pressure** which raises the ICP by reducing cerebral venous return to the heart. This obstructs venous outflow and increase in cerebral blood volume and increasing ICP by preventing normal CSF absorption.
- Higher propensity for **sleep apnea** in obese patients, causing altered respiratory mechanics due to hypoxemia that triggers cerebral vasodilation and increases cerebral blood volume
- Obesity causes **neuroendocrine disturbances** due to extraovarian production of estrone in adipose tissue. Androstenedione conversion to estrone increases as weight exceeds 50% of original weight. This relative hypoadrenalism leads to alteration in drainage channels and vacuolar transport across arachnoid villi and increase resistance to CSF flow.

Radiological features of BIH include total or partial empty sella syndrome (due to dural herniation into sellar diaphragm), others are encephaloceles, arachnoid pits, abnormalities of optic nerve sheath complex, dilated Meckel's cave and dural ectasia. **Ommaya's theory** proposes that tumors can cause CSF fistula in two ways one is by direct erosion of meninges or bone and another is indirectly by the pressure erosion of anatomically fragile areas (dura of sellar diaphragm, perforations in cribriform plate, adjacent to natural foramina of skull base). Most common area for spontaneous leaks and encephaloceles is in the lateral recess of sphenoid sinus and next along cribriform plate. Spontaneous leaks occur in well-pneumatised sphenoid sinuses where sinus pneumatises into the sphenoid wing under maxillary nerve. This brings sphenoid sinus in close contact with temporal lobe region with a thin bone in between them.

- **TRAUMATIC**

They constitute around 96% of cases. Can occur from blunt or penetrating trauma. It can result from anterior skull base fractures. In fractures of middle and posterior fossa; if fractures extend from petrous bone to middle ear it can lead to CSF otorrhea if tympanic membrane is torn. And otorhinorrhea can also occur while tracking along Eustachian tube. It can present immediately as leak (within 48 hours) or years later as meningitis, encephalocele, delayed leak. Causes of delayed post traumatic leak are 1) delayed increase in intracranial pressure, 2) lysing of clot that plugged the defect 3) soft tissue edema resolution 3)maturation and contraction of wound edges 4)loss of vascularity

causing necrosis of soft tissue and bone around the wound 5)herniation of dura matter via fracture line resulting in collection of CSF.

Iatrogenic causes include functional endoscopic sinus surgery, transphenoidal surgeries and neurological procedures. Areas of skull base vulnerable for leak include lateral lamella, fovea ethmoidalis and posterior wall of frontal sinus, they are less than 1mm thick. An expansile tumor or mucocele can cause dehiscence that makes it more susceptible to iatrogenic leak during instrumentation. Initial management is conservative as most of the leaks usually cease by 10 days post injury. But if they persist more than 10 days it should be closed. Common cause of continued CSF leak is rotation of a bony spicule that holds the edges of torn dura apart.

- **CONGENITAL**

Congenital encephaloceles are divided into sincipital (also anterior or frontoethmoidal) and basal encephaloceles. Basal type are intranasal in location and have been divided into transethmoidal, sphenoethmoidal, spheno-maxillary, spheno-orbital, trans-sphenoidal, transtemporal encephaloceles. Trans-sphenoidal encephaloceles are the only congenital type found in the sphenoid sinus. Transethmoidal encephaloceles commonly originate at foramen caecum and a variable posterior extension into cribriform or ethmoid roof.

Meningoceles can be spontaneous (acquired or congenital) or following trauma. Posttraumatic meningoceles have a funnel shaped defect in the skull base.

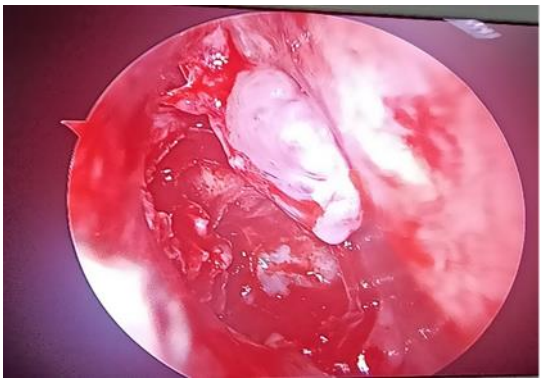


Fig3: Intraoperative finding of meningocele

- **NEOPLASMS**

Sinonasal and skull base tumors cause direct erosion of anterior or middle cranial fossa or can occur indirectly following therapeutic treatments. It is challenging to have water tight seal between sinonasal and intracranial cavities after tumor removal. Barrier is usually created using pericranial flap. But tears in the flap that occurs during elevation or devascularisation or due to inadequate coverage can result in leak postop.

ROUTES OF CSF RHINORRHEA

Fig 4: Leak from the cribriform plate

- From anterior cranial fossa
  - Frontal sinus
  - Roof of cribriform plate
  - Ethmoid sinus
  - Sphenoid sinus
- From middle cranial fossa
  - Sphenoid sinus
  - Mastoid air cells, Eustachian tube and middle ear

- ❖ From posterior fossa
  - Sphenoid sinus
  - Mastoid air cells , Eustachian tube and middle ear

CSF leak from mastoid air cell system reaches middle ear from where it is transported via Eustachian tube to the nasopharynx and reaches the nose as CSF rhinorrhea.

HISTORY AND EXAMINATION

Patient's history provides important clues about CSF rhinorrhea. History of clear, watery discharge usually unilateral, which could not be sniffed back and aggravated on straining or bending forward. Rhinorrhea has characteristic met allic or salty taste. Diagnosis is easy in those cases with history of recent onset of trauma or surgery. But if rhinorrhea occurs many years after the provoking incident diagnosis becomes difficult. .In these cases it can be misdiagnosed as vasomotor or allergic rhinitis History of typical postural variation is noted, like lowers his or her head like while tying the shoes. Drainage may be intermittent as the fluid accumulates in the paranasal sinuses and drains externally with changes in head position (reservoir sign). Paradoxical rhinorrhea occurs when midline structures that act as separate barriers (Eg. crista galli or vomer) are dislocated. This causes leak to occur from the opposite side.

Patient may have associated headache. In case of idiopathic non traumatic CSF rhinorrhea patients may have diffuse headache that improves when rhinorrhea occurs and worsens when it stops. These are associated with changes in ICP. Chronic headache may be also due to other causes increased ICP like benign intracranial hypertension or endoscopic sinus surgery. Rarely there may be an underlying neoplasm. Severe chronic headache can also occur due to low ICP caused by chronic depletion of CSF through a persistent leak. Here patient complaints of headache when sitting and relieved while lying down, the etiology is due to low ICP. Commonly seen with dural defects along the spine not along anterior cranial fossa. Raised intracranial pressure CSF leak patient can have visual disturbances along with headache.

If skull base defect involves the cribriform plate or olfactory area, then patients may complain of parosmia, hyposmia or anosmia. Optic nerve defects may suggest lesion in the region of tuberculum sellae, sphenoid sinus, or posterior ethmoid cells unexplained weight loss suggests neoplasm.

PHYSICAL EXAMINATION:

- Examiner must attempt to demonstrate unilateral rhinorrhea by asking patient to lean forward.
- **Reservoir sign:** Place patient in supine position for some time and bring to upright position with neck flexed. A sudden gush of clear fluid is characteristic of CSF leak.
- "**Halo sign/target sign/double ring sign**" is an important marker for traumatic CSF leak. Halo is considered when a clear ring surrounds a

central blood spot after the nasal discharge is dropped upon a handkerchief, filter paper or towel. Occurs due to a difference in the osmolarity of CSF and blood. But presence of tears or saliva gives a false positive halo sign.

- **Tea pot sign**: leakage seen on tilting head forward, suggestive of defect in sphenoid sinus or via Eustachian tube.

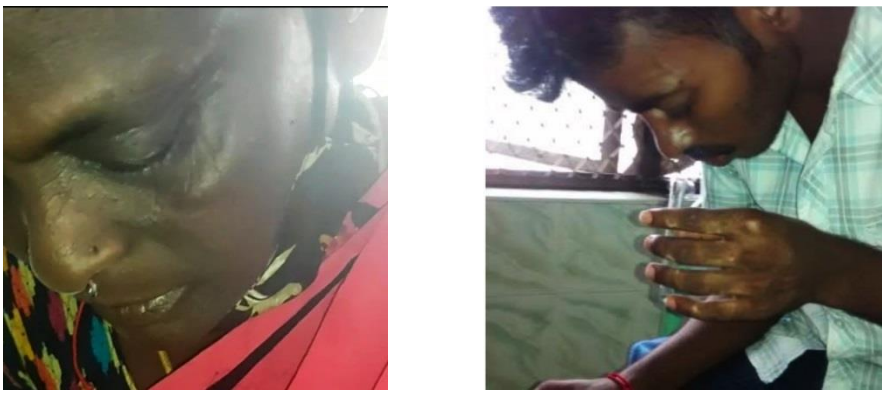


Fig.5,6 : Tea Pot Sign

- Anterior rhinoscopy is not specific. Occasionally glistening or moist nasal mucosa may be seen.
- Nasal endoscopy may show glistening, moist nasal mucosa that may be identified on the side of leak. A small meningocele may be visualized at the junction of nasal septum and cribriform plate. Endoscopy also helps to differentiate other conditions that mimics CSF leak.
- Ophthalmological examination reveals papilledema in case of raised ICT. Abducens palsy may also be developing in case of elevated ICP.
- Check for signs of meningitis neck rigidity, Kernig's sign(flex hip to 90 degrees and flex the knee now slowly extend the knee positive test if the

patient has back pain), Brudzinski's sign (lift head while supine; positive test if patient flexes the knees), straight leg raising test.

INVESTIGATIONS

Nasal endoscopy:

Used to detect leak site, by asking patient to do Valsava manoeuvre that causes a gush of CSF from the leak area. Leak can be from different sites (cribriform plate, middle meatus- leak is in anterior ethmoid; superior meatus- leak is in posterior ethmoids; sphenoethmoidal recess –leak is in sphenoid; eustachian tube orifice- leak is from middle ear).

Glucose concentration:

It is a rapid but highly unreliable test hence not recommended as a screening test. Concentration of more than 30mg/mL in the discharge is suggestive of CSF leak. Glucose concentration more than 5mg/dl will give positive reaction in this test. Here discharge is applied on to glucose oxidase impregnated test strips, colour change in the strips is suggestive of CSF rhinorrhea. Drawbacks of this tests are

1) Reducing substances in the lacrimal gland secretions and nasal mucus may cause false positive results.
2) Active meningitis can lower glucose level in CSF and may lead to false negative results.
3) It is not specific to site or side of leak

Chloride assay:

Chloride level in CSF is about 120mEg/L, it is higher than serum glucose

Beta trace protein:

Otherwise called prostaglandins D synthase, this protein is synthesized by arachnoid cells, oligodendrocytes, and choroids plexus within the CNS. Beta trace protein is also found in human testes, heart and serum. It is elevated with renal insufficiency, multiple sclerosis, myocardial infarction, cerebral infarcts and CNS tumors. If serum level is less than 1mg/L and nasal discharge has more than 2mg/L then is considered to be positive for CSF. It has a specificity of 100% and sensitivity of 92%. It is easy to perform but cannot detect site and side of leak and also if the leak is intermittent.

Beta 2 transferrin:

This protein is solely produced in the central nervous system. It is produced by neuraminidase activity. This is a noninvasive and rapidly detectable marker. Locations of beta transferrin are CSF, perilymph, and aqueous humor. Around 0.5mL is only needed for the electrophoresis. Specimen remains stable at room temperature for around four hours, if refrigerated it can last for 3 days but should not be frozen. Hence delay in transportation can degrade the sample. Report is available within 3 hours. Certain conditions cause abnormal transferrin metabolism and can appear in the blood leading to false positive results. These are chronic liver disease, inborn

errors of glycogen metabolism, genetic variant forms of transferrin, rectal carcinoma. Main limitation is its unavailability in many centers.

IMAGING TECHNIQUES

a) **COMPUTED TOMOGRAPHY**:

Coronal, sagittal and axial tomography helps to detect CSF leak and identify dehiscences in the skull base. CT scans are performed in axial plane with 1mm cuts and they are reformatted to sagittal and coronal planes. Three dimensional reconstruction helps to analyse the depth of defect in the anterior and middle cranial fossa. Pneumocephalus in CT suggests a dural tear. In some cases CT shows evidence of skull base defect but there may not active leak.

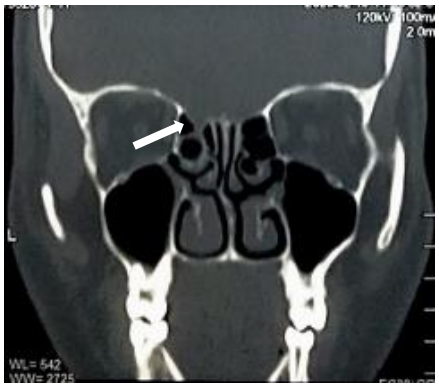


Fig 7: CT showing cribriform plate erosion

Fig 8: CT showing Cribriform plate and Lateral wall of sphenoid erosion

b) **CT CISTERNOGRAM** :

Helps to improve the diagnostic efficacy of computed tomography. It helps to diagnose CSF rhinorrhea and otorrhea by assessing defects in the skull base. Procedure starts by taking a precontrast CT with thin slices. About 3-10mL of iodinated non-ionic contrast (iohexol) is injected into the thecal sac after performing a lumbar puncture at the L3-L4 level. Previously used contrast is metrizamide but it is no longer used because of neurotoxicity. After contrast injection patient is made to lie in Trendelenburg position (foot end elevation) and CT scans are performed in thin slices. Manoeuvres that provoke active leaks are performed (like head hanging, sneezing) to demonstrate intermittent or occult leaks.

Post and precontrast CT are compared to check for leaking out of contrast. Around 80% of CSF leaks can be detected by CT cisternography.

Fig: 9 and 10 CT cisternogram showing defect in the cribriform plate.

c) **RADIONUCLIDE CISTERNOGRAPHY**:

It is another type of cisternogram using intrathecal injection of radioactive marker. Nasal cotton pledgets are placed near suspected sites of CSF leak like olfactory slit, middle meatus, sphenoethmoidal recess, Eustachian tube. Few radionucleide markers are radioactive iodine (I^{131}), radioactive iodinated serum albumin (RISA), technetium (99mTc) labelled albumin, diethylene-triamterene-penta-acetic acid (DTPA) and Indium (In^{111})-labelled DTPA. The radionuclide tracer will be injected by lumbar puncture. They will diffuse via spinal column and to intracranial ventricles and subarachnoid spaces. Diffusion monitoring is done with scintillation camera. Images are taken immediately, at 6hours, and at 24hours.follow up scans may be also taken after 48-72 hrs. Pledgets will be removed and imaged with gamma camera or counted using gamma counter. If tracer has leaked onto the pledgets it will be found in the gamma camera. Pledget counts should be determined per unit mass of dry pledget also a radionuclide ratio that compares tracer counts in the pledget against counts in a unit volume of peripheral blood. Elevated ratio is suggestive of CSF fistula. This technique requires active CSF flow for documentation. In the technique of overpressure radionuclide cisternography (ORNC), a constant infusion of tracer to increase intrathecal pressure is given to enhance flow and thus increasing sensitivity. Sensitivity is around 50-100% and 100% specificity[11]. Headache is common following these procedures which will settle in 3-5 days.

d) **MAGNETIC RESONANCE (MR) CISTERNOGRAPHY**:

It is a non-invasive technique for assessing the presence of intranasal or intrasinus leaks. Here T2 weighted imaging with fat suppression and video reversal is used to image CSF. It useful in case of encephalocoele to detect the contents and vascularity of the sac. It is very useful in case of active CSF leak. In case of spontaneous intracranial hypertension (SIH), brain MRI shows thickening and contrast enhancement in pachymeninges. Injection of 0.5mL gadopentetate dimeglumine diluted in 3-5mL of CSF is found to have high sensitivity and specificity for detection of active leaks. Advantages over CT are it provide multiplanar images and does not involve radiation exposure. But if the leak is very small or intermittent it may give false negative results, also its expensive, cause claustrophobia and not good in detecting bony defects. In routine set up MRI cisternography is reserved in cases where high resolution CT is nonspecific.

e) **INTRATHECAL FLOURESCEIN**:

It is another method in the detection of CSF leaks. It was introduced by Kirchner and Proud in 1960's and later popularized by Messerklinger. Separate consent has to be obtained as it is not an FDA approved drug. Fluorescein dye stains CSF bright yellowish green, and is visualised with nasal endoscopy. The recommended dilution of CSF is 0.1mL of 10% fluorescein (intravenous preparation) in 10mL of patients own CSF and its infused slowly over 30 minutes. After introducing to the intrathecal space by lumbar puncture, patient is made to lie in the head down position and nasal endoscopy is performed with

zero degree and angled scopes. Even minute quantities of fluorescein can be identified due to its peculiar colour. Specific blue filters are used for enhanced detection of fluorescein. Hence flourescein is commonly administered intraoperatively, thus helping in localising defects and to get a watertight closure. The injected fluorescein will be later diluted and excreted based on CSF turnover rates. Few complications of fluorescein are knee and ankle clonus, seizures especially following rapid injection. Sensitivity of detection varies between 57.7% and 85.6% and the specificity is 100%. Its false negative rate is between 15.8 to 43.5% [28] .

RECENT TRENDS:

Positron emission tomography (PET) can be used to determine site of CSF leak. Superimposition of CT and PET images helps in localizing leak sites.

MANAGEMENT

Decision regarding the management of CSF rhinorrhea depends on etiology and natural history and location of leak. Treatment includes multidisciplinary approach of otorhinolaryngology, neurosurgery and neuroradiology.

MEDICAL MANAGEMENT:

Indications of medical management

- Immediate post-traumatic leak within 48 hours
- Small leaks occurring after surgery

- ❖ No indications for intracranial exploration
- ❖ Old and those who are medically unfit for surgery

Following are included in the medical management:

Bed rest: 7-10 day trial of bed rest with head end elevation of around 15-30 degree. This helps to reduce the CSF pressure at basal cisterns.

Avoid coughing, sneezing, straining, lifting of heavy weights. Avoid wearing tight collar

Stool softeners has to be given twice or thrice daily to decrease strain and increased ICP associated with bowel movements.

Prophylactic antibiotics: If there is a communication between a sterile (intracranial) and non-sterile (sinonasal) environment, it will lead to infection in the sterile compartment. Incidence of meningitis in CSF leakage is 19% with 10% mortality rate [7]. Streptococcus pneumoniae and Hemophilus influenza are the most common causes of meningitis in CSF leak. Two large meta-analyses of patients presenting with nonsurgical traumatic leaks showed no difference in rates of ascending meningitis in the group treated with conservative measures and in those treated with prophylactic antibiotics. Brodie reported that the risk of meningitis with and without antibiotics are 2.5% and 10% respectively [6].

Role of diuretics: Acetazolamide is helpful in CSF rhinorrhea patients especially with elevated intracranial pressure. It inhibits carbonic anhydrase, thus it prevents conversion of water and CO_2 to bicarbonate and hydrogen ions.

This deficiency of hydrogen ions within the epithelial cells leads to decreased Na/K ATPase activity that causes decreased efflux of water into the CSF reducing CSF volume.

Lumbar drain: it is useful for many things in relation to CSF rhinorrhea. Help in preoperative injection of intrathecal fluorescein, lower elevated ICP, and to facilitate in graft placement. Subarachnoid lumbar drain will drain around 5-10mL per hour. Average duration of drainage is 6.5 days. Continuous lumbar drainage (CLD) is preferred than intermittent to avoid CSF pressure fluctuations. It was first introduced by Voursh in 1960's. It is a safe, effective method with high success rates in about 98% patients, by prevention of CSF leakage or accumulation at the surgical site [8]. Few complications include headache, meningitis, pneumocephalus and transtentorial herniation.

SURGICAL MANAGEMENT:

INDICATIONS:

Unless a medical or surgical contraindication exist, surgical repair is recommended for all cases with spontaneous and iatrogenic CSF rhinorrhea in order to prevent ascending meningitis. Any fistulae persisting for more than 7 days will have increased risk of developing meningitis. In case of traumatic and iatrogenic leaks conservative management may be tried for 2 weeks [50]. Iatrogenic defects mostly requires surgical repair as spontaneous closure is less likely. Primary spontaneous defects also has to be closed surgically. Success rate of CSF leaks for intracranial approach is around 70-90% and for transnasal

endoscopic technique it is 87-100% [11]. Higher chances of wound infection, severe headache and anosmia are seen following intracranial approach.

TECHNIQUES:

Intracranial:

Indicated for patients with extensive bone defects in skull base, multiple fractures of ethmoid bone and posterior wall of frontal sinus, if leak is associated with intracranial lesions and also if leak is severe, recurrent or not amenable to endoscopic treatment. Neurosurgeons usually prefer this approach. Frontal craniotomy can cause loss of smell and rarely, postoperative intracranial edema, haemorrhage, epilepsy, frontal lobe dysfunction and osteomyelitis. Success rate is reported to be upto 90% after first intracranial approach [11].One of the approaches to lateral temporal bone spontaneous leaks include middle cranial fossa approach which provides better visualisation of entire skull floor, placement of multilayer grafts and avoidance of removal of ossicles for repair of tegmen tympani defects[12]. Hospital stay and return to normalcy is longer.

Extracranial:

Extracranial approach was first performed by Dohlman in 1948 for cribriform plate CSF leak by naso-orbital dissection. External ethmoidectomy is done and the defect can be closed by mucoperiosteal flap and free fascia. It can be used for repair of leakage from frontal sinus, cribriform plate, ethmoid roof, sphenoid sinus, petrous bone. Defects in the posterior table of frontal

sinus more than 2cm above the floor and lateral to the lamina papyracea is approached via a coronal incision and osteoplastic flap. Other external approaches include transethmoidal sphenoidotomy, transseptal sphenoidotomy and transantral approach to skull base.

Endoscopic approach:

Endoscopic approach has revolutionized the management of CSF rhinorrhea. Length of stay in hospital is reduced. Smell is preserved, avoids craniotomy. Its best suited for defects located in the sphenoid sinus, cribriform plate, anterior and posterior ethmoid sinus. It is preferred for uncomplicated CSF leaks. Endoscopic repair was first reported by Wigand in 1981.Success rates are found to be more than 90% with less morbidity.

Preoperative evaluation:

Thorough history, physical examination, nasal endoscopy and radiographic imaging. Image-guided surgical navigation CT and MRI if available must be used. Need for lumbar drain should be decided.

General principles of CSF leak repair:

Basic principles are identifying the site of leak, preparing the site, proper placement of the graft and proper postoperative management. Clear field of vision is required. Topical decongestants and injection of lignocaine with epinephrine are needed for better visualisation and approach. In case of difficulty in visualisation of leak site, following intrathecal fluorescin administration, anaesthetist can assist by providing Valsalva manoeuvre. It

increases intracranial pressure resulting in increased extrusion of CSF from defect and better visualisation. If still difficult, a blue light filter is fixed to camera for allowing small quantities to be visualised [13].

Recipient bed is prepared by removing few millimetres of mucosa (~5mm) around the defect because mucosa contains exogenous mucus glands and the mucus causes lifting of graft from the recipient bed. Mucosal stripping also favours osteogenesis. Due to the risk of mucocele formation mucosal graft is avoided as an underlay graft. Bone surrounding the defect has to be abraded with rotating burr to stimulate osteogenesis if bone graft is planned. Dura above bony skull base defect is elevated to define epidural space for underlay graft placement. Bone grafts are preferred if there is increased intracranial pressure or large defects. Bone grafts are not recommended for skull base reconstruction following tumor resection as they can undergo osteoradionecrosis, if patient requires radiotherapy. After preparation of recipient bed encephaloceles are reduced with bipolar cautery.

TYPES OF GRAFTS AND FLAPS USED FOR RECONSTRUCTION:

Various techniques exist for closure of CSF leaks. For free grafts include underlay, onlay, combined and obliteration techniques. Onlay grafts are placed outside the skull base and is supported with nasal packing. Underlay graft is between skull and dura in epidural space and is kept in place by pressure of cerebrospinal fluid.

Grafts include cartilage, bone, turbinate (middle/inferior), acellular dermis (alloderm), collagen matrix (Duragen), temporalis fascia, conchal cartilage, abdominal fat.

• **Fat**: it can be harvested from earlobule, abdomen, and thigh. It can be also used for sinus obliteration. It gets completely obliterated when it loses vascularisation. Fat has expansile properties providing a mass effect

• **Temporalis fascia**: Provide water tightness due to high collagen content. It can be placed extradurally, such that 5 mm of graft lies around the defect area extradurally in the plane between the dura and the bone as underlay technique.

• **Cartilage/bone**: acts as rigid buttresses. It provides support for large bony defects. Composite graft: it is composed of bone covered with mucosa usually obtained from middle turbinate. It is useful for defects more than 0.5cm to provide better support. Rigid support is needed for defects with high pressure leaks.

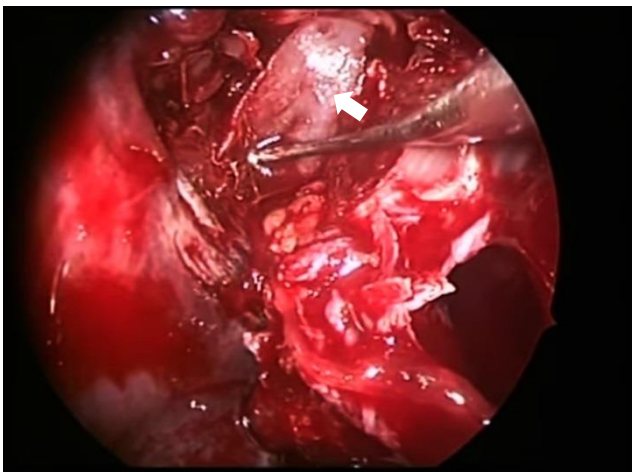


Fig 11: Septal cartilage graft

• **Nasoseptal (Hadad- Bassagasteguy) flap**: It is the workforce of skull base reconstruction. It is pedicled on nasoseptal artery a branch of posterior septal artery. It is a vascular flap of nasal septum with mucoperichondrium and mucoperiosteum. If less than 10 years of age it is not adviced.

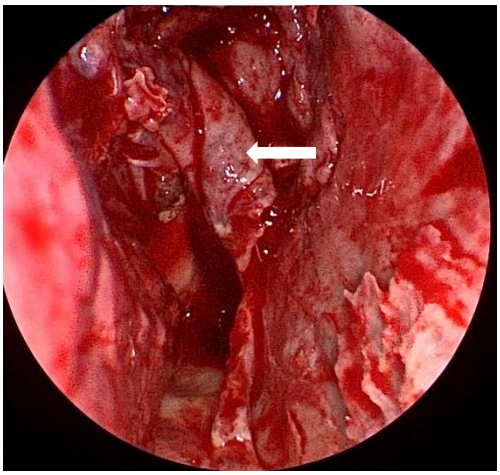


Fig 12: Hadad – Bassagasteguy Flap

• **Inferior turbinate flap or middle turbinate flap**: They are pedicled from inferior and middle turbinate artery both are branches of posterior lateral nasal artery. ITF is more suited for small defects (<1cm) posterior defects of sella, parasellar areas. MTF due to its superior position is better used for defects of planum sphenoidale, sella and fovea ethmoidalis. It is used as a second option for NSF [14].

• **Boyden nasal atrium mucosal flap**: lies in front of middle turbinate. Reaches upto posterior wall of frontal sinus.

• **Regional extranasal flaps**: Frontal or occipital pericranial flap (based on supraorbital and supratrochlear arteries), temporopariet al fascial flap, palatal flap (based on greater palatine artery), buccinator flap (on facial artery) [15].

• **Distal pedicle myocutaneous flaps** include pectoralis major, trapezius, latissimus dorsi, sternocleidomastoid flaps [15].

• **Nasoseptal rescue flap**: here Hadad flap is only partially raised permitting access to sphenoid face without interrupting the feeding vessels. Nasoseptal rescue flap is fully harvested and converted to Hadad flap once if intraoperative leak is noted. Otherwise the elevated mucosa is placed back and thus minimizing donor site morbidity.

EMERGING TECHNIQUES [44]:

Newer techniques of pedicled grafts have been described in cadaveric studies with clinical testing only in a small cohort of patients. Posterior pedicle lateral nasal wall flap (**Carrau-Hadad flap**) based on branches of sphenopalatine artery. Anterior pedicled lateral nasal wall flap (Hadad-**Bassagasteguy flap-2**) this is also based on branches of facial and anterior ethmoidal artery. **Nasal floor pedicled flap**, based on sphenopalatine artery. Turbinal flap utilized mucosa of middle and superior turbinates based on anterior and posterior ethmoidal arteries. Bipedicled anterior septal flap to repair frontal defects pedicled on superior labial and nasopalatine arteries.

BATH PLUG TECHNIQUE [16]:

It is a mainstay for closure of most of the cases especially in cases with defect size less than 15mm. Wormald and McDonogh developed this technique. Once leak site is identified dural defect is enlarged until bony rim of skull base is seen. Occasionally bone of skull base may be fractured and has to

be removed before repair, but large fragments has to be left in place to provide support for the graft. Once bony rim is identified mucosa around defect is removed for 5mm. Fat is harvested from ear lobe as the fat lobules are closely knitted and easy to work. Other options are fat from region of greater trochanter or abdominal fat. 4-0 Vicryl suture is knotted through one end and passed down the length of plug. Fat plug is placed below the defect and is slowly introduced into defect with malleable frontal sinus probe. Once plug is introduced it is stabilized with a probe and suture is pulled. This expands the fat plug intracranially.

SANDWICH TECHNIQUE [17]:

Repair was done using two layers of fascia lata (underlay and overlay) interposed with a layer of septal cartilage or conchal bone in between for repair. This is three layer technique. If there is ethmoid roof leak, a trap door flap of middle turbinate is formed where lateral aspect of vertical part of middle turbinate is removed and medial lamella is rotated to cover sandwich graft.

MULTILAYER CLOSURE METHOD [18]:

It included inlay and outlay fascia grafts with fat tissue graft and synthetic materials. Large number of small skull base defects (<10mm) can be closed by multilayer method with success rate of >90%. First layer involves fat/fascia, second layer of fascia, third layer of surgicel, followed by gelfoam

and tissue sealant. These layers are further augmented with pedicled and composite grafts.

GASKET SEAL CLOSURE [19]:

It is used in the closure of skull base defects following extended endonasal approaches. It provides watertight closure of skull base defects. Here an autologous graft is kept in direct contact with the dura and a rigid buttress provides the support. It can be associated with intracranial fat graft, lumbar drain tissue sealants, nasoseptal flap.

DURAL SUTURING:

For water-tight dural closure, fascial graft is sutured with the dura using 5-0 nylon. It is used mainly for larger defects and in patients with raised ICP.

SURGICAL APPROACH:

- **SPHENOID SINUS**:

For defects involving central sphenoid sinus standard parasagittal endoscopic approach with wide sphenoidotomy is done. Additional lateral exposure is provided by endoscopic ethmoidectomy and identification of sphenoid ostium or endoscopic transseptal approach and intersinus septectomy. It is unnecessary to remove all sinus mucosa as it creates risk for injury to carotid or optic nerve. Abdominal fat is preferred for sphenoid sinus compared to other areas. Nasoseptal flap is used for larger defects. Lateral wall of sphenoid sinus require transpterygoid approach for closure.

- **ETHMOID ROOF/CRIBRIFORM PLATE**:

Most common sites for iatrogenic CSF leaks are lateral lamella of middle turbinate and posterior ethmoid [20]. Exposure of the defect requires ethmoidectomy alone. Encephaloceles and CSF leaks in the region of olfactory cleft and cribriform plate are more problematic. A management protocol has been developed. In case of associated meningoencephalocele a bony underlay graft with free mucosal or pedicled septal graft is placed. If there is defect alone and is less than 5mm; free graft with pedicled septal flap is placed. In case of defect more than 5mm; a bony underlay graft with free mucosal or pedicled septal graft is placed [21].

- **FRONTAL SINUS**:

Two major factors in frontal sinus leak repair are successful repair of defect another is either to maintain patency of frontal sinus or obliterating sinus with meticulous removal of mucosa. Frontal sinus CSF leaks are divided into three anatomic sites (1) those immediately adjacent to frontal recess (2) those with direct involvement of frontal recess (3) located within frontal sinus proper. When defect is closer to midline, modified endoscopic Lothrop procedure improves surgical access and bilateral drainage. Defects in the lateral recess need osteoplastic or trephine approach. Superior and lateral posterior table defect is repaired with osteoplastic flap method without obliteration. Those posterior table defects extending to the frontal isthmus need combined approach [2].

POSTOPERATIVE CARE:

Patient is given broad spectrum antibiotics for 5 days. Instructed to avoid straining, not to blow nose for 2-3 weeks post surgery. Stool softeners to be given and light activity for 6 weeks. Head end elevation to 45 degree. Lumbar drains are adjunctive treatment for lowering elevated ICP, facilitate graft placement. Those with suspected elevated ICP or high opening pressure on initial tap needs lumbar drain. If CSF pressure is elevated over 15cm H_2O medical management with diuretic (acetazolamide) is adviced. It pressure is more than 35cm H_2O or inadequate response to medical therapy permanent ventriculo-peritoneal shunt is needed. Drainage has to be adjusted to 5-10mL per hour. Patients are reviewed in ever 1-2 weeks postoperatively for conservative endoscopic debridement.

STEPS IN MULTILAYER CSF LEAK CLOSURE WITH PEDICLED GRAFTS

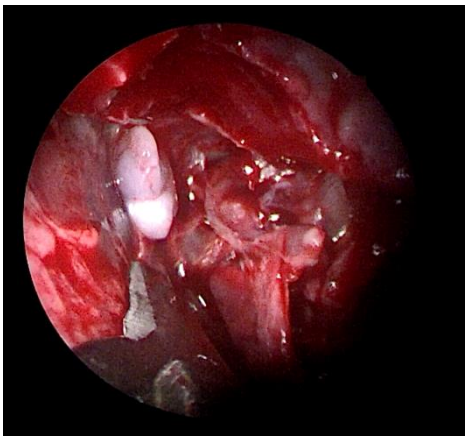


Fig 13: Defect in Cribriform plate with dural prolapse

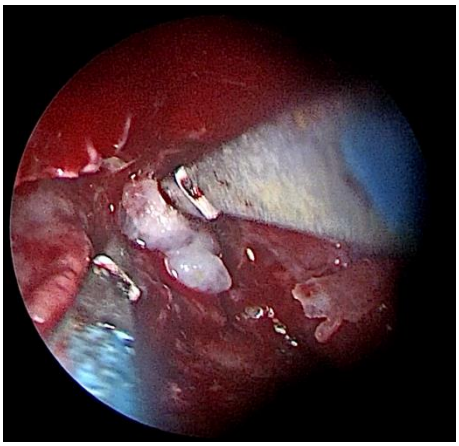


Fig 14: Cauterisation

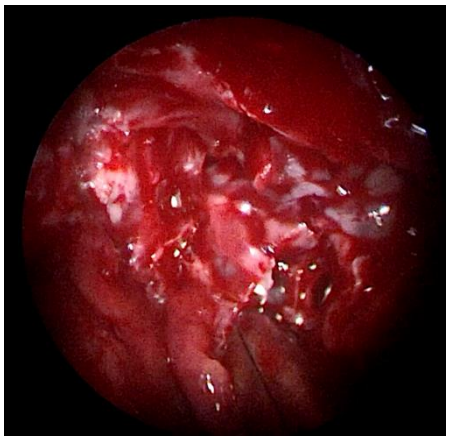


Fig 15: Graft bed formed

Fig 16: Fat tucked into the defect

Fig 17: Fascia lata as underlay

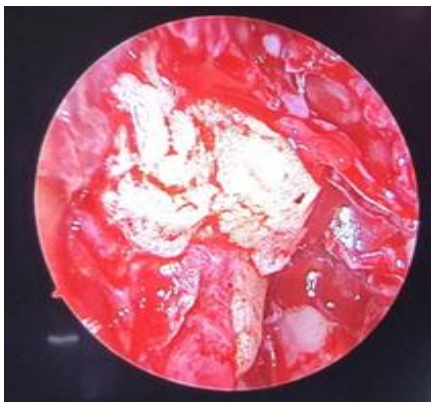


Fig 18: Fat placed

Fig 19: Surgicel placed

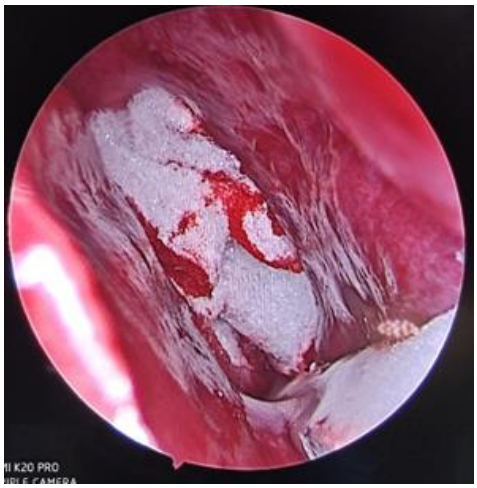


Fig 20: Gelfoam placed

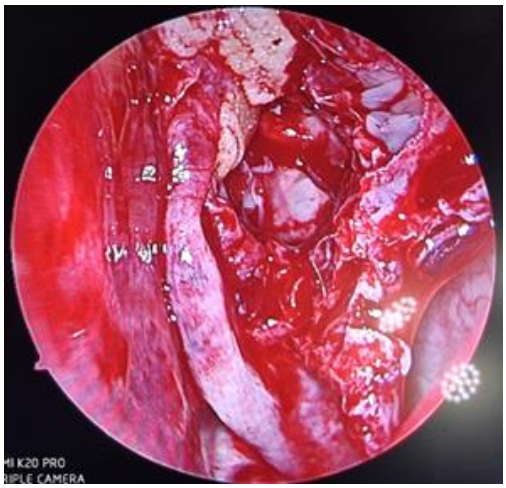


Fig 21: Middle turbinate flap placed

STEPS IN MULTILAYER REPAIR WITH FREE GRAFT

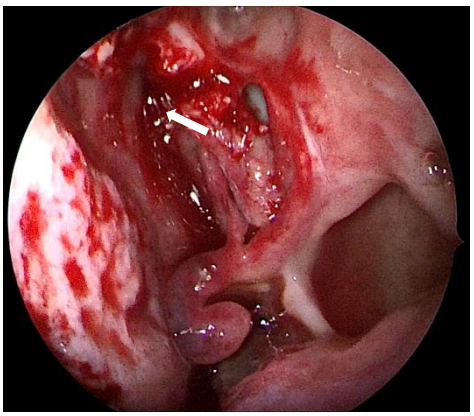


Fig 22 : Defect in left olfactory fossa

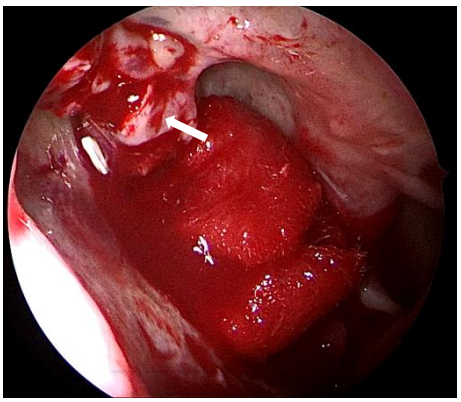


Fig 23 :Prolapse of dura

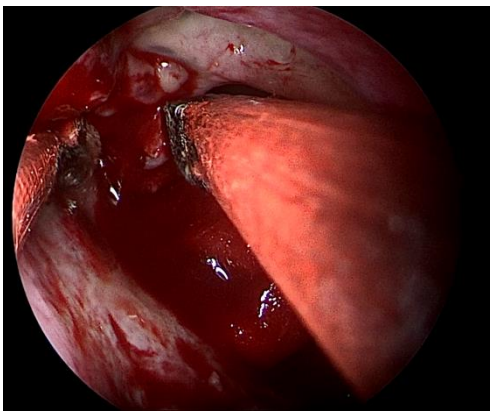


Fig 24 : Dura cauterised

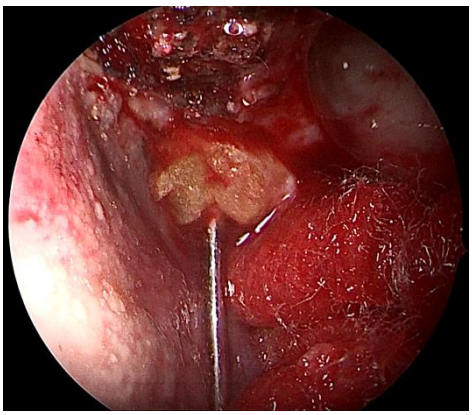


Fig 25 :Fat tucked into the defect

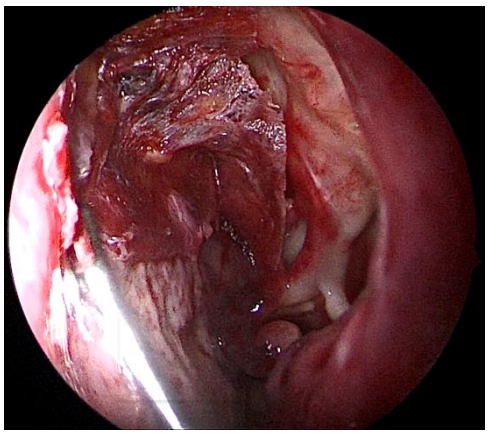


Fig 26 : Fascia kept as underlay

AIMS AND OBJECTIVE

- Study of different types of grafts and pedicled flaps used in CSF rhinorrhea repair.
- Analysis of the efficacy and success rates of pedicled and free grafts.
- Efficacy based on site and size of leak.

MATERIALS AND METHODS

STUDY PLACE: Rajiv Gandhi Government General Hospital, Chennai-600003.

COLLABORATING DEPARTMENT: Upgraded Institute Of Otorhinolaryngology

STUDY DESIGN: Prospective study

STUDY PERIOD: February 2020- July 2021

SAMPLE SIZE: 30

BENEFIT TO THE COMMUNITY:

- ❖ Regular post surgical follow up for the patients.
- ❖ Detection of the use of which graft yields better results

CONFLICT OF INTEREST: Nil

FINANCIAL SUPPORT: Nil

INCLUSION CRITERIA:

1) Both the genders above the age of 12 yrs. and below 70yrs
2) Defects detected endoscopically or radiologically
3) Failure of conservative management
4) Etiology- Traumatic, iatrogenic and spontaneous CSF leaks
5) Skull base defects less than 3cm

EXCLUSION CRITERIA:

1) Age below 12yrs and above 70 yrs.
2) Defects not detected endoscopically or radiologically
3) Leaks requiring intracranial approach
4) Sinonasal and intracranial malignancy
5) Generalised systemic illness (not fit for anaesthesia)
6) Laterally placed leaks where endoscopy is not feasible
7) History of surgery to turbinates or sphenopalatine artery ligation

INVESTIGATIONS:

a) Routine blood investigations
b) CSF analysis
c) Diagnostic nasal endoscopy
d) Radiological investigations- CT-PNS, CT-cisternogram, MRI (if needed)

METHOD:

After obtaining ethical committee approval. 30 patients satisfying inclusion criteria were selected. History, examination findings noted. Routine blood investigations, CSF analysis, nasal endoscopy, CT paranasal sinuses, CT cisternogram and MRI (optional) were done to diagnose CSF leak. Out of 30

patients, CSF repair was done with free grafts for 15 cases and with pedicled grafts for another 15. Post surgical follow up of patients were done in the immediate postoperative period, first, second week, first and third month. Intraoperative complications was assessed by the presence of excessive bleeding, orbital complications, pneumocephalus etc. Postoperative assessment was done by history taking, diagnostic nasal endoscopy, and checking for the development of complications like headache, infection, meningitis, duration of postoperative stay, recurrence, crust formation on endoscopy. Data was collected and entered in Microsoft Excel. Later for categorical variables frequency distribution were calculated and for association Chi square test were used. Statistical analysis was done using SPSS software version 18.Results were finally concluded.

STATISTICAL ANALYSIS AND RESULTS

Table - 1: Distribution of study participants as per age group

Age	TYPE OF GRAFT		Total n (%)
	Free graft n(%)	Pedicled graft n (%)	
<30	3 (20)	2 (13.3)	5 (16.7)
30-50	10 (66.7)	10 (66.7)	20 (66.7)
>50	2 (13.3)	3 (20)	5 (16.7)
Total	15(100)	15(100)	30(100)
MEAN	41.73	40.93	
STANDARD DEVIATION	11.53	12.5	

The above table shows the distribution of our study participants as per the age group in both the groups. Among both free graft and pedicled graft group majority (66.7%) of the study participants belonged to 30-50 years and 16.7% belonged to >50 years of age and 16.7% to <30 years of age. Mean age group of free graft group was 41.73±11.5 and for pedicled graft group it was 40.93±12.5.

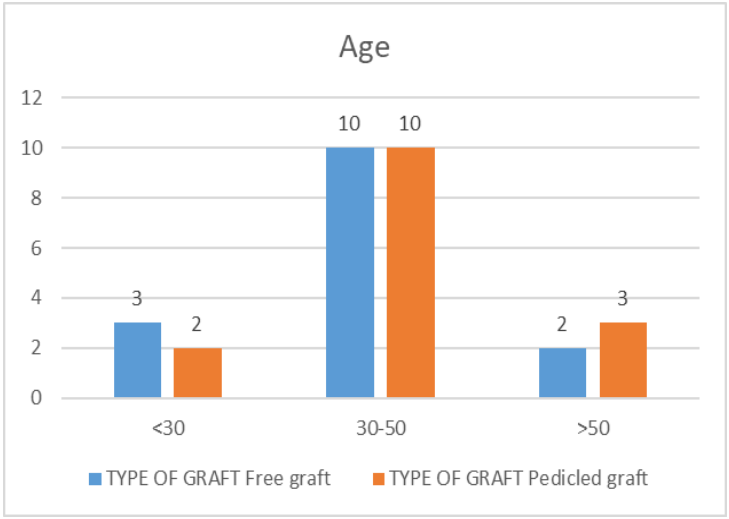


Figure - 27: Distribution of study participants as per age group

Table-2: Distribution of study participants as per gender

Gender	TYPE OF GRAFT		Total n (%)
	Free graft n (%)	Pedicled graft n (%)	
Male	5 (33.3)	7 (46.7)	12 (40)
Female	10 (66.7)	8 (53.3)	18 (60)
Total	15(100)	15(100)	30(100)

The above table determines the distribution of study participants as per gender in both the groups. Among our study participants majority of them were female in both the groups of about 66.7% and 53.3% in free graft and pedicled graft respectively.

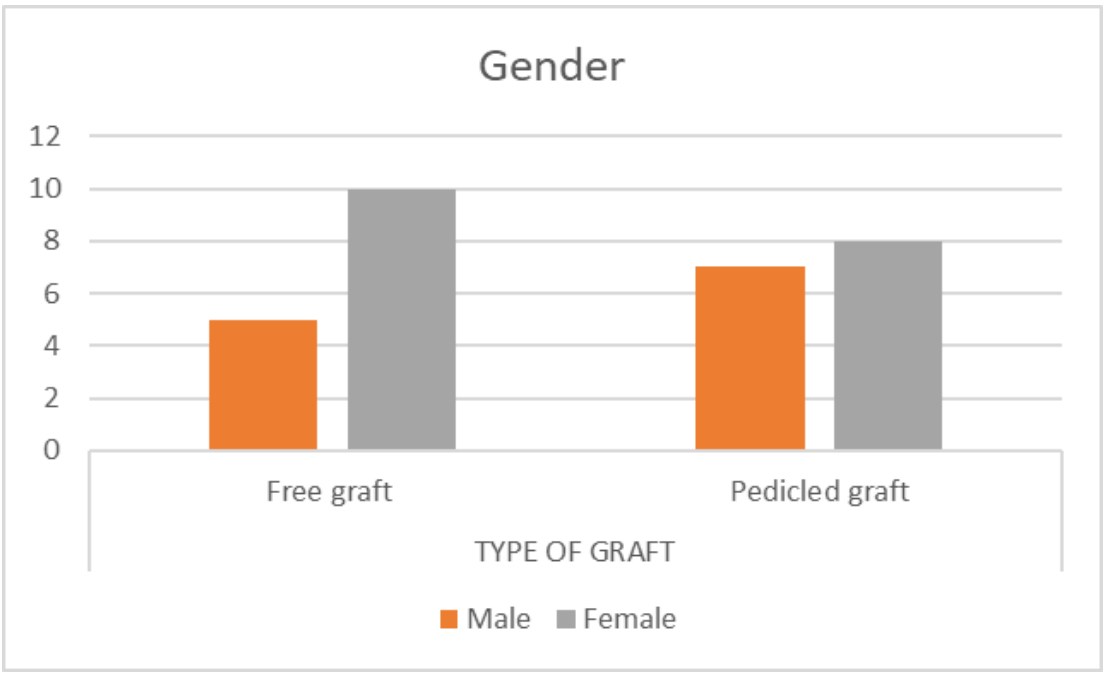


Figure-28: Distribution of study participants as per gender

Table-3: Distribution of study participants as per their occupation

Occupation	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
Coolie	2(13.3)	1(6.7)	3(10)
Driver	3(20)	2(13.3)	5(16.6)
Unemployed	4(26.6)	7(28)	11(36.7)
Seller	4(26.6)	3(20)	7(23.3)
Student	2(13.3)	2(13.3)	4(13.3)
Total	15(100)	15(100)	30(100)

Figure-29: Distribution of study participants as per their occupation

Table-4 Distribution of study participants as per aetiology of disease

ETIOLOGY	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
Spontaneous	10 (66.7)	8 (53.3)	18 (60)
Traumatic	5 (33.3)	7 (46.7)	12 (40)
Total	15(100)	15(100)	30(100)

The above table depicts the distribution of our study participants as per aetiology of the disease. Majority of our study participants had spontaneous etiology (60%) and among them 66.7% were belonging to free graft group and 53.3% to pedicled graft. Next common was traumatic etiology 12(40%).

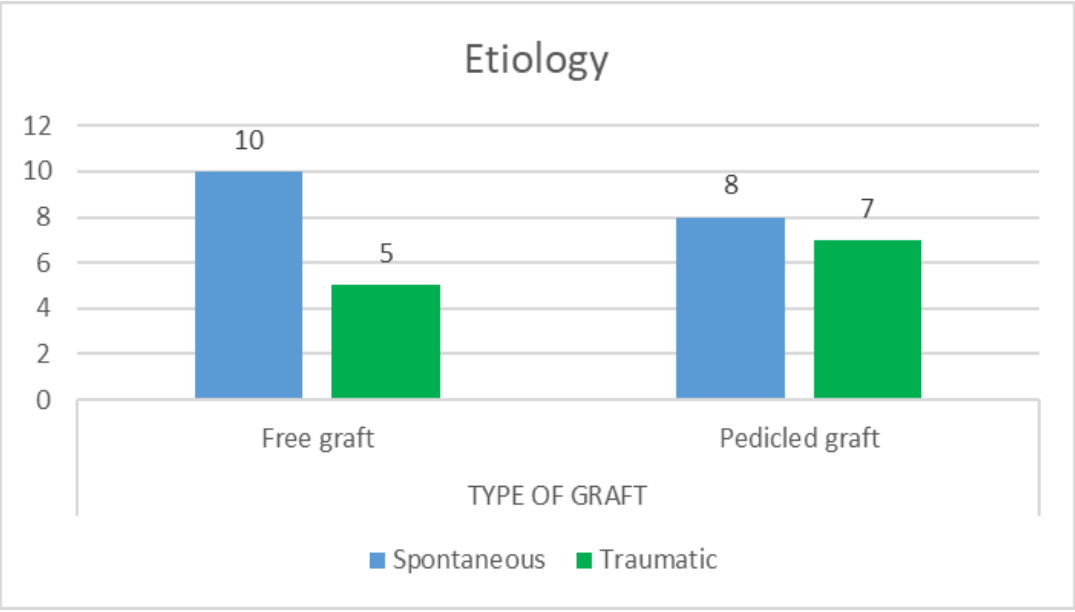


Figure-30 Distribution of study participants as per aetiology of disease

Table-5: Distribution of study participants as per comorbidities

Comorbidity	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
HTN	3 (20)	2 (13.3)	5 (16.7)
DM	3 (20)	4 (26.7)	7 (23.3)
Post COVID	0 (0)	1 (6.7)	1 (3.3)
RTA	1 (6.7)	0 (0)	1 (3.3)
No	8 (53.3)	8 (53.3)	16 (53.3)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of our study participants as per type of graft in both the groups. Among our study participants majority had no comorbidities. About 23.3% had diabetes mellitus among them 20% and 26.7% were belong to free graft and pedicled graft groups respectively. Similarly, about 16.7% had hypertension of which 20% and 13.3% were belong to free graft and pedicled graft group respectively.

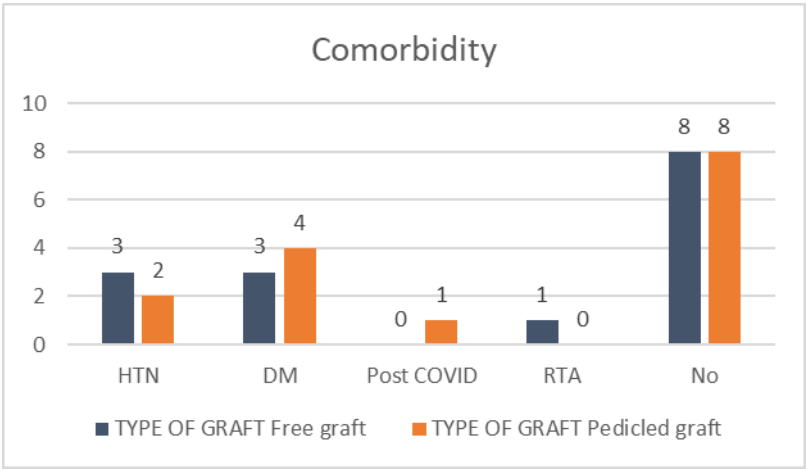


Figure-31: Distribution of study participants as per comorbidities

Table-6: Distribution of study participants as per the Duration of the disease

DURATION	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
Acute	1(7%)	4 (27%)	5 (17%)
Chronic	14 (93%)	11 (63%)	25 (83%)
Total	15(100)	15(100)	30(100)

The above table provides information regarding the distribution of our study participants as per duration of the disease. Majority had chronic duration among our study participants of which 93% and 63% were belong to free graft and pedicled graft respectively among our study participants.

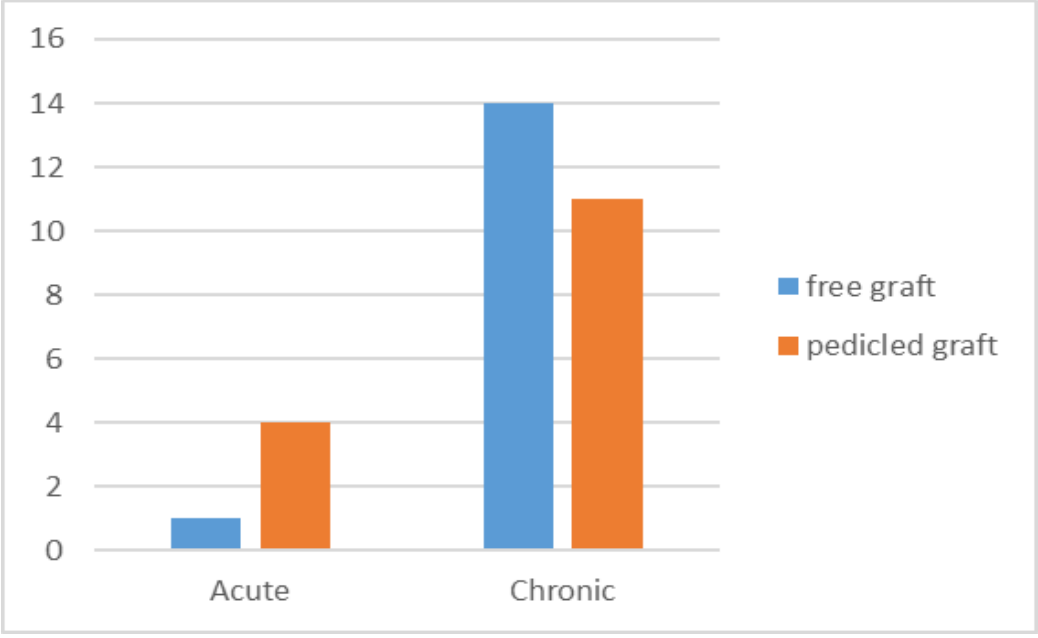


Figure-32: Distribution of study participants as per the Duration of the disease

Table-7: Distribution of the study participants having Nasal Obstruction

NASAL OBSTRUCTION	TYPE OF GRAFT		Total
	Free graft n (%)	Pedicled graft n (%)	
Unilateral	2 (13.3)	6 (40)	8 (26.7)
Bilateral	1 (6.7)	2 (13.3)	3 (10)
No	12 (80)	7 (46.7)	19 (63.3)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of our study participants as per nasal obstruction in both the groups. Majority of our study participants had not had any nasal obstruction in both the groups. Unilateral obstruction seen about 13.3% and 40% in free graft and pedicled graft respectively. Similarly bilateral obstruction seen about 6.7% and 13.3% in free graft ad pedicled group respectively.

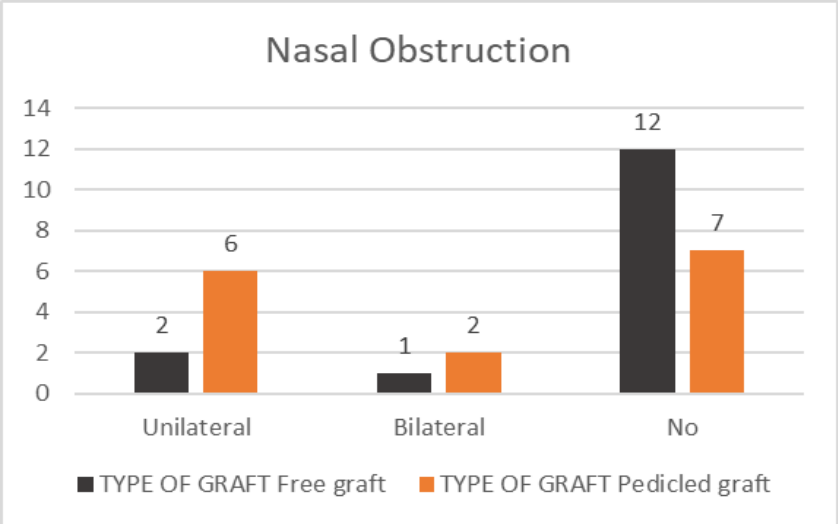


Figure-33: Distribution of the study participants as per the Nasal Obstruction

Table-8: Distribution of study participants as per symptom of fever

FEVER	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
Yes	2 (13.3)	5 (33.3%)	7 (23.3%)
No	13 (86.7)	10 (66.7%)	23 (76.7%)
Total	15(100)	15(100)	30(100)

The above table depicts the distribution of our participants based on presence of fever. Majority of study participants does not have fever symptoms. 7(23.3%) of cases had associated fever (13.3% in free graft group and 33.3% in pedicled graft group)

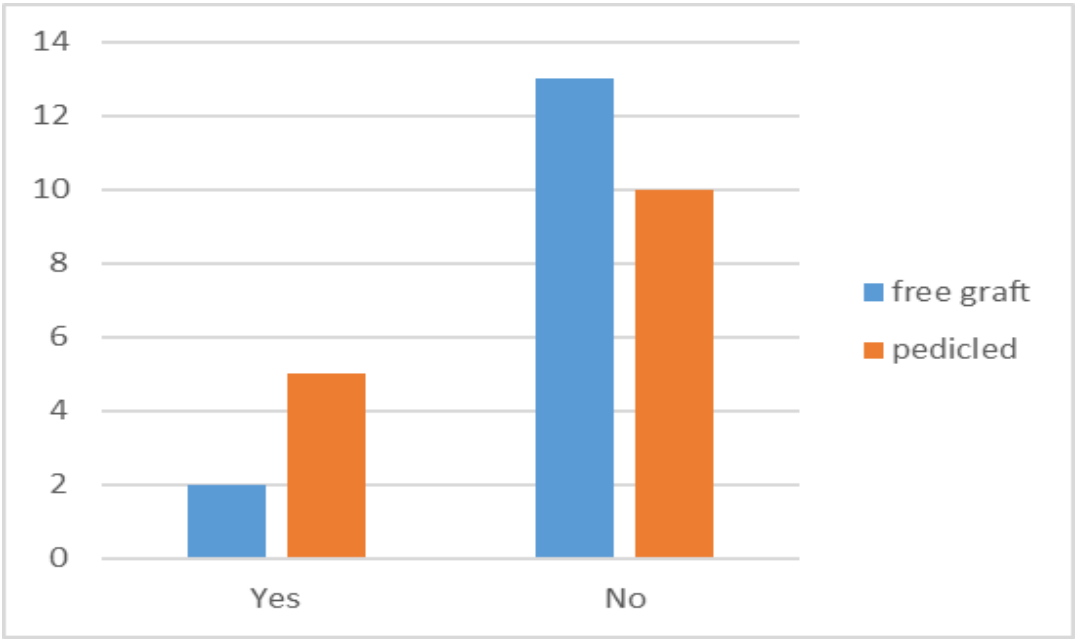


Figure-34: Distribution of study participants as per symptom of fever

Table-9: Distribution of our study participant as per associated mucormycosis

Associated Mucor-mycosis	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
Yes	2(13.3)	5(33.3)	7(23.3)
No	13(86.7)	10(66.7)	23(76.7)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of our study participants with associated mucormycosis. 23% of the study population had associated mucormycosis.

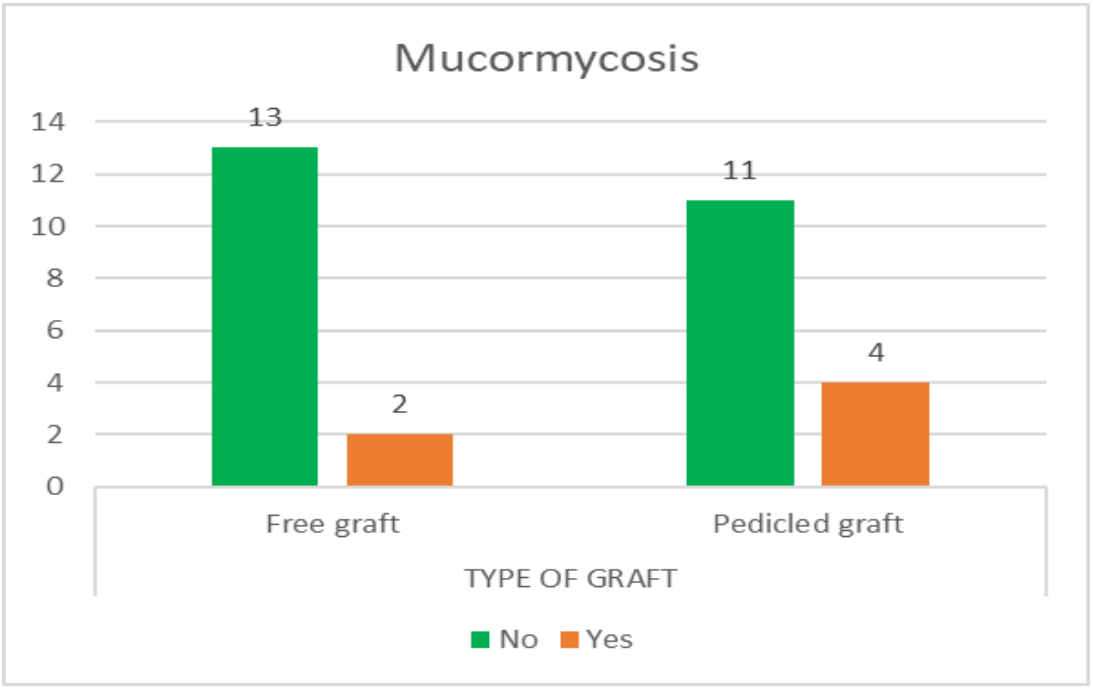


Figure-35: Distribution of our study participant with associated mucormycosis

Table-10: Distribution of our study participants as per previous nasal surgeries

Previous nasal surgeries	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
No	13 (86.7)	10 (66.7)	23 (76.7)
Post ESS	2 (13.3)	5 (33.3)	7 (23.3)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of our study participants as per previous nasal surgeries. Majority of study population had not had any previous nasal surgeries. 7(23%) had previous history of endoscopic sinus surgeries (13.3% of free graft group and 33.3% of pedicled graft group).

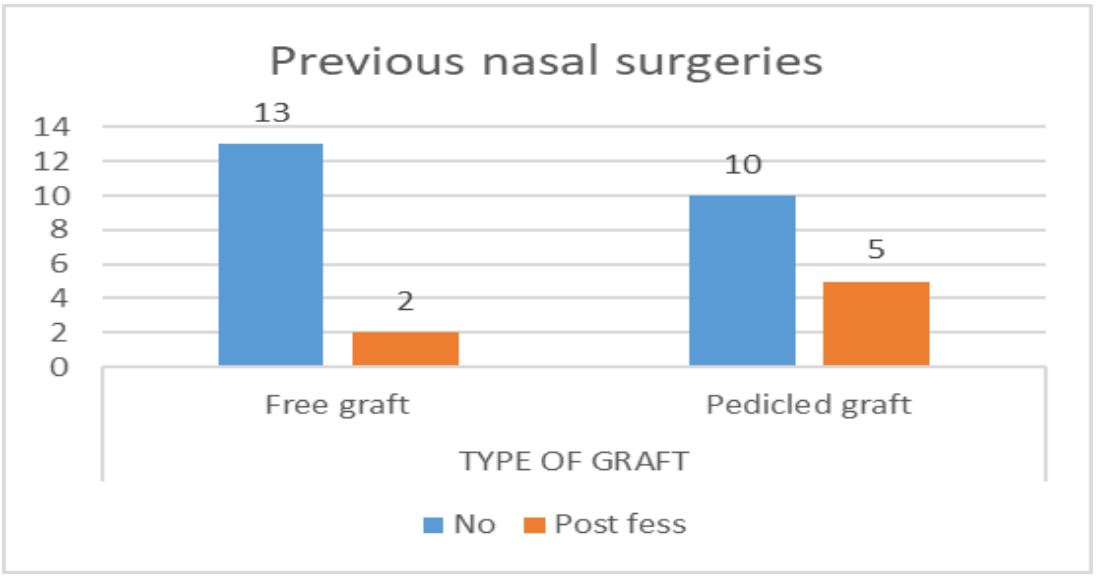


Figure-36: Distribution of our study participants as per previous nasal surgeries

Table-11: Distribution of our study participants as per previous history leak repair

PREVIOUS HISTORY OF LEAK REPAIR	TYPE OF GRAFT		Total
	Free graft n(%)	Pedicled graft n(%)	
No	13 (86.7)	15 (100)	28 (93.3)
Once with middle turbinate graft	1 (6.7)	0 (0)	1 (3.3)
Done twice with pedicled flap	1 (6.7)	0 (0)	1 (3.3)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of study participants as per previous history of leak repairs. Only 2 patients had history of prior leak repair; for one it was done with middle turbinate graft and with pedicled graft twice for the other patient.

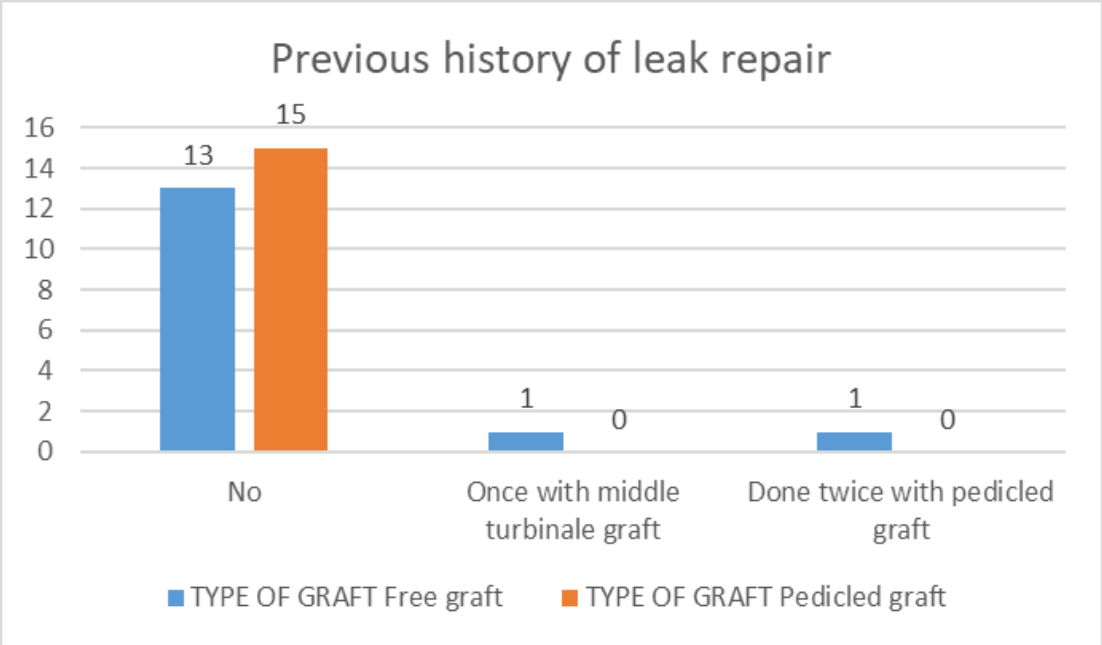


Figure-37: Distribution of our study participants as per previous history of leak repair

Table-12: Distribution of our study participants as per size of defect

Size of leak	TYPE OF GRAFT		Total
	Free graft	Pedicled graft	
3-6 mm	14 (93.3)	9 (60)	23 (76.7)
6-9 mm	1 (6.7)	3 (20)	4 (13.3)
9-12 mm	0 (0)	3 (20)	3 (10)
Total	15(100)	15(100)	30(100)

The above table distribution of study participants as per size of defect. Majority of our study participants had free graft for 3-6mm of size of defect than pedicled graft. But in case of size of defect with 6-9mm, of about 3 patients had pedicled graft similarly, in case of size of defect 9-12 mm, no patients had free graft and about 3 patients had pedicled graft.

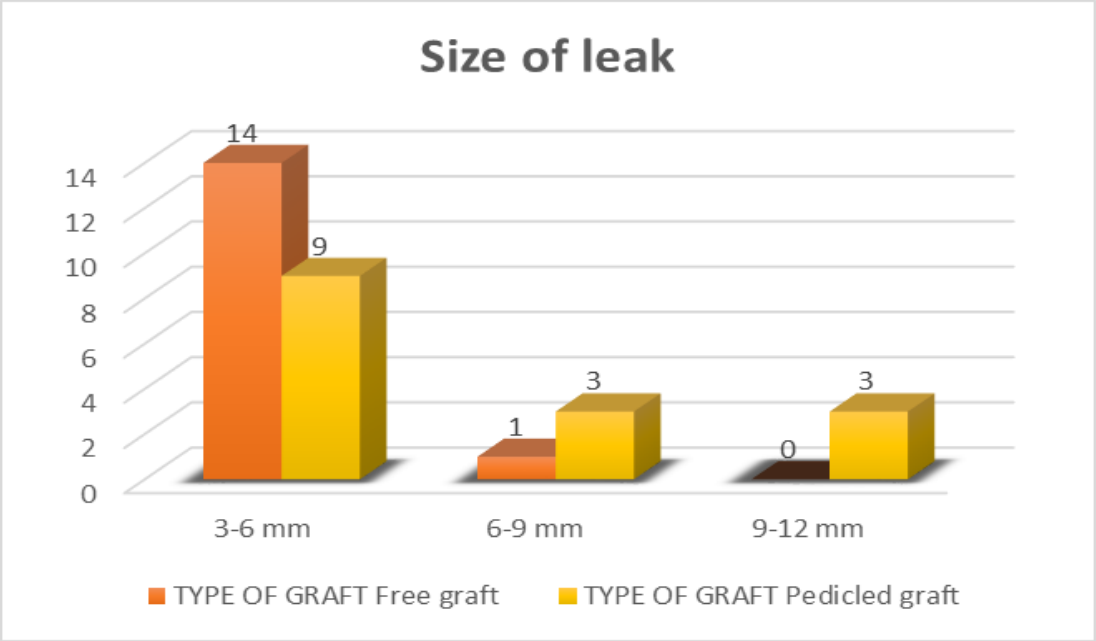


Figure-38: Distribution of our study participants as per size of defect

Table-13: Distribution of our study participants as per site of defect

SITE	TYPE OF GRAFT		Total
	Free graft	Pedicled graft	
Cribriform plate	9 (60)	10 (66.7)	19 (63.3)
FE-LL	3 (20)	4 (26.7)	7 (23.3)
Olfactory fossa	1 (6.7)	1 (6.7)	2 (6.7)
Sphenoid	1 (67)	0 (0)	1 (3.3)
Frontal	1 (6.7)	0 (0)	1 (3.3)
Total	15(100)	15(100)	30(100)

The above table depicts the distribution of study participants as per site of defect. As from the table it is clear that majority of the cases defect is at the cribriform plate 19(63.3%).Lateral lamella was the next common site 7(23.3%). Next is the olfactory fossa, sphenoid, and frontal sinus.

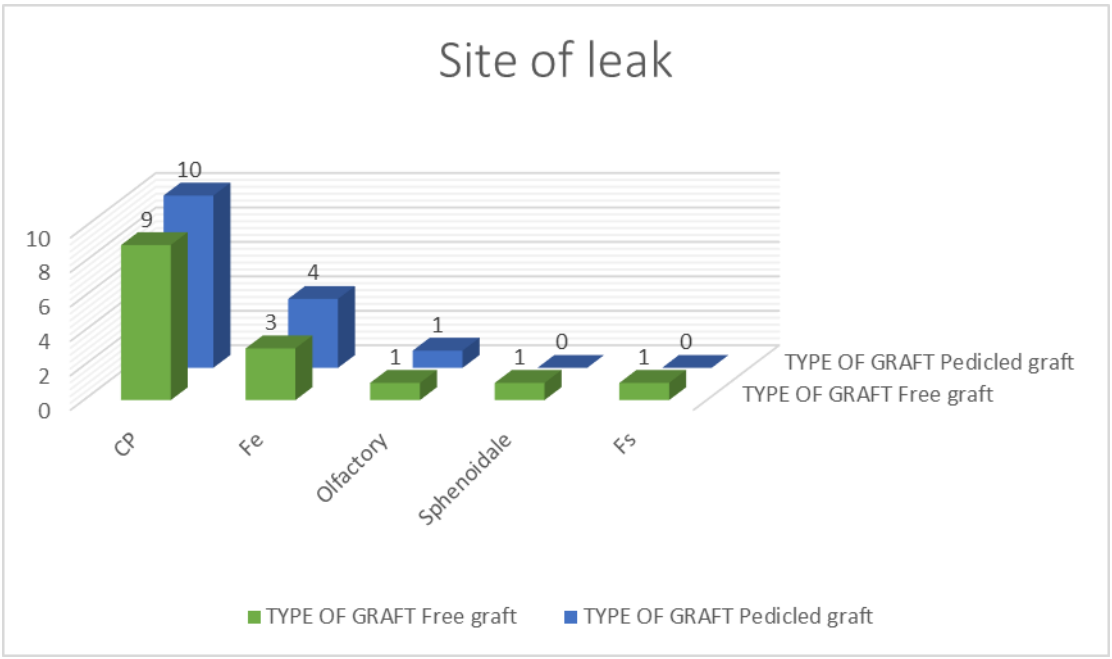


Figure-39: Distribution of our study participants as per site of defect

Table 14- Distribution of our study participants as per KEROS classification.

KEROS CLASSIFICATION	TYPE OF GRAFT		Total
	Free graft	Pedicled graft	
Type 1	7(46.7)	7(46.7)	14 (46.7)
Type 2	5(33.3)	6(40)	11 (36.7)
Type 3	3 (20)	2 (13.3)	5 (16.6)
Total	15(100)	15(100)	30(100)

The above table shows the distribution of study participants as per KEROS classification. Majority of about 46.7% belonged to type1 of KEROS classification of which 7 patients each in free graft and pedicled graft groups. Type 2 Keros classification seen in 36.7% and type 3 present in 16.6% of the total study population.

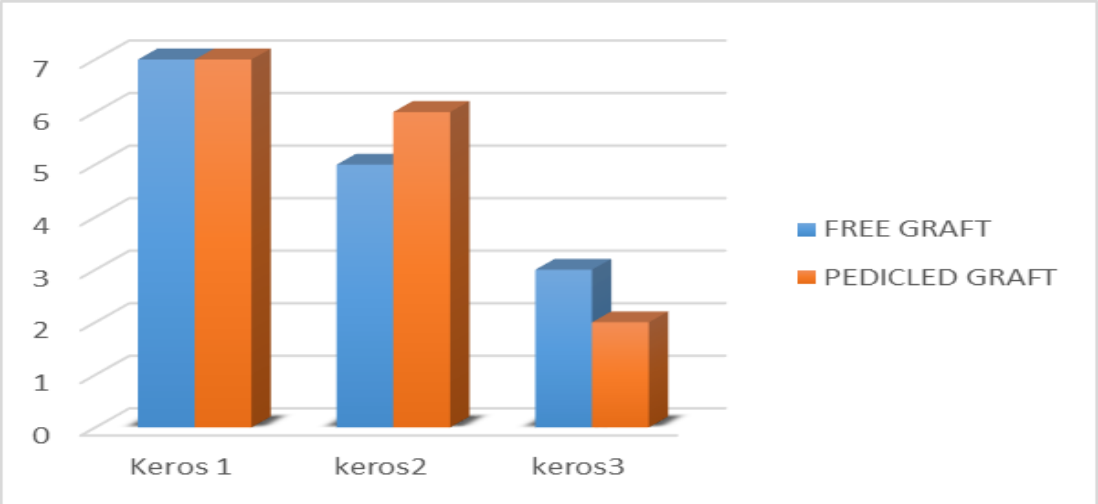


Figure 40 - Distribution of our study participants as per KEROS classification.

Table-15: Distribution of our study participants as per presence of MEC

MEC	TYPE OF GRAFT		Total
	Free graft	Pedicled graft	
Yes	3 (20)	8 (53.3)	11 (36.7)
No	12 (80)	7 (46.7)	19 (63.3)
Total	15(100)	15(100)	30(100)

The above table depicts the distribution of our study participants as per presence of MEC. Out of the total study population 36.7% (11) had associated meningocele of which 3 cases (20%) were repaired using free graft and 53.3% with pedicled graft.

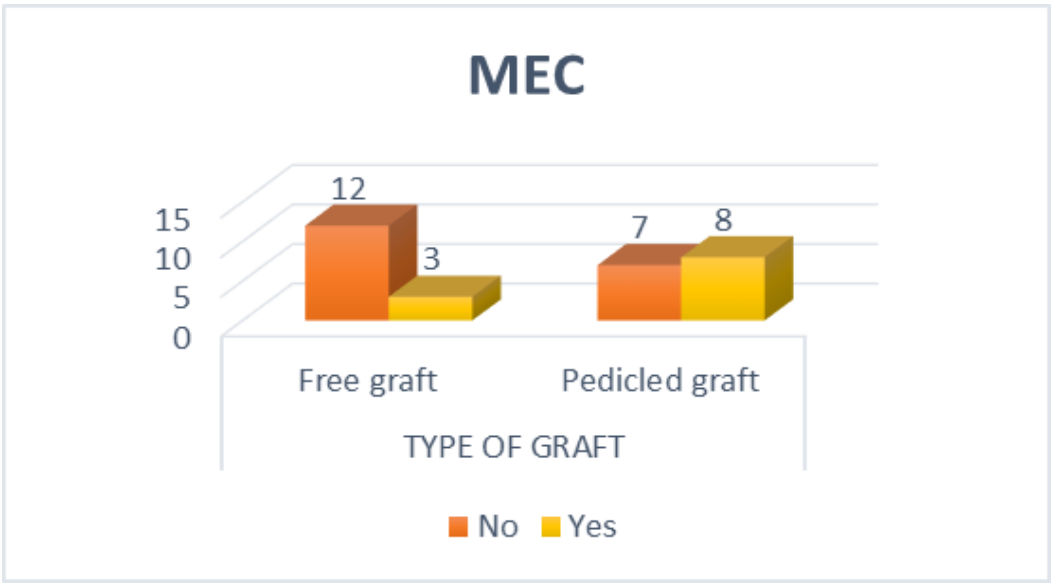


Figure-41: Distribution of our study participants as per presence of MEC

Table-16 : Distribution of the type of free grafts used in the study

Types of free grafts	Frequency	Percentage
Fascia lata	7	46.7
Middle turbinate graft	5	33.3
Tragal cartilage	1	6.7
Septal cartilage	1	6.7
Inferior turbinate bone	1	6.7

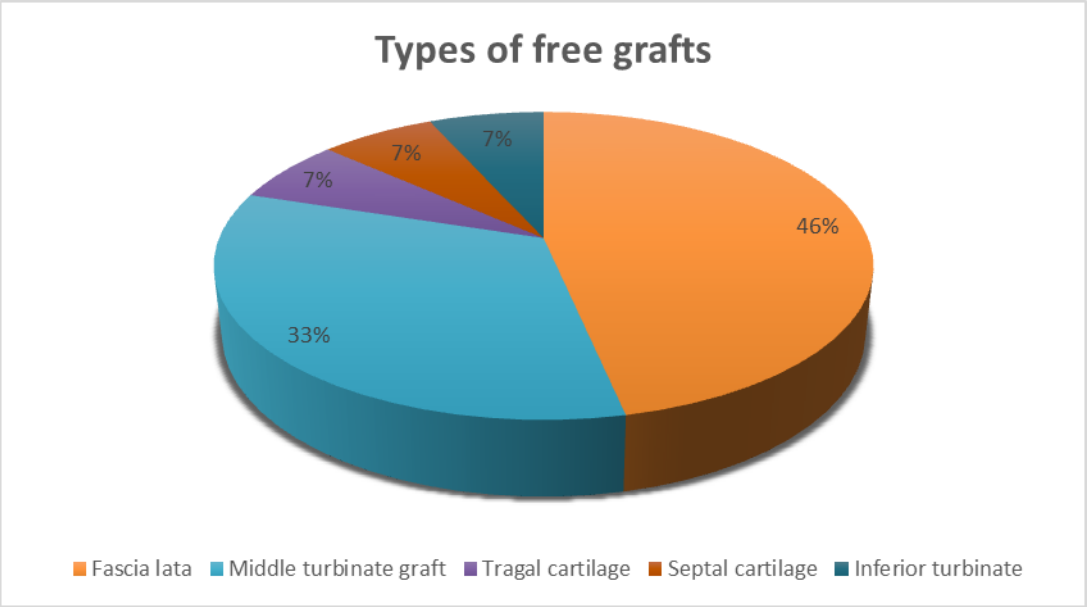


Figure-42: Distribution of the types of free grafts used in the study

In this study fascia lata was the most commonly used free graft (46.7%). The next comes middle turbinate graft (33.3%) then sliced tragal cartilage (6.7%), septal cartilage (6.7%) and inferior turbinate bone (6.7%).

Table-17 : Distribution of the type of pedicled flaps used in the study

Types of pedicled grafts	Frequency	Percentage
Middle turbinate flap	6	40
Hadad flap	9	60

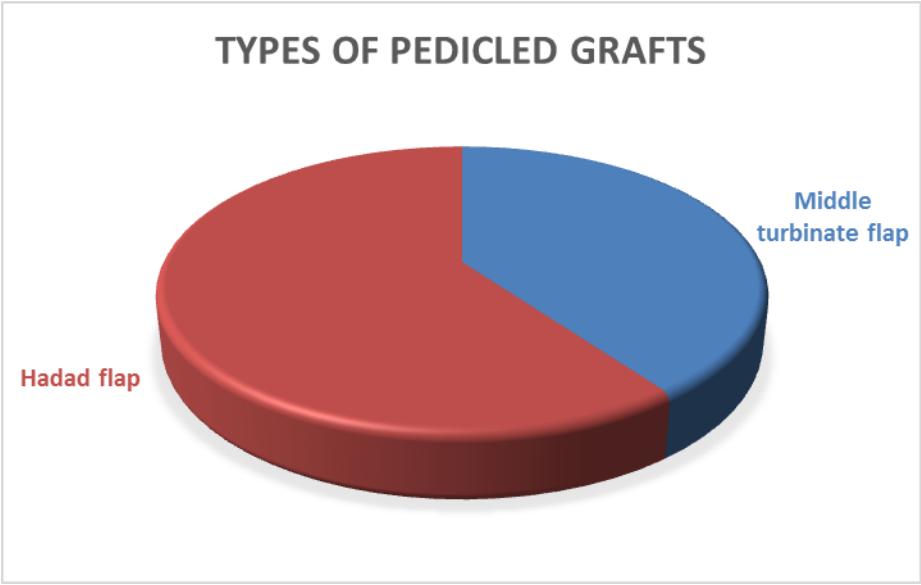


Figure-43: Distribution of the types of pedicled grafts used in the study

Among the pedicled flaps, Hadad flaps were used in 60% of cases and middle turbinate flaps in 40% cases.

Table-18 : Distribution of our study participants as per time of crust formation

Crust formation	Free graft	Pedicled graft	Percentage
Yes	9(60%)	7(46.7%)	16(53.3%)
No	6(40%)	8(53.3%)	14(46.7%)
Total	15	15	30

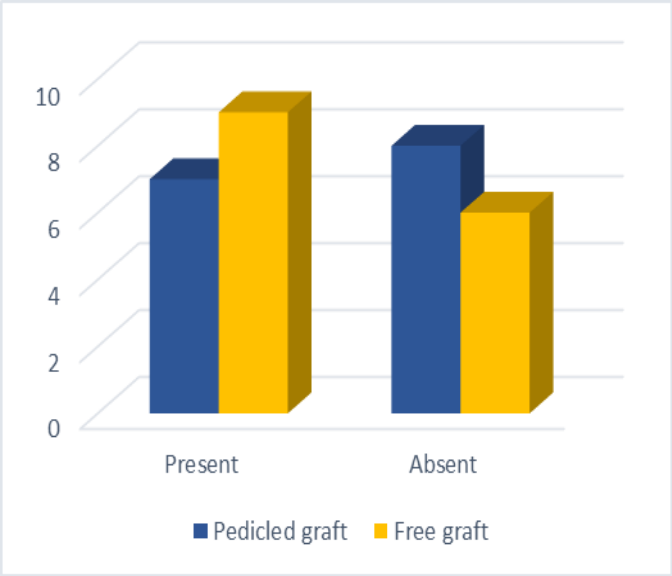


Figure- 44: Distribution of our study participants as per time of crust formation.

This table shows the crust formation among the pedicled and free graft groups in the follow up period. In the pedicled graft group 7(46.7%) had crust formation in the follow up, while 8(53.3%) were not having crust formation. In free graft group, 9(60%) had crust formation and 6(40%) did not have crust formation.

Table-19: Relationship between Aetiology and MEC

Etiology	MEC		Total	P value
	Yes	No		
Spontaneous	9 (81.8)	9 (47.4)	18 (60)	0.063
Traumatic	2 (18.2)	10 (52.6)	12 (40)	

The above table shows the relationship between aetiology of disease and MEC among our study participants. Majority of our study participant with spontaneous etiology had MEC when compared to traumatic but it is not much statistically significant.

Table-20: Relationship between MEC and Recurrence

Recurrence	MEC		Total	P value
	Yes	No		
Yes	1 (9.1)	0 (0)	1 (3.3)	0.181
No	10 (90.9)	19 (100)	29 (96.7)	

The above table provides the relationship between MEC and recurrence of disease. From the table it is clearly proven that there is no relation between MEC and recurrence of the disease since the p value is more than 0.05 which is not statistically significant

Table 21: Relationship between Size of defect and type of graft used.

SIZE	Type of graft		Total	P value
	Free graft	Pedicled graft		
3-6 mm	14 (93.3)	9 (60)	23 (76.7)	**0.04**
6-9 mm	1 (6.7)	3 (20)	4 (13.3)	
9-12 mm	0 (0)	3 (20)	3 (10)	

The above table shows the relationship between size of defect and type of graft used. In 3-6mm of size of defect free grafts were used in 14(93.3%) of cases and 9(60%) pedicled grafts were used. But for 9-12mm defects pedicled grafts were used for all 3 patients. So, from the table it is evident that as the size of defect increases pedicled graft is used more when compared to free graft and it is found to be statistically significant.

Table -22 Relationship between type of free graft and size of defect

Type of free graft	Size			Total	P value
	3-6 mm	6-9 mm	9-12 mm		
Fascia Lata	6 (42.9)	1 (100)	0 (0)	7 (46.7)	0.874
Middle turbinate graft	5 (35.7)	0 (0)	0 (0)	5 (33.3)	
Tragal cartilage	1 (7.1)	0 (0)	0 (0)	1 (6.7)	
Septal cartilage	1 (7.1)	0 (0)	0 (0)	1 (6.7)	
Inferior turbinate bone	1 (7.1)	0	0 (0)	1 (6.7)	

The above table shows the relationship between the site of graft and size among free graft group. For 3-6mm defects, fascia lata was used in 6(42%) of patients, middle turbinate flap about 5 patients, sliced tragal cartilage, septal cartilage, turbinate bone for 1 patient each. Free grafts were not used for defects more than 9mm in my study.

Table 23 - Relationship between type of pedicle graft and size of defect:

Type of graft	Size			Total	P value
	3-6 mm	6-9 mm	9-12 mm		
Middle turbinate flap	4 (44.4)	1 (33.3)	1 (33.3)	6 (40)	0.912
Hadad flap	5 (55.6)	2 (66.7)	2 (66.7)	9 (60)	

The above table shows relationship between site of graft and size of defect among pedicle flap group. For defect size of 3-6mm middle turbinate flap was used in closure for 4 cases (44.4%) and Hadad flap for 5 cases (55.6%). While for defect size more than 9mm; 2(66.7%) cases were repaired with Hadad flap and only one with middle turbinate flap.

Table-24: Relationship between Site of defect and type of graft used.

Site of defect	Type of graft		Total	P value
	Free graft	Pedicled graft		
Cribriform plate	9 (60)	10 (66.7)	19 (63.3)	0.700
Fovea ethmoidalis-lateral lamella	3 (20)	4 (26.7)	7 (23.3)	
Olfactory fossa	1 (6.7)	1 (6.7)	2 (6.7)	
Sphenoid	1 (6.7)	0 (0)	1 (3.3)	
Frontal	1 (6.7)	0 (0)	1 (3.3)	

The above table depicts the relationship between the site of defect and type of graft. For cribriform plate defects, free grafts and pedicled flaps are used in almost equal numbers; 60% and 66.7% respectively. While for defects in olfactory, sphenoid and frontal regions free grafts were used. But p- value is >0.05 hence statistically not significant.

Table-25: Relationship between type of graft and recurrence

Recurrence	Type of graft		Total	P value
	Free graft	Pedicled graft		
No	15 (100)	13 (86.7)	28 (93.3)	0.241
Yes	0 (0)	2 (13.3)	2 (6.7)	

The above table shows the relationship between type of graft used and incidence of recurrence of symptoms only 2 patients with pedicled grafts had recurrence, while none of the other patients had. But the relationship was not statistically significant.

Table – 26: Relationship between technique of grafting and type of graft

Grafting technique	Type of graft		Total	P value
	Free graft	Pedicled graft		
Underlay	10 (66.7)	12 (80)	22 (73.3)	0.184
Sandwich technique	3 (20)	0 (0)	3 (10)	
Overlay	2 (13.3)	3 (20)	5(16.7)	

The above table provide information regarding the relationship between the types of graft and grafting technique. Among our study participants about 10 patients of free graft (66.7%) and 12(80%) patients of pedicled graft had underlay grafting technique. For 3 patients with free graft sandwich technique was used. Overlay technique were used for 2 patients of free graft and 3 patients of pedicled graft. Since p value is >0.05, no association was found between the technique of grafting and the type of graft used.

Table-27: Relationship between number of layers and the type of graft

Number of layers	Type of graft		Total	P value
	Free graft	Pedicled graft		
5-6	5 (33.3)	4 (26.7)	9 (30)	0.500
7-8	10 (66.7)	11 (73.3)	21 (70)	

The above table depicts the relationship between number of layers and type of graft used. Among our study participants about 5-6 layers were used for repair in 33.3% of free graft group and 26.7% of pedicled graft group. While 73.3%

of pedicled graft group were repaired with 7-8 layers. But the association was statistically insignificant.

Table-28: Relationship between Postop complications with type of graft.

Postop complications	Type of graft		Total	P value
	Free graft	Pedicled graft		
No	14 (93.3)	12 (80)	26 (86.7)	0.475
Meningitis	1 (6.7)	2 (13.3)	3 (10)	
Thigh wound dehiscence	0 (0)	1 (6.7)	1 (3.3)	

Majority of our study participants does not had any post complication. About 1 patient among free graft and 2 patients among pedicled graft had meningitis. But the relationship between type of graft and post op complications was not found significant.

DISCUSSION

The main objective of my study is to study about various types of grafts used in the endoscopic repair of CSF leak repair. Their efficacy based on the size, cause and severity of the leaks and thus analyzing the efficacy and success rates.

AGE:

In this study the mean age and standard deviation was found to be 41.73±11.53 in the group of free grafts and 40.93±12.5 in the group of pedicled grafts. Though age between 12-70 years were included in the study most of the study population were in the age of 40 years. This is similar to the mean age group in study conducted by **Carrau et al**[27]., the mean age was found as 41 years similar to our study were the age group under study was 8-22years. In another study by **Hasan et al** [37] mean age group was found as 30.7 years.

GENDER:

In this study incidence of CSF rhinorrhea was found to be higher in females. 66.7% in free grafts and 53.3% in pedicle grafts. This is in corroboration to the studies by Verma et al. and Jiang et al. In the study conducted by **Verma et al.** [3] out of 32 cases of CSF rhinorrhea 18 (56.25%) were females and males were 14(56.25%). In another study by **Jiang et al.** [38] out of 48 patients 94% (45) were females.

OCCUPATION:

Most of the study population were unemployed in both the groups (26.6% and 23%).

CO-MORBIDITIES:

Most of the study population were not having any associated illnesses. Diabetes mellitus and hypertension (23.3% and 16.7%) were found to be the common comorbidities. None of the patients had history of epilepsy, Meniere's disease, glaucoma, psychological disorders.

ETIOLOGY:

The common causes of CSF rhinorrhea are spontaneous, traumatic, congenital and neoplastic. In this study, etiology for CSF rhinorrhea was found to be spontaneous for 60% of the study population (66.7% in free graft group and 55.3% in the pedicled graft group). And traumatic cause was found in 40 % (33.3% in the free graft group and 46.7% in pedicled graft group). Out of the traumatic cause, 7(58.3%) were iatrogenic (post endoscopic sinus surgery for mucormycosis) and 5(41.6%) were post road traffic accident. This was similar to a study conducted by **Saafan et al.** [28] where 55% of study were having spontaneous etiology,30% due to trauma and 15% iatrogenic. A study conducted in 92 patients by **Mcmains et al.** [39] the etiology of CSF leak was found to be from prior functional endoscopic sinus surgery (FESS) in 23 (25%)

patients, idiopathic in 19 (21%), traumatic in 18 (20%), neurosurgical in 17(18%).

DURATION:

Out of the total study population of 30 patients, 25(83%) where having chronic history of symptoms (more than 2 weeks) with 14 members (93%) in free graft group and 11(63%) in pedicled graft group and most of the patients presented around 2 months. While acute duration of symptoms were for 8(26.7%) out of the total study population and common time of presentation was around 7 days. In cases with acute onset of symptoms surgery was done on failure of medical management or impending intracranial complications. In the study conducted by **Hasan et al.** [37] 75% (30) patients ranged between 2 and 22 months thus had chronic symptoms.

ASSOCIATED SYMPTOMS

In this study 8 (26.7%) of patients had symptoms of unilateral nasal obstruction and 3(10%) had bilateral nasal obstruction. 24 (80%) had history of fever, but no features of suggestive of meningitis. None in the study group had high pressure symptoms like headache, vomiting or blurring of vision. In a study by **Tahir et al.** [40] symptoms other than watery rhinorrhea was epistaxis, anosmia and visual complaints in 11.6% of patients. Headache, fever, altered sensorium, nausea and vomiting in 51.2% of cases. 35% has meningitis proven from CSF culture.

MUCORMYCOSIS:

In the study, 7 patients (23%) had associated mucormycosis with 5(33.3%) repaired with pedicled graft and 2(13.3%) with free graft. Mucormycosis causes devitalisation of tissues and bone hence we found that it was more appropriate to use pedicled flaps than free grafts as its healing is independent on the vascularity of the adjacent tissues.

SIZE OF DEFECT:

In this study defects less than 3cm where included. Out of this, 23(76.7%) had defects in the range of 3-6mm .4(13.3%) had defects of 6-9mm and only 3 patients had defect of 9-12mm. In a similar study by **Shoeb et al.**[41] 50% of the study group had defect size of 6-10mm and 12.5% with 0-5mm defects.

SITE OF DEFECT:

In this study defect in cribriform plate was present in 63.3% cases with 9(60%) in free graft group and 10(66.7%) in pedicled graft group. Lateral lamella was the next common site of leak 7(23.3%) of cases. Next is the olfactory cleft 2(6.7%), then planum sphenoidale 1(3.3%) and posterior table of frontal sinus 1(3.3%). One case had two defects, one in cribriform plate and another in lateral recess of sphenoid. Then one case had multiple leaks from cribriform plate. This is similar to study by **Shoeb et al.** [41] and **Okasha et al.** [42] were the incidence of cribriform plate leaks were higher 50%(4) and 52.7%(29) respectively. While in the study by **Mcmains et al.** [39] the most common defect site was sphenoid sinus(n=36; 39%) ,following which

is ethmoid roof (n=27,29%), then cribriform plate(24%) and posterior frontal recess (3%).

KEROS CLASSIFICATION

In this study 46.7% (14) of cases were of type I Keros classification, 36.7 % (11) type II, and 16.6 %(5) of type III. In cases of traumatic CSF leaks type 2(58.3%) and type3 (33.3%) were the common types found. In case of iatrogenic leaks also type2 and 3 were the most common. Keros classification denotes the depth of olfactory fossa. Thus as the length of lateral lamella increases the risk for iatrogenic injury also increases. **Preti et al.** [43] conducted a study to analyse the risk of CSF leak with Keros classification. Type 2 was found to be the most common type associated with iatrogenic CSF leak (54.2%).

TYPES OF GRAFTS

In this study different types of free grafts were used, fascia lata in 7(46.7%) cases, middle turbinate graft in 5(33.3%), sliced tragal cartilage in 1(6.7%), sliced septal cartilage in 1(6.7%) and inferior turbinate bone in 1(6.7%). In the group of pedicled grafts, Hadad flap (based on nasoseptal artery) was used in most of the cases 9(60%) and then middle turbinate flap (based on posterior lateral nasal artery) in 6(40). In study conducted by **Mcmains et al.**[39] in 92 patients, the average size of defect was 4.5mm (2-25mm), free grafts were used for the repair it included, turbinate mucosa in 59 patients(64%), temporalis fascia in 7 patients(7.5%), septal cartilage in 4(4.3%) ,septal mucosa in 3(3.2%) and turbinate bone in 3(3.2%). In a

metanalysis by **Hegazy et al.**[33] statistically no significant was found between the type of grafts used.

TIME OF CRUST FORMATION AND GRAFT TYPE:

In this study 60% (9) of the free graft group had crust formation in the follow up period while in pedicled graft group it was 46.7 %(7). There was no crust formation in 53.3% cases of pedicled graft group. In the pedicled graft group, crust formation was found in 4(26.6%) cases and they had associated mucormycosis, which interferes with the normal graft uptake due to the devitalisation of tissues. Hence pedicle grafts are better when compared to free grafts in graft uptake and healing, which is attributed to their intrinsic vascular supply. **Prickett et al.** [49], studied about graft materials and the postoperative healing. Mucosal grafts were compared to acellular dermis and collagen matrices. Healing was assessed by time for graft and donor site crusting. None of the cases had mucosal grafting in this study.

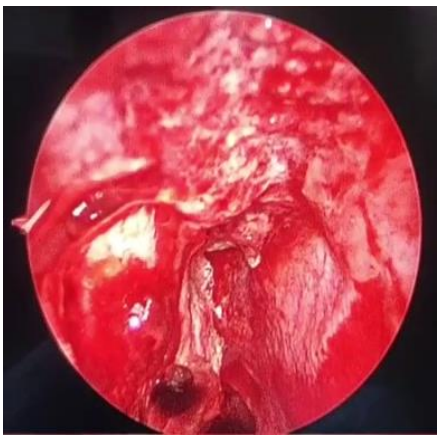


Fig 45: Graft mucosalization

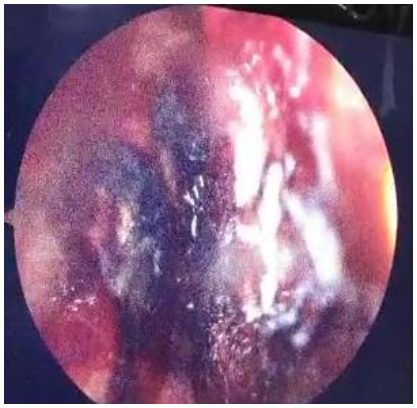


Fig 46: Crust formation

RELATIONSHIP:

ASSOCIATION WITH MENINGOENCEPHALOCELE:

In this study we found that out of the total study population 11(36.7%) had associated meningocele. Out of it 9 were associated with spontaneous etiology and 2 were associated with traumatic etiology. But no statistical association was found between the etiological factor and the presence of meningocele. 3 patients (20%) were repaired with free grafts and 8 patients (53.3%) with pedicled grafts. One case among the pedicled graft group had recurrence at 8 weeks. But this was not found to be statistically significant ($p>0.05$). Similarly, in a study conducted by **Mattox and Kennedy** [5] on CSF leaks and encephaloceles, a case series of 7 patients were done. Out of this, two cases (with traumatic etiology) had associated encephaloceles and they were closed with free mucoperichondrial flap from contralateral side of septum and the other case with pedicled septal flap and bone from middle turbinate respectively. No recurrence were found in both cases. Hence to conclude both pedicled and free grafts can be used in the management of CSF leaks with meningoceles in specific size limits.

ASSOCIATION WITH SIZE OF DEFECT AND GRAFTS USED

In this study there is an increased use of pedicled grafts than free grafts as the defect size increases. This association was found to be statistically significant ($p<0.05$). Among the free graft group; fascia lata and middle turbinate graft were commonly used for 3-6mm defects and less commonly by

sliced tragal cartilage, septal cartilage and inferior turbinate bone. Similarly in pedicled grafts group Hadad flap was more frequently used than middle turbinate flap especially in large size defects. But this was found statistically insignificant.

In a study conducted by **Hasan et al.** [37] free grafts were alone used, for the defect size less than 1cm tensor fascia lata and fat were used and for defects more than 1cm bone was added to it. Success rates was found to be 87.5%. **Cassano et al.** [46] in his study found that lower turbinate flaps has good success rates for defects larger than 2cm. **Yadav et al.**[11] found that composite mucochondrial flap and middle turbinate graft as separate bone and mucosal grafts, both can be used in the repair of large defects. Thus many studies shows that the pedicled and free grafts can be used independent of the size of defect, but in our study pedicled grafts were used more for larger defects.

ASSOCIATION BETWEEN SITE OF DEFECT AND TYPE OF GRAFT USED:

In this study for cribriform plate defects, pedicled grafts 10(66.7%) were used slightly more than free grafts 9(60%). Among pedicled grafts both Hadad flap and middle turbinate flaps were used in equal frequency and among free grafts, fascia lata was used in 55.5% cases, 33.3% used middle turbinate graft, and for the rest (11.1%) inferior turbinate bone was used. For lateral lamella defects, pedicled grafts were used in 4(26.7%), of which Hadad flap was used in 75% of cases. For olfactory cleft defect both the grafts were used in equal frequency (6.7%), among pedicled grafts one case was closed with reverse

Hadad flap and free graft repair was done with fascia lata. For sphenoid and frontal sinus defects free grafts were preferred, tragal and septal cartilage respectively. But the association between the site of defect and graft type used was statistically insignificant ($p>0.05$). Hence the type of graft used is independent of the site of defect. Thus all the cases in this study had anterior skull base defects and of which 28 (93.3%) cases had midline defects and 2 cases had lateral defects. Pedicled and free grafts were used in equal frequencies for both defects, no significant difference was noted between them.

TECHNIQUE OF GRAFTING AND TYPE OF GRAFT:

In this study underlay technique was most frequently used 10(66.7%) in free grafts and 12(80%) in pedicled grafts. Overlay technique was used in 2(13.3%) of free grafts and 3(20%) in pedicled grafts. For 3 cases of free grafts sandwich technique was used. But the association was found to be statistically insignificant ($p=0.184$). Recurrence was found, one case each in underlay and overlay technique. It was also found in significant. This is in corroboration with studies conducted by **Okasha et al.** [42] and **Weber et al.** [47] In the study of **Okasha et al.** [42] 55 cases of CSF rhinorrhea were repaired by transnasal endoscopic method. Underlay repair was done in 38 patients (69.1%) and onlay closure were done with no underlay graft insertion in 17 patients (30.9%). No significant difference was found between onlay with underlay repair and onlay repair alone in correlation to recurrence ($p = 0.886$). **Weber et al.** [47] described the use of underlay technique in 25 patients and onlay in 22 patients and both had similar success rates.

POSTOP COMPLICATIONS AND TYPE OF GRAFT:

In this study majority were not having postop complications 26(86.7%). Only 3(10%), out of which one case from free graft group (6.7%) and two cases from pedicled graft group (13.3%) cases had postoperative meningitis which settled with adequate hydration, broad spectrum antibiotics and bed rest. had meningitis. But no association was found between the development of postoperative complications and type of graft used (p=0.475). **Hegazy et al.**[33] in a meta-analysis reported postoperative complications of endoscopic skull base reconstruction as meningitis 0.3%, brain abscess 0.7%, subdural hematoma 0.3%,smell disorders 0.6%,headache in 0.3%. Here also no association with the graft type was found.

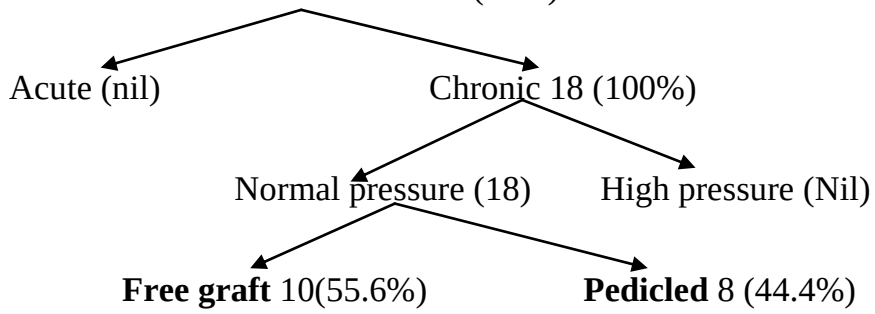
TYPE OF GRAFT AND RECURRENCE:

Among our study participants only two (13.3%) had recurrence which occurred at 8 and 12 weeks postoperatively both of them belonged to the group of pedicled grafts(one was with Hadad flap and another with middle turbinate) While none of the cases from free graft group had recurrence. But the association was not statistically significant (p=0.241). Hence its recurrence rates is not related to the type of grafts used. **Burns et al**. [50] and **Marks et al.** [51] in their studies reported the middle turbinate mucosa with and without free bone grafts had closure rates of 83% (35 of 42) and 94% (16 of 17) respectively. In another study by **Horiguchi et al.** [25] eleven patients underwent reconstructions using fat grafts or the fascia lata (non flap group) and twenty one patients underwent reconstructions with nasal septal flap(flap

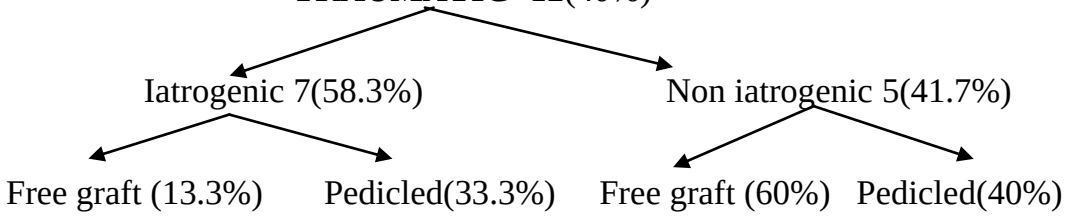
group). Incidence of postoperative CSF leak found as 2(9.5%) in the flap group and 3(27.3%) in the non-flap group. **Gassner et al.** [26] found a statistically significant increased post op recurrence of CSF leak with pedicled flaps when compared with free grafts. Hence as mentioned in the meta-analysis by **Hegazy et al.** [33] the choice of the surgical approach and the grafting materials used during the endoscopic closure of CSF leaks depends on the availability of the material and the experience of the surgeon with various techniques and it's not the types that alters the outcome.

ALGORITHM:

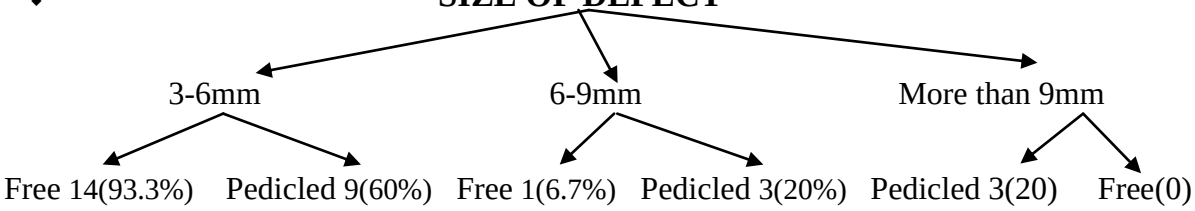
❖ **SPONTANEOUS -**18 (60%)



❖ **TRAUMATIC -**12(40%)

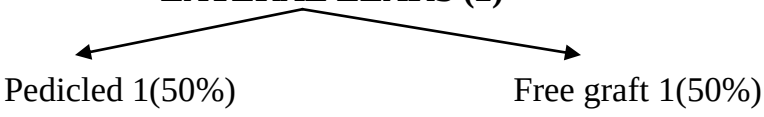


❖ **SIZE OF DEFECT**



❖ **MIDLINE LEAKS (28)**

❖ **LATERAL LEAKS (2)**



CONCLUSION

CSF rhinorrhea repair is important to prevent the development of meningitis and resulting morbidity and mortality. In this study we wanted to study of the success rates of different grafts used in CSF repair. Graphs were made and the data were analysed**.**

- In this study incidence of CSF rhinorrhea was found to be more among females, mostly around the age of 40 yrs
- Most of the cases were of spontaneous etiology, second commonest cause was due to trauma.
- Placement of grafts depends on the site of the defect hence it was important to find the level of cribriform plate and thus the importance of Keros classification. In this study iatrogenic trauma were commonly associated with Keros type 2 and 3.
- Fascia lata, middle turbinate, sliced septal cartilage, tragal cartilage autograft, and inferior turbinate bone were used in this study. Among them fascia lata was commonly used. But no much difference was found among them in relation to the outcome.
- Hadad-Bassegasteguy flap based on nasoseptal artery and middle turbinate flap based on posterior lateral nasal artery, were the pedicled flaps used in our study. Hadad flap was most commonly used. But no significant difference was found in between them regarding outcome.

- ❖ Pedicled flaps were more preferred for larger sized defects.
- ❖ Both midline and lateral defects, had equal outcome with pedicled and free grafts.
- ❖ Type of graft used was found to be independent of the site of defect, incidence of postoperative complications and recurrence.
- ❖ In mucormycosis, since there is devitalisation of tissues, pedicled grafts had better uptake than free grafts due to its intrinsic blood supply.
- ❖ Crust formation which is an indicator of poor healing was found more common among free grafts. Thus regarding postoperative healing pedicled grafts are better.
- ❖ Thus the successful repair of CSF rhinorrhea repair relies on multiple factors. Besides the skill of the surgeon and sterility of the procedure, associated comorbidities, site, size of the defect, approaches used and the tissues used for repair are the deciding factors.

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PATIENT PROFORMA

STUDY GROUP (pedicled/free grafts)

CASE No. : **DATE:**

PATIENT DETAILS:

Name:	Ward/ Unit :
Age:	Occupation
IP.No. :	Residence:
Contact No.	

ADMISSION DETAILS:

Date of Admission:

Date of surgery:

Date of discharge:

Duration of hospital stay:

DETAILS OF PRESENT ILLNESS:

Chief complaint:

Duration :

Mode of onset :

History of trauma:

Features of intracranial hypertension (headache ,projectile vomiting ,seizures, blurring of vision):

History of fever:

COMORBIDITIES:

History of diabetes mellitus , hypertension ,thyroid disorders, Previous history of surgeries :

CLINICAL EXAMINATION:

Consciousness: Orientation:

Febrile :

Pulse rate : BP:

Central Nervous System: Features of increased intracranial pressure (Papilledema)

Cardiovascular system:

Respiratory system:

Per abdomen:

EXAMINATION OF NOSE:

Septum:

Reservoir sign:

Halo sign:

INVESTIGATIONS:

Diagnostic nasal endoscopy findings:

Blood investigations

Radiological investigations (Simple/contrast enhanced)

Biochemical Investigations:

PROCEDURE DETAILS:

Operative notes:

Type of Graft : Pedicled graft / Free graft

Site of harvesting graft/flap:

Layers of repair:

Type of nasal pack:

Duration of surgery:

Intraoperative complications:

(Bleeding / Orbital injury)

Need for Lumbar drain :

POST-OPERATIVE FOLLOW UP:

Immediate postoperative period :

Any complaints of fever , headache ,vomiting, anterior or post nasal bleeding, blurring of vision.

1st week:

Any specific complaints(recurrence , fever, neck stiffness ,vision disturbances)

Diagnostic nasal endoscopy findings (first pass, second pass, third pass)

2nd week:

Any specific complaints (recurrence, fever, neck stiffness, vision disturbances)

Diagnostic nasal endoscopy findings:

1st Month:

Any complaints of recurrence, headache etc…

Diagnostic nasal endoscopy findings:

3rd Month :

Any complaints of recurrence, headache etc…

Diagnostic nasal endoscopy findings:

PATIENT CONSENT FORM

Title of the Project : ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs. FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR

Institution : Upgraded Institute of Otorhinolaryngology,
Madras Medical College,
Chennai – 600003.

Name : Date :

Age : IP No. :

Sex : Project Patient No. :

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study.

_____	_____	_____
Name of the subject	**Signature**	**Date**
_____	_____	_____
Name of the Investigator	**Signature**	**Date**

INFORMATION SHEET

- We are conducting **"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS Vs. FREE GRAFT FOR CSF RHINORRHEA REPAIR"** at the Upgraded Institute of Otorhinolaryngology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 600003.

- In this study the a comparative study is done between the pedicled grafts and free flaps used in CSF rhinorrhea repair regarding their success rates , the efficacy and the complications developing by periodic follow up of patients post CSF rhinorrhea repair satisfying inclusion criteria.

- Name and identity of the patients will be confidential.

- Photographs of patient , nasal endoscopies ,CT, MRI scan may be taken for diagnostic purposes. Periodic follow up may be needed after surgery for the completion of the study

- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator **Signature of Participant**

DATE :

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

மூளை தண்டுவட திரவம் மூக்கின் வழியே கசியும் நோய்க்கான சிகிச்சை - பெடிகிள் மடல் மற்றும் ஒட்டுக்குவின் வெற்றி விகிதங்களின் ஒப்பீட்டு ஆய்வு

ஆராய்ச்சி நிலையம் : இராஜீவ் காந்தி அரசு பொது மருத்துவமனை மற்றும்
சென்னை மருத்துவக் கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் : உறவுமுறை :

பங்கு பெறுபவரின் எண். :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்ஆய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்ஆய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லாத எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்..... இடம்..... தேதி
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம்..... இடம்..... தேதி

ஆய்வாளரின் பெயர்.....

ஆராய்ச்சி தகவல் தாள்

ஆய்வு செய்யப்படும் தலைப்பு :

மூளை தண்டுவட திரவம் மூக்கின் வழியே கசியும் நோய்க்கான சிகிச்சை - பெடிகிள் மடல் மற்றும் ஒட்டுக்குவின் வெற்றி விகிதங்களின் ஒப்பீட்டு ஆய்வு.

ஆராய்ச்சியாளர் பெயர் :

பங்கேற்பாளர் பெயர் :

சென்னை ராஜீவ் காந்தி அரசு மருத்துவமனைக்கு, இந்த ஆராய்ச்சியின் நோக்கம்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியால் உங்கள் சிகிச்சைக்கு பாதிப்பு ஏற்படாது என்பதை தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்ளலாம்.

இந்த ஆராய்ச்சியின் முடிவுகளையும் நோயின் தன்மைப்பற்றியும் ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

S.No	NAME	AGE/SEX	OCCUPATION	ETIOLOGY	DURATION	PAST HISTORY	NASAL OBSTRUCTION	HEADACHE/ VOMITING/ BLURRING OF VISION	PAPILLEDEMA	FEVER	Associated mucormycosis	Previous nasal surgeries	PREVIOUS HISTORY OF LEAK REPAIR	LUMBAR DRAIN	MEDICAL MANAGEMENT	SITE	SIZE	KEROS CLASSIFICATION	MEC	**TYPE OF GRAFT**	SITE OF GRAFT	GRAFTING TECHNIQUE
1	SUGUNA	47/F	HOUSEWIFE	SPONTANEOUS	2months	T2DM	UNILATERAL	NIL	NIL	present	nil	nil	NIL	NIL	YES	LEFT CP	4mm	type1	yes	**pedicled**	middle turbinate flap	overlay
2	LALITHA	37/F	HOUSEWIFE	SPONTANEOUS	2yrs	nil	UNILATERAL	NIL	NIL	NIL	nil	nil	NIL	NIL	YES	LEFT CP	6.5mm	type2	yes	**pedicled**	Hadad flap	overlay
3	SHOBHA	41/F	HOUSEWIFE	SPONTANEOUS	50days	nil	NIL	NIL	NIL	NIL	nil	nil	NIL	NIL	YES	LEFT CP	4.5mm	type1	yes	**pedicled**	posterior nasoseptal(HADAD flap)	underlay
4	SELVI	43/F	HOUSEWIFE	SPONTANEOUS	3mths	nil	UNILATERAL	nil	nil	nil	nil	nil	nil	nil	YES	RIGHT CP	10mm	type1	no	**pedicled**	middle turbinate flap	underlay
5	DINESH	20/M	STUDENT	traumatic	1mth	nil	NIL	nil	nil	nil	nil	nil	nil	nil	YES	LEFT FE LL	4mm	type3	yes	**pedicled**	hadad flap	underlay
6	KABALI	60/M	COOLIE	TRAUMATIC	10 DAYS	T2DM,HTN	NIL	NIL	NIL	PRESENT	yes	post fess	NIL	NIL	YES	left olfactory cleft	6mm	type3	no	**pedicled**	hadad flap	underlay
7	SEKAR	36/M	SELLER	TRAUMATIC	12 DAYS	Postcovid,	BILATERAL	NIL	NIL	present	yes	post fess	NIL	nil	YES	left CP	4mm	type3	no	**pedicled**	middle turbinate flap	underlay
8	SUBRAMANI	59/M	DRIVER	TRAUMATIC	20 DAYS	T2DM	UNILATERAL	nil	NIL	nil	yes	post fess	nil	nil	YES	RIGHT CP	3mm	type 2	no	**pedicled**	middle turbinate pedicled flap	underlay
9	SUNDARAVEL	45/M	SELLER	TRAUMATIC	12 DAYS	T2DM	UNILATERAL	NIL	NIL	PRESENT	yes	post fess	NIL	nil	YES	1)LEFT CP 2) LEFT LATERAL RECESS OF SPHENOID	1)6mm 2)3mm	Type 2	no	**pedicled**	1)posterior nasoseptal(HADAD flap)	underlay
10	NAREN	21/M	STUDENT	TRAUMATIC	2months	nil	nil	nil	NIL	nil	nil	nil	nil	nil	YES	RIGHT FE,LL	12mm	type 2	no	**pedicled**	posterior nasoseptal(HADAD flap)	underlay
11	KALAISELVI	43/F	SELLER	SPONTANEOUS	1MTH	NIL	NIL	NIL	NIL	NIL	nil	nil	NIL	NIL	YES	RIGHT CP	7mm	type1	yes	**pedicled**	middle turbinate flap	overlay
12	MURUGESAN	56/M	DRIVER	TRAUMATIC	1 WEEK	T2DM,Mucormycosis	UNILATERAL	nil	NIL	present	yes	post fess	nil	nil	YES	MULTIPLE LEAKS AT CP	10mm	type 1	yes	**pedicled**	hadad flap	underlay
13	KAMALA	38/F	HOUSEWIFE	SPONTANEOUS	3mths	HTN	NIL	nil	nil	NIL	nil	nil	NIL	NIL	YES	LEFT FE,LL	4mm	type2	yes	**pedicled**	hadad flap	underlay
14	REVATHY	38/F	HOUSEWIFE	SPONTANEOUS	3mths	nil	UNILATERAL	NIL	NIL	nil	nil	nil	nil	nil	YES	RIGHT FE,LL	4mm	type1	nil	**pedicled**	middle turbinate	underlay
15	ANURADHA	42/F	HOUSEWIFE	SPONTANEOUS	3mths	nil	NIL	nil	nil	nil	nil	nil	nil	nil	YES	RIGHT CP, LL	7mm	type1	yes	**pedicled**	hadad flap	underlay
16	MOTCHAMARY	52/F	COOLIE	TRAUMATIC	2weeks	T2DM	UNILATERAL	NIL	NIL	NIL	yes	post fess	NIL	nil	YES	LEFT CP	4mm	type 3	no	**FREE graft**	FASCIA LATA	overlay
17	KOLANJI	50/M	HOUSEWIFE	SPONTANEOUS	3 mths	NIL	UNILATERAL	NIL	NIL	NIL	nil	nil	DONE TWICE WITH PEDICLED GRAFT	nil	YES	LEFT OLFACTORY FOSSA	3.5mm	type 2	no	**FREE graft**	FASCIA LATA	underlay
18	MALLIGA	43/f	DAILY WAGER	TRAUMATIC	2mths	HTN	NIL	NIL	NIL	NIL	nil	nil	NIL	NIL	YES	RIGHT FE,LL	3mm	type3	nil	**FREE graft**	middle turbinate	underlay
19	KOTHANDAM	45/M	DAILY WAGER	TRAUMATIC	10 days	T2DM	BILATERAL	NIL	NIL	nil	yes	post fess	NIL	nil	YES	RIGHT CP	4mm	type 2	no	**FREE graft**	middle turbinate graft	underlay
20	NITHYAKALYANI	35/F	SELLER	SPONTANEOUS	2mths	nil	NIL	nil	nil	nil	nil	nil	NIL	nil	YES	RIGHTCP	4mm	type1	yes	**free graft**	facia lata graft,	sandwich technique
21	JAGADEESHWARI	38/F	SELLER	SPONTANEOUS	1MTH	RTA-10yrs back	NIL	NIL	NIL	NIL	nil	nil	NIL	nil	YES	BILATERAL FE,LL LEAK	right-3mm left-4mm	type2	no	**FREE graft**	middle turbinate graft(for both)	underlay
22	GEETHA	48/F	HOUSEWIFE	SPONTANEOUS	1mth	CKD,T2DM	NIL	NIL	nil	present	nil	nil	nil	nil	YES	RIGHT CP	3mm	type1	yes	**free graft**	middle turbinate graft	overlay
23	CHANDRA	40/f	housewife	SPONTANEOUS	2mths	nil	NIL	nil	nil	nil	nil	nil	nil	nil	YES	RIGHT CP	3mm	type3	no	**free graft**	fascia lata	sandwich technique
24	UMA	48/F	SELLER	SPONTANEOUS	2mths	HTN	NIL	NIL	NIL	NIL	nil	nil	nil	NIL	YES	RIGHT CP	6mm	type1	no	**free graft**	fascia lata	underlay
25	RATHIDEVI JENNIFER	38/F	DAILY WAGER	SPONTANEOUS	3 weeks	nil	NIL	nil	NIL	nil	nil	nil	NIL	NIL	YES	LEFT PLANUM SPHENOIDALE	5mm	type2	no	**free graft**	tragal cartilage	underlay
26	CHELLAMAL	65/F	SELLER	SPONTANEOUS	2mths	HTN	NIL	NIL	NIL	NIL	nil	nil	NIL	NIL	YES	RIGHT FE,LL	8mm	type1	yes	**FREE graft**	fascia lata	underlay
27	AMUDHA	48/F	HOUSEWIFE	SPONTANEOUS	3months	nil	nil	nil	NIL	nil	nil	nil	nil	nil	YES	RIGHT CP	3mm	type1	no	**FREE graft**	middle turbinate graft	underlay
28	SATHYARAJ	23/M	student	TRAUMATIC	1mth	nil	NIL	nil	nil	nil	nil	nil	nil	nil	YES	RIGHT FS	6mm	type2	no	**FREE graft**	septal cartilage	sandwich technique by Draf3
29	RANJITH	24/M	COOLIE	TRAUMATIC	20 days	nil	NIL	NIL	nil	present	nil	nil	nil	nil	YES	RIGHT CP	4mm	type2	no	**FREE graft**	fascia lata	underlay
30	TEJA	17/M	STUDENT	SPONTANEOUS	20 days	NIL	NIL	NIL	NIL	NIL	nil	nil	ONCE WITH MIDDLE TURBINATE graft (12/7/19)	NIL	YES	LEFT CP	3.5mm	type1	no	**FREE graft**	inferior turbinate bone	underlay

S.No	LAYERS OF REPAIR	No. of layers	INTRAOP COMPLICATIONS	POSTOP COMPLICATIONS	TIME OF CRUST FORMATION	RECURRENCE	TIME OF RECURRENCE	REVISION SURGERY
1	TFL+FIBRIN GLUE+MT FLAP+SURGICEL+GELFOAM+TISSEL+ MEROCEL	7	NIL	NIL	no crust	NIL	nil	NIL
2	TFL+FIBRIN GLUE+MT+POSTERIOR SEPTAL FLAP+SURGICEL+GELFOAM+TISSEL+ MEROCEL	8	NIL	NIL	6 weeks	YES(8 weeks)	2 nd month	reclosure done
3	ABDOMINAL FAT+SURGICEL+HADAD FLAP+SURGICEL+TISSEL+GELFOAM+MEROCEL	7	NIL	NIL	no crust	NIL	NIL	NIL
4	septal cartilage+surgicel+middle turbinate flap+surgicel+tissel+gelfoam+merocel	7	nil	nil	no crust	NIL	nil	nil
5	hadad+surgicel+tissel+gelfoam+merocel	5	nil	nil	no crust	nil	nil	nil
6	THIGH FAT+TFL+SURGICEL+HADAD FLAP+TISSUE GLUE +SURGICEL+merocel	7	NIL	NIL	no crust	NIL	NIL	NIL
7	thigh fat+TFL+surgicel+tissue glue+middle turbinate flap+gelfoam+surgicel+,merocel	8	NIL	thigh wound dehiscence	4 weeks	nil	nil	nil
8	fat+fascia lata+surgicel+middle turbinate flap+gelfoam+tissel+merocel	7	nil	nil	6 weeks	nil	nil	nil
9	1)Thigh fat+fascia lata+surgicel+Hadad flap+surgicel +gelfoam	6	nil	meningitis	4 weeks	nil	nil	nil
10	fat+fascia lata+surgicel+hadad flap+gelfoam +tissel+merocel	7	nil	nil	no crust	nil	nil	nil
11	tragal cartilage+middle turbinate+surgicel+tissel+gelfoam +merocel	6	NIL	NIL	6 weeks	yes	12 weeks	done
12	fat+fascia lata+surgicel+tissel+hadad flap+gelfoam merocel	7	nil	nil	5 weeks	nil	nil	nil
13	fat+fascia lata+surgicel+hadad flap+gelfoam +tissel+merocel	7	nil	nil	no crust	nil	nil	nil
14	fat+surgicel+tissel+middle turbinate flap+tissel+merocel	6	nil	nil	no crust	nil	nil	nil
15	ear lobule fat+septal cartilage+hadad flap+surgicel+tissel+gelfoam+merocel	7	nil	nil	6 weeks	nil	nil	nil
16	Fascia lata+surgicel+gelfoam+tissel+merocel	5	nil	nil	4weeks	nil	NIL	nil
17	Fat+fascia lata+surgicel+gelfoam+tissel+merocel	6	nil	nil	no crust	nil	nil	nil
18	fat+fascia lata+surgicel+tissel+middle turbinate++gelfoam+ merocel	7	nil	nil	no crust	nil	nil	nil
19	fat+fascia lata+middle turbinate+surgicel+gelfoam+tissel+merocel	7	nil	nil	5weeks	nil	nil	nil
20	fascia lata+ septal cartilage+fat+surgicel+tissel+merocel	6	nil	nil	4 weeks	nil	nil	nil
21	THIGH fat+surgicel+middle turbinate graft+surgicel+gelfoam+tissel+merocel	7	NIL	NIL	6 weeks	NIL	NIL	nil
22	fascia lata+surgicel+middle turbinate graft+surgicel+tissel+gelfoam+merocel	7	nil	meningitis	no crust	nil	nil	nil
23	fascia lata+septal cartilage+fascia lata+surgicel+tissel+gelfoam+merocel	7	nil	nil	no crust	nil	nil	nil
24	fat+fascia lata+surgicel+tissel +gelfoam+merocel	6	nil	nil	4 weeks	nil	nil	nil
25	FAT+TFL+ tragal cartilage+TFL+SURGICEL+GELFOAM+TISSEL+ MEROCEL	8	NIL	NIL	no crust	Nil	nil	NIL
26	fascia lata+ surgicel+fat+tissel+gelfoam+merocel	6	NIL	NIL	4 weeks	nil	nil	nil
27	fat+fascia lata+surgicel+middle turbinate flap+gelfoam+tissel+merocel	7	nil	nil	6 weeks	nil	nil	nil
28	fascia lata+ septal cartilage+fascia lata+surgicel+tissel+surgicel+gelfoam+merocel	8	nil	nil	5 weeks	nil	nil	nil
29	fat+TFL+fat+surgicel+tissel+gelfoam+merocel	7	nil	nil	6 weeks	nil	nil	nil
30	ABDOMINAL FAT+SURGICEL+TISSUEGLUE+INFERIOR TURBINATE BONE+SURGICEL+TISSUE GLUE+MEROCEL	7	NIL	NIL	no crust	NIL	NIL	NIL

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

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CERTIFICATE OF APPROVAL

To
Dr.AMALU THOMAS,
MS (ENT), Post Graduate,
Upgraded Institute of Otorhinolaryngology,
Madras Medical College &
Rajiv Gandhi Govt. General Hospital,
Chennai – 600 003.

Dear Dr. AMALU THOMAS,

The Institutional Ethics Committee has considered your request and approved your study titled **"ANALYSIS OF THE SUCCESS RATES OF PEDICLED FLAPS VS. FREE GRAFT FOR ENDOSCOPIC CSF RHINORRHEA REPAIR"- NO.05112020.** The following members of Ethics Committee were present in the meeting held on **03.11.2020** conducted at Madras Medical College, Chennai 3.

1. Prof.P.V.Jayashankar :Chairperson
2. Prof.N.Gopalakrishnan,MD.,DM., FRCP, Director, Inst.of Nephrology,MMC,Ch : Member Secretary
3. Prof. K.M.Sudha, Prof. Inst. of Pharmacology,MMC,Ch-3 : Member
4. Prof. Alagarsamy Jamila ,MD, Inst. of Patholoy, MMC, Ch-3 : Member
5. Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai : Member
6. Prof.S.Lakshmi, Prof. of Paediatrics ICH Chennai :Member
7. Tmt.Arnold Saulina, MA.,MSW., :Social Scientist
8. Thiru S.Govindasamy, BA.,BL,High Court,Chennai : Lawyer
9. Thiru K.Ranjith, Ch- 91 : Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003.

Curiginal

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