“Outcome of mastoid cavity obliteration using Post-auricular Fibro- periosteal soft tissues following Canal Wall Down Mastoidectomy.”

By

DR. AUSEKAR SHAHRUKH FEROZ ALI

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY

IN

OTORHINOLARYNGOLOGY

Under the Guidance of

DR. K. C. PRASAD

M.S, FELLOWSHIP IN OTOLOGY

PROFESSOR AND HEAD OF DEPARTMENT

DEPARTMENT OF OTORHINOLARYNGOLOGY,

SRI DEVARAJ URS MEDICAL COLLEGE

TAMAKA, KOLAR-563103

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I hereby declare that this dissertation entitled **"Outcome of mastoid cavity obliteration using Post-auricular Fibro- periosteal soft tissues following Canal Wall Down Mastoidectomy."** is a bonafide and genuine research work carried out by me under the guidance of **DR. K.C. PRASAD,** Professor and Head of Department Otorhinolaryngology, Sri Devaraj Urs Medical College, Kolar, in partial fulfillment of University regulation for the award "**MASTER OF SURGERY IN OTORHINOLARYNGOLOGY**". This has not been submitted by me previously for the award of any degree or diploma from the university or any other university.

Place:
Date:

DR. AUSEKAR SHAHRUKH FEROZ ALI
Postgraduate in Otorhinolaryngology
Sri Devaraj Urs Medical College
Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR, KARNATAKA

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Place: Kolar

Date:

DR. K.C. PRASAD,

M.S., FELLOWSHIP IN OTOLOGY
Professor and HOD
Department of Otorhinolaryngology
Sri Devaraj Urs Medical College
Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR, KARNATAKA

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Date:

Place: Kolar

DR.K.C PRASAD

Professor and Head of the DepartmentDepartment of Otorhinolaryngology

Sri Devaraj Urs Medical College Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR, KARNATAKA

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DR.K.C PRASAD
M.S ENT, Fellowship in Otology

Professor and Head of the Department
Department of Otorhinolaryngology

CollegeSri Devaraj Urs Medical College

Tamaka, Kolar

Date:

Place:

DR. P. N. SREERAMULU
M.S. Surgery, FMAS, FIAGES

Principal
Sri Devaraj Urs Medical

Tamaka, Kolar

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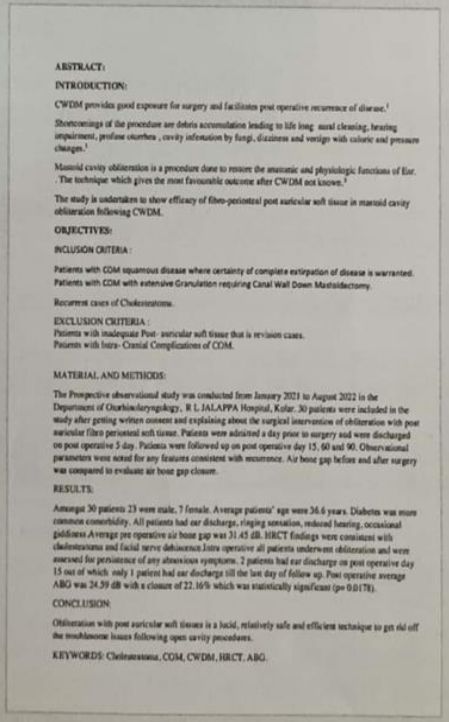

ABSTRACT:

INTRODUCTION:

CWDM provides good exposure for surgery and facilitates post operative recurrence of disease.[1]

Shortcomings of the procedure are debris accumulation leading to life long aural cleaning, hearing impairment, profuse otorrhea , cavity infestation by fungi, dizziness and vertigo with caloric and pressure changes.[2]

Mastoid cavity obliteration is a procedure done to restore the anatomic and physiologic functions of Ear. . The technique which gives the most favourable outcome after CWDM not known.[3]

The study is undertaken to show efficacy of fibro-periosteal post auricular soft tissue in mastoid cavity obliteration following CWDM.

OBJECTIVES:

INCLUSION CRITERIA :

Patients with COM squamous disease where certainty of complete extirpation of disease is warranted.
Patients with COM with extensive Granulation requiring Canal Wall Down Mastoidectomy.

Recurrent cases of Cholesteatoma.

EXCLUSION CRITERIA :
Patients with inadequate Post- auricular soft tissue that is revision cases.
Patients with Intra- Cranial Complications of COM.

MATERIAL AND METHODS:

The Prospective observational study was conducted from January 2021 to August 2022 in the Department of Otorhinolaryngology, R L JALAPPA Hospital, Kolar. 30 patients were included in the study after getting written consent and explaining about the surgical intervention of obliteration with post auricular fibro periosteal soft tissue. Patients were admitted a day prior to surgery and were discharged on post operative 5 day. Patients were followed up on post operative day 15, 60 and 90. Observational parameters were noted for any features consistent with recurrence. Air bone gap before and after surgery was compared to evaluate air bone gap closure.

RESULTS:

Amongst 30 patients 23 were male, 7 female. Average patients' age were 36.6 years. Diabetes was more common comorbidity. All patients had ear discharge, ringing sensation, reduced hearing, occasional giddiness Average pre operative air bone gap was 31.45 dB. HRCT findings were consistent with cholesteatoma and facial nerve dehiscence.Intra operative all patients underwent obliteration and were assessed for persistence of any atmoxious symptoms. 2 patients had ear discharge on post operative day 15 out of which only 1 patient had ear discharge till the last day of follow up. Post operative average ABG was 24.59 dB with a closure of 22.16% which was statistically significant (p= 0.017E).

CONCLUSION:

Obliteration with post auricular soft tissues is a lucid, relatively safe and efficient technique to get rid off the troublesome issues following open cavity procedures.

KEYWORDS: Cholesteatoma, COM, CWDM, HRCT, ABG.

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Place: Kolar **Signature of the Candidate:**

Date: **DR. AUSEKAR SHAHRUKH FEROZ ALI**

ABSTRACT

INTRODUCTION:

Canal wall down mastoidectomy provides good exposure for surgery and avoids post operative recurrence of disease.[1] Shortcomings of the procedure are debri accumulation leading to life long aural cleaning, hearing impairment, profuse otorrhea , cavity infestation by fungi, dizziness and vertigo with caloric and pressure changes.[1]

Mastoid cavity obliteration is a procedure done to restore the anatomic and physiologic functions of the ear. The technique which gives the most favourable outcome after CWDM is not known.[3] The study is undertaken to show efficacy of fibro-periosteal post auricular soft tissue in mastoid cavity obliteration following CWDM for addressing cavity related problems and having better functional outcomes .

OBJECTIVES:

1. To evaluate the outcome of mastoid obliteration in patients undergoing Canal Wall Down Mastoidectomy using Post-auricular Fibro-Periosteal soft tissue.
2. To assess hearing improvement by Pure Tone Audiometry in above mentioned patients.

MATERIAL AND METHODS:

The Prospective observational study was conducted from January 2021 to August 2022 in the Department of Otorhinolaryngology, R L JALAPPA Hospital, Kolar. 30 patients were included in the study after getting written consent and explaining about the surgical intervention, obliteration with post auricular fibro periosteal soft tissues. Patients were admitted a day prior to surgery and were discharged on post- operative day 5. Patients were followed up on post operative day 15, 60 and 90. Observational parameters were noted for any

features consistent with any abnoxious sequelae. Air bone gap before and after surgery were compared to evaluate air bone gap closure aiding in hearing improvement.

RESULTS:

Amongst 30 patients, 23 were male and 7 female. Average patients' age were 36.6 years. Diabetes was more common comorbidity. All patients had ear discharge, ringing sensation, reduced hearing and occasional giddiness.Average pre operative ABG was 31.45 dB. HRCT findings were confirmed, the presence of cholesteatoma and other features like facial nerve dehiscence, ossicular discontinuity, aural polyp.Intra operative all patients underwent obliteration with post auricular soft tissues. Later, we assessed for persistence of any troublesome symptoms. 2 patients had ear discharge on post operative day 15 out of which only 1 patient had ear discharge till the last day of follow up. Post operative average ABG was 24.59 dB with a closure of 22.16% which was statistically significant (p= 0.0178).

CONCLUSION:

Obliteration with post auricular soft tissues is a lucid, relatively safe and efficient technique to get rid off the troublesome issues following open cavity procedures.

KEYWORDS: Cholesteatoma, Chronic otitis media, Canal wall down mastoidectomy, HRCT, Air Bone Gap.

LIST OF ABBREVIATIONS

1.	CWDM	Canal Wall Down Mastoidectomy
2.	COM	Chronic otitis media
3.	HRCT	High Resolution Computed Tomography
4.	ABG	Air Bone Gap
5.	WHO	World Health Organization.
6.	MCO	Mastoid cavity obliteration
7.	MEC	Middle Ear Cleft
8.	TC	Tympanic Cavity
9.	ET	Eustachian tube
10.	MAC	Mastoid Air Cell
11.	PA	Petrous Apex
12.	M	Malleus
13.	I	Incus
14.	S	Stapes
15.	FN	Facial Nerve
16.	ETM	Epitympanum
17.	TT	Tensor Tympani
18.	Sup	Superior
19.	Med	Medial
20.	Lat	Lateral
21.	Post	Posterior
22.	LSC	Lateral Semi Circular Canal

23.	FI	Fossa Incudis
24.	L	Ligament
25.	MF	Mucosal Fold
26.	Ant	Anterior
27.	PT	Pars Tensa
28.	PF	Pars Flaccida
29.	R	Retraction
30.	OW	Oval Window
31.	RW	Round Window
32.	FR	Facial Recess
33.	ST	Sinus Tympani
34.	AD	Aditus
35.	AT	Antrum
36.	MA	Mastoid Antrum
37.	CTN	Chorda Tympani Nerve
38.	PSC	Posterior Semi Circular Canal
39.	GN	Glossopharyngeal Nerve
40.	AL	Annular Ligament
41.	SF	Stapes Footplate
42.	PC	Processus Cochleariformis
43.	GG	Geniculate Ganglion
44.	GSPN	Greater Superficial Petrosal Nerve
45.	IMA	Internal Maxillary Artery

46.	EAC	External Auditory Canal
47.	TA	Tympanic Annulus
48.	EJV	External Jugular Vein
49.	ATN	Auriculo Temporal Nerve
50.	ICA	Internal Carotid Artery
51.	ECG	Electrocardiogram
52.	TLR	Toll Like Receptors
53.	Ig	Immuno globulin
54.	HSC	Horizontal Semi Circular Canal
55.	SNHL	Sensori Neural Hearing Loss
56.	CT	Computed Tomography
57.	PTA	Pure Tone Audiometry
58.	HA	Hydroxylapatite
59.	TMF	Temporalis Muscle Flap
60.	CSF	Cerebrospinal Fluid
61.	TPFF	Temporo Parieto Facial Flap
62.	BP	Bone Pate
63.	TP	Total perforation
64.	CP	Central perforation
65.	ICW	Intact Canal Wall
66.	SCC	Semi circular canal
67.	AOM	Acute Otitis Media
68.	OME	Otitis Media with effusion

69.	CHL	Conductive Hearing Loss
70.	VT	Ventilating Tubes

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INTRODUCTION

INTRODUCTION

Chronic otitis media has affected 65-330 million people world wide. More than half of population suffers from hearing disability and on an average twenty-eight thousand deaths/ year are attributable to its sequelae as estimated by WHO.

Canal wall down mastoidectomy is the modality for squamous variant of Chronic otitis media. It usually presents with Cholesteatoma.[1] It provides optimum access to eradicate disease and helps in controlling post operative residual disease.

The after effects of CWDM creates a huge cavity that is easily trapped by debris that require endless aural hygiene, hearing disability, profuse otorrhea , fungal infestations, giddiness, vertigo with calorie change .[1]

Mastoid cavity obliteration is a procedure done to restore the anatomic and physiologic functions of Ear. Mastoid cavity was first obliterated by Mosher.[1,2] Obliteration is performed to improve hearing outcomes, to facilitate hearing aid trail and to substantiate better outcomes.

Extensive options exists for mastoid cavity obliteration following canal wall down mastoidectomy like autologus grafts, such as fat, cartilage, bone pate, musculo- periosteal flaps, temporalis fascia graft, plasma rich protein, synthetic materials like hydroxyapatite, bioglass and so on.

There is a need for obliterating technique that can fulfil all the required outcomes following

canal wall mastoidectomy. The technique which gives the most favourable outcome after canal wall down mastoidectomy is still unknown.[3]

The study is carried to document the outcome of mastoid cavity obliteration with fibro-periosteal post auricular soft tissue following CWDM.

OBJECTIVES OFTHE STUDY

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3. To evaluate the outcome of mastoid obliteration in patients undergoing Canal Wall Down Mastoidectomy using Post-auricular Fibro-Periosteal soft tissue.

4. To assess hearing improvement by Pure Tone Audiometry in above mentioned patients.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Chronic otitis media, squamous variant is a persistent disease capable of causing a variety of intra- temporal or intra- cranial manifestations and cholesteatoma or granulation tissue leading to irreversible sequelae like Deafness and Discharge.[1]

In developing countries, cases present late due to economical issues, fear of surgery and amongst those operated fail to follow up. CWDM becomes the modality to achieve stable ear.[1,4]

Canal wall down mastoidectomy poses problems like otorrhea in about 56% of cases, making the patient 'Otological cripple' cosmetically ugly looking meatus and difficulties during hearing rehabilitation as a result of large mastoid bowl.[2]

Mastoid cavity obliteration using autologous grafts has been in practice since many years and has concluded to be an economical and easy technique with low recurrence rates.[5]

Yet controversies still exists to choose the method of obliteration, in the form of obliteration with reconstruction of posterior canal wall or by reconstruction alone.[6-8]

These warrants understanding anatomical principles, physiology and pathogenesis of squamous type of chronic otitis media, dreadful sequelae, surgical procedures and methods to minimize the complications leading to improvement in quality of life in affected individuals.
Hence, understanding anatomical concepts with pathophysiology of disease process is indeed necessary to know the sequelae of performed surgery and need for obliteration following

procedure.

Anatomy Of Middle Ear Cleft:

Includes the Tympanic cavity, the ET and the Mastoid air cell system that extends into anterior and posterior Petrous Apex.[9]

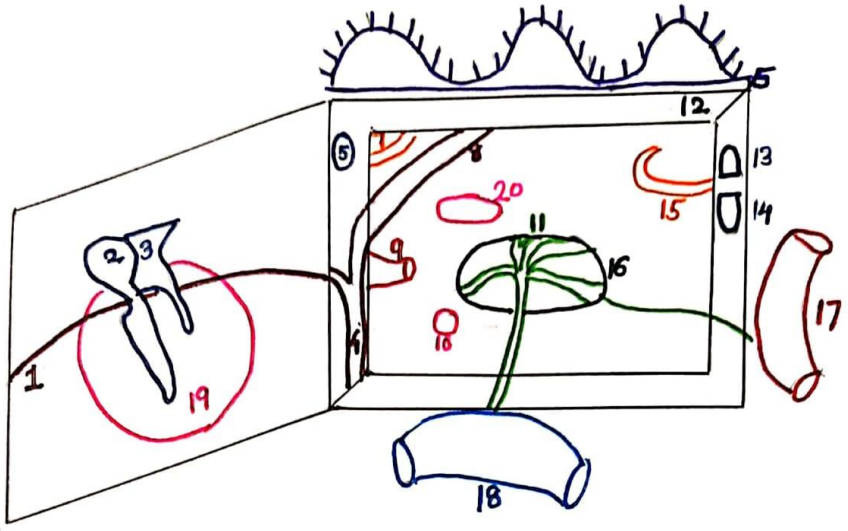

Diagram 1 showing middle ear anatomy and its relations.[10]

a.Tympanic Cavity:

Air filled cavity, like a box made of 4 walls , roof and floor.

Contents: Auditory ossicles (M,I,S)

Tendons.

Tympanic segment of the FN

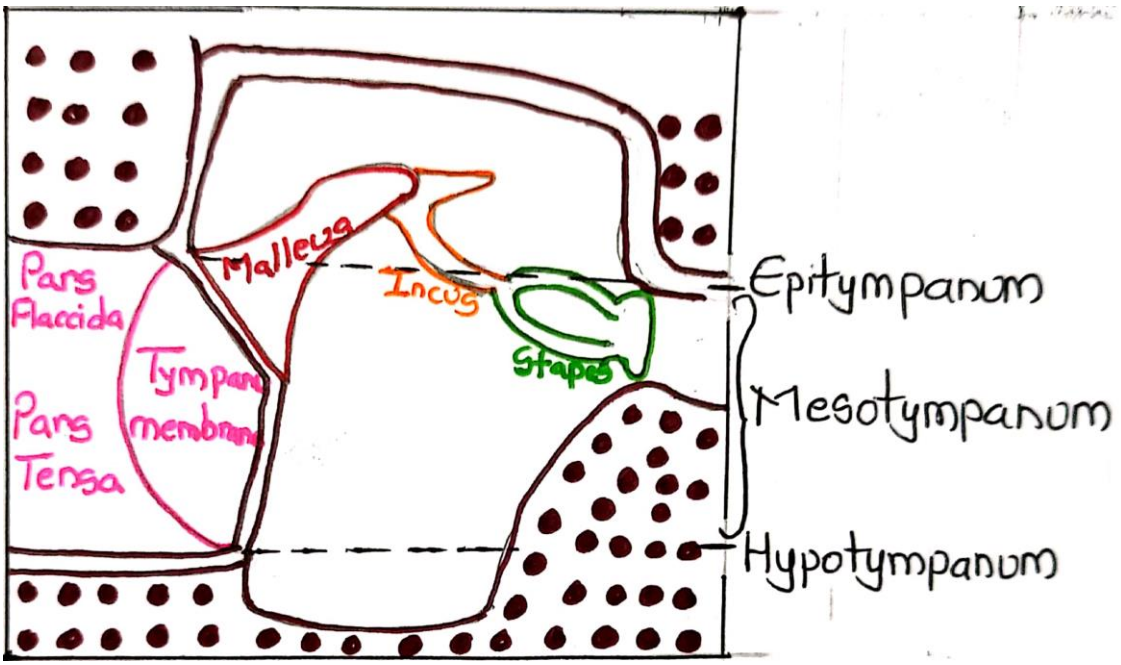

Diagram 2 :Division of middle ear [10]

I. Epi tympanum (upper)- Lies above the level of the malleolar folds or short process of malleus.

- Boundaries: Sup –Tensor Tympani.

  Med- Prominence of Lateral semi circular canal, horizontal part of FN.

  Lat – Scutum.

  Post- Fossa Incudis.

- Contents: M head, I body and their associated ligaments and malleolar folds.
- Epitympanum lies within a fan shaped dehiscence – Rivinus notch.
- Post by tympano-mastoid line and ant by tympano-squamous line.
- TM is deficient in middle layer of PT.

- PF lacks strong composition, so retraction is more common.
- So the propensity for cholesteatoma to form in ETM is more common.

II. Meso- tympanum (middle)- In horizontal plane between upper and lower edges of PT.

- Contents: S, long processes of M and I, oval and round window.
- ET exits from its ant aspect.
- Two crescent shaped recess ie the facial recess and sinus tympani are the most common locations for cholesteatoma persistence.

III. Hypo-tympanum (lower)- Situated below the TS and is continuous with meso-tympanum above.

a. Ant Wall:

1. Divided into: Upper, middle and lower one third.
2. Upper 1/3rd - Usually pneumatized

   Lodges supra-tubal recess
3. Middle 1/3rd - Tympanic orifice of the ET.

   Canal containing the tensor tympani muscle.
4. Lower 1/3rd- Bone(3mm) covering the CA and has carotico- tympanic nerves.

b. Posterior wall:

1. It has an opening in its upper part– the Aditus Antrum,
2. Aditus:
   i. Origin from posterior ETM into the mastoid antrum.
   ii. Below it is fossa incudis.
3. Fossa Incudis:

i. Lodges the I short process and its suspensory ligament.

ii. Pyramid lies medial to chorda tympani.

4. Pyramid:

i. S muscle and tendon.

iii. The canal joins the descending portion of the FN canal.

5. Facial Recess:

i. Present between the pyramid and FN.

ii. Lateral- Tympanic annulus, with Chorda tympani nerve running between the 2.

iii. CTN is medial to the TM, allowing a posterior tympanotomy.

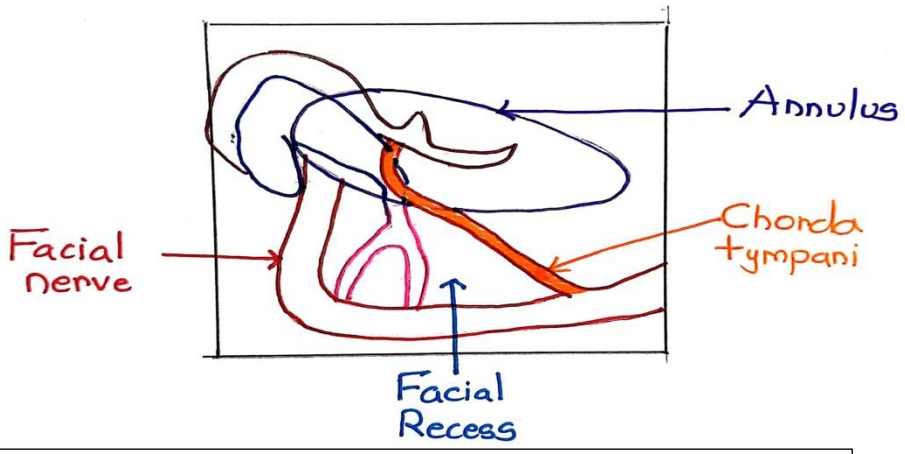

Diagram 3 showing anatomical relations of facial recess.[10]

6. Sinus Tympani:

i. Posterior extension of the meso-tympanum into posteriro wall .

ii. It is an unaccessible area in the middle ear making cholesteatoma extremely difficult to treat.

iii. Boundaries: Superior- Ponticulus

Inferior- Subiculum.

iv. Sinus can extend upto 9 mm as measured from the pyramid tip hence retro

facial dissection inferior to PSC may warrant for the disease eradication by conventional trans- canal approach

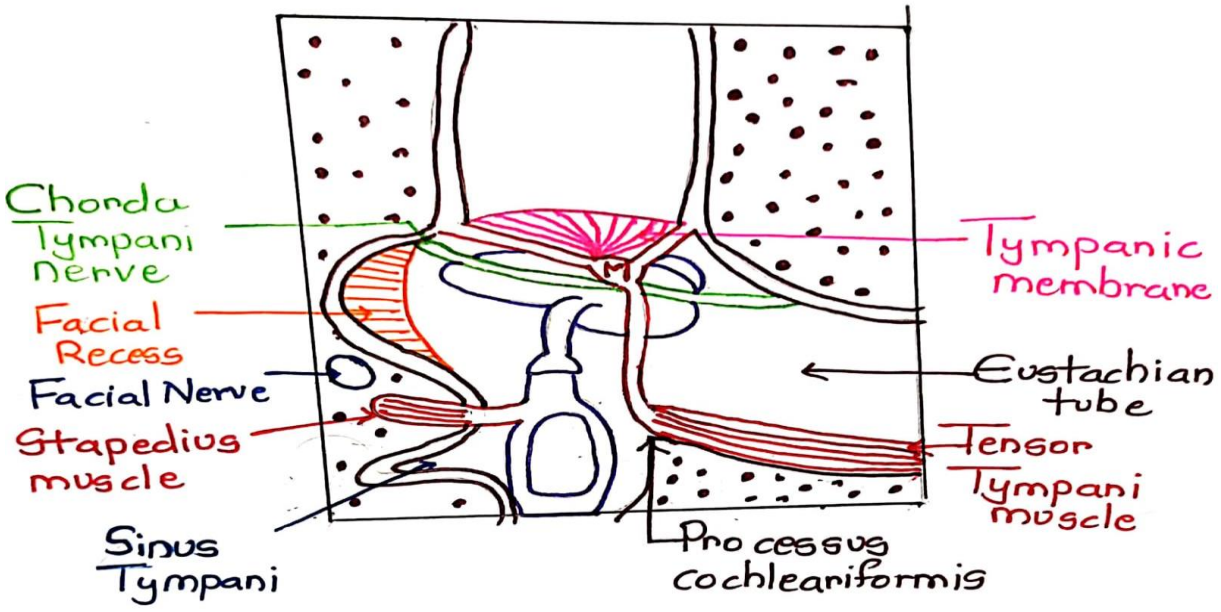

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Diagram 4 showing anatomy of sinus tympani and its relations.[10]

C. Med wall:

1. Separates middle and inner ear.
2. Promontory:
   i. Rounded elevation occupying major central portion of medial wall.
   ii. Covers the basal cochlea and contains nerves forming tympanic plexus.
   iii. Occassionally, there might be a groove containing tympanic branch of GN.
   iv. It merges with anterior wall in pro-tympanum but is more steep posteriorly.

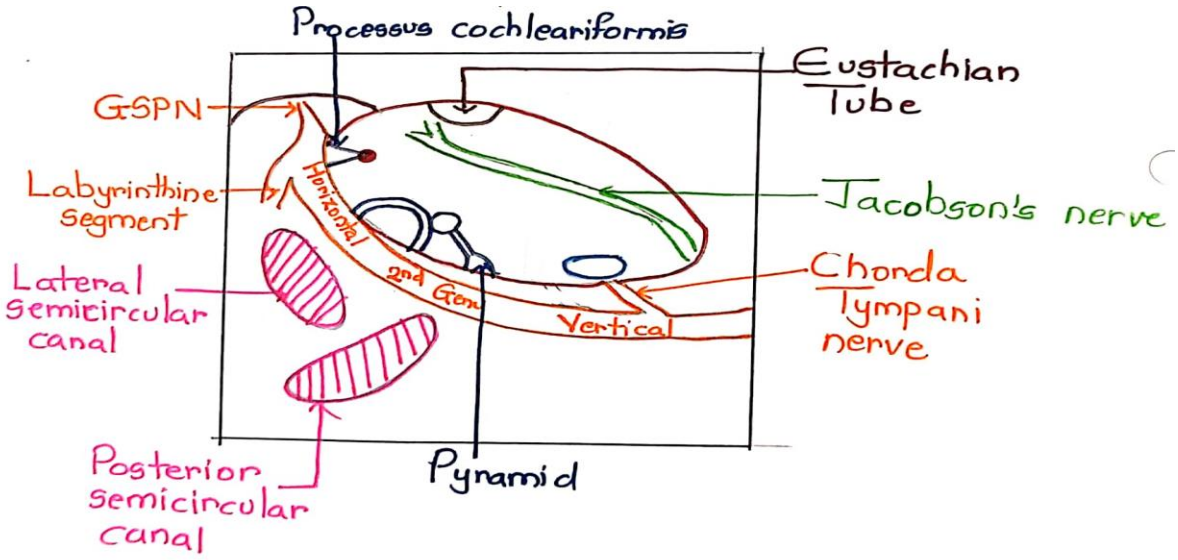


Diagram 5 showing anatomy of middle ear[10]

3. Oval window (Fenestra vestibuli):

   i. It is situated behind promontory.

   ii. Appears bean shaped connecting TC with vestibule.

   iii. It is covered by foot plate of stapes, surrounded by annular ligament.

   iv. Dimensions: 3.25 mm long, 1.75mm wide.

   v. It lies at the bottom of depression ,depending on position of FN superiorly and promontory inferiorly.

4. Round window(Fenestra cochlea):

   i. It lies behind the oval window niche at right angle to plane of SF.

   ii. Oval in shape, about 2.3x1.9 mm.

   iii. Curved towards scala tympani gives concave appearance and divides in ant and post portion by transverse thickening.

   iv. RW niche is triangular in shape with ant, postero superior and postero inferior walls.

   v. Separated from the OW niche by subiculum.

vi. Another bony ridge, ponticulus leaves promontory from above and relays over pyramid on posterior wall.

5. Facial nerve (Fallopian canal):

i. It is above oval window and promontory in an antero-posterior direction.

ii. Boundaries: Anterior- Processus cochleariformis, lodges tensor tympani tendon.

iii. Behind OW, it starts to turn inferiorly and traverses into the posterior wall of the TC.

iv. Area above FN canal forms epi tympanum medial wall.

6. Lateral semi circular canal dome :

i. It is the posterior portion of the epi-tympanum,that lies posterior and lateral to facial canal.

ii. Relationship of the LSC, I short process and the seventh nerve are identified during surgery.

7. Geniculate ganglion:

i. It lies above processus cochleariformis in front and a little below.

ii. Includes the bony canal of the GSPN.

d. Lateral wall:

i. Consists of :

I. Epitympanum bony lateral wall superiorly-

- The lateral ETM wall is sharp inferiorly called scutum.
- Easily eroded by cholesteatoma.

II. The TM centrally.

III. Bony lateral wall of the hypo-tympanum inferiorly.

ii. Petro-tympanic fissure :

I. It is a fissure running from the temporo-mandibular joint to the TC.

II. The mandibular fossa is split in two parts by petro- tympanic fissure.

III. It lodges M ligaments, and gives passage to the anterior tympanic branch of the IMA.

IV. Contents: - Communications of VII nerve to the infratemporal fossa.

- CTN, later joins lingual nerve.

V. CTN enters medial surface of the fissure by canal of Huguier.

II. Tympanic Membrane:

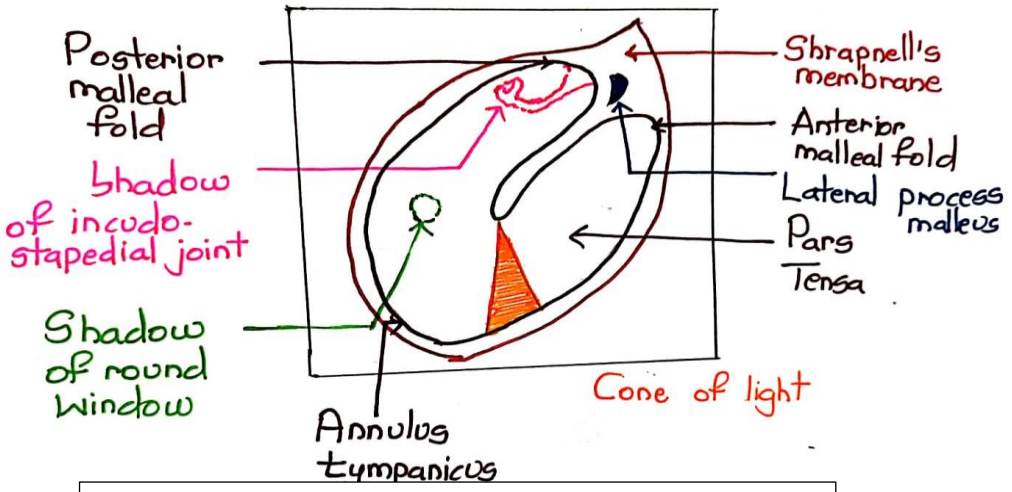


Diagram 6 showing anatomy of tympanic membrane.

i. It is situated over EAC medial end and forms TC lateral wall.

ii. Oval in shape, being broader above forms an angle of 55 degree with the floor of the meatus , and the light directed appears coned antero-inferiorly .

iii. It lies oblique.

iv. Dimensions: Postero-superior to antero-inferior is 9–10 mm, shortest diameter is 8–9 mm.

v. Semi- translucent, pearly white in color.

vi. Annulus runs centrally as ant and post malleolar folds , leaving a small, triangular region of TM above the MF within the notch of Rivinus, called the PF Sharpnell's membrane.

vii. Parts: PT and PF separated by anterior & posterior malleolar folds.

viii. The PT forms the rest of the tympanic membrane and is concave towards the ear canal.

ix. Layers of TM:

1- Outer epithelial layer.

2- Inner mucosal layer.

3- Middle, fibrous layer.

x. PF has less lamina propria.

xi. Average total area of TM- 70 to 80 mm2 .

xii. Average vibrating surface of TM 55mm2.

xiii. 0.1 mm thickness.

xiv. Umbo: It is the point of greatest curvature:

xv. Blood supply:

I. Deep auricular branch of the maxillary artery.

II. Ant tympanic branches of the maxillary artery.

III. The stylomastoid branch of the post auricular artery .

xvi. Venous drainage:

I. Outer surface: External jugular vein.

II. Venous plexus located around the ET.

xxi. Nerve supply:

I. Branches of the auriculo temporal nerve, vagus, gloosopharyngeal nerve

e. Roof:

i It separates the middle ear space from the middle cranial fossa.

ii. It is continuous with roof of the antrum .

iii. Both the petrous and squamous portions of the temporal bone form it.

iv. Petro-squamous suture line, can be an access for infection into the extradural space in children.

f. Floor :

i. It consists of compact bone that separates hypo-tympanum from jugular bulb.

ii. Its thickness can vary.

iii. Floor if not present , the jugular bulb is dehiscent.

g. Ossicles:

I. Malleus:

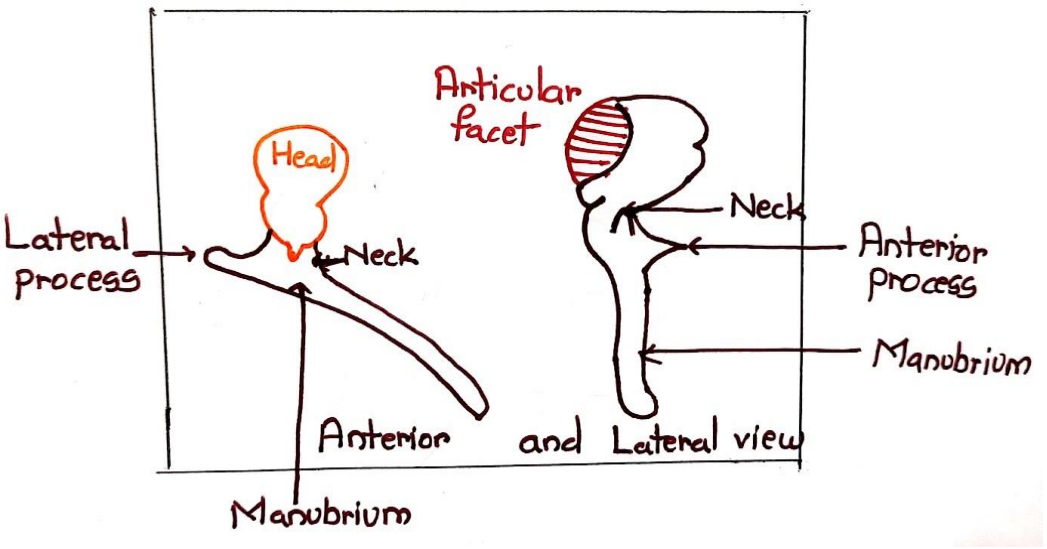


Diagram 7 depicting anatomy of malleus

- Largest ossicles.
- Measures- 9mm in length.
- Parts: Head, neck and handle or manubrium.
- Head:
- Lies in the epi-tympanum.
- It has a saddle-shaped facet on its postero-medial surface to articulate with the body of the I by a synovial joint.
- Neck:-
- It connects the handle with head.
- Below it is the lateral process, the anterior process and the handle.
- The lateral process is a prominent landmark on the tympanic membrane and receives anterior and posterior malleolar folds from TA.
- Its postero-medial has incudo -malleolar joint.
- The handle is embedded between the mucosal and fibrous layers of TM

II. Incus:

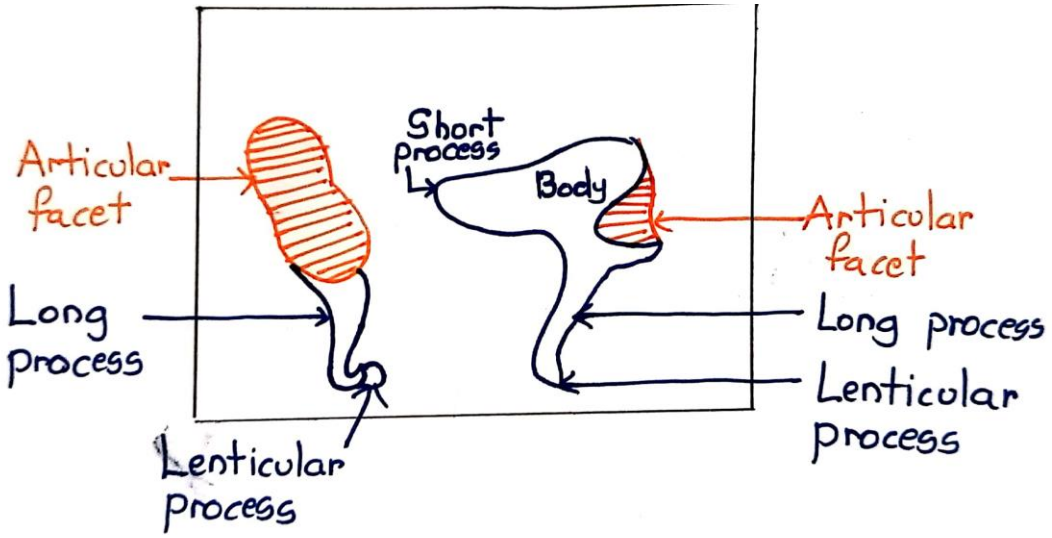


Diagram 8 Incus anatomy

- Parts: Body and two processes.
- Body lies in ETM with a cartilage covered facet for incudo-malleolar joint.
- Short process projects backwards to FI.
- Tip of long process – the lenticular process forms ball and socket joint with the S head.

III. Stapes:

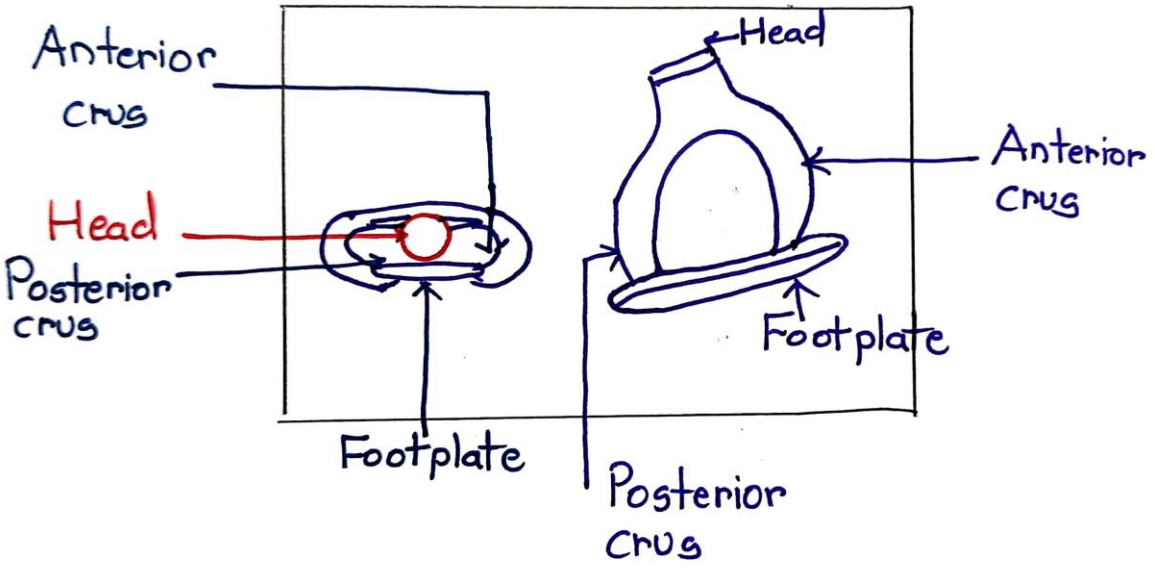


Diagram 9 showing Stapes anatomy

- Parts: Head, neck, two crura and a foot plate.
- Two crura arise from the neck, and join the foot plate which covers the OW.

h. Mastoid :

- It is a pyramidal bone within the petrous part of the temporal bone with its apex directed caudally.
- It contains mastoid air cell system.
- Lining epithelium :non- ciliated epithelium without goblet cells or mucus glands.

- Divided into three types : 1. Pneumatic: Cellular 85%.

  2. Diploic: Less cellularity.

  3. Sclerotic: Acellular 15%

i. Mastoid air cells:They are arranged in groups :

1. Mastoid antrum :

- Communicates with the middle ear by aditus.
- Aditus is a short canal connecting epitympanum with mastoid antrum.
- Floor- Short process of I.
- Medial wall- LSC.

  2 elevations: the bulge of the semi circular canal, and the 2nd genu of the FN.

- Roof- Forms the floor of middle cranial fossa.
- Base- Posterior belly of the digastric.

  The periosteum of the digastric groove on the undersurface of the mastoid bone continues anteriorly forms stylomastoid foramen and FN canal.

  Lateral wall: MacEwen's triangle (suprameatal triangle) that is formed by Temporal line of supra-mastoid crest, Postero- superior border of the EAC and a tangential line between them.

- Other air cells:

2.Sino-dural air cells :Between the dura of the roof and sigmoid sinus.

3. Tip cells : At the tip of the mastoid .

4. Retro-facial cells: Behind the facial nerve vertical segment .

5. Peri-sinus cells : Over sigmoid sinus .

6. Petrous Apex:

- It is shaped like a pyramid.
- Postero-medial surface is part of the posterior cranial fossa.
- Superiorly forms the floor of middle cranial fossa.
- Internal carotid artery and the internal auditory meatus run through the bony PA.

- Apex is by trigeminal nerve
- Accessory group:

o Squamous

o Zygomatic (arch of zygoma)

o Styloid

o Occipital

RELATIONS OF Middle Ear Cleft:

1. Temporal lobe of brain and meninges are above the antrum, aditus and epitympanum separated by tegmen plate.
2. Cerebellum is postero-medial to mastoid air cell.
3. Inner ear is medial to the antrum , aditus, tympanum.
4. Facial Nerve :-Its horizontal part runs downwards in the medial wall of the tympanum and horizontal semicircular canal runs postero-superior to it. Vertical part behind terminal.
5. 5 th &6th Cranial Nerve- lie close to the apex.
6. Jugular bulb at the floor.
7. ICA anterior to tympanum.
8. Lateral sinus: posterior to mastoid cells .

Physiology of Hearing and Impedance matching:

Sound is vibratory energy that is transmitted from the source through surrounding medium in the form of pressure waves.

Sound signals are collected by pinna and are transmitted to tympanic membrane.

The vibrations are transmitted to the ossicular chain and stimulate the footplate of stapes.

This leads to pressure changes in labyrinthine fluids and movement of basilar membrane.

Owing to this hair cells in organ of Corti are stimulated conducting impulses in auditory nerve.[9]

Impedance matching:

Sound waves when propagate from air medium to liquid, majority of the energy is lost.

But this is prevented by the compensatory mechanism by middle ear via:

1. Hydraulic action of tympanic membrane-

   Effective vibratory area of tympanic membrane= 55 mm2

   Foot plate area= 3.2 mm2.

   Areal ratio= 17

2. Lever action of ossicles.

   Handle of malleus is 1.3 times longer than long process of incus.

   Product of areal and lever ratio is 22.1.

3. Curved membrane effect.

   Movements of tympanic membrane are more at the periphery than at the centre.

Definition of Chronic Otitis Media:

Chronic otitis media is chronic inflammation of middle ear and mastoid mucosa, with recurrent discharge for at least 2 weeks through a chronic perforation of the tympanic membrane.[11,12]

It can be distinguished on histopathology by middle ear pathologies like granulation tissue, cholesterol granulomas or cholesteatoma formation.

Chronic otitis media is the long term sequelae of acute otitis media or otitis media with effusion.

It is multifactorial in nature, caused by involvement of innate immunity (TLR, cytokines, surfactant), adaptive immunity (Ig), non-specific immunity (epithelial barriers and mucin production), inflammatory regulation, craniofacial abnormalities and genetic predisposition.

Types of Chronic Otitis Media:

1. COM inactive mucosal (dry perforation):

   PT perforation but middle ear mucosa and mastoid are not inflamed

2. COM active mucosal (perforation with otorrhoea):

a. Infection of middle ear mucosa and mastoid with oedema, submucosal fibrosis, hyper-vascularity and an inflammatory cells.
b. These includes lymphocytes, plasma cells, histocytes, goblet cells and basal cell hyperplasia in the middle ear epithelium.

c. Granulation tissues if present **are** referred as ‘aural polyps’ that protrude through perforated TM.

d. It is often that there is destruction of the ossicular chain.

e. The affected ossicles appear like areas of hyperemia with proliferation of capillaries and prominent granulation tissue.

f. The order of frequency of involvement is long process of the I> S crura> body of I> manubrium of I.

g. Bone resorption occurs by osteoclastic activity due to bone-modelling

3. Inactive squamous epithelial COM (retraction, atelectasis and epidermization):

a. Static negative middle ear pressure results in retraction of the TM.

b. A retraction pocket is an invagination of TM into the middle ear space that may be fixed or free depending on the state of inflammation of the middle ear.

c. Epidermization is an advanced type of retraction wherein there is replacement of the middle ear mucosa by keratinizing squamous epithelium without keratin debris.

4. Active squamous epithelial COM (acquired cholesteatoma):

a. Muller J coined Cholesteatoma.

b. Cholesteatoma is a benign keratinizing epithelial lined cystic structure found in the middle ear and mastoid.

c. It destroys vital structures like ossicular chain and otic capsule.

d. Complications like hearing loss, vestibular dysfunction, facial paralysis and intracranial disease or infection may occur.

e. Cholesteatoma may be defined as presence of a squamous epithelial packet or sac filled with keratin debris within the middle ear cleft. Types:

1. Congenital cholesteatoma:

   It is an epithelial cyst occurring within one of the temporal bone without in contact with the external ear.

2. Primary acquired cholesteatoma:

   It develops in PF of the TM.

   It involves Prussack's space and occupies attic, mastoid antrum and portions of the middle ear.

3. Secondary acquired cholesteatoma:

   It follows an active middle ear infection wherein the keratinizing epithelium has migrated through a perforation into middle ear.

PATHOGENESIS OF CHOLESTEATOMA:

Cholesteatoma is a cystic lesion formed from keratinizing stratified squamous epithelium, the matrix of which is composed of epithelium that rests on a stroma of varying thickness, the peri-matrix.

In 1683, Duverney published the first description of cholesteatoma.[13]

He described cholesteatoma as an abscess of the bone originating from the auditory canal that opened behind the auricle, forming a fistula above the mastoid process, shedding the small sheets composed referred as scales.[13]

In 1855, Virchow classified it as squamous cell carcinoma and atheroma.

Von Troeltsch considered it to be epidermal in origin.

Many theories have been proposed, but none as yet has been shown to be entirely causative in this disease

1. Habermann (1889) : Migration of stratified squamous epithelium from the skin of meatus through a perforation into the middle ear leading to the development of a secondary acquired keratoma.
2. Bezold (1908) : Attic retraction type of keratoma due to Eustachian tube occlusion causing retraction of Shrapnell's membrane into Prussak's space and then in the attic.
3. Wittmack (1933): Persistence of hyperplastic embryonic muco-periosteum in the attic causes adhesions forming retraction pockets.

   As the pocket deepens, desquamated keratin fails to get cleared from the recess and cholesteatoma formation occurs.
4. Ruedi (1963) : Reported two predisposing factors to develop acquired keratoma.
   i) Special growth potential of basal cells in stratum germinativum in the zone of meatal skin adjoining the upper margin of tympanic membrane.
   ii) Submucous connective tissue layer in middle ear spaces associated with incomplete pneumatization of preformed spaces.
5. Wendt (1873): Theorized that simple squamous or cuboidal epithelium of middle ear cleft can undergo a metaplastic transformation into keratinizing epithelium.
6. Sade (1971): Supported Wendt theory, stating that epithelial cells are pleuripotent and can be stimulated by inflammation to become keratinizing.

COMPLICATIONS OF COM AND CHOLESTEATOMA:

Extratemporal (extracranial) complications

1.Subperiosteal abscess

It is the most common extratemporal complication that occurs with COM.

This abscess occurs over the mastoid cortex and extends into the subperiosteal space.[14]

2.Bezold's abscess

A Bezold's abscess is a cervical abscess that develops from pathology similar to subperiosteal abscess.

The mastoid cortex is violated at its tip, as opposed to its lateral cortices, an abscess will develop in the neck, deep to the sternocleidomastoid, causing mastoid vein phlebitis.[15]

Intratemporal (extracranial) complications

1.Labyrinthine fistulae

It continues to be the most common complications of chronic otitis media with cholesteatoma, and have reported in approximate 7% of cases. [16-18]

2.Petrous apicitis

The petrous apex comprises the anterior, medial portion of the temporal bone, and is reported to be pneumatized in 30% of individuals.[14]

3.Facial paralysis

Otogenic causes of facial nerve paralysis include AOM, COM without cholesteatoma, and cholesteatoma carrying worst prognosis.[14]

4.Coalescent mastoiditis:

It is mucosal thickening or effusion as a result of AOM, COM appreciated on CT.

Intracranial complications

1.Meningitis:

Although this remains a significant complication, the mortality rate from otitic meningitis has declined significantly. from 35% in the preantibiotic era to 5% in the postantibiotic era.[19]

Meningitis can arise from three distinct otogenic routes:

A. Hematogenous seeding of the meninges and subarachnoid space,
B. Spread from the middle car or mastoid
C. Through bony erosion and direct extension. [14]

2. Brain abscess

It is the second most common intracranial complication of otitis media but is the most lethal.

The clinical progression is seen in three named stages: Encephalitic stage, Quiescent, or latent stage and final stage characterized by abscess rupture.[14]

3.Lateral sinus thrombosis

It is a well-known complication of otitis media that compromises 17% to 19% of intracranial complications.[20]

4.Otitic hydrocephalus

It is described as signs and symptoms indicative of increased intracranial pressure with normal CSF studies on lumbar puncture,

It is a misnomer because this condition can be found in the absence of otitis, and patients do not have dilated ventricles indicative of true hydrocephalus.

Symonds, who coined the term otitic hydrocephalus, felt that this condition developed from infection of the lateral sinus, with extension of thrombophlebitis into the confluence of sinuses to involve the superior sagittal sinus.[21]

Inflammation of the superior sagittal sinus prevents CSF absorption through the arachnoid villi, resulting in increased intracranial pressure.

This infectious thrombophlebitis usually occurs as a result of otologic infection, but multiple cases have been described in the absence of otitis or otologic surgery.

5.Epidural abscess:

It develops from bony destruction by cholesteatoma.

Signs and symptoms overlap COM.

It is usually an incidental finding on CT.

ROLE OF HRCT TEMPORAL BONE:

With the advent of helical scanning techniques, CT is widely accepted choice for imagining studies for the definitive preoperative bone imagining.[22]

Improvements in the high-resolution CT (HRCT) and advancements in radiological techniques have bettered the studies of temporal bone in patients with COM.[23]

HRCT is noninvasive technique which can help to get the details of presence, location, and extent of disease also, it may prove useful in suspicion of birth anomalies and in subjects with a previous surgery leading to loss of surgical landmarks.[22,23]

HRCT is a golden tool in patients with otitis media while evaluation of ossicular chain, the tympanic and mastoid bony wall.[22,23]

HRCT is of useful diagnostic assistance as noninvasive and relatively inexpensive tool prior to actual surgical procedure. [23]

Further, it is also valuable and knows details of the extent of disease, the presence of anatomical variations and to predict potential complications.[23]

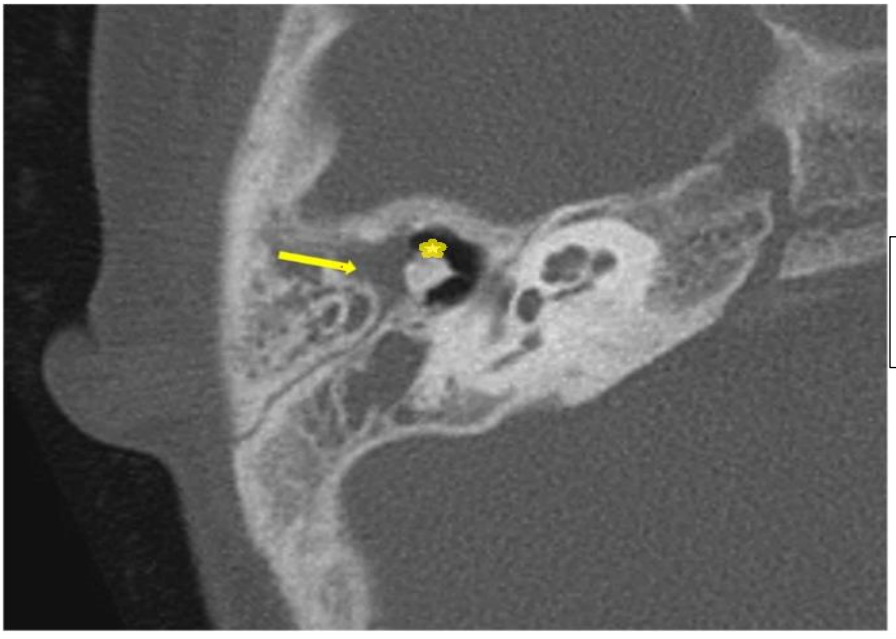


Figure 10 showing HRCT depicting cholesteatoma.

Purpose of HRCT:

Pneumatization of mastoid.

Extent of disease.

Tegmen erosion.

Sinus plate erosion.

Facial canal dehiscence.

Lateral semi circular canal dehiscence

Ossicular presence.

Disease of middle ear cleft.

Drawbacks of HRCT:

Cannot differentiate between granulation tissue and polyps.

Radiation exposure.

The presence of cholesteatoma can only be made at the time of surgery; prior radiological investigations may influence the decision and duration of exploration in a positive way.

Therefore, CT findings enable the surgeon to be informed of the risk factors and to be prepared for the possibility of upcoming complication.[22,23]

ROLE OF PURE TONE AUDIOMETRY:

Sound is produced by pressure variations created by the vibrating objects, that are transmitted by air.

In COM, due to the perforation in the TM and erosion of the ossicular chain, there is

defective middle ear function leading to hearing loss.

Human ear can perceive sound between 20 to 20,000 Hz.

Most of the sound waves range between 500 to 4000 Hz, and the normal conversation is in between 45 and 60 Db.

USES:

PTA helps us to identify hearing thresholds of an individual based on volume and pitch of the sound waves.[9]

It is a sensible investigation in assessing hearing loss and integrity of ossicular system in patients of COM.

It is an important screening and diagnostic tool to assess the degree of reduced hearing.

When AC and BC are less than 15, with ABG <10 dB , it is considered as normal hearing.

AC> 15 dB and BC <15 dB, ABG >10 dB , indicates conductive hearing loss.

AC> 15 dB and BC >15 dB, ABG < 10 dB , indicates sensorineural hearing loss.

AC> 15 dB and BC> 15 dB, ABG > 10 dB, indicates mixed hearing loss.

Degree of hearing loss (Modified Goodsman Classification) [24]

Normal Hearing	10 to 15 dB
Minimal hearing loss	16 to 20 dB
Mild hearing loss	26 to 40 dB
Moderate hearing loss	41 to 55 dB
Moderately severe hearing loss	61 to 70 dB
Severe hearing loss	71 to 90 dB
Profound hearing loss	>90 dB

Table 1 showing hearing loss degree by Modified Goodsman Classification

WHO CLASSIFICATION (2021)[24]:

Normal hearing 0 to 25 dB.

Mild hearing loss 26 to 40 dB.

Moderate hearing loss 41 to 55 dB.

Moderately severe hearing loss 56 to 70 dB.

Severe hearing loss 71 to 90 dB.

Profound hearing loss > 90 dB.

It also helps in early diagnosis and proper planning for surgery to repair the defect in the tympanic membrane and to improve the quality of life.

History of Mastoidectomy:

Mastoid surgeries have an astonishing and interesting history.

Galen (130-200 AD) proposed drainage from an infected ear.[25,26]

Politzer A removed diseased bone by addressing post aural route .[25-29]

The first attempt was done by Pare A a French physician mentioned draining of an infected ear by a surgery in the sixteenth century.[30,31]

Riolanus J the younger an anatomist and dissector at Paris documented recommendation of trephining the mastoid bone.[32]

Jean Louis Petit , in 18th century a French surgeon developed a successful technique to operate mastoid in view of evacuating pus.

Sir William Wilde from Ireland popularized the post auricular incision and still bears his name used world wild for eradicating disease from mastoid cavity.[33]

In 1873, Schwartze H and Eysell A published an article outlining the surgical opening of mastoid.[34]

Later, Schwartz mastoidectomy was performed to connect mastoid and tympanic cavity.
In certain situations, simple mastoidectomy was not sufficient hence Kuster E and Bergmann VE both developed Radical mastoidectomy leading to conversion of attic, antrum, middle ear and EAC into a single larger cavity.[35]

Emanual Zaufal removed of EAC posterior wall.

Tide soon turned towards conservative canal wall procedures due to intowards complications.

In 1910, Gustave Bondy suggested a technique today popular as modified radical mastoidectomy.[36]

This procedure intended to preserve pars tensa and ossicles by exteriorizing disease restricted to attic and antrum.[36]

Zeiss otologic operating scope in 1953 made dissection possible.

Wullstein made the first attempt to reconstruct TM via tympanoplasty.[37]

Intact canal wall mastoidectomy was first done by William House.[38]

DEFINITIONS AND CLASSIFICATIONS OF MASTOIDECTOMY

Simple Mastoidectomy:

It involves removal of mastoid cortex and underlying air cells.

Usually done in cases sub-periosteal abscess.

Intact Canal Wall Mastoidectomy:

It involves removal of air cells lateral to FN and otic capsule bone sparing the superior and posterior external auditory canal walls.

It affords to access epitympanum and maintains barrier between EAC and mastoid cavity.

Along with facial recess approach, it is useful for facial nerve repair.

Radical Mastoidectomy:

It involves the middle ear and mastoid converted into a single cavity with no attempt of reconstruction.

Atticotomy (Epitympanotomy)

Opening of the attic, performed via trans meatal route.

Lateral wall of the attic is drilled.

Atticoantrotomy

It is an extension of the atticotomy in a posterior direction through the trans-meatal route.

The lateral attic and the aditus walls are removed and the antrum is entered.

The postero-superior bony EAC wall is removed and the access to the antrum is gradually widened.

Bondy's Operation

An attico-antrotomy is described as Bondy's operation if the TC is not entered.

The lateral part of the cholesteatoma matrix removed and the medial part is left in place marsupializing the cholesteatoma.

Approaches and Routes

2 most frequently used approaches are the retro-auricular and end-aural ones and the common routes are the trans-cortical and trans-meatal.

End-aural approach

In this approach the instruments pass through the lateral part of the EAC, which remain intact during the surgery, but has to be stretched by an ear speculum.

Retro-auricular approach

Incision made behind the auricle, which is pulled anteriorly and the surgery takes place initially behind the auricle.

The exposure is generally wider.

Trans-cortical route (outside-in route)

It starts on the surface of the cortical bone of the mastoid process behind the bony ear canal which can remain intact either temporarily or permanently.

Trans-meatal route(inside-out route)

The trans-meatal(trans-canal) route for drilling starts in the bone of the ear canal, either laterally or medially.

Intact Canal Wall AND CWDM:

Depends on preservation of posterior wall.

Sub-classification of or synonyms for canal wall down mastoidectomy techniques are: Atticotomy, Bondy's operation, atticoantrostomy, classical radical operation, retrograde mastoidectomy and several variations of intact bridge techniques by Paparella and Jung.

Sub-classification of canal wall up techniques are:

Simple mastoidectomy, cortical mastoidectomy, classic intact canal wall mastoidectomy, combined approach tympanoplasty or modifications of these canal wall up techniques.

Open technique:

Cavity may be open, neither obliterated nor with reconstruction.

Exposed bone is simply covered with fascia or skin.

Closed technique:

Cavity can be partly or totally obliterated or the ear canal partly or totally reconstructed.

CWDM:

This is defined as removal the posterior bony canal wall thus making the entire mastoid antrum and the middle ear into a single cavity.

There are several modifications depending on the preservation or partial preservation of the bony bridge, resulting in intact bridge techniques.

OSSICULOPLASTY:

There are various surgical techniques to treat pathologies affecting the middle ear that help to remove disease but preserves normal hearing function.

Various insults in the form of injury, cancer, inflammation, and cholesteatomas destroys and changes the normal middle ear and hender transmission of sound energy to the internal ear.

For ossiculoplasty there are two types ie natural and synthetic materials.

NATURAL PROSTHESIS:

Jansen C Uber used cartilage to repair ossicles.[39]

They have good results but had issues like maintainence for surgery and the transmission of HIV, Creutzfeldt- Jacob disease.

Some studies suggests homo-graft materials may be involve MEC , making them more difficult to remove while re- surgery in comparison to allo-grafts.[40]

SYNTHETIC PROSTHESIS:

Wullstein H used an artificial material in ossiculoplasty.

It was kept between the TM graft and the S footplate.

Since then a large number of agents used, but majorly abandoned.[41,42]

Goldenberg RA. Emmet JR showed an increasing trend in the use of prostheses for ossiculoplasty.[43]

Hydroxyl-apatite (HA) :

It is a calcium phosphate bio-ceramic that is similar to the mineral matrix of bone.

This material has good biocompatibility properties.

It does not need cartilage as needed in plastipore and titanium implants.

Grote used the first HA implant for ossiculoplasty.[44]

Later, HA was found to be efficient, biocompatible, stable.[45,46]

Occurrence of extrusion observed is 4% to 16%.[47,48]

Interposition of cartilage between the implant and tympanic membrane has shown to decrease extrusion rate.[49]

The hearing success rates ABG $\leq$20 dB.

TITANIUM:

It was proposed by Branemark in the 1970s.

It is superior to HA in manufacturing of different shapes and sizes.

Cartilage must be placed between the TM and the prosthesis to prevent extrusion.

Low extrusion rates, ranging from 1% to 2% .[50-52]

BONE CEMENT OSSICULOPLASTY:

Distal erosion of the incus with an intact stapes super-structure represents a challenge to reconstruct.

It is used in reconstructing the incudo-stapedial interface.

It is not a novel material in surgery or otology.

Useful to reconstruct cranium, tegmen, EAC, and craniofacial defects.

There are a number of different types of bone cements used for ossiculoplasty including Dahllite , HA, and glass ionomeric.[53,54]

Glass ionomeric preparations (eg, OtoCem: Oto-Tech. Raleigh, North Carolina) have good initial hearing results but are associated with unfavorable toxicity and biocompatibility profile.

Gel-foam protects areas surrounding the reconstruction, especially the footplate, during application.

No extrusions have been reported.

Good hearing results have shown an ABG closure of 20 dB or better.[54]

Requirements for Ossiculoplasty:

Presence of normal middle ear mucosa.

Patent Eustachian tube.

Mobile foot plate.

Myringostapedopexy / short columella:

Absence of incus with presence of stapes supra structure irrespective of malleus handle.

Assembly can be done via malleus stapes assembly using original malleus or neo malleus, tympanic membrane to stapes assembly.

Usually performed using allogenic septal spur cartilage or autogenic incus.

Myringoplatinopexy:

1. Absence of stapes supra structure and incus with or without malleus.

2. Assembly can be done by malleus footplate using neo malleus, tympanic membrane to footplate assembly and Wullstein type 4 tympanoplasty.

3. Usually performed using allogenic septal spur cartilage.

Austin's Classification:

Group A – Malleus and stapes present.

Group B- Malleus and footplate of stapes present.

Group C – Malleus absent , stapes present.

Group D- Malleus and stapes supra structure absent.

TYMPANOPLASTY: .

It can be defined as the surgical repair of the tympanic membrane.[55]

In the majority cases the damage is due to a persisting perforation but there are conditions where a thin or retracted drum may need to be reinforced or repaired.

Wullstein in 1956, classified tympanoplasty with myringoplasty as a Type I tympanoplasty.[12]

In ancient times, artificial animal-based plugs were used to cover perforated tympanic membranes that served the purpose of keeping the ear dry hence preventing infections.[12]

Yearsley described an artificial eardrum consisting of moistened cotton wool which was inserted into the perforation and plugged in, providing improvement in hearing.[12]

Toynbee described an artificial eardrum to be comprising of a gutta percha disc and a silver wire.

William Wilde and Roosa were advocating the use of cautery to the remnant tympanic membrane to encourage healing.

Blake first described the paper patch in repairing the perforation and showed improvement in

hearing in 1887.

In 1950s, Wullstein's graft and Zollner's graft showed higher rates of successful repair (71%) of tympanic membrane.[56]

Using skin grafts was associated with a high rates of re perforation, inflammation and cholesteatoma formation.[57]

Simultaneous contribution by great workers like Wullstein, Heerman the list of eligible grafting materials includes perichondrium, cartilage, periosteum, fat, subcutaneous tissue, amniotic membrane, dermal matrix, fibroblasts, animal pericardium and sclera.

ETIOPATHOGENESIS:

1. Infections:

   Common cause is perforation by an episode of acute otitis media.

   Spontaneous healing seen in 70- 80% cases within 30 days.[58,59]

2. Trauma:

   A direct blow to the ear can result in rupture of the tympanic membrane.

   There can be an isolated injury, can be associated with fractures of the temporal bone and damage to middle ear.

   Barotrauma due to air pressure changes with air travel or water pressure and direct trauma with a cotton bud.

3. Iatrogenic:

   It results following extrusion of a ventilating tube (VT) .

   The risk of a chronic perforation in short-term VT is 2.2%, while in long-term VTs increasing the risk to 16.6 %.[60]

4. Symptoms:

   Ear discharge: Most frequently sought problem.

   Can be mucoid or mucopurulent.

   Common organisms include Pseudomonas, Staphylococcus aureus and Moraxella.[61]

   Hearing loss: Depends on size and location of perforation

   Larger defects can cause moderate conductive hearing loss (CHL) by loss of surface area available to absorb sound energy.

   Perforations tend to affect the lower frequencies.

- GRAFTING MATERIALS:

  In 1878 following Berthed's usage of full thickness skin graft many grafts have been tried.[62,63]

  Although there are many allogenic, autologous and heterologous materials none of them has proved ideal.[64]

  Temporalis fascia is the most frequently utilized for all perforations given its availability, the abundance of tissue and ease of use.

  Success rates (77–99% in adults) and (35–94% in children) are quoted, depending on

experience and technique, though multiple other factors may be influential.[65,66]

It is easily harvested via a post auricular or end-aural approach, a separate scalp incision, hidden in the hairline.

Cartilage, from the tragus or concha, is also reliable material.

A composite graft from tragus provides good thickness and curvature for use in tympanoplasty and a very low metabolic rate.[67]

Fashioning butterfly shaped cartilage has been proposed for smaller perforations less than 6 mm, with the cartilage disc being circumferentially incised by 1 mm showed effective results in 94% cases.[68]

Hearing gain obtained with cartilage is inferior to that of fascia or other more flexible material.[67,68]

TECHNIQUE:

There are two main techniques mainly Over-lay and under-lay.

But there is no difference in uptake of graft by the two techniques.[69]

Controversies exists in underlay technique in regards to placement of graft owing to medialized handle of malleus.

Graft should pass under the malleus though, with a subtotal or central perforation with an exposed umbo, some advise a small hole in the centre of the graft through which the umbo can pass to try to prevent the 1.4% risk of graft lateralization.[70]

TYPES[12]:

Type I	Repair of tympanic membrane without altering ossicular chain.
Type II	Repair of ossicular chain with restoration of lever mechanism.
Type III	Repair of ossicular chain by placing graft from the stapes capitulum to tympanic membrane.
Type III	Repair of ossicular chain using a single graft interposed between mobile footplate and tympanic membrane.
Type III	Repair of ossicular chain by placing graft over capitulum of stapes.
Type IV	Mobile stapes footplate , graft placed over round window.
Type Va	Fenestration of lateral semi circular canal so as to bypass ankylosed footplate.
Type Vb	Stapes footplate removed and oval window is sealed by tissue graft.

COMPLICATIONS:

Re perforation, retraction of drum head, anterior blunting by antero inferior raising of flap with both techniques.[69]

Iatrogenic cholesteatoma and myringitis are also reported to occur.[70,71]

MASTOID CAVITY OBLITERATION:

Mosher obliterated large mastoid bowls to promote healing. [72]

Development of a variety of techniques of obliteration has been witnessed.

The vast majority of obliteration techniques consist of :

a. Local flaps (Palva's flap, temporalis muscle, temporo-parietal flap, superiorly based musculo-periosteal flap)
b. Free grafts (bone, cartilage, hydroxyapatite,) .

Mosher's original description was that of a superiorly based post-auricular soft tissue flap.

Kisch used a pedicled TMF later popularised by Rambo .[73,74]

Popper proposed periosteal flap to line the cavity.[75]

Palva modified Popper's flap as a musculo-periosteal flap. [76]

Palva used bone chips and bone pate in combination with a musculo-periosteal flap. [77]

In addition, other materials were also studied.[78-82]

Indications:

1. CWDM for COM (to reduce vertigo).[83]
2. Trans-labyrinthine approach.
3. CSF leak.[84]
4. Malignancies of the temporal bone.

5. Defect created by lateral, subtotal, or total temporal bone resection require pedicled flaps.[85]
6. Cochlear implantation requires tympano mastoid obliteration as a result of removing posterior wall .[86-88]
7. Non serviceable ear.

Contra indications:

1. Cholesteatoma.

Moffat and colleagues used bone pate and a superiorly based temporalis musculoperiosteal flap for mastoid obliteration.[89]

Some author advocate performing the mastoid obliteration for canal wall-up mastoidectomy in an attempt to prevent retraction pockets and recurrent cholesteatoma.[90,91]

Montandon and colleagues used cartilage to block the aditus and an abdominal fat graft for the canal wall-up mastoidectomy cavity.[90]

Gantz and colleagues described canal wall reconstruction with mastoid obliteration.[92]

This technique consisted of removal of the posterior bony canal wall with a micro-sagittal saw.[93]

The mastoid cavity is obliterated with bone pate and bone chips followed by replacing the posterior canal wall segment.

East and colleagues and Cheney and colleagues describe the successful use of this robust flap

(TPFF) for mastoid obliteration.[93,94]

TPFF provides an excellent option when standard pedicled muscle or periosteal flaps are unavailable as in revision cases with scar tissue or in patients with previous irradiation.

Hartwein and colleagues used hydroxyapatite to obliterate the mastoid bowl while reconstructing the posterior canal wall with autologous conchal cartilage.[95]

Yung and colleagues describe 34 cases of mastoid obliteration using hydroxyapatite granules and an inferiorly based periosteal flap.[96]

Proponents for using synthetic materials like hydroxyapatite point out the minimal resorption of these materials over time.[97]

Mahendran and colleague used hydroxyapatite cement for mastoid obliteration.[98]

In their series, however. there was a significant 50% incidence of post operative infections requiring revision surgery and removal of the foreign material.[98]

- Total tympanomastoid obliteration.

It consists of obliteration of the entire MEC.

Rambo obliterated with TMF followed by suturing shut the EAC.

Histopathology

Palva first described the histopathologic fate of tissues used in mastoid obliteration.[100]

Linthicum studied 17 temporal bones that had undergone mastoid obliteration with a variety of techniques.[99]

Bone pate with a Palva type musculo-periosteal flap provided the best obliteration of a mastoid cavity.

Relevant studies:

Tawalbeh M et al used periosteal peri cranial flap in 64 patients and had overall success of 82.8%.[101]

Yamamoto Y et al reported 118 cases, where bone pate was used as an obliterating agent and had a success rate of 95.8%.[103]

Cal J LF obliterated with bioactive glass and found that SSI was 4.5%.[113]

Senugupta A concluded that average air bone was 5.2 dB following canal wall down mastoidectomy with ossicular reconstruction.[114]

Krol B, Cywka B K, Skarzynski H P did a pilot study on 11 patients using S53P4 as an obliterating agent and noted no audiological improvement.[115]

Mohammad Farmarzi MD et al used silicone blocks to fill the large cavities and found the necessity to implicate anti fungal ear drops to achieve healthy cavity.[116]

Platelet rich plasma was used as an obliterating agent by Sherif M Askar , Ibrahim M Saber, Mohammad Omar in 21 cases reported 85% success.[117]

MATERIALS

AND

METHODS

MATERIALS AND METHODS

SOURCE OF DATA :

All patients undergoing canal wall down mastoidectomy for chronic otitis media, squamous disease in the Department of Otorhinolaryngology , R.L Jalappa Hospital & Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar from January 2021 to August 2022.

TYPE OF STUDY:

Prospective observational study

Sample size: **: 30 patients**

Based on average Air- Bone Gap pre and post operative as reported in the study. The study reported an average variance estimate sigma(∑)= 10.8^2 standard deviation. To detect a reduction by 22% in Air Bone Gap post operative with the powerof 80% and alpha(α)= 5%estimated sample size is 28 cases. Presuming a drop out rate of 5-10% during study. Final sample size is estimated as 30 cases.

- The outcome variable is continuous.
- The sampling distribution of the sample observation is approximately normal.
- The observations are paired.

Formula

$$N_{pairs} = \frac{\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\Delta^2} + \frac{z^2_{1-\alpha/2}}{2}$$

$$\Delta = \frac{(\mu_2 - \mu_1)}{\sigma} \qquad \sigma = \frac{\sigma_1 + \sigma_2}{2}$$

Where,

μ_1 : Pre-test mean

μ_2 : Post-test mean

σ_1 : Standard deviation in the pre-test

σ_2 : Standard deviation in the post-test

Δ : Effect size

α : Significance level

$1-\beta$: Power

INCLUSION CRITERIA :

1. Patients with COM squamous disease where certainty of complete extirpation of disease is warranted.
2. Patients with COM with extensive Granulation tissues.
3. Recurrent cases of Cholesteatoma.

EXCLUSION CRITERIA :

1. Patients with inadequate Post- auricular soft tissue in revision cases.
2. Patients with Intra- Cranial Complications of chronic otitis media.

METHOD OF COLLECTION OF DATA

- Patients undergoing CWDM after fulfilling the inclusion criteria and exclusion criteria were taken up for the study .
- A detailed written informed consent was taken prior to the procedure.
- A thorough detailed clinical history was noted and patient underwent detailed ENT examination.
- All patients were subjected to general physical examination, as a part of which vitals, systemic examination and otological examination were performed.
- A detailed otological examination was performed under microscope to look for the condition of external auditory canal, presence of retraction pockets and perforations of tympanic membrane, middle ear status, cholesteatoma , granulation tissues and other features like aural polyp, keratosis.

- High Resolution Computed Tomography Temporal bone was performed in all patients pre operatively to know the mastoid status, ossicular presence, cholesteatoma, granulation tissue extent, polyp if present to delineate the lesion.

- All patients were subjected to Pure Tone Audiometry, to quantify hearing loss and to know the type of hearing loss.

- Based on the audiogram, Air Bone gap was evaluated by taking an average of all frequencies at 0.5, 1 , 2 and 4 kHz.

- Complete blood count (CBC), Renal function test (RFT), Serum Electrolytes, Coagulation profile, Electrocardiogram(ECG), Chest X-Ray (CXR), were done as a part of pre anesthetic evaluation work up in all patients.

- Intra operative findings were documented and radiological findings HRCT were confirmed.

- **Surgical technique:**

Following induction of general anesthesia, under strict aseptic precautions, patient positioned parts painted and draped with diseased ear turned upwards..

Figure 11 Positioning of patient after painting and draping

External auditory canal wash was instilled with lignocaine 4% 10 minutes prior to the onset of surgery.

Local anesthesia infiltration with a combination of 15 ml Lignocaine 2% premix diluted with normal saline was administered over tragus and post auricular groove.

Figure 12 Infiltration administered over post auricular area

Canal infiltration given at 3, 6, 9 and 12 O' clock position over bony cartilaginous junction until entire skin blanches.

Figure 13 Canal infiltration

Canal wash was given with Lignocaine 4% and povidone iodine.

Figure 14 canal wash with lignocaine 4% and povidone iodine.

Canal incision was taken from 6'o clock to 12'o clock position , 5mm from the fibrous annulus.

Posterior meatal skin was elevated upto bony cartilaginous junction.

William Wilde post aural incision taken from the helix to the mastoid tip.

Figure 15 Post aural incision.

Temporalis fascia graft harvested via hydro dissection. .

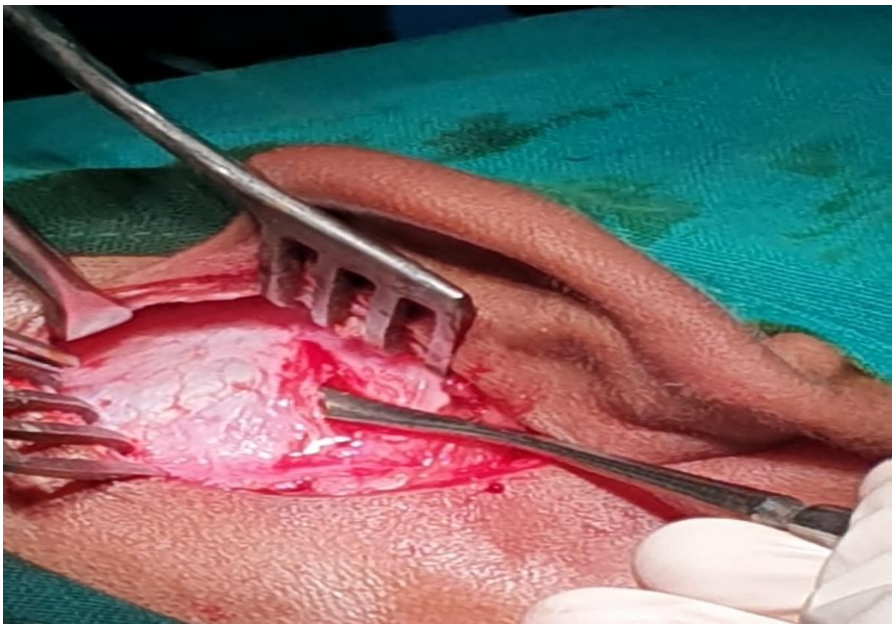


Figure 16 Harvesting temporalis fascia graft.

Margins of perforation were freshened.

Tympano meatal flap was raised:

Perisoteum was elevated over mastoid using Parabeuff's peri osteal retractor

Figure 17 Elevation of musculo periosteum

Cortical mastoidectomy was performed demarcating tegmen plate (superiorly), posterior bony canal wall (anteriorly), sinus plate (posteriorly) and digastric ridge (inferiorly) .

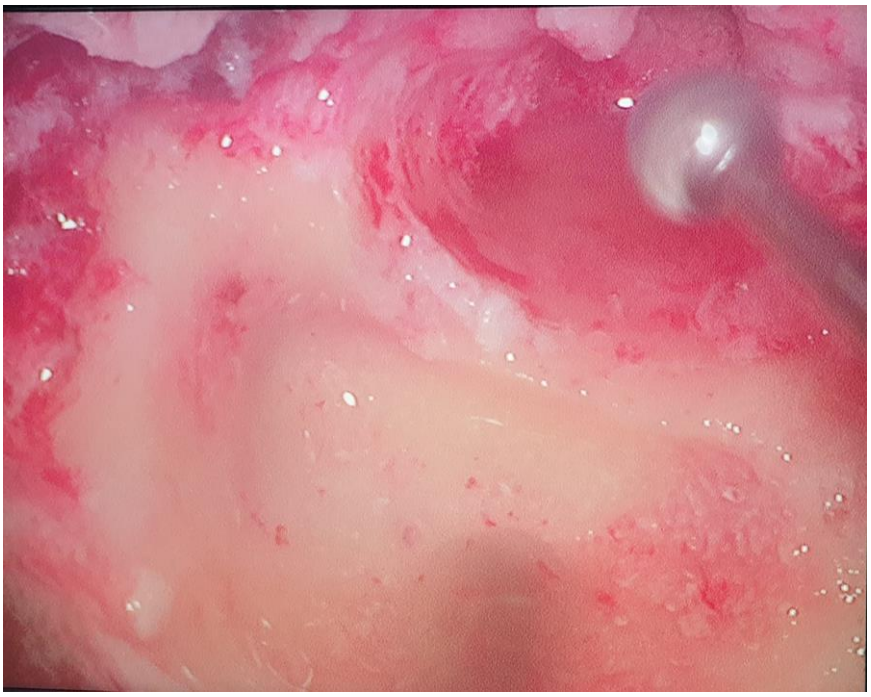


Figure 18 Cortical mastoidectomy

Mastoid antrum was identified superior to spine of Henle. It was found to be involved with the disease process, and was checked for the areas that were involved with disease. Simultaneously elevation of cholesteatoma sac performed.

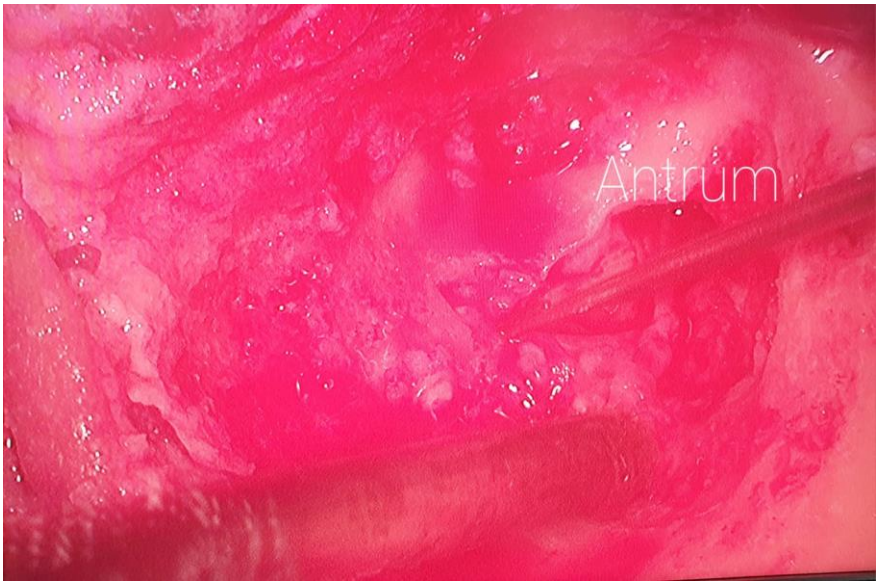


Figure 19 Identification of antrum

After identifying lateral semi circular canal, antrum examined and before reduction posterior canal wall was taken down. Status of incudo stapedal joint noted if intact, incus was dislocated following which the ridge was reduced and bridge was removed. Drilling was done till anterior and posterior buttress to have uniform cavity. The floor of ridge is reduced till bony external canal and floor of EAC was made in line with mastoid.

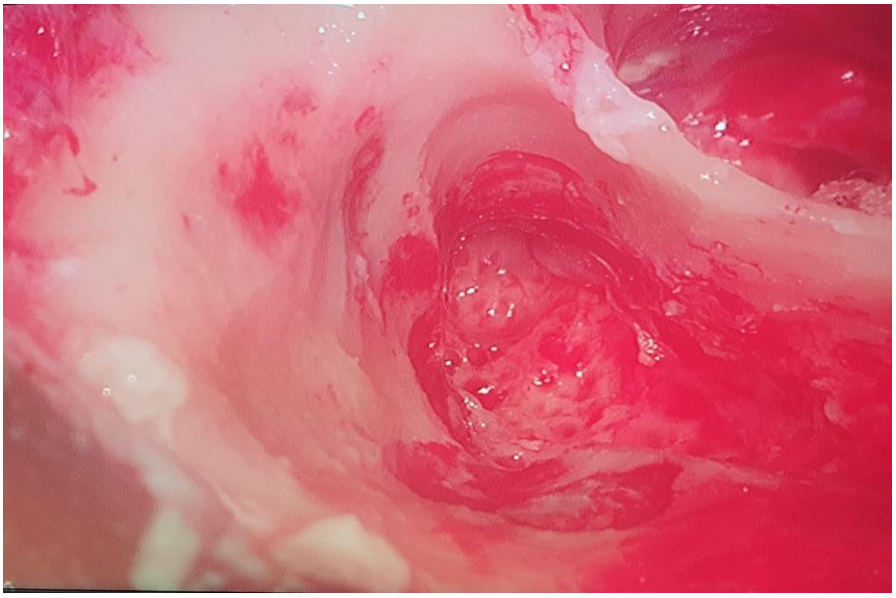


Figure 20 Procedure of CWDM.

Bridge was removed and ridge was lowered.

Figure 21 bridge broken, ridge reduced

Canal incision taken at 6'o and 12'o clock position and tympanomeatal flap raised Cholesteatoma and granulation tissues in middle ear cavity were addressed and sent for histopatholgical examination.

Figure 22 cholesteatoma insitu intra operative.

Granulation tissues if present were excised and addressed.

Figure 23 Intra operative granulation tissues.

Following canal wall down mastoidectomy, a single large mastoid cavity was created.

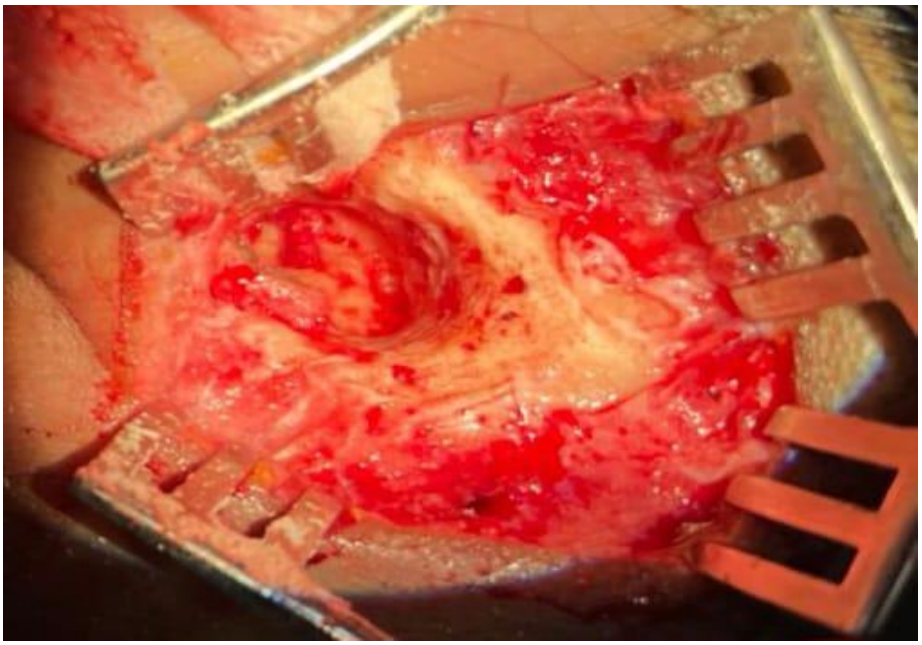


Figure 24 Large mastoid cavity following CWD.

Underlay temporalis fascia grafting was performed.

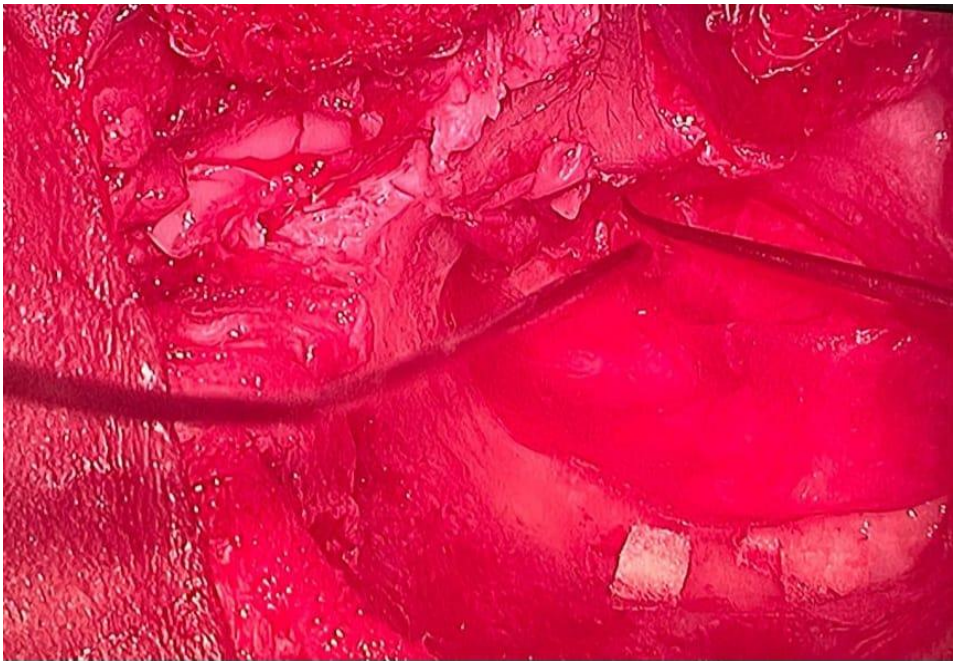


Figure 25. Temporalis fascia grafting.

Relevant ossiculoplasty with septal cartilage (Myringostapedopexy, myringoplatinopexy) was performed based on the availability of ossicles.

Figure 26. Carving of cartilage for ossiculoplasty.

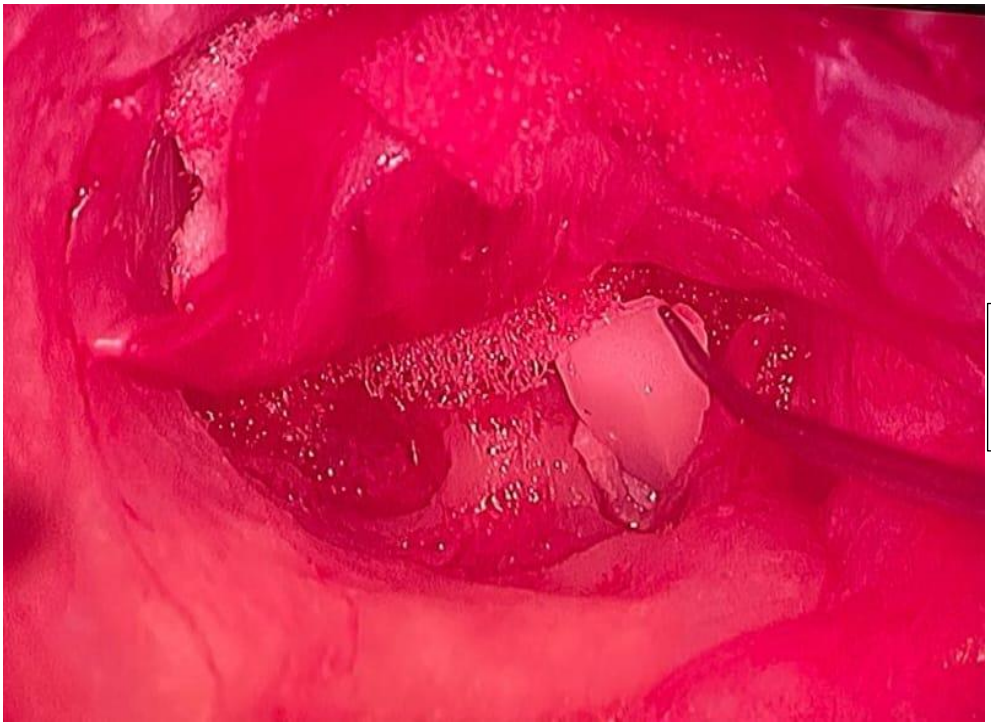


Figure 27. Ossiculoplasty performed.

Soft tissue from the post auricular region were freed from the skin and lengthened, in order to obliterate the posterior aspect mastoid cavity and free harvested soft tissues were used to obliterate in prime areas (supra labyrinthine and sino dural angle area).

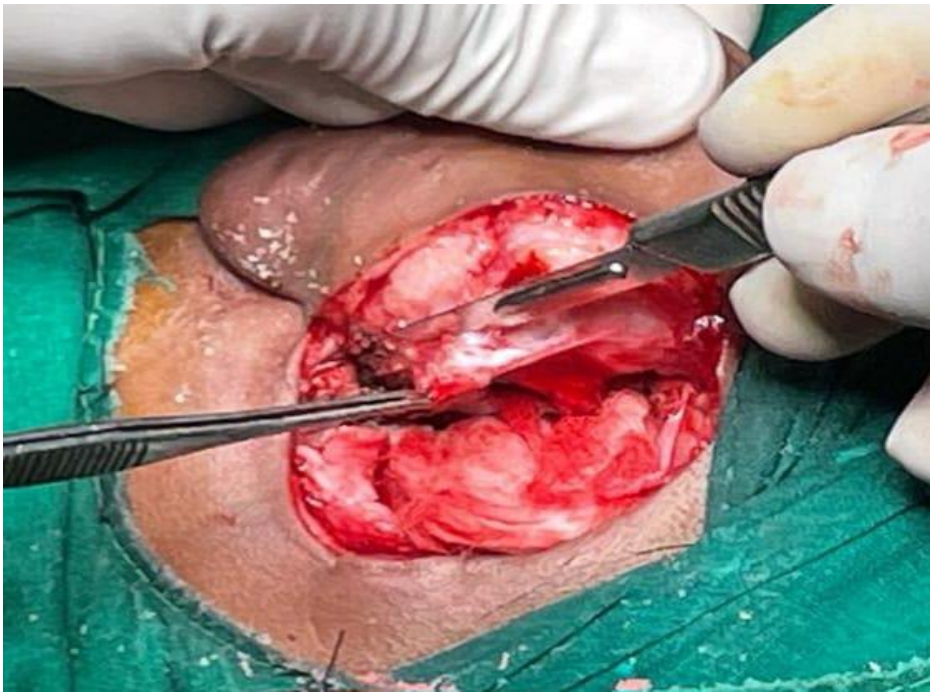


Figure 28. Mastoid cavity obliteration using post auricular soft tissues.

Figure 29. Mastoid cavity obliteration using post auricular soft tissues.

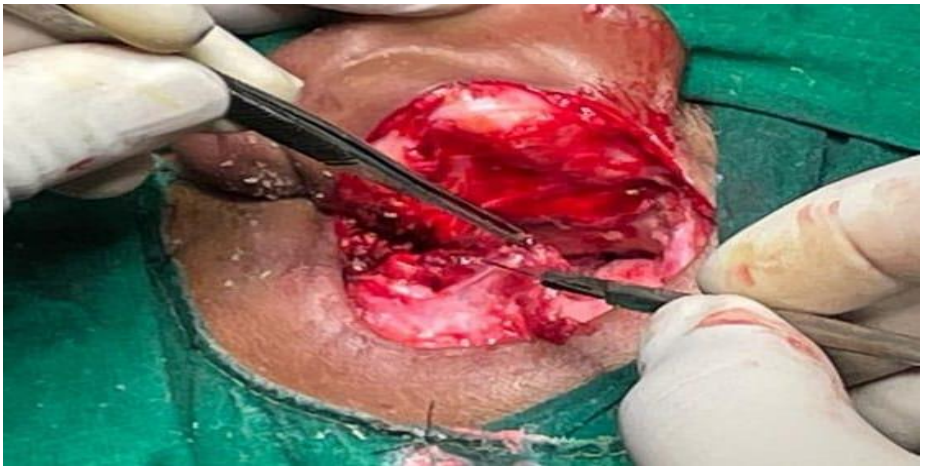


Figure 30. Mastoid cavity obliteration using post auricular soft tissues.

Gel foam soaked in antibiotic ear drop(Betamethasone and neomycin) was used in addition to post auricular soft tissues.

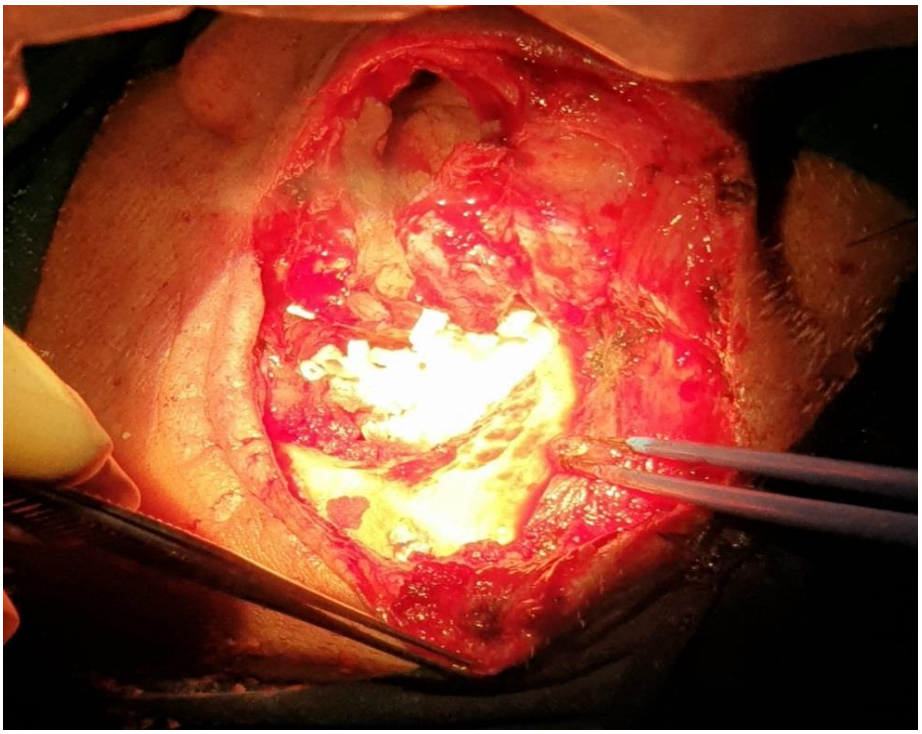


Figure 31. Mastoid cavity obliteration using gel foam along with post auricular soft tissues..

Wide meatoplasty was done .

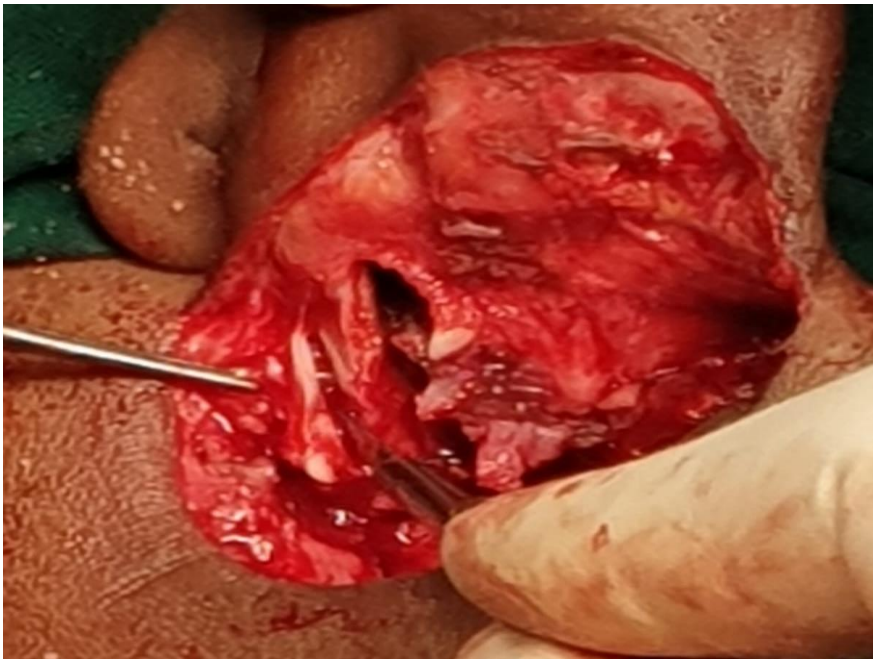


Figure 32. Meatoplasty.

In addition to these steps, facial nerve if dehiscent was repaired and decompressed .

Figure 33. Facial nerve decompression.

Post operatively all patients were shifted to step down intensive care unit to ensure adequate monitoring.

All patients were treated with intra venous antibiotics in the post operative period as per the antibiotic guidelines for a period of 5 days and were discharged on post operative 5 day with

removal of mastoid dressing.

On post operative day 10 , post auricular sutures were removed.

Figure 34. Post auricular surgical wound.

Patients were called on post operative day 15, for canal pack removal and parameters like pus from the post operative surgical scar, keratin debris, granulation tissue, wound dehiscence and epithelization of the cavity were noted.

Figure 35. Post op day 15. Canal pack removed .

Patients were recalled on post operative day 60 (2 month) and day 90 (3 month) to assess the same parameters in addition to audiological investigation (Pure tone audiometry) to evaluate air bone gap closure on post operative 90 day.

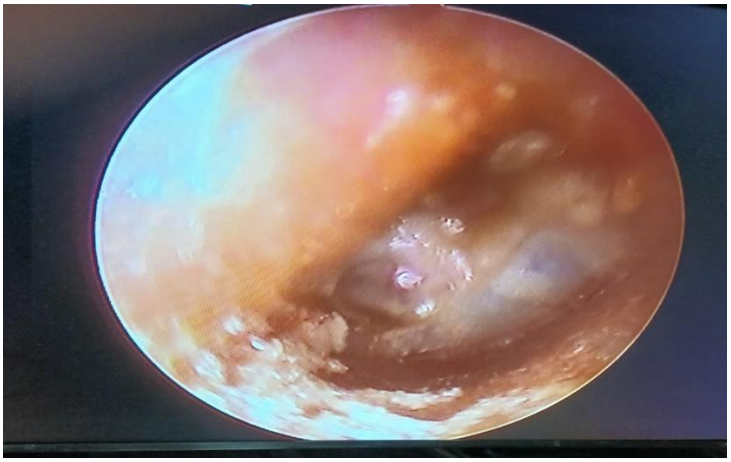


Figure 36. Post op day 60. Neotympanum.

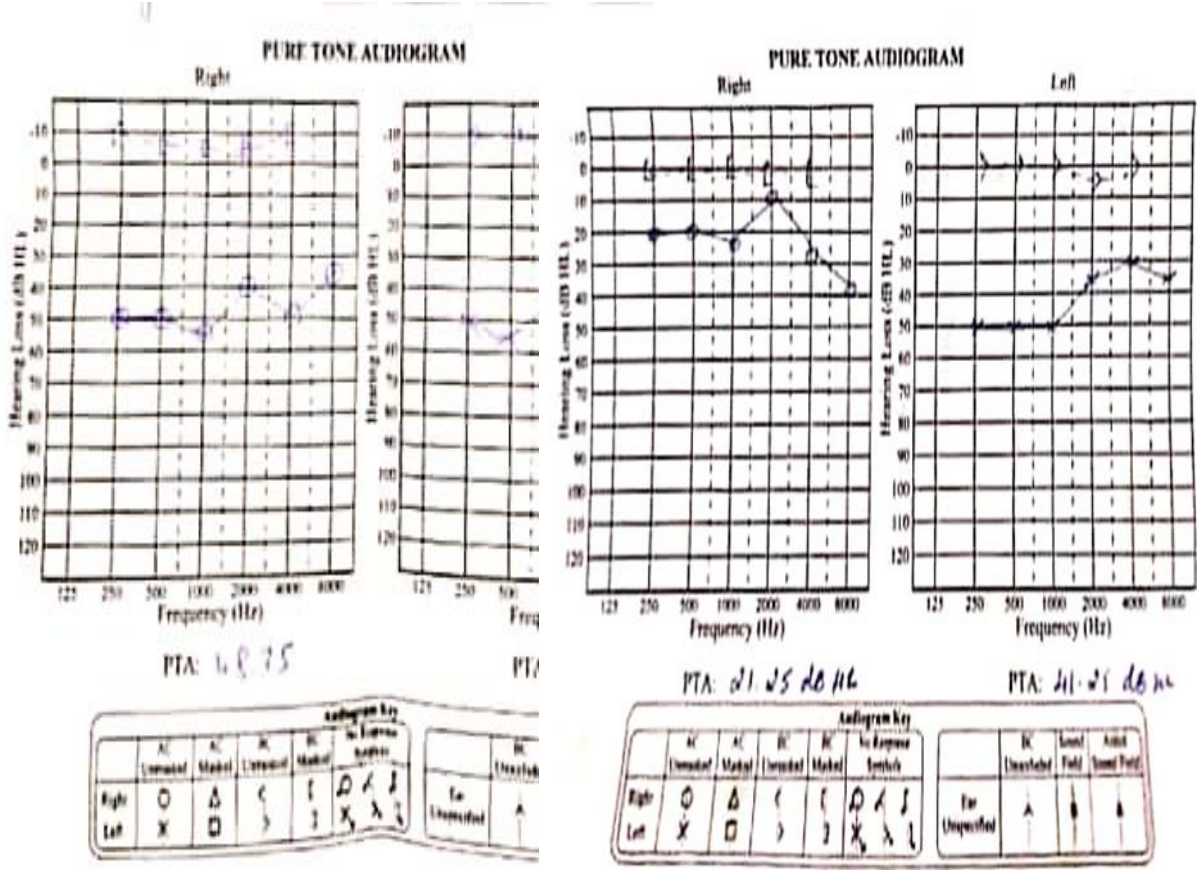


Figure 37. Comparison of pre and post op day 90 Pure Tone Audiogram indicating reduction in ABG.

Figure 38. Healthy cavity post op day 90.

Figure 39. Persistent ear discharge in 1 patient on post op day 90.

Graphical representation of data: Micro Soft Excel and Micro Soft Word were used to obtain various types of graphs.

Statistical analysis:

A comparison of pre operative and post operative parameters were performed , p value (p= 0.05) with 95% confidence interval was considered statistically significant.

Relevant graphs and tables were plotted to have a comparison between the observed parameters.

RESULTS

RESULTS

GENDER DISTRIBUTION:

Total number of patients included in our study were 30.Of these, 21 were male and 9 were female (Chart 1).

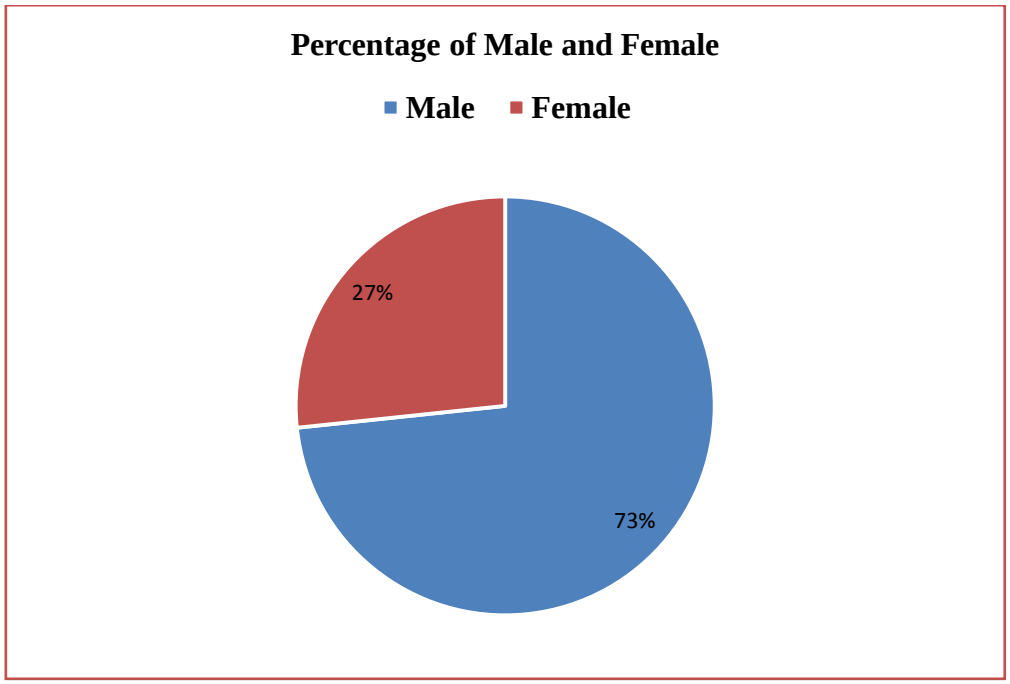


Chart 1: Gender Distribution

In the present study, male patients accounts for 73% and female patients accounts for 27%.

The average age of the patients were 36.6 years. Majority of patients were in the age group between 20-30 years (11 patients) while there were relatively less patients in the age group above 50 years (4 patients).

There were a less patients in the age group between 50- 70 years (Chart 2).

AGE WISE DISTRIBUTION OF PATIENTS UNDER STUDY:

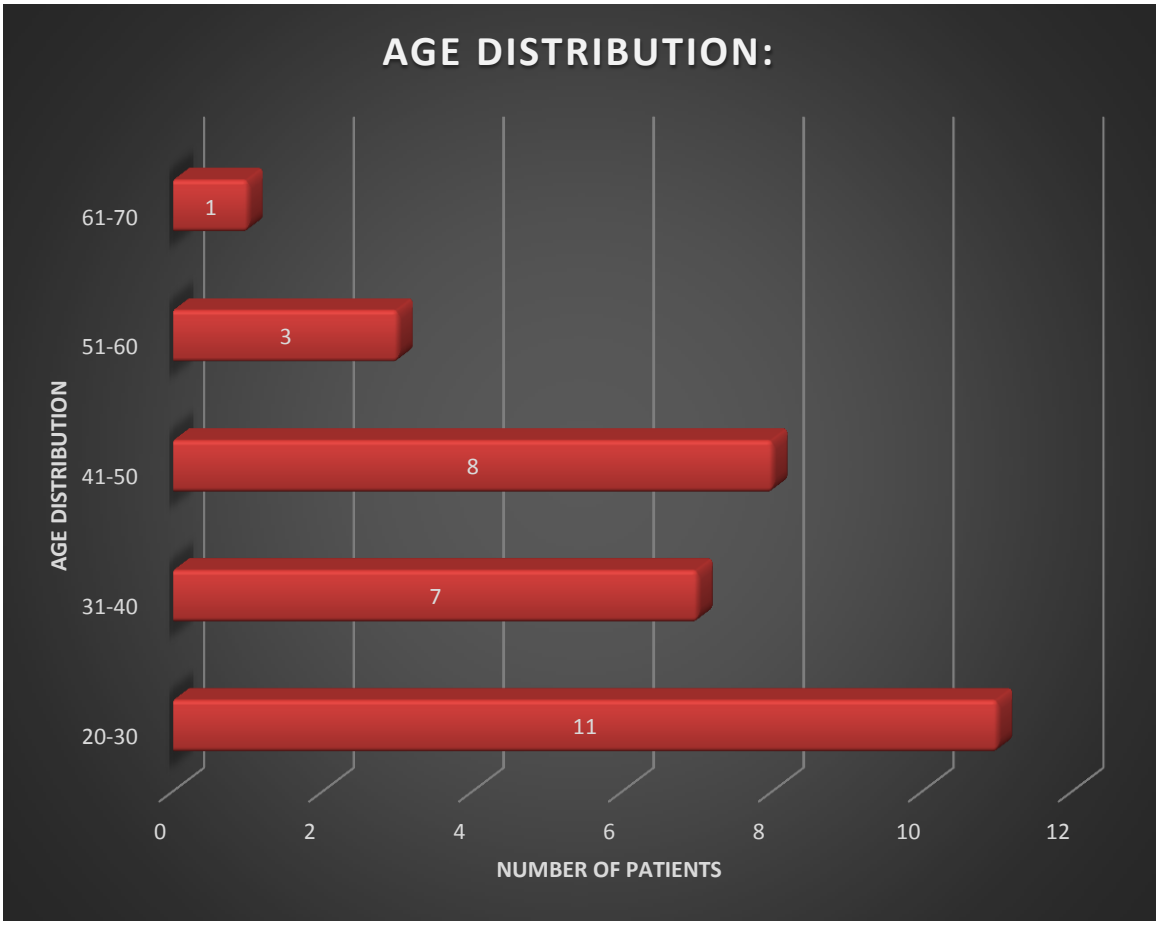


Chart 2:In the present study, a greater number of patients fall in the age group of 20-30 years and least in above 60 years.

There were varied comorbid conditions encountered in our study. These were diabetes mellitus, hypertension, chronic kidney disease and ischemic heart disease (Table 3).

Table 3: Demographic characteristics

S. No.	Parameters	No. of Patients
1	Male Patients Female Patients	22 8
2	Mean Age	37.23 years
3	Ear Discharge	30 patients
4	Ear Pain	30 Patients
5	Reduced Hearing	30 patients
6	Tinnitus	26 patients
7	Giddiness	8 patients
8	Facial Nerve Weakness	2 patients
9	Type II Diabetes	9 patients
10	Hypertension	4 patients
11	Chronic Kidney Disease	1 patient
12	Ischemic Heart Disease	1 patient

Prevalence of diabetes was seen in 30% patients (9 patients) with a mean glycosylated hemoglobin value of 7.2% that were managed prior with oral hypoglycemic agents, later were changed to injectable insulin before procedure. of these, 4 patients (44.44% patients)

had uncontrolled blood sugar levels that we managed with a combination of short and long acting insulin under strict blood glucose monitoring.

Hypertension was seen in 10 patients (33.33%) that was managed well with anti hypertensive agents (Amlodipine 10 mg once daily) that was evident from the blood pressure recording performed twice daily.

Chronic kidney disease was encountered in 2 patients (6.66%) that required additional monitoring of renal parameters along with restricted fluid intake. Both these patients were managed with utmost precautions and were given due consideration in the choice of antibiotics as well as analgesics considering the nephrotoxic property.

Ischemic heart disease was noted in 2 patients (66.6%) were additionally on cardiac medications. For both these patients pre operatively, 2 dimensional echocardiogram was performed to quantify the cardiac parameters mainly ejection fraction and valve anomalies. 2 dimensional echocardiogram was fair, permitting fitness for general anesthesia.

The most common presenting complaints of all the patients were purulent, scanty, foul smelling and blood tinged ear discharge, reduced hearing, ringing sensation (tinnitus), ear pain and giddiness (Chart 3).

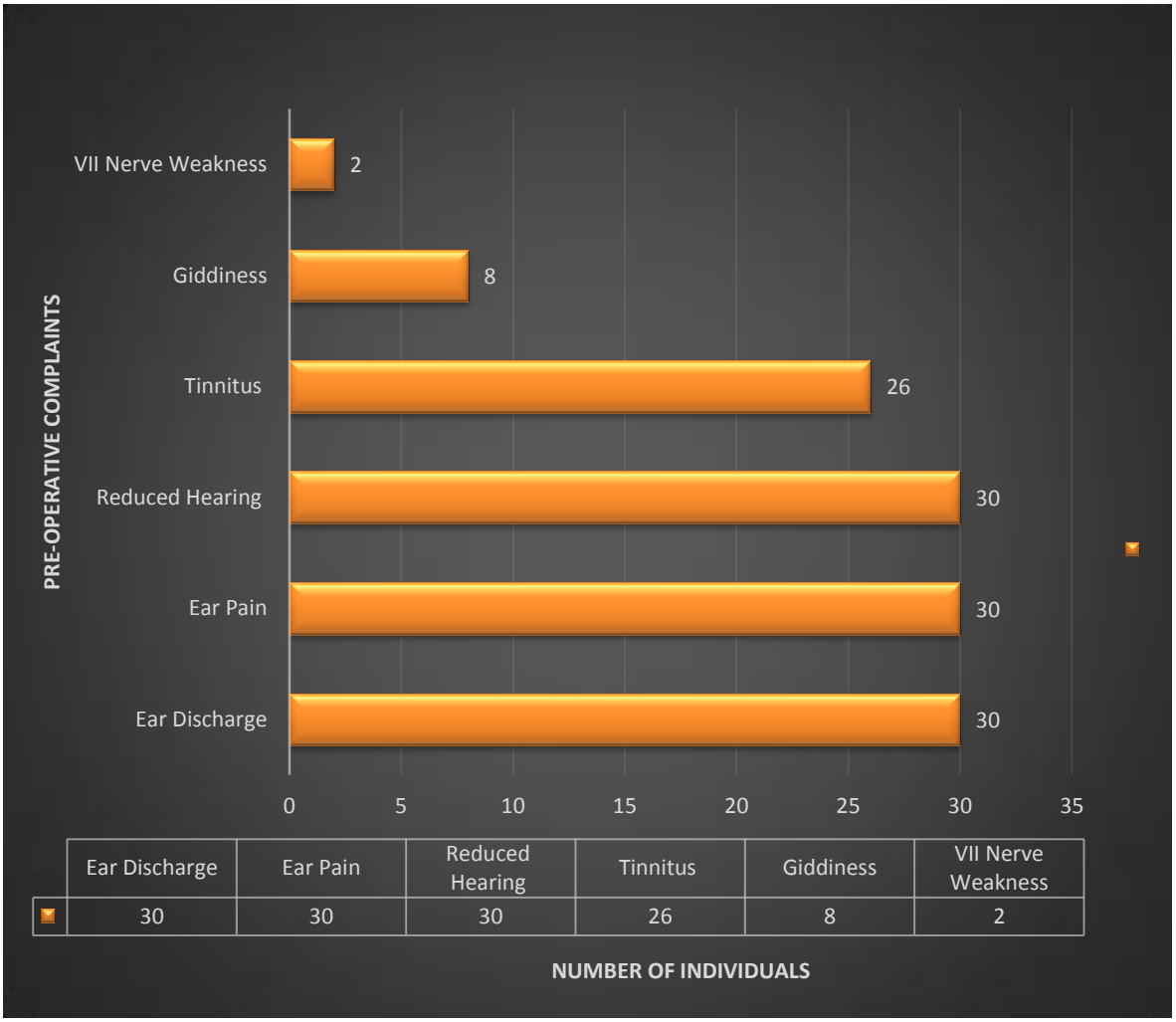


Chart 3: Pre-operative Issues

Figure showing pre-operative complications like Ear Discharge, Ear Pain and Reduced Hearing

Ear discharge was seen in 100% patients, which was intermittent, purulent in nature (100% patients), foul smelling (86.66% patients),blood tinged (70% patients) occassionally, which did not relieved with oral antibiotics (Amoxycillin+ clavulanic acid) and topical aural antibiotic drops(Ciprofloxacin).

Reduced hearing (93.33% patients) which was insidious in onset, gradually progressive, leading patients to appreciate sound upon speaking loudly but did not permit them to have telephonic conversations. Amongst these, 10 patients (35.7%) had difficulty in speech discrimination.

Ringing sensation was present in 93.33% patients which was continuous, low pitch, aggravated during episode of ear discharge and had no relieving factors.

Ear pain (93.33% patients) was the next frequently encountered complain in our patients which was dull aching, intermittent, aggravated before episodes of ear discharge and relieved partially with oral analgesics and topical ear antibiotics. In 2 patients, diagnosed as Malignant Otitis Externa there was excruciating ear pain typically at night, not relieved on oral analgesics, needed administration of intravenous analgesics (Diclofenac 75 mg) two to three times daily.

Giddiness was reported to be in 46.4% patients which was insidious in onset, lasted for a minute, with no diurnal variation, without aura, aggravated with sudden change in position mostly experienced on bending forwards and resolved spontaneously. Giddiness was the less frequently sought complaint in our study.

Facial nerve involvement is the most common complication owing to the disease per se. In our study only 2 patients (6.66%) had facial nerve palsy of House Brackman Grade 4. Both these patients had features of Skull base osteomyelitis along with features of COM .

All patients underwent detailed ENT examination on the day of presentation to Out patient department and findings were documented. Otological examination was performed under microscope. Findings as per Table 4.

PRE OPERATIVE FINDINGS ON EXAMINATION:

Serial No.	Findings	Number of Patients
1.	Pre auricular region (sinus, fistula)	Nil
2.	Pinna anomalies	Nil
3.	Post auricular region	Nil
4.	Tragal tenderness	08
5.	Mastoid tenderness	21
6.	External Auditory Canal Oedema Normal Narrow	 21 09 21
7.	Aural polyp	03
8.	Scutum Normal Eroded	 06 24
9.	Retraction: a. Pars Flaccida- I. TOS Grade 3 II. TOS Grade 4 b. Pars Tensa- I. Sade Grade 3	 14 10 04 08 08
10.	Tympanic Membrane: a. Pars Tensa I. Postero superior quadrant marginal II. Subtotal III. Total IV. Large Central b. Pars Flaccida	 19 10 06 02 01 11
11.	Middle ear a. Normal Mucosa b. Polypoidal mucosa c. Cholesteatoma (Attic)	 09 21 30

Table 4 showing pre operative findings on ENT examination.

On aural examination, tragal tenderness was present in 8 patients (26.66%) indicating involvement of external ear due to otitis externa. Such patients received a course of antimicrobials (Amoxycillin clavulanic acid 625 mg twice daily for a week) along with analgesics and topical antimicrobial drops (Ciprofloxacin Ear Drops).

Mastoid tenderness was elicited in 70% patients (21 patients) implying the pathology involving mastoid without sagging of posterior canal wall. External auditory canal was narrow in 21 patients (70%) owing to edema, being a common indicator of inflammatory process. In remaining 9 patients (30%), external auditory canal was unremarkable.

Aural polyps are usually seen secondary to long standing abnoxious stimuli, was noted in 3 patients (10%). Polyps observed in all cases presented as a mass protruding through external auditory canal with inspissated aural discharge and congestion of skin. Scutum was eroded in 24 patients (80%) signifying the osteoclastic activity of cholesteatoma while in remaining 6 patients (20%) it was normal.

Cholesteatoma was seen in all cases (100%), which was coupled with other pathologies like aural polyps, keratosis obturans, granulation tissue, dehiscent facial nerve. Owing to presence of cholesteatoma all patients were arbitarily planned for Canal wall down mastoidectomy to know the extent of involvement of the pathology.

Retractions usually occur secondary to sustained negative pressure. Pars flaccida retractions were more observed than pars tensa (Chart 4). A total of 14 patients (46.66%) had pars flaccida retraction while 8 patients (26.66%) had pars tensa retraction. Amongst these, Tos grade 3 and 4 pars flaccida retractions were present in 10 and 4 patients respectively (Chart 5). Sade's grade 3 pars tensa retraction was seen in 8 patients. Remaining 8 patients had no retractions.

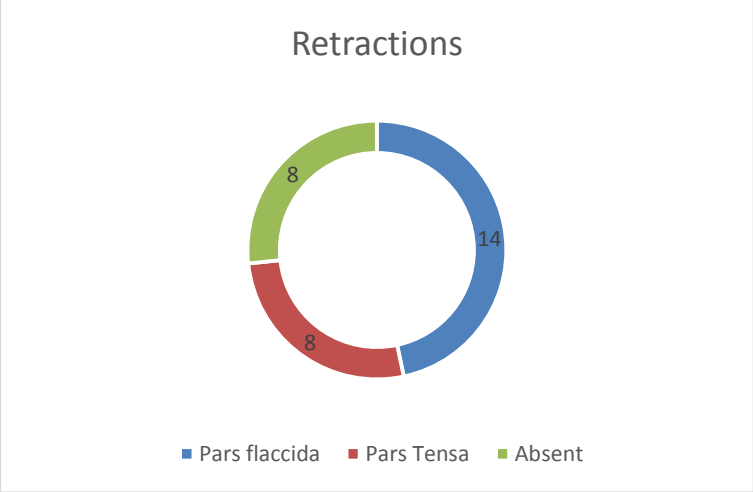


Chart 4 showing Retractions on pre operative examination.

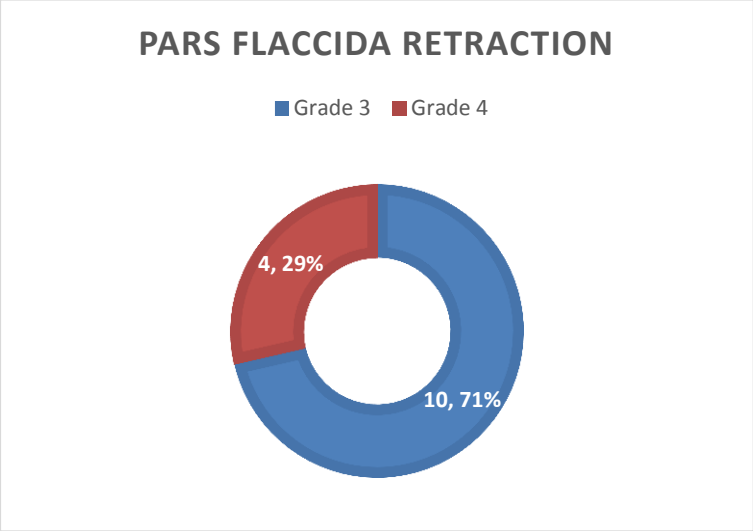


Chart 5 showing Retractions in Pars Flaccida Grade 3 in 10 patients and Grade 4 in 4 patients

Tympanic membrane perforations are the most sought findings in long standing cases of Chronic otitis media. In our study, there were almost all types of perforations revealed on oto microscope examination. We encountered pars tensa perforations that were more in number. Amongst them, postero superior quadrant marginal perforations were seen in 10 patients(33.33%) while 6 patients had subtotal perforation, TP was seen in 2 patients and large CP was seen in 1 patient. Attic perforations (pars flaccida) were seen in 11 patients (36.66%). In these patients, the remaining tympanic membrane was found to be sclerosed. Chart 6

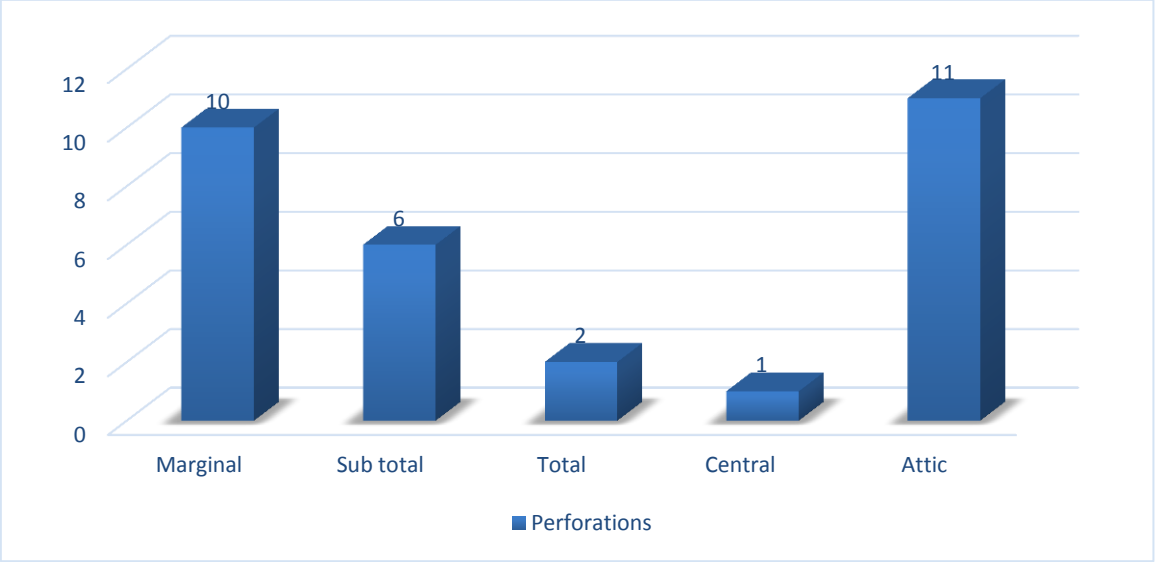


Chart 6 showing different types of perforations on pre operative evaluation.

HRCT temporal bone 0.6 mm cuts was done in all patients in order to understand nature of disease progress, extent and to appreciate other features like aural polyp, granulation tissue extent, facial nerve dehiscence, presence of ossicles and condition of mastoid cavity (Chart 7).

Cholesteatoma was present in all the patients with attic as the most common site of involvement. Ossicles (malleus,incus,stapes) were absent as a result of osteoclastic activity of cholesteatoma in 5 patients (16.67%) while remaining patients showed presence of ossicles. The most common ossicle to be affected was incus.

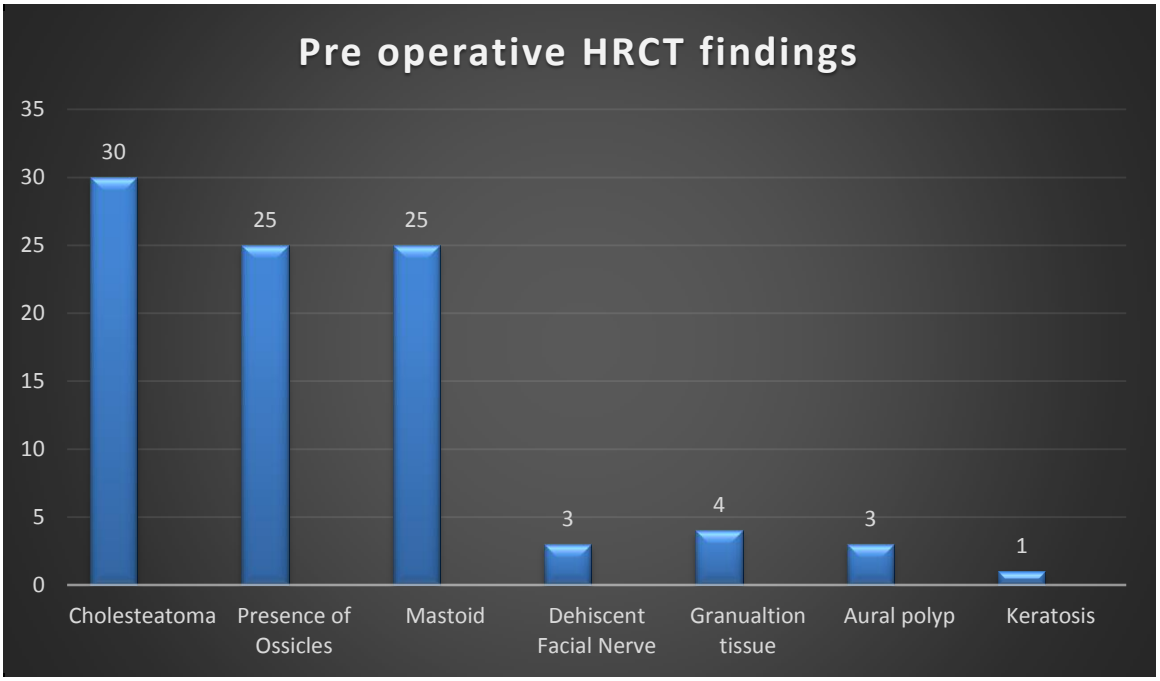


Chart 7 showing pre operative HRCT Temporal bone.

Typically,mastoid gives a honeycomb appearance on High resolution computed tomography in well pneumatized mastoid. In our study, mastoid was sclerosed in 25 patients (83.33%) while diploeic in remaining 5 patients (16.67%).

Facial nerve is the most common nerve to be involved as the disease progresses. Facial nerve was found to be dehiscent in 3 patients (10%) but only 2 patients had facial nerve palsy.

Granulation tissues are the end result of inflammatory process. Granulation tissues were present in mastoid antrum, aditus, attic, middle ear and Eustachian tube. Only 4 patients had extensive granulation tissues. Amongst these, 3 patients had aural polyp signifying deep seated pathology incurred as the dreaded sequelae of disease process.

Based on the HRCT, we were able to arrive at a probable diagnosis for decision making and planning surgical procedure. We encountered other pathologies as well in adjunction to commonly sought COM (squamous disease) like malignant otitis externa (skull base osteomyelitis), aural polyps and keratosis obturans.

Patients were subjected to audiological evaluation by PTA after performing aural toileting. Average air bone gap was deduced by taking average of air and bone conduction at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz and subtracting mean average of air and bone conduction.

Mild conductive hearing loss was seen in 12 patients(40%), moderate conductive hearing loss in 15 patients(50%), mild mixed hearing in 2 patients (6.66%) and moderate mixed hearing in 1 patient(3.33%). Chart 8

Air Bone Gap was assessed pre operatively, that ranged between 20 dB to 47.5 dB. Average Air bone gap was found to be 31.45 dB (Chart 9). Few patients (10) were found to have sensori neural component pre operatively, hence they were councelled regarding the fair prognosis with respect to hearing outcome.

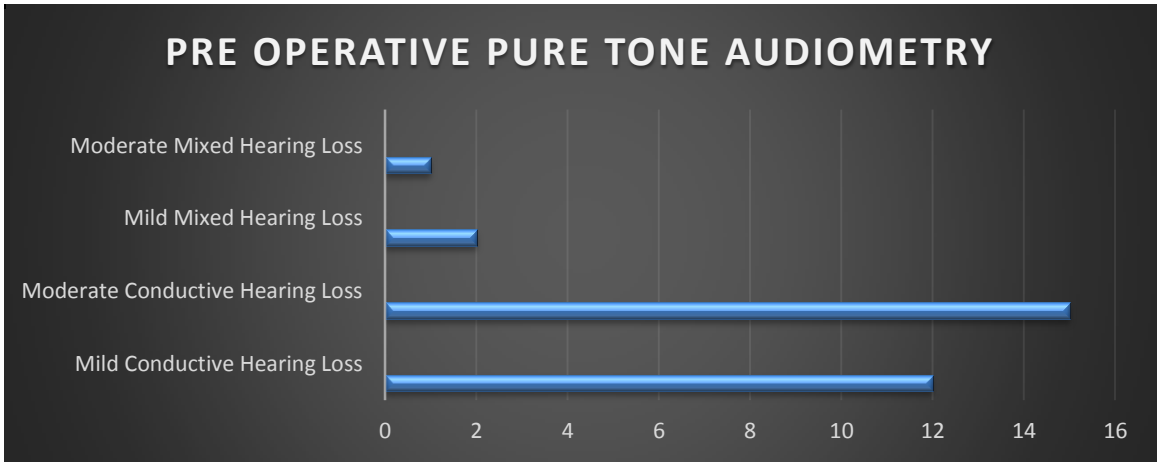


Chart 8 showing Pre Operative Pure Tone Audiometry.

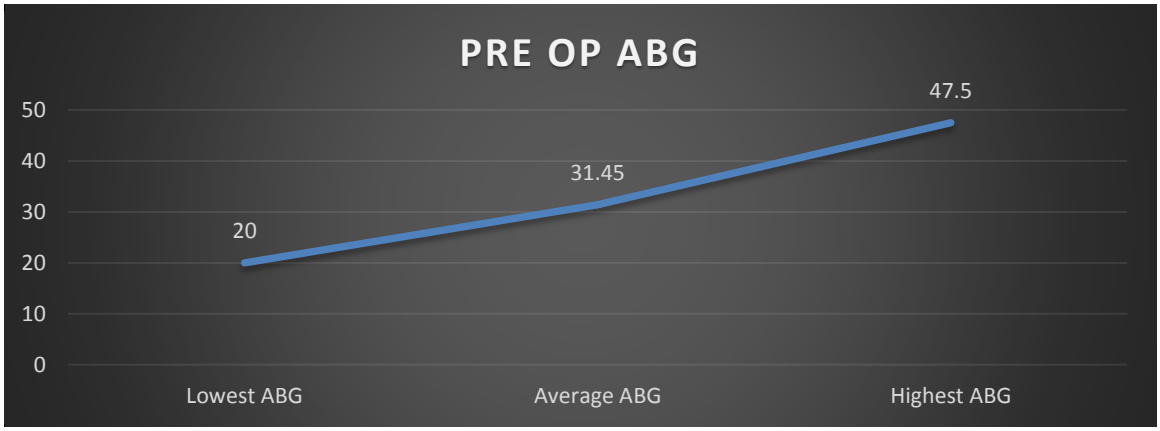


Chart 9 showing Pre Op ABG range.

All cases were subjected to blood investigations as a part of pre anesthetic evaluation check up. Physician opinion was sought for all patients and were later admitted one day prior to surgery. A written inform consent was taken from all patients about the surgical procedure and were explained about the intervention in the form of mastoid cavity obliteration using post auricular soft tissues.

All patients underwent CWDM permitting an excellent exposure aiding in disease clearance.In addition to CWDM, patients underwent ossiculoplasty (100% patients), tympanoplasty(100%), meatoplasty(100%), facial nerve decompression(10%) and aural polypectomy(10%) Chart 10.

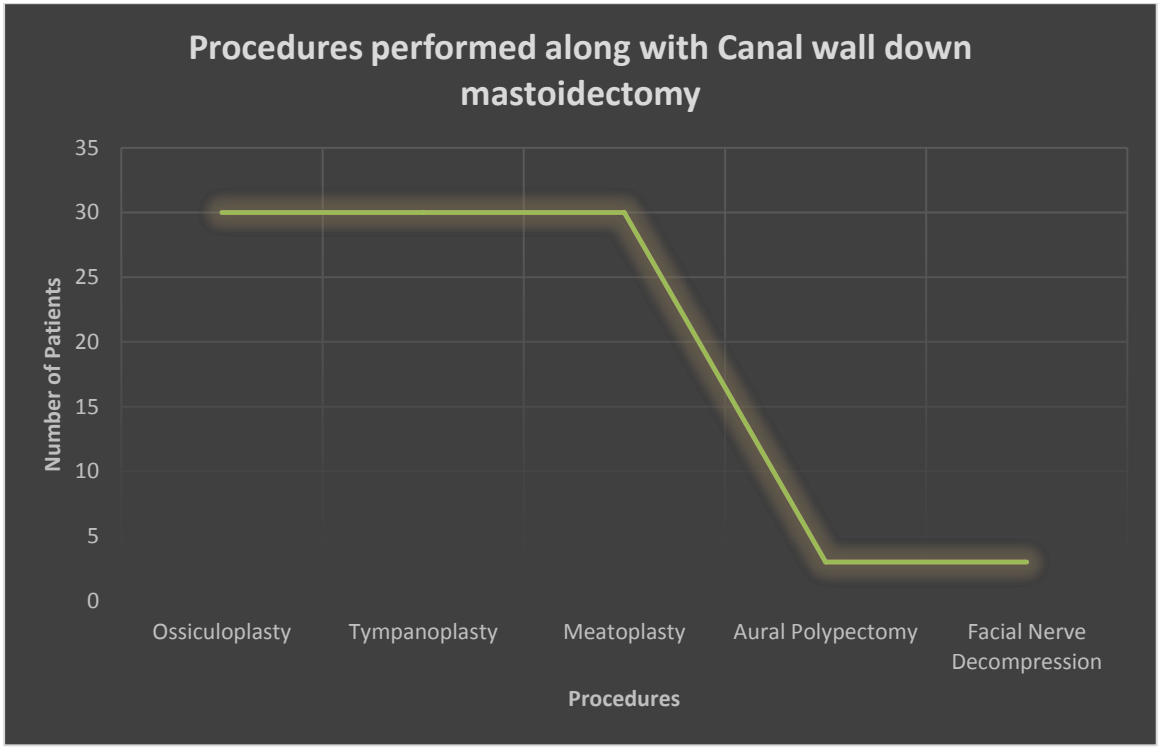


Chart 10 showing additional procedures done along with canal wall down mastoidectomy.

We encountered vivid intra operative findings like ossicular erosion (30 patients), aural polyps (3 patients), granulation tissues (4 patients), dehiscent facial nerve (3 patients), cholesterol crystals over stapes head (2 patients) and high jugular bulb (2 patients) Chart 11.

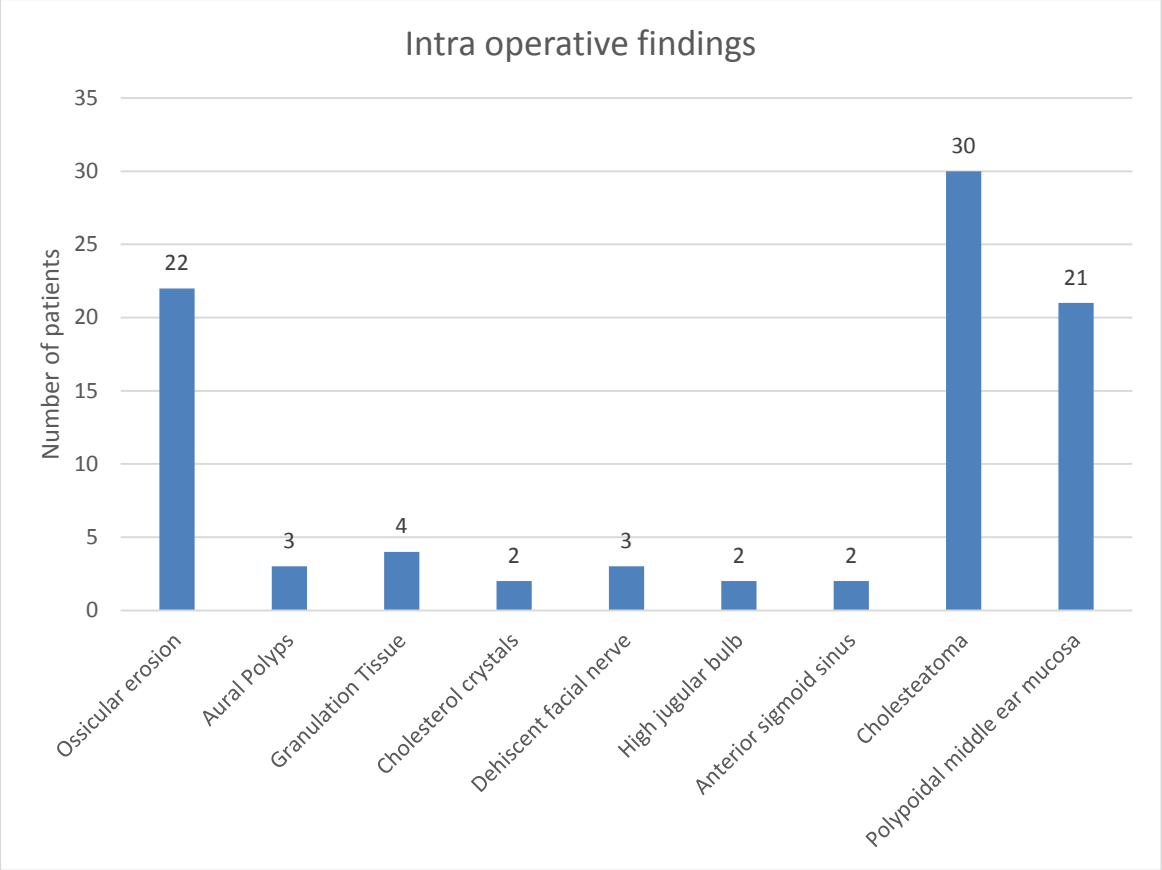


Chart 11 showing intra operative findings.

Most common ossicle to be involved was incus (22 patients), followed by malleus (5 patients) and stapes supra structure(3 patients) Chart 12. In all such patients, ossiculoplasty was performed based on the availability of ossicles in the form of myringostapedopexy (76.67% patients) and myringoplationopexy(23.33% patients).

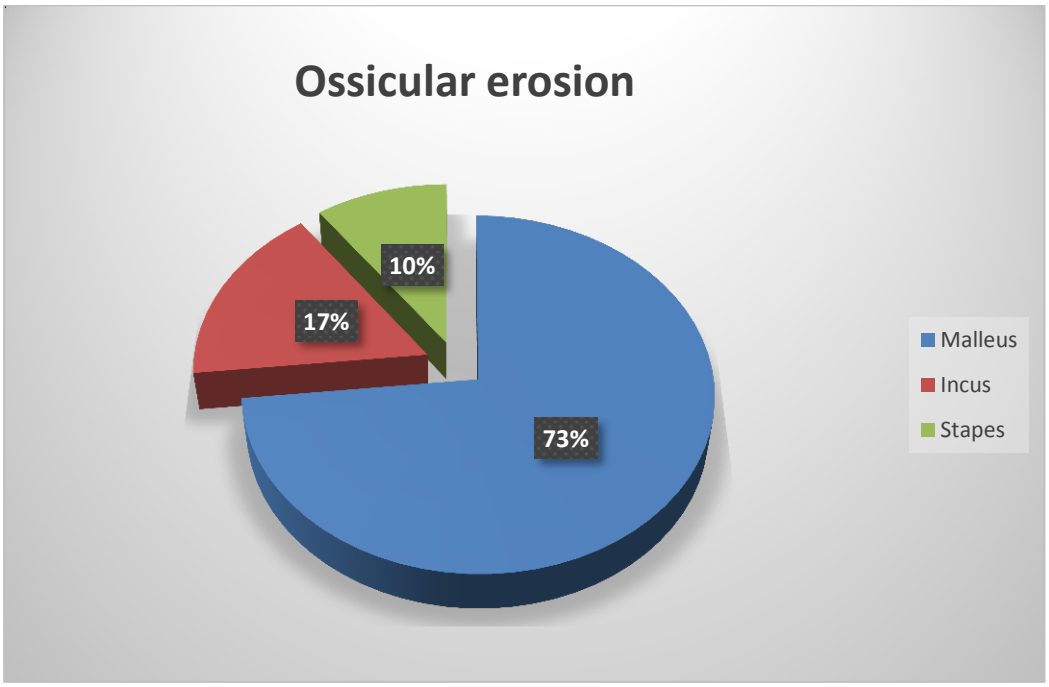


Chart 12 showing ossicular involvement during intra operative exploration

Extensive granulation tissues are the hallmark of the pathological disease involving middle ear that were encountered in 13.33% patients. It involved the ossicles, facial nerve and occasionally Eustachian tube and prussack's space.

Aural polyps were present in 10% patients that required meticulous attempts while attempting for disease clearance.

Facial nerve was found to be dehiscent (10% patients) was repaired with grafting by temporalis fascia, removal of granulation tissues aided in nerve decompression. High jugular bulb was seen in 2 patients(6.67%) demanding additional expertise while operating such

extensive diseases.

Anteriorly placed sigmoid sinus was present in 2 cases, so additional precautionary measures were taken while drilling. Cholesterol crystals were present in 2 patients over stapes head that were excised and sent for histopathological examination.

Middle ear mucosa often reflects the status of disease process in long run. Polypoidal mucosa was present in 21 patients (70%) while remaining had normal mucosa. In all patients, cholesteatoma was present in the attic region sculpted as classically described as sac, aditus and antrum were not patent, that was achieved during the surgical procedure. CTN was preserved in all cases. Finally, all patients underwent mastoid cavity obliteration using post auricular fibro periosteal soft tissue.

Patients received intra venous antibiotics with oral anti histamines for a period of 5 days except for 2 patients diagnosed with malignant otitis externa requiring a period of 4 weeks of higher antibiotics (Meropenem, Ceftazidime). Patient's mastoid dressing was removed on post operative day 5. Later patients were discharged on the same day with advice for oral antibiotics for a period of 5 days and were reviewed on post operative 15 day.

Post operative 2 week, canal pack was removed and assessment of all patients was carried out using parameters like pus from the post aural surgical wound, ear discharge, wound dehiscence, granulation tissue, epithelization of cavity (Chart 13). Oto microscopy was performed in all patients. Amongst them, only 1 patient had pus from the post operative surgical wound with ear discharge . Patient was treated with aural drops (Ciprofloxacin).

Second assessment was done on post operative 60 day using the same parameters used initially. 1 patient continued to have the same features as on post operative 15 day hence pus

from the wound was sent for culture and sensitivity later was started with the organism sensitive antibiotics (Ciprofloxacin) Chart 14

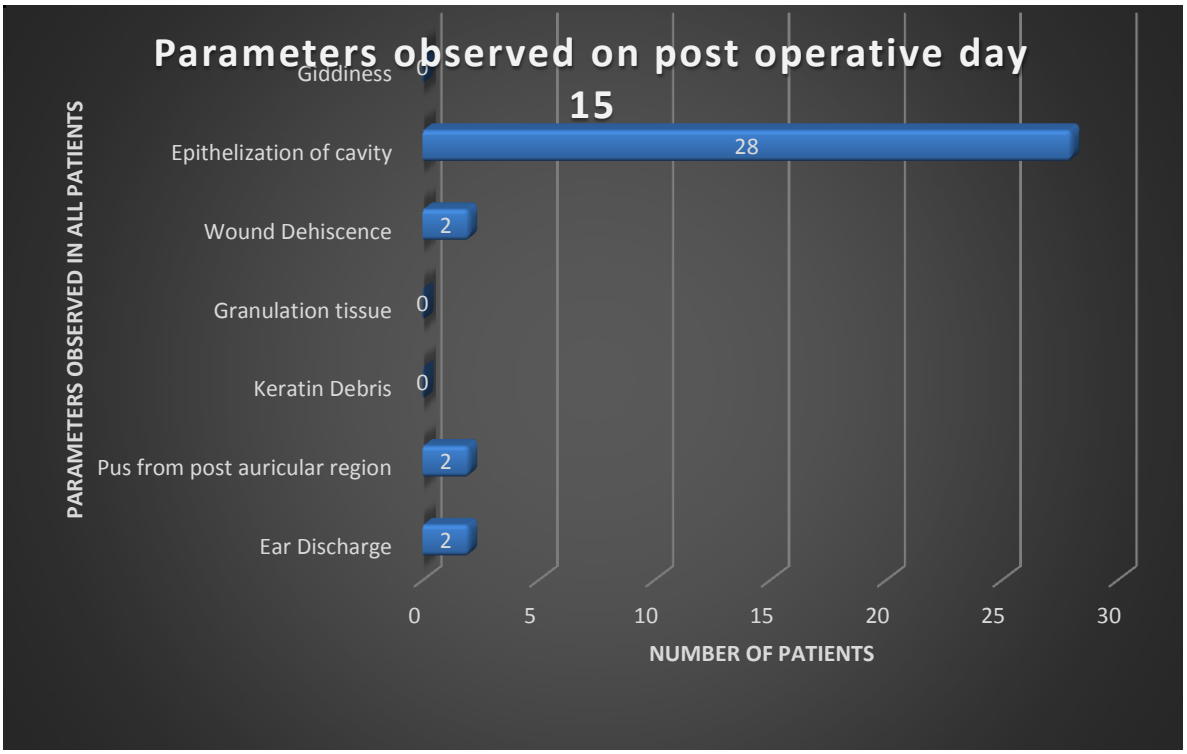


Chart 13 showing parameters observed on Post operative day 15.

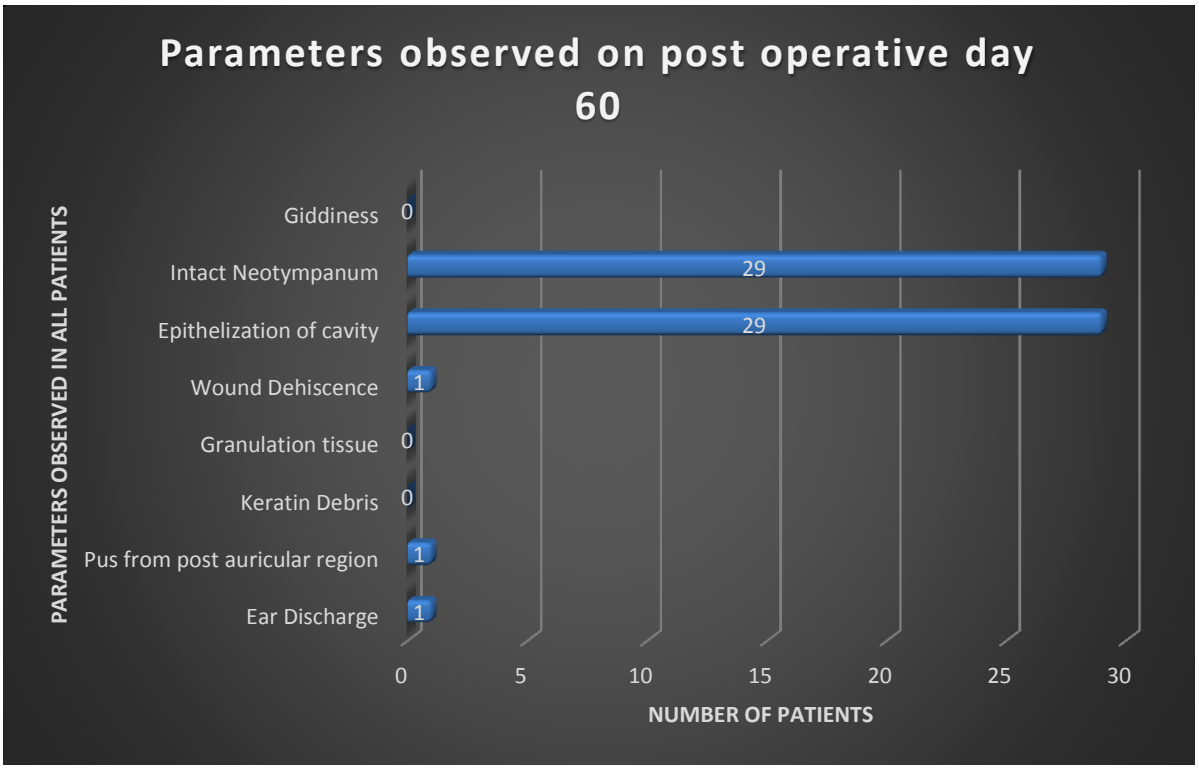


Chart 14 showing parameters observed on post operative 60 day.

Third assessment was performed on post operative day 90, on prior measuring parameters. By this time we managed to achieve a regular , even, epithelized mastoid cavity with intact neotympanum free from cavity related issues. Only 1 patient continued to have ear discharge, was treated symptomatically. Chart 15

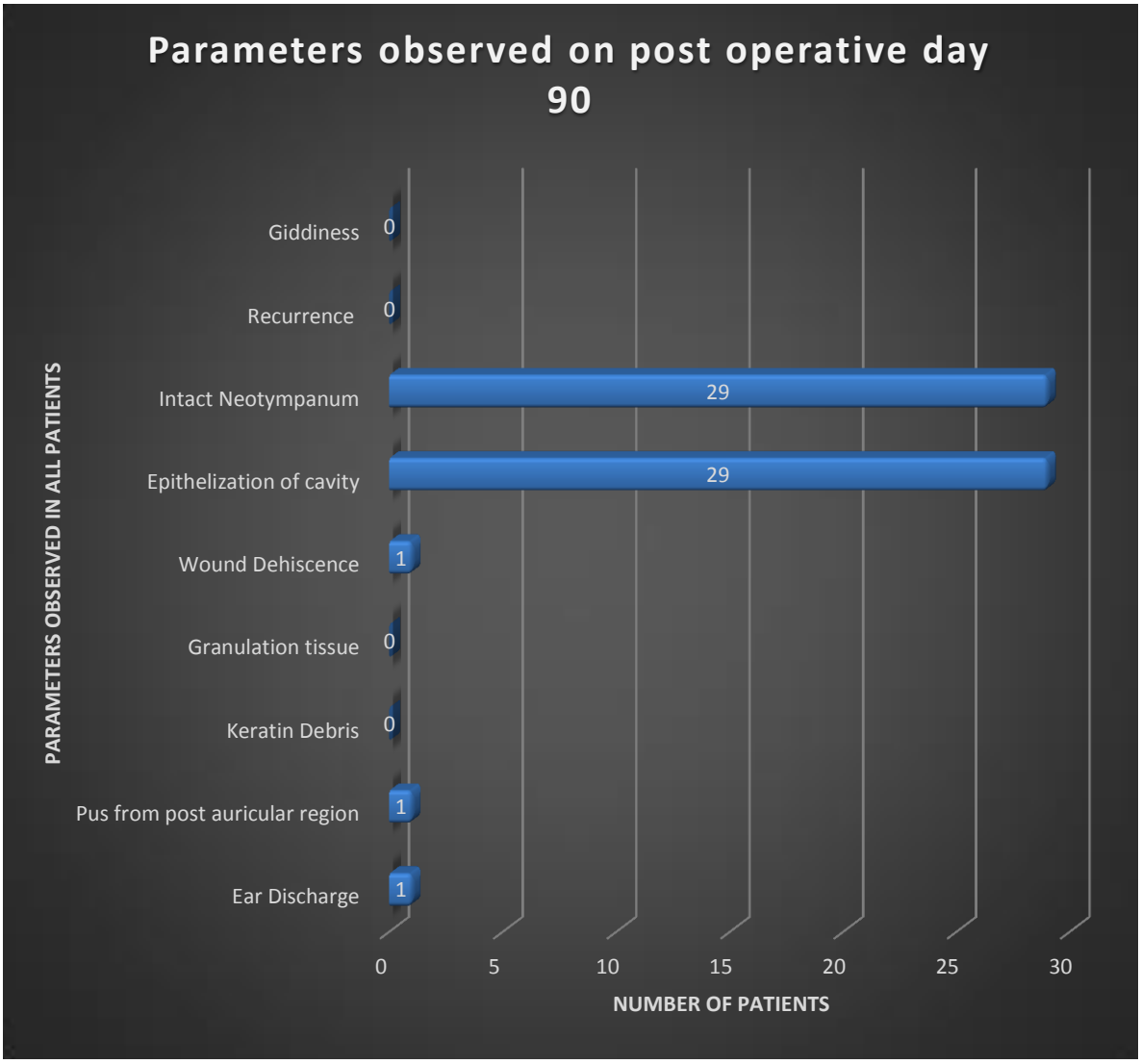


Chart 15 showing post operative day 90 parameters

PTA was performed to evaluate air bone gap. Average air bone gap on pre and post operative 90 day was found to be 31.34 Db and 24.59 dB respectively.

The average air bone gap difference(Pre operative – Post operative 90 day) was found to be 6.80 dB. Finally percentage closure of air bone gap was calculated and was found to be 22.16%. Following comparison between pre operative and post operative day 90 air bone gap closure, p value was p= 0.0178 (p<0.05) showing statistically significant. Table 5, Chart16.

Table 5: Comparison of Pre and Post Operative day 90 Air Bone Gap

Average Air Bone Gap in Decibel	Pre-Operative	Post operative 90 days	P value
Conductive Hearing Loss	40	20	0.0178*
Sensorineural Hearing Loss	58	38	
Mixed Hearing Loss	53	33	

Comparison of Pre and Post op ABG is made and it was found that there was significant air bone gap with P=0.0178*.

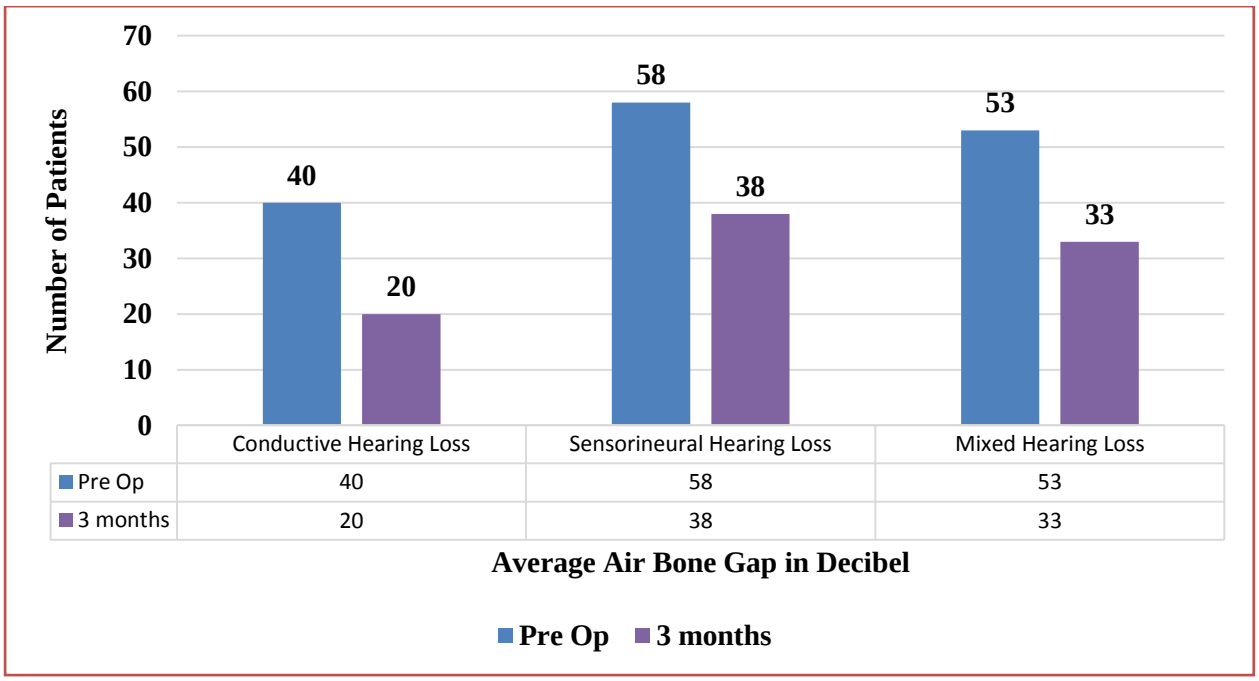
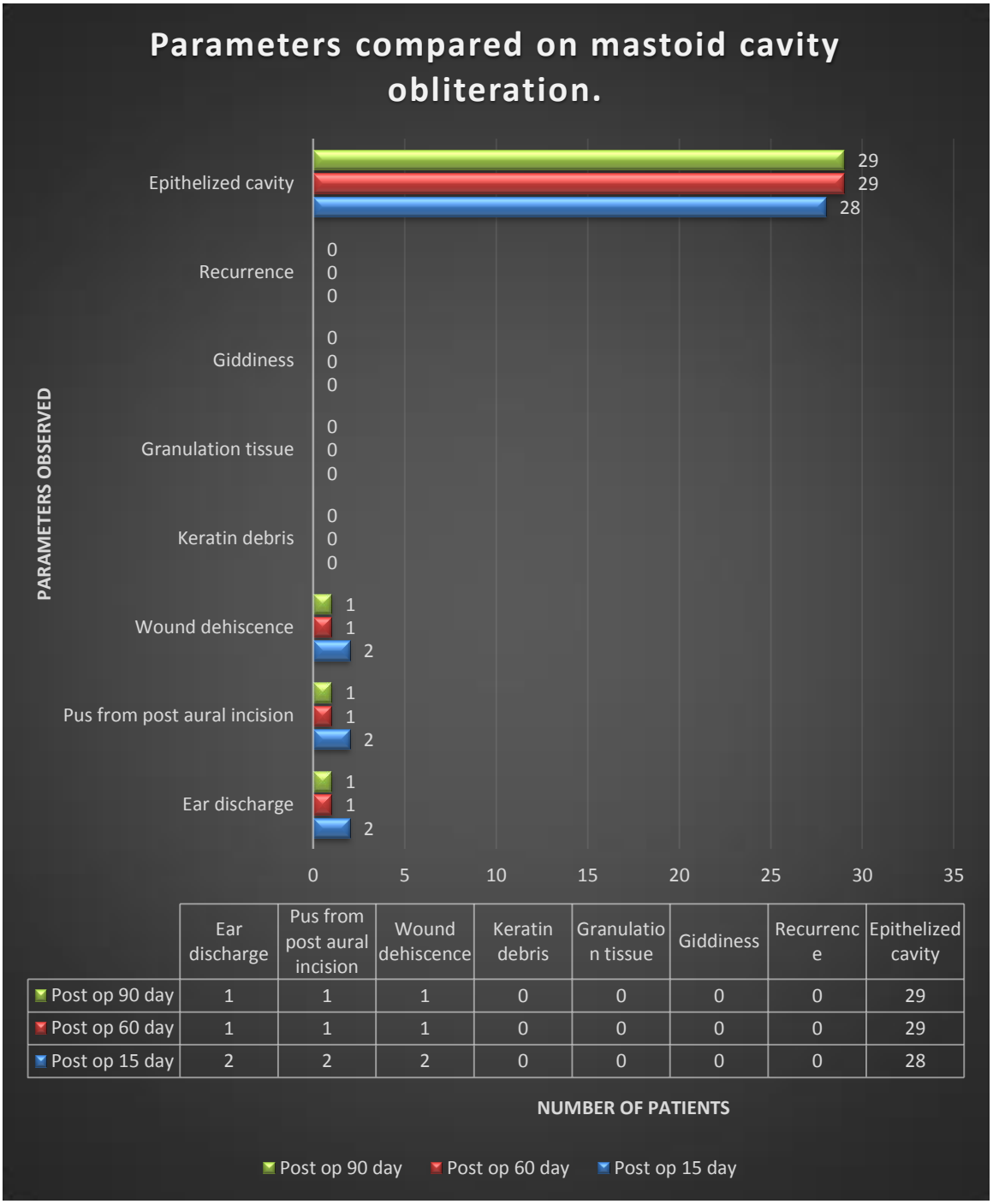


Chart16 showing average air bone gap in decibel pre and post operative day 90.

Following canal wall down mastoidectomy, obliteration of the newly created cavity aids in reducing the troublesome problems like ear discharge, accumulation of keratin debris, giddiness and so on Chart 17.



	Ear discharge	Pus from post aural incision	Wound dehiscence	Keratin debris	Granulation tissue	Giddiness	Recurrence	Epithelized cavity
Post op 90 day	1	1	1	0	0	0	0	29
Post op 60 day	1	1	1	0	0	0	0	29
Post op 15 day	2	2	2	0	0	0	0	28

Chart 17 showing parameters compared to show the effect of mastoid cavity obliteration by improvement in post canal wall down mastoidectomy.

With our technique we were able to control all unpleasant symptoms except for ear discharge that was present in 2 patients on post operative 15 day. Later only 1 patient continued to have persistent ear discharge till last follow up visit still p value was found statistically significant(<0.00001) Table 6.

Table 6: Comparison of Ear Discharge

S. No.	Parameter	P value
01	Pre-operative Ear Discharge	< .00001*
02	Post-operative Ear Discharge	

It was found that, there was significant decrease in ear discharge after surgery with p=0.00001*

Apart from ear discharge, overall there was an improvement in other pre intervention complaints like tinnitus, facial nerve weakness (House Brackman scale from 4 to 2) and the p value was statistically significant. Table 7

Table 7: Comparison of Tinnitus before and after surgery

S. No.	Parameter	P value
01	Pre-operative Tinnitus	< .00001*
02	Post-operative Tinnitus	

It was found that, there was significant reduction in tinnitus after surgery with p=0.00001* Average in patient stay was around 7.4 days. Graft survival rate was 100%.

So we concluded that our technique was not only efficient but also a promising one while addressing cavity related issues following canal wall down mastoidectomy since no patients had recurrence and had a good response in hearing improvement as evident from p value in Table 8.

Ear Examination Findings	**15 days post op**	**60 days post op**	**90 days post op**	**P Value**
Ear Discharge	2	1	1	0.00*
Pus from Suture Site	2	1	1	0.00
Keratin debris	0	0	0	-
Granulation Tissue	0	0	0	-
Cholesteatoma	0	0	0	-
Wound Dehiscence	2	1	1	0.00*
Recurrence	0	0	0	-

Table 8:From the observations of obliteration of mastoid cavity, it was found that there was significant observation noted in Ear discharge and wound dehiscence with p<0.05.

DISCUSSION

DISCUSSION

COM squamous disease is a routinely encountered phenomena and known since antiquity, yet the morbidity and mortality is unevitable.[1] It is often cited as an inflammatory process involving middle ear and mastoid. Although the pathogenesis of disease is well established, yet the diagnosis is made in the late phase due to delayed presentation of patients owing to financial constraints, underdeveloped rural health care facilities and fear of surgery.[1,2]

Surgical modality in the form of canal wall down mastoidectomy, becomes the choice of treatment with the primary aim of disease clearance.[1] Recently, with the advent of modern techniques, surgery has got a secondary aim of improving quality of life by reducing the abnoxious symptoms of large mastoid cavity. This is achieved by reconstructing the middle ear anatomy.[2]

Canal wall down mastoidectomy has an upper hand over the intact canal wall procedures, in terms of disease exposure, eradication of residual cholesteatoma, low recurrence and disease monitoring on follow up visits.[3] On the contrary, intact canal wall procedures have better post operative functional outcomes due to preserved anatomy and excellent hearing results.

Decision regarding the choice of surgery between CWD and ICW procedures warrants the inclusion of several factors. These include disease extent, ventilation capacity of middle ear, cholesteatoma, hearing, opposite ear functions, comorbidities of patient, follow up and surgeons preference. [4]

Current literature is still under debate between the choice of surgical procedure. In terms of recidivism and recurrence canal wall down is the demand of the extensive disease pathology. Risk of both the phenomena are very minimal in this procedure.[4,5]

Canal wall down mastoidectomy though beneficial has pitfalls like recurrent ear discharge, accumulation of wax, keratin debris, vertigo due on exposure to cold or hot water, need for frequent aural toileting, difficult hearing aid placement making patients 'Otologic cripple'. [4-6]

Hence, need to combine the beneficial functional effects of intact canal wall procedures to excellent disease eradication by canal wall down procedures was achieved by mastoid cavity obliteration popularized by Mosher in 1911.[3,4]

Since then, the quest of materials need to obliterate the large mastoid cavities came into existence and still is an ongoing process. Traditionally, materials utilised to obliterate the mastoid cavity were classified as free flaps (biologic and non biologic) and local flaps. These include a range from cartilage, bone, bioactive glass, silicone blocks to Palva's flap, Hong Kong flap.[7,8]

Although there is a vast contribution to the literature of mastoid obliteration, but there is no such agent sufficing the demands of being the ideal one. In view of this, we undertook our study with the purpose of reflecting the efficacy of obliterating mastoid cavity with post auricular soft tissue as also to add evidence in literature.

In our cohort of 30 cases, an average age of patients were 36.6 years similar to a study done by Tawalbeh M et al. He reported an average age of 32.4 years in contrast to Yamamoto Y (48.4 years) and Bhat S M , Vuppula R (21.19 years). [101-103]Male preponderance was noted, which was consistent with other studies reported in literature.[101-103]

Maximum patients were in the age group between 20-30 years which was similar to Saraf et al who had maximum cases in the same age group while Malali R had patients between 31-45 years undergoing surgery.[104,105] COM is a multifactorial disease hence its associations with co morbid conditions is not an unusual finding. In our study, we observed this co relation

with type 2 diabetes and hypertension similar to a study conducted by Park M. [106]

Pre operative complaints of all patients included otorrhea (100%), aural pain(100%), reduced hearing(100%), tinnitus(86.66%), occasional giddiness(48.6%) and facial nerve palsy (6.66%). Similarly, S Chappola et al cohort had otorrhea (95%), reduced hearing (87.5%), tinnitus(15%) and vertigo (5%).[107]

Oto microscopic evaluation revealed scutum erosion (86.66% patients) and cholesteatoma was visualized in attic, in contrast to a study done by Bhat S M , Vuppula R. Other features noted were canal wall oedema as a result of involvement of external ear, retractions, tympanic membrane perforations.[102]

We encountered more retractions in pars flaccida(14 patients) as compared to pars tensa(8 patients). Pars flaccida retractions were more of Grade 3 Sade (10 patients) than Grade 4 Sade (4 patients). All pars tensa retractions were of Tos grade 3 that were consistent with a study done by Navjot et al.[108]

In our present study, we encountered various types of perforations, pars tensa(19 patients) were more in comparison to pars flaccida (11 patients). Amongst pars tensa, postero superior quadrant perforations(10 patients) were seen in majority followed by subtotal (6 patients), total (2 patients) and large central (1 patients). While in pars flaccida 11 patients had attic perforation. The two findings were similar to a study.[108]

HRCT was performed in all patients pre operatively to elucidate details like ossicular presence, granulation tissues, facial nerve dehiscence, cholesteatoma, other soft tissue densities in the form of aural polyps, keratosis and the mastoid nature. Cholesteatoma was present in 100% patients and its osteoclastic activity was evident from the bony erosion.

Other features like sclerotic mastoid (25 patients), diploeic mastoid (5 patients), facial nerve dehiscence(3 patients), granulation tissues(4 patients), presence of ossicles(25 patients), aural polyp(3 patients), keratosis(1 patients) . The HRCT findings co related with our intra operative observations.

Similar was the observation by Agarwal R, Pradhananga R, Das Dutta H, Poudel S in study of 156 patients co related HRCT and intra operative findings and found it statistically significant.[109] The study also reported sensitivity of HRCT in diagnosing cholesteatoma and presence of ossicles to be 100% and 81.3% respectively.[109]

Audiological evaluation (PTA) was performed in all patients to know the type of hearing impairment and to identify degree of hearing loss. Majority had moderate conductive hearing loss (15 patients) followed by mild conductive hearing loss (11 patients) while others mild(2 patients) and moderate mixed hearing loss (1 patient).Pre operative air bone gap was calculated by taking an average of frequencies at 0.5, 1, 2, 4 kHz and was found to be 31.45 dB.

CWDM provides an outstanding access of the surgical field. Ossicular discontinuity was noted in majority patients who underwent type 3 tympanoplasty via myringostapedopexy (76.67% patients) and myringoplatinopexy (23.33% patients).

Similarly, a study conducted by Ali S et al concluded that type 3 tympanoplasty had a marginal improvement for 120 cases.[110] Sami S M et al in 50 patients noted that canal wall down mastoidectomy with type 3 tympanoplasty showed significant improvement in COMQ12 scores.[121]

Apart from ossiculoplasty, few patients were subjected to facial nerve decompression (2 patients) and aural polypectomy (2 patients). Two patients were diagnosed with malignant

otitis externa underwent debridement of granulation tissues.

Intra operative ossicular evaluation revealed incus necroses in majority of patients (22 patients) followed by malleus (5 patients) and stapes suprastructure (3 patients). The findings were consistent with a study carried by Mocanu H et al who followed up patients for eight years following radical mastoidectomy.[111]

Following first visit on post operative day 15, only 2 patients had ear discharge in contrast to a study by Juvekar M and Sarkar B who reported 10 cases with active ear discharge.[112]Amongst our two patients, both had uncontrolled blood sugar levels and appropriate measures were taken.

On second post operative visit i.e on post operative 60 day, only 1 patient continued to have ear discharge while other had no further episodes. Similarly, Juvekar M and Sarkar B reported 5 cases with ear discharge on their second follow up visit.[112]

Later while 3 post operative visit, the same patient continued to have otorrhea and yet his blood sugars were still elevated with HbA1c of 8.5% suggesting a crucial need to control blood sugar levels in the immediate post operative period as also the possibility of surgical site infections. Cals J LF conducted a search in 336 cholesteatoma surgeries and found chances of surgical site infections to be 4.5%.Furthermore the study, advocated the prevalence of SSI was more with bioactive glass.[113]

Additionally, all patients underwent audiological investigation in the form of pure tone audiometry , using the same procedure as in pre operative period, mean ABG was calculated.The difference between pre (31.34 dB) and post op ABG(24.59 dB) was found to be 6.8 dB with air bone closure of 22.16% which was statistically significant . Similar findings were noted in an another study.[112]

In a study carried by Senugupta A showed that average air bone gap was 5.2 dB following canal wall down mastoidectomy with ossicular reconstruction.[114] Our approach towards obliteration proved fruitful in terms of controlling abnoxious ear discharge, giddiness, keratin debris, retraction of neo tympanum and most important of all no recurrence or recidivism.

Krol B, Cywka B K, Skarzynska B M, Skarzynski H P conducted a similar study but used S53P4 bioactive glass in 11 patients and concluded by last follow up that use of bioglass reduces risk of infection but does not ensures field sterility. There was no audiological improvement and implicated need to instill anti fungal aural drops and antibiotics to render a healthy cavity.[115]

Mohammad Farmarzi M D et al implicated use of silicone blocks to reconstruct and obliterate mastoid in 39 patients. The study reported 1 case of granulation tissue presence and 2 cases with extrusion of blocks needing revision mastoidectomy. No hearing improvement was noted in their study.[116]

Sherif M Askar, Ibrahim M Saber, Mohammad Omar devised a novel approach to obliterate the mastoid cavity in 21 cases with platelet rich plasma. They observed no immediate post operative complications but later 1 patient had persistent ear discharge and 2 patients had tympanic membrane perforations. No patient had any other complications and reported 85% success in graft uptake and achieving dry ear. The study concluded that PRP with bone pate is a better option to obliterate mastoid cavity.[117]

Middle temporal artery and inferior musculo periosteal flaps were used in combination by Arthur Dexian Tan, Jia hui Ng, David Yong- Ming Low, Heng Wai Yuen in 75 cases and followed patients for 29 month. Merchant system of grading was used in this study. Grade 2 was achieved by all except one patient who developed recurrence. Their study concluded with 98.7% patients with disease free ear.[118]

Vivian Singh and Marcus Atlas used middle temporal artery flap in 51 cases and reported healthy dry cavity with occasional ear discharge managed by topical therapy. Follow up duration in their study was 12 months. [119]

Tawalbeh M et al used periosteal peri cranial flap in 64 patients out of which 82.8% had healthy cavity .In this study otorrhea, meatal stenosis, granulation tissues were post operative complications noted. The study concluded that this technique was efficient.[101]

A randomized parallel group study was performed by Mishra K A et al in 68 patients. Of these bone pate and bioactive glass was used as an obliterating agent. 2 patient in bone pate and 1 patient in bioactive glass group had recidivism. But there was a significant ABG reduction but by Glasgow Benefit Inventory no difference was noted in both groups.[120]

Yamamoto Y et al reported 118 cases wherein bone pate was used to reconstruct the canal wall showed a success rate of 95.8% but 2.5% patients had features of otorrhea and 1 patient had exposure of bone pate. The follow up duration in this study was for 5 years.[103]

In our study with the most lucid technique and precise nature of surgery we were able to manage all the detrimental after effects of CWDM. The success rate in our study was 96.67% but the only affected individual had no recurrence but was later stabilized. Majority of our patients did not mentioned any troublesome issues making our intervention a unique one.

Thus in a robust of all the promising obliterating agent, none of them has been proved successfully ideal and inert. Hence, there is still a dilemma in opting the type of material needed to obliterate the cavity. Studies in literature have a low level of evidence rendering the topic to be a pandora's box.[122]

We recommend our technique of obliteration owing to the easy surgical technique of harvesting, no need for an additional incision, cost effective, no fear of extrusion or giant cell

body reaction, no recidivism or recurrence of disease. In addition to these, as evident from our results we managed to achieve a dry cavity by the last follow up visit, good improvement in hearing and the outcome of prime importance seen with cavity related issues due to excellent obliterating technique.

Strengths of the study:

The main strategy of the study that was Prospective in nature and patients were followed up till the last expected day.

All surgeries were performed by a single experienced surgeon.

There was co- relation in our findings between clinical, radiological, audiological and intra operative findings.

All patients mastoid cavity were uniformly saucerized, obliterated with post auricular soft tissue till the level of EAC to make a uniform cavity.

There was statistical significance in air bone gap closure on comparison between pre and post operative intervention.

Limitations of study:

Small sample size.

Shorter follow up period.

No control group to have adequate comparison.

Future scope for study:

Randomized control trials with larger sample size and longer follow up period should be done to evaluate the efficacy of obliteration in overcoming the troublesome large cavity issues.

Other promising materials can be inculcated like bone dust, silicone glass, bioactive glass, plasma rich platelet.

Studies can also be taken in regards to time taken by the cavity to epithelize and any adverse complications like recidivism and recurrence.

Health related questionnaires can be incorporated to know the functional aspects of the surgical intervention.

Recent concepts like reconstruction of posterior canal wall are taking root.

SUMMARY

SUMMARY

Our study was taken up with a prime objective of evaluating the intervention in the form of obliteration with post auricular soft tissues following disease eradicating procedures rendering a large mastoid bowl. Surgically created mastoid cavity though aid in complete exposure and disease eradication but, has other horrid complications like otorrhea, giddiness, cosmetically large meatus, need to frequently visit otologists. In this regards, traditionally disease eradication was the need of hour but now the concepts are heading towards the quality of life.

A cohort of 30 patients after fulfilling the inclusion criteria was selected with prior written consent explaining the due course of surgical intervention. Relevant blood investigations along with radiological and audiological investigations were done as a part of pre anesthetic check up. We addressed other pathologies like aural polyps, keratosis obturans, malignant otitis externa apart from cholesteatoma. There were varied co morbidities observed in our patients , diabetes being the most common followed by hypertension, chronic kidney disease, ischemic heart disease. Pre op ABG was evaluated by taking average at 0.5, 1 ,2 and 4 kHz.

Surgical intervention was not only planned to eradicate the disease but also to have better functional outcomes in regards to quality of life post operatively. Intra operative findings were consistent with clinical and radiological findings that aided in prompt management of the encountered pathologies . After complete saucerization of the large cavity and performing the relevant ossiculoplasty , we obliterated the mastoid cavity with harvested post auricular fibro periosteal tissues with the prime concern in areas of interest.

Post operatively all cases were subjected to intravenous antibiotics as per the hospital policy for a minimum period of 5 days. In this period no complications were observed and patients were re-called on post operative 15 day. Canal pack was removed in all patients and the cavity was assessed under microscope to look for any evidence of keratin debris, granulation tissues, cholesteatoma, retraction of neo tympanum. 2 patients had ear discharge, who were treated with oto antibiotic drops. Rest all patients had no other complications and were called upon post operative 60 day.

Similar parameters were assessed and only 1 patient continued to have ear discharge owing to uncontrolled glycemic levels. Hence, oral antibiotics were implemented for the same. Later, all cases were recalled on post operative day 90, in adjunction to oto microscopy, audiological investigation in the form of PTA. Mean ABG was calculated using the same frequencies as in pre operative period.

Air bone gap closure in percentage showed 22.16% with p value of 0.0178 which was statistically significant. In addition to the hearing outcome, we assessed other parameters like ear discharge, tinnitus intensity, granulation tissues, keratin pearls, retraction of neo tympanum, giddiness. Statistically there was a significant p value for each which was <0.05 implying the excellent response of patients undergoing the intervention.

Hence our technique with pedicled post aural soft tissue flap along with free harvested post auricular soft tissues , not only reduced the volume of cavity but also provided with better functional outcomes on ear discharge, hearing improvement and other antagonizing symptoms. So we highly recommend our technic.

CONCLUSION

CONCLUSION

Chronic otitis media, an entity known since the existence of mankind, still continues to pose a great threat to human race with its aggressive morbidity and mortality.

COM and its dreaded complications are like a nightmare for otologists demanding additional expertise while intervening with an aim to eradicate the disease pathology.

Surgical modality of treatment has been revolutionized from a simple trephination to more routinely sought mastoidectomies and is still nurturing.

Studies in literature have embarked unique individual experience and fallacies encountered by the researchers and has set the topic of management still under debate.

Traditional concepts pave their way towards only one prime goal to exterminate the disease pathology but not considering the functional sequelae.

With the advent of modern otological procedures and the quest amongst Otologists , tides have turned towards procedures that can be implicated for both disease eradication and socially acceptable post operative outcomes.

CWD is the elite choice in addressing the extensive disease process with proper address to hidden areas that become the nidus for the recurrence.

CWD although has excellent exposure and better eradication results but has the fearful and socially comprimising symptoms often related as ‘ Cavity issues.’

Obliteration of the large surgically created mastoid bowls, not only helps to restore anatomy but also aids in better functional outcomes.

In a gist, obliteration is a midpoint of two diverse spectrum considering CWD at one end and

CWU on other.

In due course of time, obliteration techniques have undergone a radical change from autologous agents to flaps and now xenografts.

But, none of the materials have been a promising one so the challenge for selection is based on outcomes of patients, availability and surgeons' preference.

Owing to this, there are lists of varied materials that are still under trial.

In our study, we encountered diverse range of comorbidities, disease pathologies, radiological anomalies that needed holistic approach in dealing with this dreaded entity, yet we managed to get an excellent response.

The observed pre operative abnoxious symptoms had drastically reduced on follow up visits.

In terms of hearing we managed to get a better outcome which is the prime concern of treatment seeking patients.

Cavity related issues were promptly managed by the intervention as it was evident with completely dried epithelized healthy cavity.

The present study indicates that obliteration with post auricular fibro periosteal tissues is not only a simple technique but also had an excellent functional outcomes rendering the healthy cavity free from the troublesome issues.

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ANNEXURES

ANNEXURE I

PROFORMA:

Particulars of the patients:- Serial No.

Age:

Gender:

UHID No:

Date of Admission:

Chief Complaints:

Date of Discharge:

COMPLAINTS:	YES/ NO
Ear discharge Type Quantity Foul smelling Blood tinged	
Reduced Hearing Speech intelligibility	
Tinnitus	
Giddiness	
Ear pain	
Facial Nerve Weakness	
Any symptoms pertaining to nose and throat	

Past History:	YES/NO
Diabetes Mellitus	
Hypertension	
Tuberculosis	

Personal History:

Diet	
Appetite	
Sleep	
Bowel/ bladder	
Habits Smoking Alcohol	

General Physical Examination:
Build and Nourishment-
Pallor, icterus, cyanosis, clubbing, lymphadenopathy
Vitals:
Blood pressure- Respiratory rate-
Pulse rate- Temperature-
Local Examination:

Ear	Right	Left
Pre auricle (Sinus, fistula, abscess) Tragal tenderness		
Auricle (Shape, size)		
Post auricle (Post surgical scar, sinus, fistula, abscess) Mastoid tenderness		
External auditory canal Discharge Odema Mass/ polyp Scutum		
Tympanic membrane		
Cholesteatoma		
Retraction pockets		
Facial nerve (House Brackman)		

NOSE :

External framework:

Columella:

Vestibule:

Septum:

Cavity:

PNS tenderness:

ORAL CAVITY:

Mouth Opening:

Lips:

Teeth:

Tongue:

AP/PP/PPW:

SYSTEMIC EXAMINATION:

Cardio vascular System: Respiratory System:

Per abdomen: Central Nervous System:

HRCT Temporal bone:

Pure Tone Audiometry(Pre op):

Date of Surgery:

Surgery performed:

Intra operative finding:

Condition of the patient on discharge: -

Post operatively Hearing and Cavity outcomes seen at 15 day, 2 month and 3 month.

Parameters	15 day	2 month	3 month
Ear Discharge Pus from wound Keratin debris Retraction pocket Granulation tissue Cholesteatoma Wound dehiscence Recurrence			

Pure Tone Audiometry Post operative 3 month:

Air Bone Gap =

(Pre operative Air Bone Gap- Post operative Air Bone Gap)

Percentage Air Bone Closure=

Condition of patient on Post operative 3 month:

ANNEXURE II

INFORMED CONSENT FORM

I Mr/Mrs. _____ have been explained in my own understandable language, that I will be included in a study which is**"Outcome of mastoid cavity obliteration using Fibro-periosteal Post-auricular soft tissue in Canal Wall Down Mastoidectomy"**

I have been explained that my clinical findings, investigations, intraoperative findings, will be assessed and documented for study purpose.

I have been explained my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.

I have been explained about the interventions needed possible benefits and adversities due to interventions, in my own understandable language.

I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.

I have Principal investigator mobile number for enquiries.

I in my sound mind give full consent to be added in the part of this study.

Signature of the patient:

Name: Signature of the witness:

Name: Relation to patient:

Date:

Place:

ಮಾಹಿತಿ ಕಾನ್ಸೆಂಟ್ ಫಾರ್ಮ್

ನಾನುಶ್ರೀ / ಶ್ರೀ. _____ ಅನ್ನು ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, ಇದು "ದೀರ್ಘಕಾಲದ ಓಟಿಟಿಸ್ಮೀಡಿಯಾ ರೋಗಿಗಳಲ್ಲಿ ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಟೆಂಪರೊಲಿಸ್ಫ್ಯಾಸಿಯಾ ಗ್ರಾಫ್ಟ್ ಗೆದುಕೊಳ್ಳುವಿಕೆಯ ಮೌಲ್ಯಮಾಪನ" ಎಂಬ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು ಸೇರಿಸಲಾಗುವುದು.

ನನ್ನ ಕ್ಲಿನಿಕಲ್ಆವಿಷ್ಕಾರಗಳು, ತನಿಖೆಗಳು, ಇಂಟ್ರಾಆಪರೇಟಿವ್ ಆವಿಷ್ಕಾರಗಳನ್ನು ಮೌಲ್ಯ ಮಾಪನ ಮಾಡಲಾಗುವುದು ಮತ್ತು ಅಧ್ಯಯನದ ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.
ಈಅಧ್ಯಯನದಲ್ಲಿನನ್ನಭಾಗವಹಿಸುವಿಕೆಯುಸಂಪೂರ್ಣವಾಗಿಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆಎಂದುನನಗೆವಿವರಿಸಲಾಗಿದೆ, ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಗೆ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ, ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಕಾರಣದಿಂದಾಗಿ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲತೆಗಳ ಅಗತ್ಯವಿರುವ ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.
ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕಂಡು ಬರುವ ನನ್ನ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗಿದೆ ಮತ್ತು ಸಂಶೋಧನೆಗಳನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ ಹಂಚಿಕೊಳ್ಳುವಾಗ, ನನ್ನ ವಿವರಗಳನ್ನು ಮರೆಮಾಚಲಾಗುತ್ತದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.
ವಿಚಾರಣೆಗಾಗಿ ನನ್ನ ಬಳಿ ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ ದೂರವಾಣಿ ಸಂಖ್ಯೆ ಇದೆ.
ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಸಂಪೂರ್ಣ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ.

ರೋಗಿಯ ಸಹಿ:

ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ:

ಹೆಸರು:

ರೋಗಿಗೆ ಸಂಬಂಧ:

ANNEXURE III

PATIENT INFORMATION SHEET

STUDY TITLE: "Outcome of mastoid cavity obliteration using Fibro- periosteal Post-auricular soft tissue in Canal Wall Down Mastoidectomy."

STUDY SITE: R.L Jalappa Hospital and Research Centre, Tamaka, Kolar.

This is to inform you that, you require mastoid cavity obliteration using Fibro- periosteal Post-auricular soft tissue for making treatment plan for you condition that is Chronic Otitis Media. This required for the making the diagnosis of the disease extent of the disease and for planning of the treatment

We are conducting this study to predict the onset and severity of this condition.If you are willing you will be enrolled in this study and we will do mastoid cavity obliteration using Fibro- periosteal Post-auricular soft tissue and other relevant investigations which are required.

You will receive the standard care pre and post operatively.

All investigations are done as a part of routine preoperative and postoperative protocol and no special investigation is being performed on the patient. Patient has to bear the cost of investigations and surgical expenditures.

This will facilitate identifying CHRONIC OTITIS MEDIA AND ITS COMPLICATIONS (if any) in an early stage and treating it. It will also benefit other patients with chronic otitis media undergoing surgery in future. You are free to opt-out of the study at anytime if you are not satisfied or apprehensive to be a part of the study. Your treatment and care will not be compromised if you refuse to be a part of the study. The study will not add any risk or financial burden to you if you are part of the study. In case of any complication during surgery patient will be treated accordingly .

Your identity and clinical details will be confidential. You will not receive any financial benefit for being part of the study. You are free to contact DR AUSEKAR SHAHRUKH FEROZ ALI or any other member of the above research team for any doubt or clarification you have.

Dr. AUSEKAR SHAHRUKH FEROZ ALI

Mobile no: 8147689929

E-mail id: shahrukh3594@gmail.com

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: ‘‘ದೀರ್ಘಕಾಲದ ಓಟಿಟಿಸ್ಮೀಡಿಯಾ ರೋಗಿಗಳಲ್ಲಿ ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಂಪನೊಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಟೆಂಪೊರೊಲಿಸ್ಫಾಸಿಯಾ ಗ್ರಾಫ್ಟ್ ಗೆದು ಕೊಳ್ಳುವಿಕೆಯ ಮೌಲ್ಯಮಾಪನ.’’
ಅಧ್ಯಯನ ಸೈಟ್: ಆರ್.ಎಲ್ಲಲಪ್ಪಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ, ತಮಾಕಾ, ಕೋಲಾರ.
ದೀರ್ಘಕಾಲದ ಓಟಿಟಿಸ್ಮೀಡಿಯಾದ ನಿಮ್ಮ ಸ್ಥಿತಿಗೆ ಚಿಕಿತ್ಸೆಯ ಯೋಜನೆಯನ್ನು ತಯಾರಿಸಲು ನಿಮಗೆ ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿ ಅಗತ್ಯವಿರುತ್ತದೆ ಎಂದು ನಿಮಗೆ ತಿಳಿಸುವುದು. ರೋಗದ ವ್ಯಾಪ್ತಿಯ ರೋಗ ನಿರ್ಣಯವನ್ನು ಮಾಡಲು ಮತ್ತು ಚಿಕಿತ್ಸೆಯ ಯೋಜನೆಗಾಗಿ ಇದು ಅಗತ್ಯವಾಗಿರುತ್ತದೆ.
ಈ ಸ್ಥಿತಿಯ ಆಕ್ರಮಣ ಮತ್ತು ತೀವ್ರತೆಯನ್ನು ಪೂರ್ವ ನಿರ್ದೇಶನ ಮಾಡಬೇಕು, ಆದ್ದರಿಂದ ನಾವು ಈ ಅಧ್ಯಯನವನ್ನು ನಡೆಸುತ್ತಿದ್ದೇವೆ.

ನೀವು ಸಿದ್ಧರಿದ್ದರೆ ನೀವು ಈ ಅಧ್ಯಯನಕ್ಕೆ ದಾಖಲಾಗುತ್ತೀರಿ ಮತ್ತು ನಾವು ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿ ಮತ್ತು ಅಗತ್ಯವಿರುವ ಇತರ ಸಂಬಂಧಿತ ತನಿಖೆಗಳೊಂದಿಗೆ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿಮಾಡುತ್ತೇವೆ. ಎಲ್ಲಾ ತನಿಖೆಗಳನ್ನು ವಾಡಿಕೆಯ ಪೂರ್ವಭಾವಿ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಪ್ರೋಟೋಕಾಲ್ನ ಭಾಗವಾಗಿ ಮಾಡಲಾಗುತ್ತದೆ ಮತ್ತು ರೋಗಿಯ ಮೇಲೆ ಯಾವುದೇ ವಿಶೇಷ ತನಿಖೆ ನಡೆಯುತ್ತಿಲ್ಲ. ತನಿಖೆ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ವೆಚ್ಚಗಳನ್ನು ರೋಗಿಯು ಭರಿಸಬೇಕಾಗುತ್ತದೆ.

ನೀವು ಸ್ಕ್ಯಾಂಡಲ್ಕೆರ್ಪೂರ್ವ ಮತ್ತು ಪೋಸ್ಟ್ಅನ್ನು ಆಪರೇಟಿವ್ಆಗಿ ಸ್ವೀಕರಿಸುತ್ತೀರಿ
ಇದು ಆರಂಭಿಕ ಹಂತದಲ್ಲಿ ಕ್ರೋನಿಕ್ ಒಟಿಟಿಸ್ಮೀಡಿಯಾ ಮತ್ತು ಅದರದೂರುಗಳನ್ನು (ಯಾವುದಾದರೂಇದ್ದರೆ) ಗುರುತಿಸಲು ಮತ್ತು ಚಿಕಿತ್ಸೆ ನೀಡಲು ಅನುಕೂಲವಾಗುತ್ತದೆ. ಭವಿಷ್ಯದಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ ಒಳಗಾಗುವ ದೀರ್ಘಕಾಲದ ಓಟಿಟಿಸ್ಮಾಧ್ಯಮ ಹೊಂದಿರುವ ಇತರರೋಗಿಗಳಿಗೆ ಇದು ಪ್ರಯೋಜನವನ್ನು ನೀಡುತ್ತದೆ. ನೀವು ಅಧ್ಯಯನದ ಭಾಗವಾಗಲು ತೃಪ್ತಿ ಹೊಂದಿಲ್ಲದಿದ್ದರೆ ಅಥವಾ ಭಯಪಡದಿದ್ದರೆ ನೀವು ಯಾವಾಗ ಬೇಕಾದರೂ ಅಧ್ಯಯನ ದಿಂದ ಹೊರಗುಳಿಯಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ನೀವು ಅಧ್ಯಯನದ ಭಾಗವಾಗಲು ನಿರಾಕರಿಸಿದರೆ ನಿಮ್ಮ ಚಿಕಿತ್ಸೆ ಮತ್ತು ಕಾಳಜಿಗೆ ಧಕ್ಕೆಯಾಗುವುದಿಲ್ಲ.
ನೀವು ಅಧ್ಯಯನದ ಭಾಗವಾಗಿದ್ದರೆ ಅಧ್ಯಯನವು ನಿಮಗೆ ಯಾವುದೇ ಅಪಾಯ ಅಥವಾ ಆರ್ಥಿಕ ಹೊರೆಸೇರಿಸುವುದಿಲ್ಲ. ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ತೊಡಕು ಉಂಟಾದರೆ ರೋಗಿಗೆ ಅನುಗುಣವಾಗಿ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುತ್ತದೆ.

ನಿಮ್ಮ ಗುರುತು ಮತ್ತು ಕ್ಲಿನಿಕಲ್ವಿವರಗಳು ಗೌಪ್ಯವಾಗಿರುತ್ತದೆ. ಅಧ್ಯಯನದ ಭಾಗವಾಗಿರುವುದರಿಂದ ನೀವು ಯಾವುದೇ ಆರ್ಥಿಕಲಾಭವನ್ನುಪಡೆಯುವುದಿಲ್ಲ. ನೀವು ಹೊಂದಿರುವ ಯಾವುದೇ ಅನುಮಾನ ಅಥವಾ ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ನೀವು ಡಿ.ಆರ್.ಅಶೇಕರ್ಶಹರೂಕ್ಫೆರೋಜ್ ಅಲಿ ಅಥವಾ ಮೇಲಿನ ಸಂಶೋಧನಾ ತಂಡದ ಇತರ ಯಾವುದೇ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಡಾ.ಅಶೇಕರ್ಶಹರೂಕ್ಫೆರೋಜ್ಅಲಿ

ಮೊಬೈಲ್ಸಂಖ್ಯೆ: 8147689929

ಇ-ಮೇಲ್ಐಡಿ: shahrukh3594@gmail.com

KEY TO MASTER CHART

Male	M
Female	F
HRCT	High Resolution Computed Tomography
ABG	Air Bone Gap