A DISSERTATION ON

"COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA"

Submitted to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfilment, of the requirements for the award of the degree of

M.S.BRANCH IV (OTORHINOLARYNGOLOGY)

REG NO: 221914551

DEPARTMENT OF OTORHINOLARYNGOLOGY

GOVERNMENT CHENGALPATTU MEDICAL COLLEGE

CHENGALPATTU, TAMILNADU

MAY - 2022

BONAFIDE CERTIFICATE

This is to certify that the dissertation titled "**COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA**" submitted by Dr.K.GOKUL, Register Number: 221914551 post graduate student, in the department of otorhinolaryngology, Chengalpattu medical college and hospital appearing for M.S.ENT Branch IV Degree examination in May 2022 is a bonafide record of work done by him under my guidance and supervision in partial fulfilment of the regulations of the Tamilnadu Dr.M.G.R.Medical University , Chennai. I forward this to the Tamilnadu Dr.M.G.R.Medical University , Chennai, Tamilnadu , India.

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CERTIFICATE

This is to certify that the Dissertation "**COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA"** presented by **DR.GOKUL K**, is an original work done in the Department of Otorhinolaryngology, Government Chengalpattu Medical College and Hospital, Chengalpattu in partial fulfilment of regulations of the Tamil Nadu Dr. M.G.R. Medical University for the award of degree of M.S. (Otorhinolaryngology) Branch IV, under my supervision during the academic period 2019-2022**.**

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DECLARATION

I, **DR.GOKUL.K**, solemnly declare that this dissertation titled "**COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA**" is a bonafide work done by me in Chengalpattu Medical College, Chengalpattu during the period of April 2020 to March 2021 under the expert supervision of **DR.D.SENTHAMARAI KANNAN M.S.ENT.,DNB.,** Associate Professor, Department of Otorhinolaryngology, Chengalpattu Medical College, Chengalpattu. This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the rules and regulations for the award of the degree of M.S. Otorhinolaryngology (Branch IV) examinations to be held in May 2022.

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Date : **Signature of the Candidate**

Place: Chengalpattu **(Dr.GOKUL. K.)**

CERTIFICATE

This is to certify that the Dissertation work titled "**COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA"** of the candidate **DR.GOKUL K**, with registration number **221914551** for the award of M.S. Degree in the branch of Otorhinolaryngology. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from the introduction to conclusion pages and result shows **09 percentage** of plagiarism in the dissertation.

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ACKNOWLEDGEMENT

I would like to express my deep sense of gratitude to the Dean ,Chengalpattu Medical College and Hospital **Prof.DR.J.MUTHUKUMARAN M.S.,Mch.,** for allowing me to undertake this study with much avidity.

My heartfelt gratitude to **Prof.DR.M.VENUGOPAL M.S.(ENT)**, Professor and head of the department, Department of ENT, Government Chengalpattu medical college for his constant encouragement ,motivation and expert supervision during the course of this study.

My heartfelt gratitude to **DR.D.SENTHAMARAI KANNAN M.S.(ENT),DNB**, Associate professor, Department of ENT, Government Chengalpattu medical college for his constant encouragement ,motivation and expert supervision during the course of this study.

My heartfelt gratitude to **DR.G.SOUNDARARAJAN M.S.(ENT).,DNB**., Former assistant professor, Department of ENT, Government Chengalpattu medical college for his constant encouragement ,motivation and expert supervision during the course of this study.

I would like to thank my Assistant Professors, **DR.K.SARAVANAN M.S.ENT** and **DR.V.NARENDRAKUMAR M.S.ENT.,DNB.,D.L.O** and Senior Resident **DR. B.SUDHA D.L.O** for their valuable tips and support. I am grateful to the other post-graduates who most willingly helped me during this study period.

My heartfelt gratitude to **Prof.DR.S.RAVI M.D.**, Professor and the Head of the Department, Department of Pathology, Government Chengalpattu medical college for his constant encouragement ,motivation and expert supervision during the course of this study.

I also thank the audiologist, audiometrician, the staff nurses, theatre personnel, OPD staff, Department of Otorhinolaryngology, Government Chengalpattu Medical college and Hospital for their cooperation and assistance in the conduct of this study.

I wish to extend my gratitude to my statistician for her expert assistance. Last but not the least, I am indebted and grateful to all the Patients who constitute the backbone of this study, who most willingly and selflessly subjected themselves to this study for the sake of the benefit of their community and without whom this study would not have been possible.

ABBREVIATIONS

COM	–	Chronic Otitis Media
CSOM	–	Chronic Suppurative Otitis Media
AOM	–	Acute Otitis Media
TM	–	Tympanic Membrane
PRP	–	Platelet Rich Plasma
PPP	–	Platelet Poor Plasma
PRF	–	Platelet Rich Fibrin
Hz	–	Hertz
CT	–	Computed Tomography
PRE OP PTA	–	Pre Operative Pure Tone Audiometry
POST OP PTA	–	Post Operative Pure Tone Audiometry
dBHL	–	Decibel Hearing Loss
LA	–	Local Anaesthesia

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INTRODUCTION

Chronic suppurative otitis media is defined as chronic inflammation of the mucoperiosteal lining of the middle ear cleft[1]. It is associated with a persistent or intermittent infected discharge through non intact tympanic membrane. Chronic otitis media (COM) is the term that equates with classic term "chronic suppurative otitis media" which is no longer advocated as there is no pus in all case of chronic otitis media[2]. They are now divided into active COM where there is production of pus and inactive COM where there is no pus but can become active at times.

The aim of treatment in mucosal type of COM is to eliminate infection, to prevent further infection and to restore normal functioning of middle ear. There are various nonsurgical and surgical measures available in achieving these aims[3].

Nonsurgical measures include aural toileting, use of topical and systemic antibiotics. Topical antibiotics are more effective than systemic antibiotics in treating mucosal disease. Some cases of mucosal type COM resolve with medical management itself and usually no further intervention is needed if the patient is asymptomatic[1].

If there is recurrence or persistence of otorrhoea despite the medical treatment or if the patient is handicapped by conductive hearing loss surgical treatment should be considered[4]. Ideal surgical procedure that has to be done is tympanoplasty after adequate control of infection and after the middle ear mucosa has become healthy. In this situation the chance of successful outcome is

very high. Tympanoplasty is the surgical correction of a perforated tympanic membrane with or without ossicular reconstruction.

Myringoplasty refers to simple surgical closure of a perforation in tympanic membrane without ossicular reconstruction[5].

Success rate after myringoplasty has a wide range from 70 to 80%. Therefore, there is still a need to search for methods to enhance tympanic membrane healing after myringoplasty to increase success rate[6].

We will Study about the outcomes of use of platelet-rich plasma (PRP) in myringoplasty. The platelets are best known for their importance in clotting blood[7]. However, platelets also contain hundreds of proteins called growth factors which are very important in the healing of injuries. Platelet rich plasma (PRP) with various growth factors has been proved to improve wound healing. PRP has been used in various fields like dermatology, orthopaedics, plastic surgery, dentistry for its beneficial effects[8].

PRP is plasma with many more platelets than what is typically found in blood. The concentration of platelets and, thereby, the concentration of growth factors can be 5 to 10 times greater (or richer) than usual. The study focuses on the use of prepared autologous PRP which is kept on the lateral surface of graft and TM remnant during myringoplasty and results will be noted with respect to the uptake of graft in such patients[9].

AIMS AND OBJECTIVES

1. To compare the success rate of myringoplasty with and without platelet rich plasma in inactive cases of chronic otitis media with central perforation, with a follow up period of 2 months

2. To study the efficiency of use of autologous platelet rich plasma in closure of tympanic membrane perforation during myringoplasty by

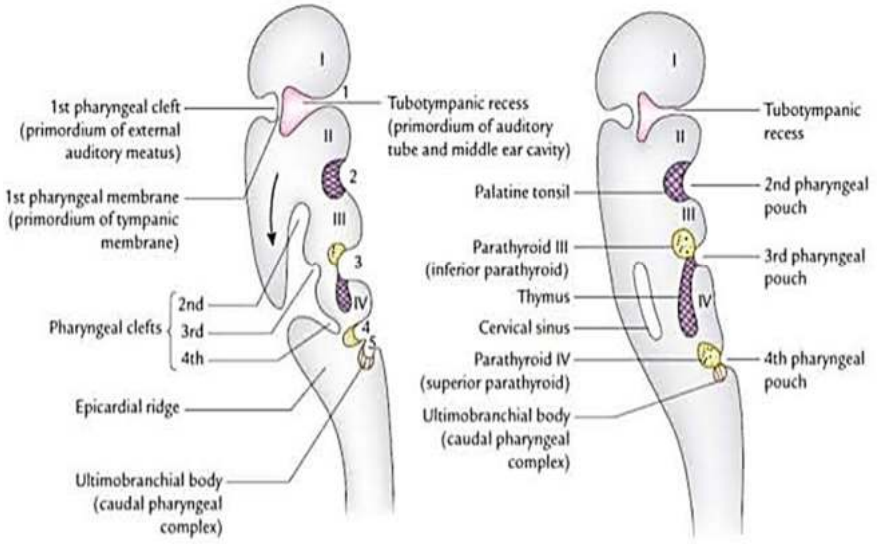
    - Preventing the graft displacement
    - Promoting quicker healing.
    - Improving the overall outcome.

REVIEW OF LITERATURE

EMBRYOLOGY OF EAR:

The human ear begins to develop from the 4th week of the embryonic life[10] (Fig.1).

Fig.1.Embryology of ear

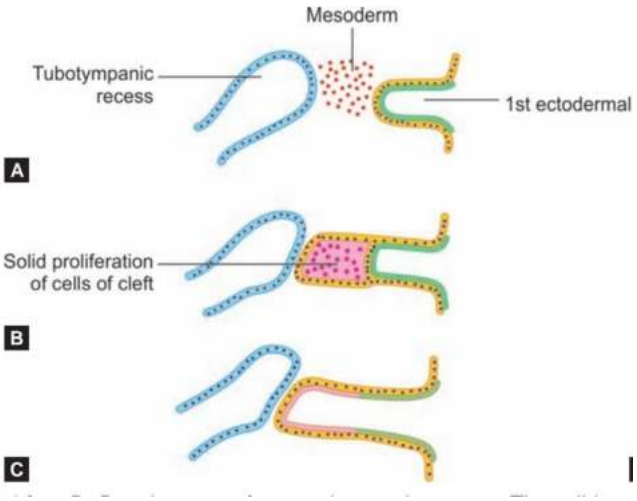


EXTERNAL EAR:

The external acoustic meatus is derived from the dorsal part of the first branchial (ectodermal) cleft[11].

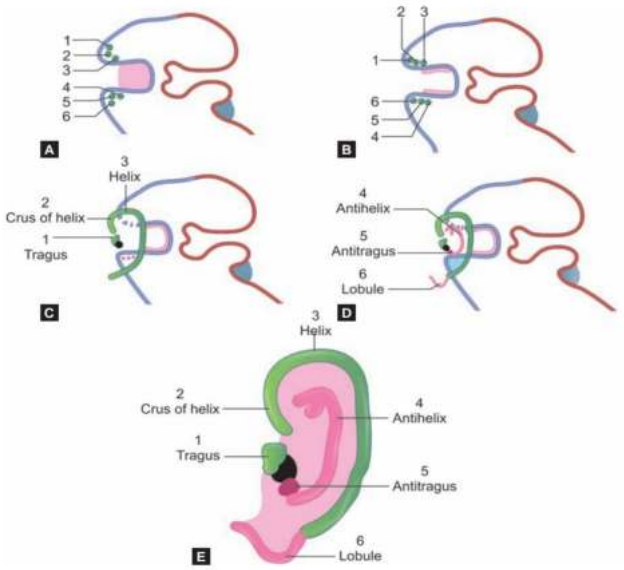
However, its deeper part is formed by proliferation of its lining epithelium, which grows toward the middle ear. This proliferation is at first solid (meatal plug), but is later canalized[12] (Fig.2).

Fig.2. Embryology of External auditory canal



The auricle, or pinna, is formed from about six mesodermal thickenings (called tubercles or hillocks) that appear on the mandibular and hyoid arches, around the opening of the dorsal part of the first ectodermal cleft (i.e. around the opening of the external acoustic meatus)[13](Fig.3).

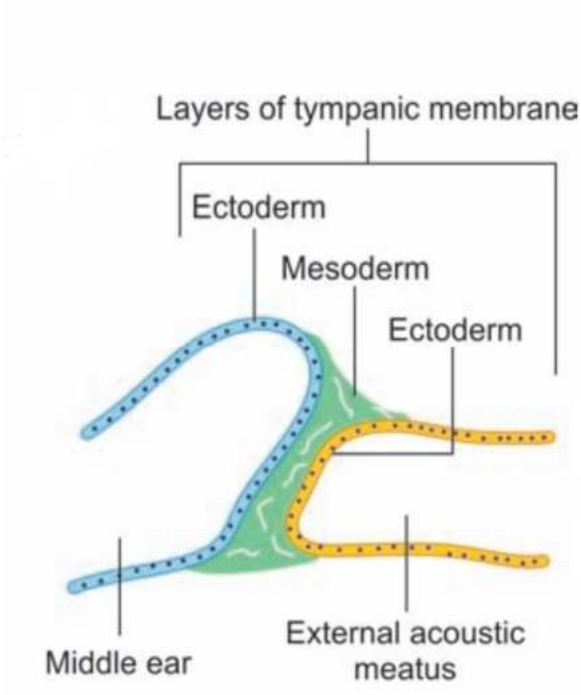
Fig.3.Embryology of pinna



TYMPANIC MEMBRANE:

- Outer cuticular layer- ectoderm of 1st branchial cleft.
- Middle fibrous layer-mesoderm of 1st and 2nd branchial arches.
- Inner mucosal layer-endoderm of 1st pharyngeal pouch (tubotympanic recess) [1,14] (Fig.4).

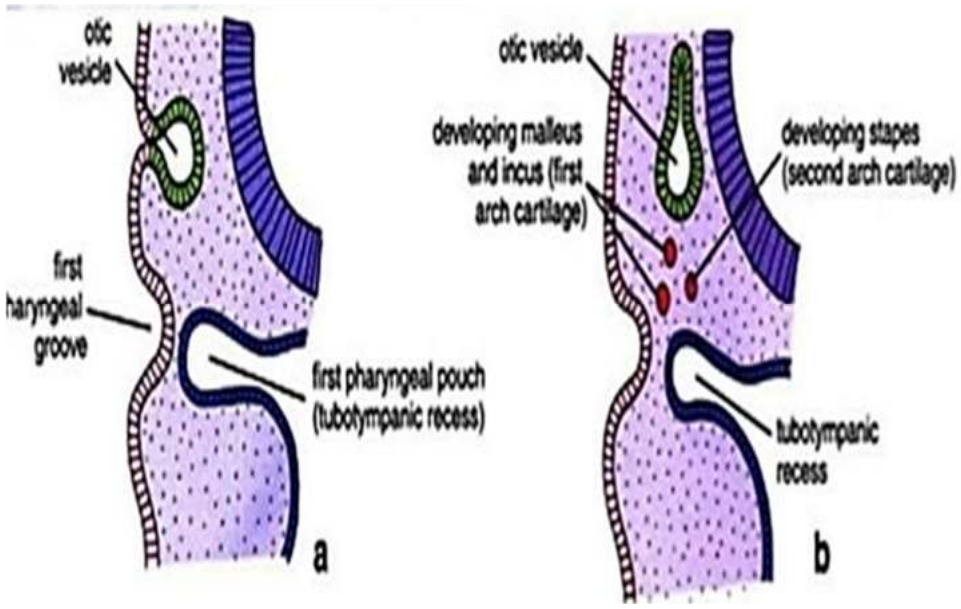
Fig.4.Embryology of tympanic membrane



MIDDLE EAR:

The epithelial lining of the middle ear and of the pharyngotympanic tube is derived from the tubotympanic recess. This recess develops from the dorsal part of the 1st pharyngeal pouch, and also receives a contribution from the second pouch. The tympanic antrum and mastoid air cells are formed by extensions from the middle ear[15] (Fig.5)

Fig.5.Embryology of middle ear

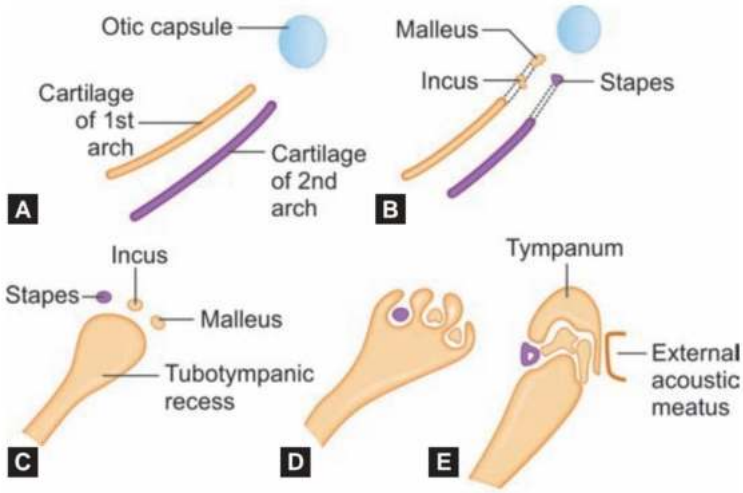


MIDDLE EAR OSSICLES:

The ossicles develop from the outer ends of the first arch (Meckel's) and second arch (Reichert's) cartilages that lie above and below the first pharyngeal pouch. The process begins at 4 weeks and adult shape, size and ossification are present by 25 weeks[15] (Fig.6).

- 1st Arch (Meckel's) Cartilage derivatives – Head of malleus
  Body of incus,
  Anterior malleolar ligament.
- 2nd Arch (Reichert's) Cartilage derivatives – Handle of Malleus,
  Long process of incus,
  Head and Crura of Stapes.
- Foot Plate of Stapes develops from Otic capsule[16].

Fig.6.Embryology of middle ear ossicles



MIDDLE EAR MUSCLES:

The tensor tympani muscle is derived from the mesoderm of the 1st pharyngeal arch(supplied by fifth cranial nerve) and the stapedius from that of the 2nd arch(supplied by the seventh cranial nerve)[17]. The chorda tympani, which is the pretrematic nerve of the second arch that supplies endodermal structures of the first arch (i.e. taste to the anterior two-thirds of the tongue and submandibular gland secretomotor fibres)[18]

ANATOMY OF EXTERNAL AUDITORY CANAL

The external auditory canal is approximately 2.4cm in length and serves a conduit for sound transmission to the middle ear. Its lateral one third is cartilaginous which is 8mm long and is oriented in an upward and backward direction. Its anterior aspect is pierced by 2 to 3 fissures known as fissures of Santorini[19]. The medial two thirds which is 16mm long of the external auditory canal is osseous and is oriented in a downward and forward direction. The narrowest portion is termed as isthmus which is located just medial to the junction of the bony and the cartilaginous canals[20].

Anteroinferior part of the deep meatus, beyond the isthmus, presents anterior recess. Anteroinferior part of the bony canal may present foramen of Huschke in children which spreads infections to and from the parotid. Because of this angulation, the tympanic membrane is approximately 6mm longer anteroinferiorly than posterosuperiorly[21].

ANATOMY OF MIDDLE EAR CLEFT

The middle ear together with the eustachian tube, aditus, antrum and mastoid air cells is called middle ear cleft. It is lined by mucous membrane and filled with air[22]. The middle ear extends much beyond the limits of tympanic membrane which forms its lateral boundary and is sometimes divided into:

1. MESOTYMPANUM: lying opposite to the pars tensa
2. EPITYMPANUM OR THE ATTIC: lying above the pars tensa (above the malleal folds) but medial to sharpnell's membrane and the bony lateral attic wall.

3. HYPOTYMPANUM: lying below the level of pars tensa

4. PROTYMPANUM: The portion of middle ear around the tympanic orifice of the eustachian tube[23]

Middle ear is made up of 6 sides(Fig.7).

1. Lateral wall,

2. Anterior wall,

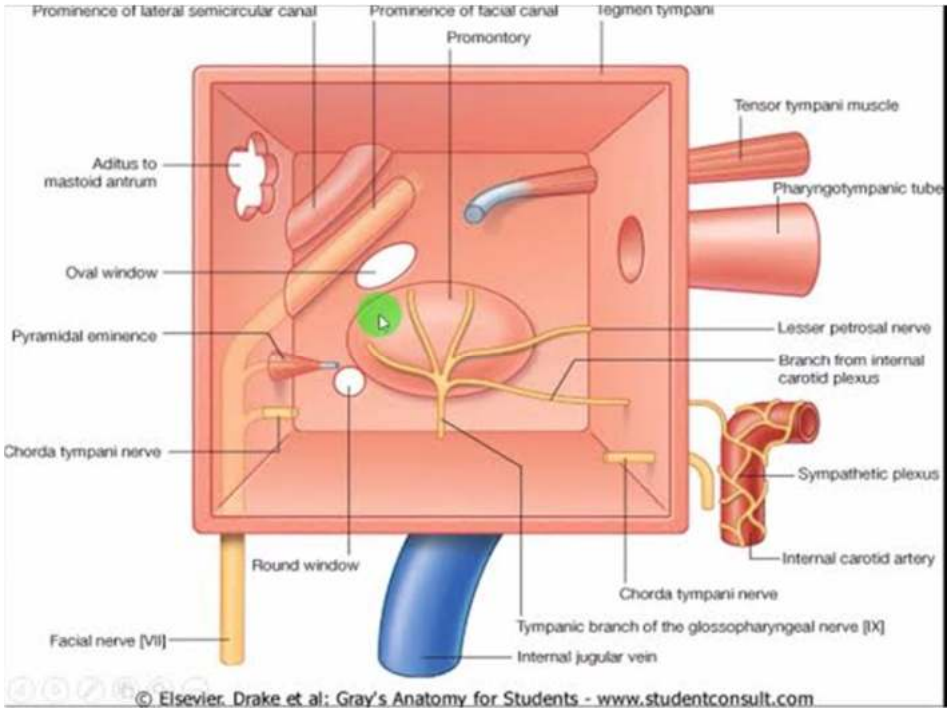
3. Roof,

4. Medial wall,

5. Posterior wall and

6. Floor.

Fig.7: walls of the middle ear



LATERAL WALL:

It is formed largely by the tympanic membrane and to a lesser extent by the bony outer attic wall called scutum. There are 2 openings present in the bony lateral wall of the tympanic cavity[24].

They are,

1**. Iter chordae posterior** through which chorda tympani nerve enters into the tympanic cavity

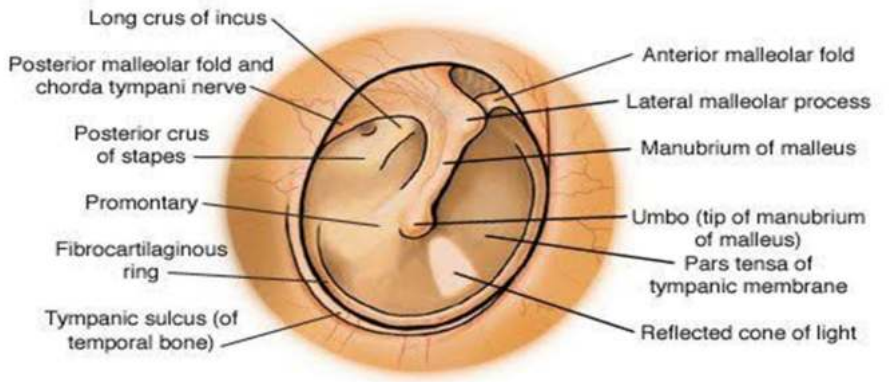
2. **Iter chordae anterior** through which chorda tympani nerve leaves the tympanic cavity[25].

TYMPANIC MEMBRANE:

Forms the partition between the external acoustic canal and the middle ear. It is obliquely set and as a result, its postero superior part is more lateral than its anteroinferior part. It is 9-10 mm tall, 8-9 mm wide and 0.1 mm thick[26]. The round window, long process of the incus, incudostapedial joint, and chorda tympani are identifiable through the intact tympanicmembrane to varying extent, depending on its translucency, extent of its retraction, and the mucosal status within the middle ear[1]. Tympanic membrane can be divided into two parts(Fig.8):

1. Pars tensa
2. Pars flaccida

Fig.8.structure of tympanic membrane



PARS TENSA:

It forms most of tympanic membrane. Its periphery is thickened to form a fibrocartilaginous ring called annulus tympanicus, which fits in the tympanic sulcus. The central part of pars tensa is tented inwards at the level of the tip of malleus and is called umbo. A bright cone of light can be seen radiating from the tip of malleus to the periphery in the anteroinferior quadrant[25]

PARS FLACCIDA:

This is situated above the lateral process of malleus between the notch of Rivinus and the anterior and posterior malleal folds (earlier called malleolar folds). It is not so taut and may appear slightly pinkish[26].

LAYERS OF TYMPANIC MEMBRANE:

Layers of Tympanic Membrane Tympanic membrane consists of three layers:

- Outer epithelial layer, which is continuous with the skin lining the meatus
- Inner mucosal layer, which is continuous with the mucosa of the middle ear.

- Middle fibrous layer, which encloses the handle of malleus and has three types of fibres—the radial, circular and parabolic[27]. In pars tensa the fibrous layer has radially oriented fibres in its outer layers and circular parabolic and transverse fibres in deep layers. In the pars flaccida the fibrous layer has thin and randomly oriented fibres[21,27].

NERVE SUPPLY:

Lateral Surface:

Auriculotemporal Nerve(anterior half).

Vagus (auricular branch) (posterior half)[28] .

Medical Surface:

Auricular branch of glossopharyngeal nerve (Jacobson nerve).

Auricular branch of vagus nerve[29].

ROOF OF MIDDLE EAR:

It is formed by a thin plate of bone called tegmen tympani. It also extends posteriorly to form the roof of the aditus and antrum. It separates tympanic cavity from the middle cranial fossa[28,30].

FLOOR:

It is also a thin plate of bone, which separates tympanic cavity from the jugular bulb. Sometimes, it is congenitally deficient and the jugular bulb may then project into the middle ear; separated from the cavity only by the mucosa[31].

ANTERIOR WALL:

The anterior wall mainly consists of three parts

1. Superiorly the opening for canal of Tensor tympani muscle
2. In the middle part there is an opening for auditory tube
3. Inferiorly there is a thin plate of bone which separates the middle ear from the internal carotid artery. This plate is traversed by the superior and inferior Carotico- tympanic nerves and the tympanic branches of internal carotid artery[32].

MEDIAL WALL:

The medial wall seperated the tympanic cavity from the inner ear. The promontory is a rounded elevation occupying most of the central portion of the medial wall. It covers part of the basal coil of the cochlea. It has small grooves on its surface containing the nerves which forms the tympanic plexus[33].

Behind and above the promontory is the oval window.it is a kidney shaped opening and is connected to the vestibule via scala vestibuli[34]. It is closed by Stapes footplate. It is surrounded by annular ligament. It is 3.25mm long and 1.75mm wide[36]. Above the oval window is facial nerve and inferiorly is the

promontory. The facial nerve runs above the oval window in the medial wall of the tympanic cavity turning inferiorly to run along the posterior wall postero inferior to the pyramid[30,37].

Round window is situated below and behind the oval window which is closed by secondary tympanic membrane. Subiculum separates these two windows. The round window niche is most commonly triangular in shape, with anterior, posterosuperior and posteroinferior walls[38]. The posterosuperior and posteroinferior walls meet posteriorly and lead to the sinus tympani.It tends to curve towards the scala tympani of the basal coil of the cochlea, so that it is concave when viewed from the middle ear[39]

A further ridge of bone inferiorly running between the basal helix of the cochlea and the bone over the jugular bulb can used as a convenient landmark to separate the retrotympanum from the hypotympanum which is termed as finiculus[40].

The facial nerve canal is marked anteriorly by the processus cochleariformis, a curved projection of bone, concave anteriorly, which houses the tendon of the tensor tympani muscle as it turns laterally to the handle of the malleus[41].

The dome of the lateral semicircular canal is the major feature of the posterior portion of the epitympanum, lying posterior and extending a little lateral to the facial canal. In front and a little below this, above the processus cochleariformis, may be a slight swelling corresponding to the geniculate ganglion[42].

POSTERIOR WALL:

Posteriorly in the upper part, a large irregular opening - the aditus ad antrum. It leads back from the posterior epitympanum into the mastoid antrum[43].

Fossa incudis is situated just below the aditus. The fossa incudis contains a ligament which connects the short process of the incus with it. Pyramid is a prominent bony projection which is related to the fossa incudis inferiorly and chorda tympani nerve laterally. Between the pyramid and the tympanic annulus is the facial recess[44].

The facial recess is bounded medially by the pyramid and laterally by the tympanic annulus, with the chorda tympani nerve running obliquely through the wall between the two. The sinus tympani lies between the ponticulus which bridges the gap between the pyramidal eminence and the promontory superiorly, and the subiculum inferiorly, the mastoid segment of the facial nerve laterally and posterior semicircular canal medially[45]. Posterior to the oval window, the facial nerve takes an inferior turn to the posterior wall of tympanic cavity. It is narrow inferiorly than superiorly[41].

MIDDLE EAR MUCOSA:

The middle ear mucosa is pseudostratified ciliated columnar epithelium near the Eustachian tube and becomes cuboidal near the facial nerve. The epithelium is flat, pavement type in the attic region[46]. Goblet cells present in the mucous membrane secrete mucus. Goblet cells are in higher concentration near

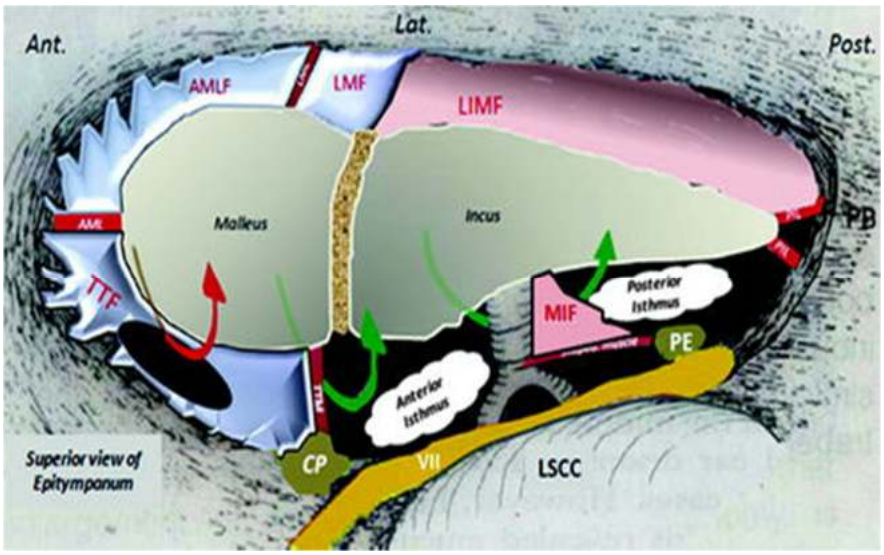
the eustachian tube. The mucous membrane lining the tympanic cavity forms various mucosal folds which divides it into numerous compartments[47].

Both the ossicular chain and associated mucosal folds partition the middle ear. Separation of mesotympanic and epitympanic regions is by the tympanic diaphragm which is formed by

- The Three malleal ligamental fold(anterior, posterior and lateral)
- The posterior incudal fold
- The Tensor Tympani Fold
- The lateral incudomalleal fold
- The medial incudal fold
- Incus and Malleus

leaving the isthmus tympani anticus and isthmus tympani posticus as the only remaining openings[47]. Other mucosal folds are superior incudal fold, superior malleal fold, anterior malleal ligament, superior malleal ligament, posterior incudal ligament(Fig.9) [48].

Fig.9.Middle ear mucosal folds



There are various pouches and spaces which are formed as the result of these mucosal folds.

PRUSSAK'S SPACE:

It is bounded

Laterally - pars flaccida

Medially - neck of malleus

Inferiorly - lateral process of malleus, Anterior Malleolar ligamental fold (anterior limit)

Superiorly - lateral malleolar fold[1]

POSTERIOR POUCH OF VON TROELTSCH:

It lies in between the tympanic membrane and the posterior malleolar fold. It opens inferiorly[4].

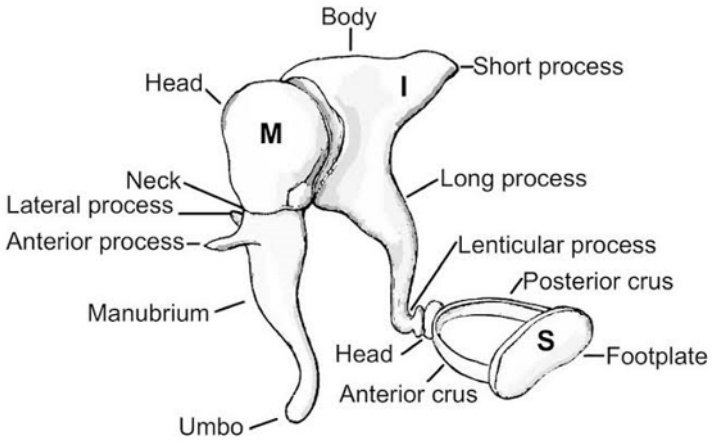
ANTERIOR POUCH OF VON TROELTSCH:

It lies in between the tympanic membrane and the anterior malleolar fold. The other middle ear spaces are superior incudal space, inferior incudal space, lateral malleal space, anterior malleal space, anterior epitympanic recess and supratubal recess[5].

OSSICLES:

There are 3 ossicles in the middle ear which conducts the sound from external ear to inner ear. They are Malleus, Incus and Stapes[34](Fig.10).

Fig.10.Middle ear ossicles



MALLEUS

It is the lateral and largest of the ossicles. It is about 8 to 9 mm long. It has the following parts[1]

1. Head – It is rounded and lies in the epitympanum. It has a saddle shaped facet on its posteromedial surface to articulate with the body of incus. It provides attachment to the superior and lateral malleolar ligaments.
2. Neck – Lies against the pars flaccida and is related medially to Chorda tympani. It connects the handle with the head.
3. Lateral process – It projects from upper end of the handle and receives malleolar folds from the tympanic annulus.
4. Handle – Extends downwards, medially and slightly backwards. it is attached to upper half of the tympanic membrane
5. Anterior process – It is connected to the petro tympanic fissure by the anterior malleolar ligament.

INCUS

It has following parts[2]

1. Body –Lies in epitympanum. Large with its articular surface directing forwards.
2. Short process – It is directed backwards and is fixed to fossa incudis just below the aditus.
3. Long process – Projects downwards into the cavity just behind and parallel with the handle of malleus. Its tip bears a lentiform process which is directed medially to get articulated with stapes head.

STAPES

This is the medial most and smallest of the 3 ossicles. It has following parts[1]

1. Head – It is a small concave facet which articulates with the lentiform process of the incus.
2. Neck – It is the narrowest part which provides insertion posteriorly to the thin tendon of stapedius.
3. Crura – They are 2 in number, the anterior and posterior one. The two crura join the footplate
4. Foot plate- it lies in the oval window where it is attached to the bony margins by the annular ligament.

STAPEDIUS:

It originates from the pyramid and inserts onto stapes neck and posterior crus and is supplied by the 7th cranial nerve[33].

TENSOR TYMPANI:

It originates from the bony part of the Eustachian tube. It enters a spoon shaped processus cochleariformis and takes a 90 degree turn laterally and inserts onto the upper part of the manubrium of the malleus. It is innervated by the 5th Cranial nerve[5]

CHORDA TYMPANI:

The chorda tympani nerve enters iter chordae posterior and travels along the medial part of tympanic membrane and is present medial to the handle of malleus and exits through iter chordae anterior and later enters the Glasserian fissure[11].

TYMPANIC PLEXUS:

It is arranged by the Jacobson's nerve which is a branch of glossopharyngeal nerve and by caroticotympanic nerve, arising from sympathetic plexus encircling the internal carotid artery[49].

BLOOD SUPPLY

ARTERIAL SUPPLY

- Anterior tympanic branch of maxillary artery gives blood supply to the tympanic membrane, ossicles, front part of the tympanic cavity.
- Stylomastoid branch of posterior auricular artery gives blood supply to the posterior portion of the tympanic cavity, mastoid air cells and the stapedius.
- Petrosal division of middle meningeal artery supplies the roof of the epitympanum.
- Superior tympanic division of the middle meningeal artery supplies the tensor tympani muscle.
- Inferior tympanic division of ascending pharyngeal artery supplies the mesotympanum.
- Branches from the artery of pterygoid canal supplies the mesotympanum and the hypotympanum.
- Tympanic branches of the internal carotid artery supplies the mesotympanum and the hypotympanum[3].

VENOUS DRAINAGE

Into the pterygoid venous plexus and superior petrosal sinus[3].

LYMPHATIC DRAINAGE:

- Retropharyngeal nodes[1]

NERVE SUPPLY: Tympanic plexus over the promontory[4].

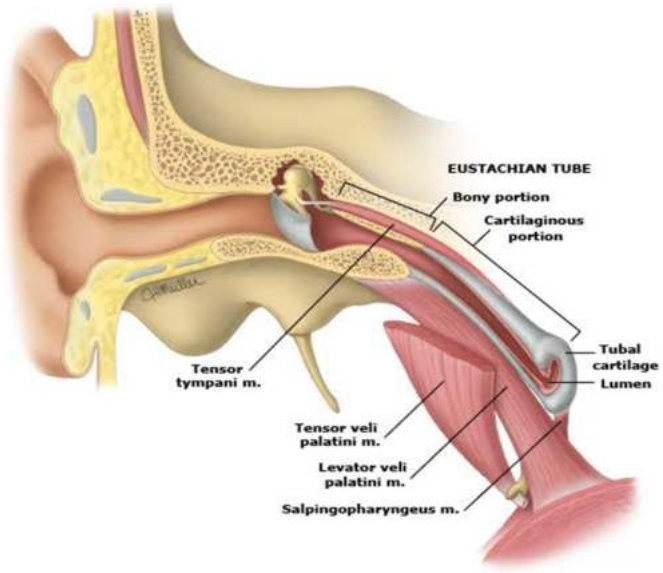
EUSTACHIAN TUBE:

Eustachian tube, also called auditory or pharyngotympanic tube, connects nasopharynx with the tympanic cavity. In an adult, it is about 36 mm long and runs downwards, forwards and medially from its tympanic end, forming an angle of 45° with the horizontal[3]. It is divided into two parts: bony, which is posterolateral, forms one-third (12 mm) of the total length and fibrocartilaginous, which is anteromedial, forms two-thirds (24 mm). The two parts meet at isthmus which is the narrowest part of the tube[6](Fig.11).

The tympanic end of the tube is bony, measures 5 × 2 mm and is situated in the anterior wall of middle ear, a little above the level of floor. The pharyngeal end of the tube is slit-like, vertically. The cartilage at this end raises an elevation called torus tubaris, which is situated in the lateral wall of the nasopharynx, 1–1.25 cm behind the posterior end of inferior turbinate[6].

Three muscles are related to the tube: tensor veli palatini, levator veli palatini and salpingopharyngeus. Ostmann's pad of fat is a mass of fatty tissues related laterally to the membranous part of the cartilaginous tube. It also helps to keep the tube closed and thus protect it from the reflux of nasopharyngeal secretions[22].

Fig.11.Eustachian tube



THE NORMAL PHYSIOLOGICAL FUNCTIONS OF EUSTACHIAN TUBE:

1. Maintain the middle ear gaseous pressure at the level that approximates atmospheric pressure.
2. Prevents reflux of nasopharyngeal contents into middle ear cleft.
3. Mucociliary clearance of middle ear secretion[50]

ROLE OF MIDDLE EAR IN HEARING:

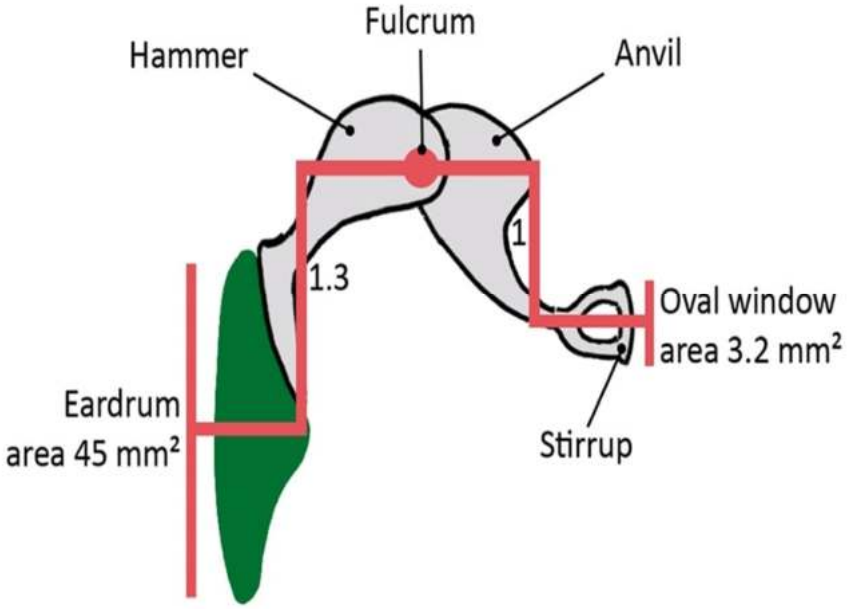
A person under water cannot hear any sound made in the air because 99.9% of the sound energy is reflected away from the surface of water because of the impedance offered by it. A similar situation exists in the ear when air-conducted sound has to travel to cochlear fluids. Nature has compensated for this loss of sound energy by interposing the middle ear which converts sound of greater amplitude but lesser force, to that of lesser amplitude but greater force.

This function of the middle ear is called impedance matching mechanism or the transformer action[33].

It is accomplished by:

i. Lever action of the ossicles. Handle of malleus is 1.3 times longer than long process of the incus, providing a mechanical advantage of 1.3(Fig.12).

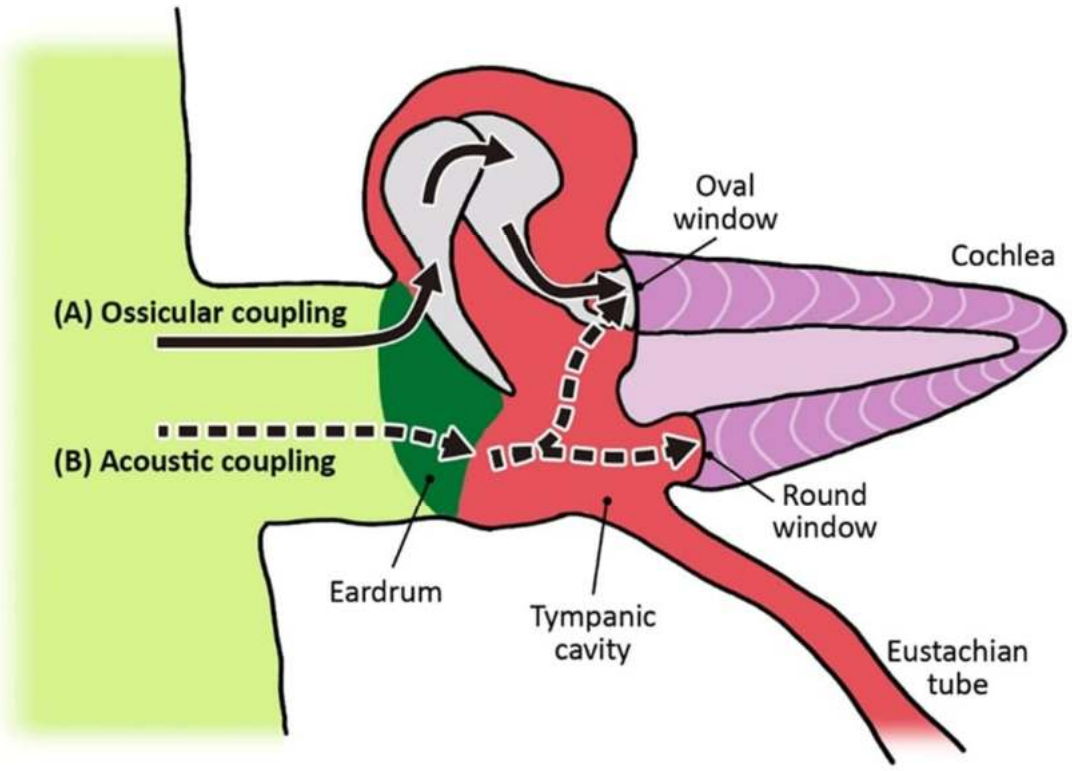
Fig.12.Lever action of the ossicles



ii. Hydraulic action of tympanic membrane. The area of tympanic membrane is much larger than the area of stapes footplate, the average ratio between the two being 21:1. As the effective vibratory area of tympanic membrane is only two-thirds, the effective areal ratio is reduced to 14:1, and this is the mechanical advantage provided by the tympanic membrane. The product of areal ratio and lever action of ossicles is 18:1[34].

iii. Curved membrane effect. Movements of tympanic membrane are more at the periphery than at the center where malleus handle is attached. This too provides some leverage[35]

Fig.13.Ossicular coupling and acoustic coupling



ACOUSTIC COUPLING:

The acoustic coupling offered by the difference in phase of sound pressure at the two windows has a little impact on hearing. It has a role to play only in cases of a compromised tympanoossicular system[36](Fig.13).

ROLE OF MIDDLE EAR MUSCLES:

The contraction of the stapedius muscle in response to sound is known as acoustic reflex. This reflex helps in speech discrimination and in protecting inner ear from acoustic trauma of loud continuous sound. Contractions of tensor tympani muscles causes inward movement of the tympanic membrane produces an increase in pressure in the middle ear and this opens the tube[36,37].

NATURAL RESONANCE:

Natural resonance of external ear canal is 3000 Hz and that of middle ear 800 Hz. Frequencies most efficiently transmitted by ossicular chain are between 500 and 2000 Hz while that by tympanic membrane is 800–1600 Hz. Thus greatest sensitivity of the sound transmission is between 500 and 3000 Hz[33,35].

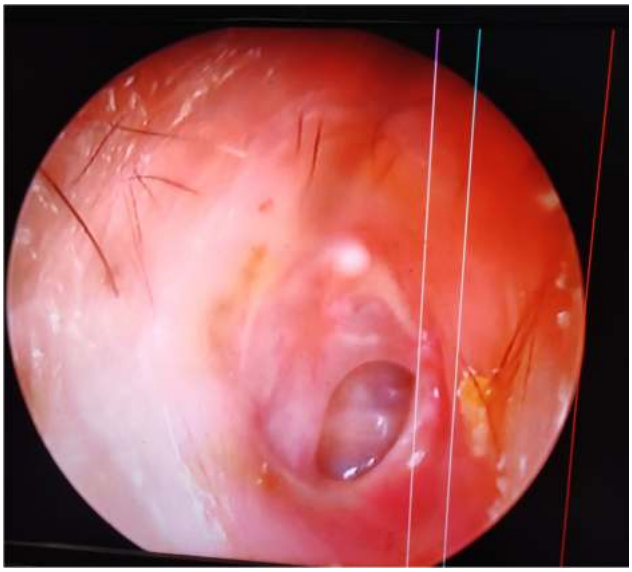
CHRONIC OTITIS MEDIA:

Chronic otitis media is defined as chronic irreversible inflammation of the middle ear cleft. The factors that allow acute infections with in the middle ear cleft to develop in to are still unclear[1,3]. Because of low socioeconomic situations, poor eating habits, and a lack of health education, the incidence of chronic otitis media is on the rise in many developing nations[39].

Genetic anomalies predisposes to chronic otitis media such as Down syndrome, Cleft palate, choanal atresia, Cri du chat syndrome,microcephaly, cleft lip and DiGeorge syndrome[1].

In the case of COM, various histological abnormalities in the middle ear and mastoid are the direct result of infection and inflammation, as well as the host's response to the disease process[35].

Fig.14.CSOM-Inactive Mucosal type



COM is classified as

1. Healed COM
2. Inactive(mucosal) COM
3. Active(mucosal) COM
4. Inactive(squamous) COM
5. Active(squamous) COM

HEALED COM:

Due to atrophy or inability to reform during tympanic membrane healing, the lamina propria of the tympanic membrane may be lost, resulting in a Dimeric tympanic membrane. Tympanosclerosis is caused by the hyalinization and calcification of collagen fibres[27]. Fibrosis and cyst formation may occur, obliterating parts of the middle ear cleft. Fibro osseus Sclerosis develops when the cystic spaces are lined by mucosal epithelium that has been overrun by proliferating connective tissue[33]

INACTIVE (MUCOSAL) COM:

Permanent perforation of the tympanic membrane without inflammation of the middle ear mucosa is seen in the inactive mucosal variety of COM, also known as dry perforation[11]. The fibrous tissue in the lamina propria gets thickened around the perforation. In most cases, the squamous epithelium migrates medially into the mucosal layer[28](Fig.14).

ACTIVE (MUCOSAL) COM:

Perforation with otorrhea occurs in active mucosal COM. Edema, submucosal fibrosis, hypervascularity, and inflammatory cell infiltrates are all characteristics of chronic inflammation of the mucosa of the middle ear. Mucosal ulceration and granulation tissue production can be found in certain regions[29]. Inflammatory oedema causes a thickening of the subepithelial layer of the middle ear. Lymphocytes are present in the mucoperiosteum. Polypoid

mucoperiosteum will develop. The growth of auditory polyps that protrude through the perforated tympanic membrane can result from the progression of these mucosal alterations[19].

This type of COM can cause resorption of part or all of the ossicles, which is known as resorptive osteitis. The long process of the incus is usually the first to be affected, followed by the stapes crura, the body of the incus, and the manubrium. Inflammatory mediators such as IL-1, IL-6, TNF, PGs, neurotransmitters, and NO contribute to disease pathology[33]. Tympanosclerotic patch can occur over the tympanic membrane or in the middle ear. It is actually hyaline degeneration of the mucoperiosteum which is followed by calcification and ossification. It manifests as a chalky white plaque on the tympanic membrane and cooled candle wax drips in the middle ear[37].

INACTIVE (SQUAMOUS) COM:

In inactive squamous COM there is retraction pocket due to static negative middle ear pressure. Retraction pocket is an invagination of the part of ear drum into the middle ear space which might be fixed or mobile. Epidermization is an advanced stage of retraction where middle ear mucosa is replaced by keratinizing squamous epithelium without accumulation of keratin debris[6].

ACTIVE (SQUAMOUS) COM:

Cholesteatoma formation occurs in the active squamous type of COM, which is characterised by the retention of keratin debris. The squamous epithelium's normal migratory pattern is disturbed as a result of retraction. Keratin debris accumulates as a result of this[24]. Chronic infection and inflammation in the sac causes biochemical changes in the local environment, which leads to more squamous epithelial development and migration, as well as increased osteoclastic bone resorption. The local inflammation produces mucosal edoema and secretion retention, which might further increase infection, perpetuating the vicious cycle[42].

The disease process affects both the mucoperiosteum and the underlying bone. The posterosuperior bony canal wall, scutum, and ossicles are all susceptible to osteitic bone erosion on a regular basis. Furthermore, erosion can affect any of the middle ear cleft's walls, including the bone labyrinth. These defects are normally filled by inflammatory vascular granulations, and new bone will grow in their place[11].

PATHOPHYSIOLOGY OF CHRONIC OTITIS MEDIA:

Chronic otitis media is caused by a poorly aerated middle ear space, long-term Eustachian tube dysfunction, multiple bouts of acute otitis media, a persistent middle-ear infection, or another chronic inflammatory stimuli[46]. The Eustachian tube appears to play a key role in the pathophysiology of all types of

COM. Obstruction of the Eustachian tube, both anatomical and functional, can result in the failure of these functions, resulting in otitis media[3].

In this study, we focus at the chronic otitis media mucosal type, which is one of the most common disorders seen in the ENT OPD. Perforation of the tympanic membrane can be caused by AOM, chronic otitis media, or trauma (injury or surgery)[3]. A dry, uncomplicated perforation can arise from a single episode of AOM in some cases (i.e., necrotizing otitis media). Perforation of the tympanic membrane, particularly of the tympanic annulus, might allow the keratinizing epithelium of the ear canal or tympanic membrane to expand, resulting in cholesteatoma[33].

Mechanisms by which persistent tympanic membrane perforation can occur:

1. The majority of cases occur after an acute otitis media episode in which the tympanic membrane has failed to repair.
2. Chronic otitis media with effusion can cause the fibrous layer of the tympanic membrane to degenerate, resulting in thinning, which increases the risk of perforation and hinders spontaneous healing.
3. After traumatic perforations of a large size
4. Following extrusion of tympanostomy tube[22,24].

CLINICAL FEATURES:

1. Hearing loss
2. Ear discharge
3. Otalgia
4. Ear fullness
5. tinnitus

EXAMINATION FINDINGS:

1. HEALED COM:

Tympanosclerosis, Healed perforation

2. MUCOSAL COM - INACTIVE STAGE:

Permanent perforation of the pars tensa. The mucosa not inflamed.

3. INACTIVE SQUAMOUS COM:

Retractions of the pars tensa (postero-superior) and pars flaccida which has the potential to become inflamed with retained debris.

4. ACTIVE MUCOSAL COM:

Permanent defects in pars tensa with an inflamed middle ear mucosa which may produce muco pus that may discharge.

5. ACTIVE SQUAMOUS COM:

Retraction of the pars flaccid or tensa that has retained squamous debris and is associated with inflammation and production of pus often the adjacent mucosa[45].

MICROBIOLOGY:

Perforation of the tympanic membrane can result in recurrent middle ear infections through the following two pathways[37].

1. Bacteria can enter the middle ear through the ruptured tympanic membrane straight from the external auditory canal.

2. A middle ear gas cushion is normally present in an intact tympanic membrane, which serves to prevent the reflux of nasopharyngeal discharge into the middle ear, which is lost in perforation[38].

I MOST COMMON AEROBIC ORGANISMS:

- Staphylococcus aureus, gram negative organisms such as E.COLI, proteus, Klebsiella, pseudomonas aeruginosa[39].

II ANAEROBIC ORGANISMS:

- Bacteroides, fusobacterium.

III FUNGUS:

- Aspergillus, candida.

Fungi may result as overgrowth after initial treatment with antibiotic drops[33].

INVESTIGATIONS:

1. SWAB CULTURE AND SENSITIVITY:
    a. Before starting any antimicrobial therapy a swab of the discharge should be sent for culture and sensitivity[3].
2. PURE TONE AUDIOMETRY:
    a. To determine the kind and severity of hearing loss, an audiologist must be consulted. The majority of the patients will suffer

conductive hearing loss. Since potentially ototoxic ear drops are frequently used, it is critical to monitor your hearing before beginning treatment[11].

3. RADIOLOGICAL EVALUATION:

To examine the cellularity of the mastoids, radiological tests, particularly X-rays of both mastoids, are helpful. CT scans are extremely helpful in displaying the bone architecture and are crucial if intracranial problems are suspected[29].

TREATMENT:

The goal of treatment for mucosal COM is to eradicate infection, prevent future infection, and restore normal middle ear function. In order to achieve these goals, a variety of nonsurgical and surgical options are available[43].

NON SURGICAL OPTIONS:

Aural toileting, as well as the use of topical and systemic antibiotics, are nonsurgical options. In the treatment of mucosal disease, topical antibiotics are more effective than systemic antibiotics. If the patient is asymptomatic, some cases of mucosal type COM resolve with medical care alone, and no additional intervention is usually required[33].

SURGICAL OPTIONS:

If otorrhea recurs or persists despite medical treatment, or if the patient suffers from conductive hearing loss, surgical intervention should be considered. After infection has been controlled and the middle ear mucosa has healed,

tympanoplasty is the best surgical treatment to do[17]. In this case, the likelihood of a favorable outcome is extremely high. Usually tympanic membrane perforation can be closed by doing a procedure called myringoplasty which can be combined with /without ossicular chain repair (tympanoplasty)[18].

Tympanoplasty is generally paired with cortical mastoidectomy in resistant cases that have failed to respond to conventional treatment. Aeration of the middle ear and mastoid, removal of persistently inflammatory tissue, and restoration of the tympanic membrane and ossicular chain are all goals of this surgery[54].

HISTORY OF MASTOIDECTOMY[35]:

Mastoid Surgery developed as a treatment for suppurative ear disease.

- 380 BC in the Hippocratic era -Infections of the ear were recorded.
- 16th century - Fabricius Hildanus - reported a case of spontaneous drainage from a post auricular abscess for which he advocated early incision and drainage.
- 1649 – Riolan - described a procedure similar to mastoidectomy,
- 1774- Jean Luis Petit - The first person to perform the surgical trephination of the mastoid. Petit described exposing the mastoid cortex, performing a trephination, and then enlarging the surgically created fistula.
- 1873-Schwartze – Repopularized the operation.

Since then, technological innovations such as the operating microscope, high-speed drills, and specialised microsurgical equipment have

resulted in considerable improvements in mastoid disease surgery. The petrous apex, the course of the facial nerve, the endolymphatic sac, and the cerebellopontine angle, which were previously thought to be inaccessible, were now accessible[34].

TYPES OF TYMPANOPLASTY:

Wullstein described 5 types of tympanoplasty[35].

Type I: There is only tympanic membrane perforation. All ossicles are intact. Graft is placed in contact with the malleus handle. It is also known as myringoplasty.

Type II: Malleus is eroded. The graft is placed over the incus. (incudopexy) or remnant of malleus.

Type III: Both the malleus and incus are absent. The graft is placed over an intact mobile stapes. It is called myringostapediopexy or columella tympanoplasty. It produces a shallow middle ear and collumella effect.

Type IV: Here superstructure of stapes is eroded, but the foot plate is mobile. Here the foot plate is left exposed to the sound waves and the graft is placed to shield the round window. A small middle ear (cavum minor) is thus created.

Type V: There is fixation of stapes foot plate but with a functional round window. A window is created on the lateral semicircular canal and it is covered with a graft, called fenestration operation. The sound wave reaches the inner ear through the lateral semicircular canal.

In **1959** L. Garcia et al proposed **TYPE VI** tympanoplasty- sonoinversion[33].

MIRKOTOS CLASSIFICATION

1. Intact chain
2. Short columella
3. Long columella
4. Sound protection

5a- Lateral semicircular canal fenestration

5b- Platinectomy

BELLUCI CLASSIFICATION

Added status of middle ear

GROUP I-Dry ear

GROUP II-Occasional discharge

GROUP III –Persistent drainage with mastoiditis

GROUP IV-Persistent drainage and nasopharyngeal malformation (cleft palate and choanal atresia)

AUSTIN/KARTUSH CLASSIFICATION

Describes the residual ossicular remnants

Malleus handle (M+, M-)

Stapes suprastructure (S+, S-)

Type A: (M+ I + S+) - INTACT OSSICULAR CHAIN

Type B: (M+/S+) OR (M+ /S-)- Good prognosis

Type C : (M- /S +) OR (M- / S+) - Poor prognosis.

Type D : (M-/S-) Poor prognosis.

GRAFTS USED:

Various graft materials are available for closing the tympanic membrane perforation. Most commonly used grafting material is temporalis fascia graft. Other grafts used are:

- Cartilage
- Perichondrium
- Periosteum
- Vein graft
- Fat
- Fascia lata
- Ear canal Skin
- Homograft Duramater
- Treated acellular dermal homografts

Though temporalis fascia and tragal perichondrium are commonly used graft material, there are lot of differences in outcome which depends upon experience of surgeon and patients own tissue repair response[39].

MYRINGOPLASTY:

There are various approaches used for myringoplasty like

1. Endaural approach,
2. Post auricular approach and
3. Transcanal approach[34].

ENDAURAL APPROACH:

Endaural approach is usually indicated for small and medium sized perforations of the tympanic membrane with good hearing and dry ear. If the anterior edge of the perforation is concealed by the anterior meatal wall then this approach can be used[35].

POST AURICULAR APPROACH:

Large perforations extending widely into the anterior margin of the tympanic membrane usually necessitate a post auricular approach[45].

TRANSCANAL APPROACH:

For small perforations in the posterior quadrant, a transcanal technique is performed, especially when the ear canal is large. The process is carried out with the use of a microscope or an endoscope. Mastoid dressing, postaural discomfort, hematoma, and infection are all avoided with this method[35].

PROCEURE:

UNDERLAY TECHNIQUE:

This is a more simple and widely used method. Ideal for repairing perforations that are minor and visible. The graft is inserted beneath the raised tympano meatal flap in this case. The major advantage is that it is simple to carry out and has a high success rate[35]. In our study we did underlay myringoplasty.

STEPS:

- Freshening of the perforation edges is done by using a sickle knife.
- A vascular strip created in the external auditory canal, by making incision at tympanosquamous and tympanomastoid suture line correspondingly 6 o clock and 12 o clock positions.
- The incision is extend upto the annulus.
- Elevation of tympanomeatal flap up to the level of the annulus is done.
- Elevation of the annulus and incising the middle ear mucosa is done.
- Then, Skeletonise the handle of malleus.
- Middle ear is packed with gel foam soaked with antibiotic.
- A proper sized graft is placed to cover undersurface of the perforation margins all around and small part should extend over the posterior canal wall.
- TM flap is repositioned.
- Gelfoam is placed around the edges of the raised Flap and over the sealed perforation.
- Closure and dressing done[34].

OVERLAY TECHNIQUE:

Done in cases of Total perforations, anterior perforations, and failed underlay surgery. The graft material is put beneath the squamous layer of the ear drum. Peeling only the skin layer away from the tympanic membrane, inserting the graft in the perforated area, and redraping the skin layer is a difficult task[35].

STEPS:

- Incision is made over the meatal skin.
- The meatal flap is raised along with all outer epithelium from the outer surface of tympanic membrane remnant which is to be preserved for later use.
- Graft is placed over the outer surface of tympanic membrane lateral to the annulus and the remaining middle fibrous layer.
- A slit is made in the graft to tuck under the handle of malleus.
- The anterior meatal recess is well visualised in this approach, which is necessary for anterior perforations to reach the anterior annulus.
- Earlier removed meatal skin is now replaced, covering the periphery of the graft.
- Graft is supported with gelfoams in External Auditory Canal[35].

After removing the undersurface epithelium, the anterior edge of the fascia graft is placed under the annulus as a variant of the overlay procedure. Blunting of the anterior canal can thus be avoided.

Failures can develop as a result of graft displacement and improper closure, resulting in residual perforation. Various biomaterials or biological tissues such as autologous serum, autologous platelet rich plasma, epidermal growth factor, alloderm, merogel, embryonic stem cell, royal jelly, seprafilm, chitosan patch, and silk patch are used during myringoplasty with varying results to improve graft take up rate[1,5].

PLATELET RICH PLASMA (PRP):

Patient-derived biological material has recently been used, with varying degrees of success. Because platelet rich plasma is an autologous platelet rich concentrate produced from the patient's own blood, we want to use it in our research[1]. Platelets can be concentrated to increase growth factors. Using platelet-rich plasma during myringoplasty can aid to prevent graft displacement and promote faster perforation healing, resulting in a better and faster result[5]

Platelet rich plasma was first used in cardiothoracic surgery. M.ferari used platelet rich plasma in 1987 after an open heart surgery. It is now widely employed in a variety of professions, including dentistry, orthopaedics, otorhinolaryngology, maxillofacial surgery, dermatology, plastic and cosmetic surgery, urology, and wound healing, among others[1,8].

Platelets are a rich autologous source of growth factors when isolated from the blood. More predictable results might be predicted when these platelets are concentrated and delivered to the surgical site. Platelet-rich plasma is an autologous platelet concentration of this type. A platelet rich plasma blood clot contains 95% of platelet, 4% of Red Blood Cells and 1% of White Blood Cells[54]

Soft tissue and bone healing were previously treated with recombinant growth factors. There are various advantages to using PRP instead of these recombinant growth factors. Platelet-derived growth factors are autologous, indicating they have a specific effect on tissues upon degranulation and interact with other growth factors in the body, resulting in gene activation and specific protein production[53]. PRP's properties are dependent on the production and

release of a variety of growth and differentiation factors that occur when platelets are activated. These factors play an important role in cellular process like chemotaxis, mitogenesis, differentiation and metabolism[1,39]. The following growth factors are released from platelets upon degranulation:

1. Platelet derived growth factors (PDGF) - Stimulates DNA and protein synthesis.
2. Platelet derived angiogenesis factor (PDAF)
    a. Mitogenic effect on endothelial cells
    b. Increases vessel permeability and angiogenesis
3. Transforming growth factor beta (TGF-b) - Stimulates angiogenesis and endothelial chemotaxis.
4. Platelet factor -4 (PF-4) - Chemo attractant for fibroblasts and neutorphils
5. Insulin like growth factor-1 (IGF-1) - Enhances rate and quality of wound healing
6. Epidermal growth factor
    a. Promotes keratinocyte production,
    b. Fibroblast chemotaxis,
    c. It stimulates angiogenesis and a provisional matrix formation.
7. Interleukin 8
8. Keratinocyte growth factor
9. Fibroblast growth factor
10. Insulin-like growth factor 2
11. Connective tissue growth factor

12. Vascular endothelial growth factor

The above mentioned growth factors are small proteic fragments belonging to cytokine group. Cytokines usually join to the membrane receptors which results in activation or inhibition of cellular functions. A type of regeneration which is specific for the tissue is produced[11]. They intervene in intercellular communication, needed function of the moment, type of cells surrounding them and their location at that moment. The growth factors promote regeneration of new functional tissue that is similar to the original one. Now it is well understood that platelets have many functions beyond simple hemostasis[3].

PREPARATION OF PRP:

PRP can be prepared by two techniques.

1. General-purpose cell separators
2. Platelet-concentrating cell separators

GENERAL-PURPOSE CELL SEPARATORS:

Large amount of blood (450 ml) is required and a well-equipped facility is needed. Blood is drawn into the collection bag which contains citrate phosphate-dextrose anticoagulant. It is first centrifuged at 5,600 rpm to separate RBCs from platelet-poor plasma (PPP) and PRP. Next the centrifugation speed is reduced to 2,400 rpm and final separation of about 30 ml of PRP is obtained from the RBCs[1,3].

PLATELET-CONCENTRATING CELL SEPARATORS:

They only take a minimal amount of blood and can be made in the clinic. In most platelet-concentrating systems, the preparation and processing of PRP are similar, but the anticoagulant utilised, as well as the speed and duration of centrifugation, may change[2,6].

- Venous blood is taken into a tube containing an anticoagulant which avoids platelet activation and degranulation
- SOFT SPIN:

  The first centrifugation, known as a "soft spin," separates blood into three layers[49]:

  i. a bottom-most layer containing RBC (55 percent of total volume),
  ii. a top-most acellular layer known as Platelet Poor Plasma-PPP (40 percent of total volume), and
  iii. an intermediate Platelet Rich Plasma layer (5 percent of total volume) known as the "Buffy coat."

- Using a syringe PPP, PRP and some RBCs into another tube without an anticoagulant[45].
- HARD SPIN:

  This tube is now subjected to a second centrifugation, this time a "hard spin," which is longer and quicker than the first. This permits the PRP to settle towards the tube's bottom, leaving only a few

RBCs. At the top is the acellular plasma (which makes about 80% of the volume)[22]

- PPP is extracted using a syringe and discarded, while the remaining PRP is thoroughly mixed.
- During the application process, this PRP is combined with bovine thrombin and calcium chloride, which causes the platelet concentrate to gel[4].

SIDE EFFECTS OF PRP:

PRP is naturally safe because it is an autologous preparation, therefore it is free from transmissible diseases such as HIV, Hepatitis etc.. In some studies, Calcium chloride and bovine thrombin are used in the preparation of PRP. The usage of this bovine thrombin has been proven to cause the development of antibodies to factors V, XI, and thrombin, which can lead to life-threatening coagulopathies[24]. Factor V is present in bovine thrombin preparations, and when the immune system is challenged with a new protein, it might result in immune system stimulation[22].

PLATELET RICH FIBRIN:

Choukroun et al. were the first to develop PRF in France. Second generation platelet rich plasma is the common name for it. It provides a number of benefits over regular PRP[13].

The main advantages are:

- The ease of preparation and

- The lack of biochemical processing of the blood, resulting in a totally autologous preparation[19].

PREPARATION OF PRF:

PRF preparation is a simple process. PRF is free of the dangers associated with bovine thrombin because it is not used in the preparation[7,8].

- Into 10ml test tubes, the needed amount of blood is drawn.
- There was no addition of an anticoagulant.
- Immediately, it was centrifuged.
- A tabletop centrifuge, which can be found in most labs, is used to centrifuge blood.
- It's spun at 2,700 rpm for 12 minutes.

The resultant product consists of the following three layers:

1. Topmost layer consisting of acellular Platelet poor plasma.
2. PRF clot is in the middle
3. RBCs at the bottom

Blood begins to coagulate very quickly as it comes into touch with the glass surface due to the lack of an anticoagulant. So, for a good PRF preparation, fast blood collection and centrifugation before the clotting cascade begins is required. The PRF can be used on the surgical site[7].

For repairing the tympanic membrane there is always a search for new biomaterials or biological tissues which has a better outcome, lower cost, safety, structure similar to tympanic membrane[1]. In our study, we have used the usually prepared platelet rich plasma(PRP).

MATERIALS AND METHODS

AIMS AND OBJECTIVES:

To compare the success rate of myringoplasty with and without platelet rich plasma in inactive cases of chronic otitis media with central perforation, with a follow up period of 2 months.

DESIGN OF STUDY:

Randomized controlled trial

DURATION OF STUDY:

12 months

PERIOD OF THE STUDY:

April 2020 to March 2021

STUDY CENTRE:

Department of Otorhinolaryngology,

Chengalpattu Medical College& Hospital,

Chengalpattu.

STUDY POPULATION:

Study was conducted in patients who underwent myringoplasty admitted at Chengalpattu Medical College Hospital, Chengalpattu during the study period.

SAMPLE SIZE:

80 subjects

CRITERIA

INCLUSION CRITERIA:

- Chronic otitis media inactive mucosal disease
- Patients greater than 18 years of age
- Central perforation
- Dry ear without discharge for at least 6 to 8 weeks
- Hearing loss less than 40dB
- Middle ear mucosa normal

EXCLUSION CRITERIA:

- Patients less than 18 years of age
- Active ear disease
- Total perforation
- Marginal perforation
- Tympanosclerosis
- Cholesteatoma
- Otosclerosis
- Atopic ear conditions
- Middle ear mucosa congested or polypoidal
- Other systemic illness like autoimmune diseases and active neoplastic diseases

PREOPERTIVE WORK UP:

1. Otoscopic examination.
2. Pure tone audiometry.
3. X ray mastoids.
4. CT nose and paranasal sinuses.
5. Diagnostic nasal endoscopy.

METHODOLOGY

This study was conducted for 80 patients of chronic suppurative otitis media in our institution from April 2020 to March 2021. The study only included patients who met the above criteria. Pre-operative information was gathered. After explaining the procedure to all of the patients, informed consent was obtained. Complete blood count, bleeding and clotting time, ECG and chest x-ray, HIV testing, and hepatitis B surface antigen test were among the tests performed prior to surgery. In our anaesthesia department, all patients had an anaesthetic workup. The patients were randomly divided into two groups.

TWO GROUPS:

1. Endoscopic temporalis fascia graft myringoplasty without PRP (Group A).

2. Endoscopic temporalis fascia graft myringoplasty with PRP (Group B).

The procedure was carried out under local anaesthetic with weight-titrated premedication. Patients positioned and draped with proper aseptic precautions. Zero degree Hopkin's rod lens endoscope was used. In all of the patients, the

underlay technique of myringoplasty by transcanal approach was done. 4 quadrants of the external auditory canal were infiltrated with 2% xylocaine and 1: 100,000 adrenaline.

ENDOSCOPIC TEMPORALIS FASCIA GRAFT MYRINGOPLASTY:

- Temporalis fascia harvested by after infiltrating 2% xylocaine with 1 : 1,00,000 adrenaline into the temporal region.
- Incision of about 2 cm made above pinna and temporalis fascia identified and harvested.
- The margins of the perforation was freshened and the under surface of the tympanic membrane remnant was also made raw.
- Rosen's incision was made and the tympanomeatal flap elevated.
- The annulus was elevated from the sulcus, middle ear cavity entered.
- The handle of malleus was skeletonized from the tip to the lateral process.
- Assessment of the middle ear mucosa was done and the ossicular integrity was assessed by establishing the round window reflex.
- The temporalis fascia graft was dried and placed medial to the handle of malleus.
- The tympanomeatal flap was repositioned.

Fig.15.Temporalis fascia graft harvesting

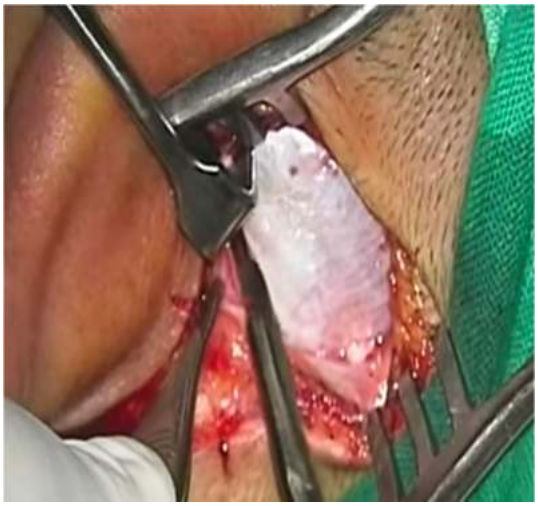
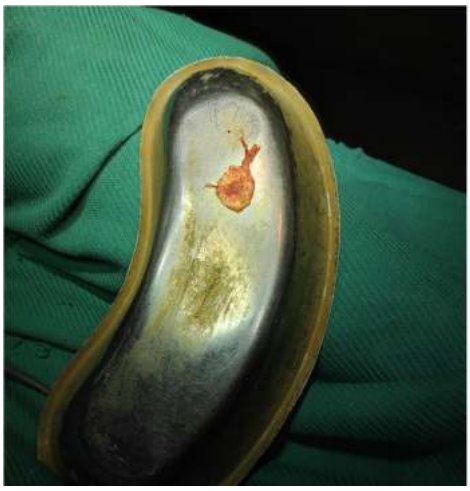


Fig.16.Temporalis fascia graft



APPLICATION OF PRP:

Platelet rich plasma was prepared and it was applied over the perforated margins, external auditory canal over the surface of the graft and tympanic membrane remnant and the graft. Ear canal was packed with gel foam.

Fig.17.Platelet rich plasma (PRP)

POST OPERATIVE CARE:

All the patients were under antibiotic cover in the post operative period. On the seventh postoperative day, the sutures were removed, and the patients were given oral antibiotics and antihistaminics. The patients were followed up for a period of 2 months.

FOLLOW UP:

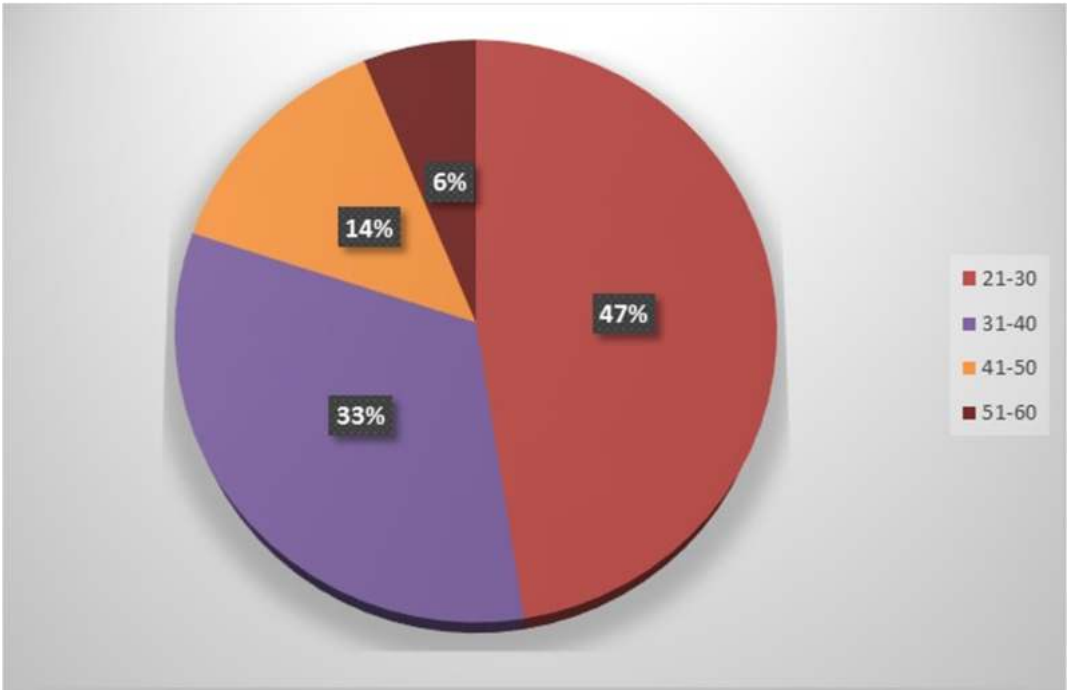
Pure Tone Audiogram was done for the patients postoperatively and otoendoscopic examinations were done on 2^{nd} week and then weekly once for 2 months postoperatively. Then the postoperative graft uptake and healing outcome of the patients were analysed. Successful closure of tympanic membrane perforation or a successful graft uptake was defined as a well healed and intact tympanic membrane visualised by otoendoscopic examination at the end of 6^{th} week postoperatively.

RESULTS

TABLE 1: AGE DISTRIBUTION

AGE IN YEARS	NO OF PATIENTS	PERCENTAGE
21-30	38	47%
31-40	26	33%
41-50	11	14%
51-60	5	6%

FIG.18.AGE DISTRIBUTION

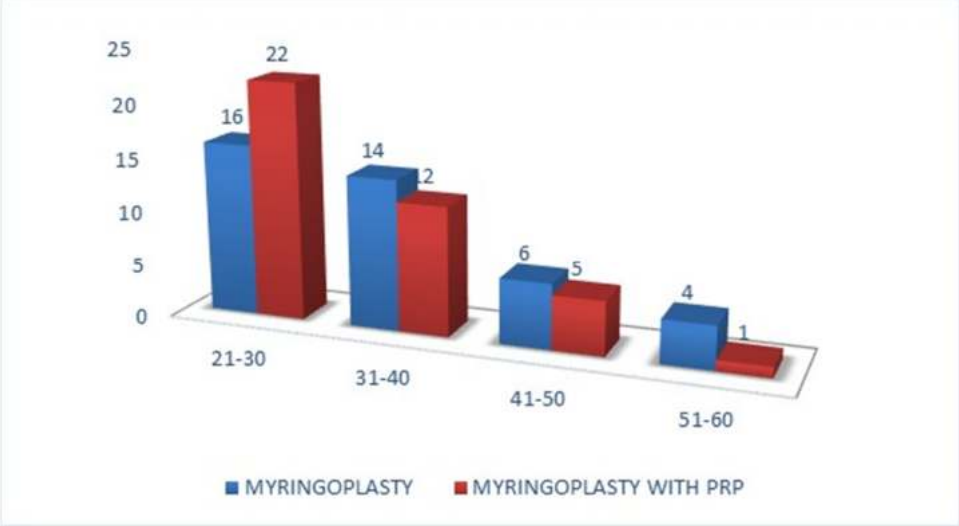


MEAN AGE 32.37±10.53

TABLE 2: AGE DISTRIBUTION BETWEEN TWO GROUPS

AGE IN YEARS	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)
21-30	16	22
31-40	14	12
41-50	6	5
51-60	4	1
CHI SQUARE TEST		
P VALUE - 0.393		
NON SIGNIFICANT		

FIG.19. AGE DISTRIBUTION BETWEEN TWO GROUPS

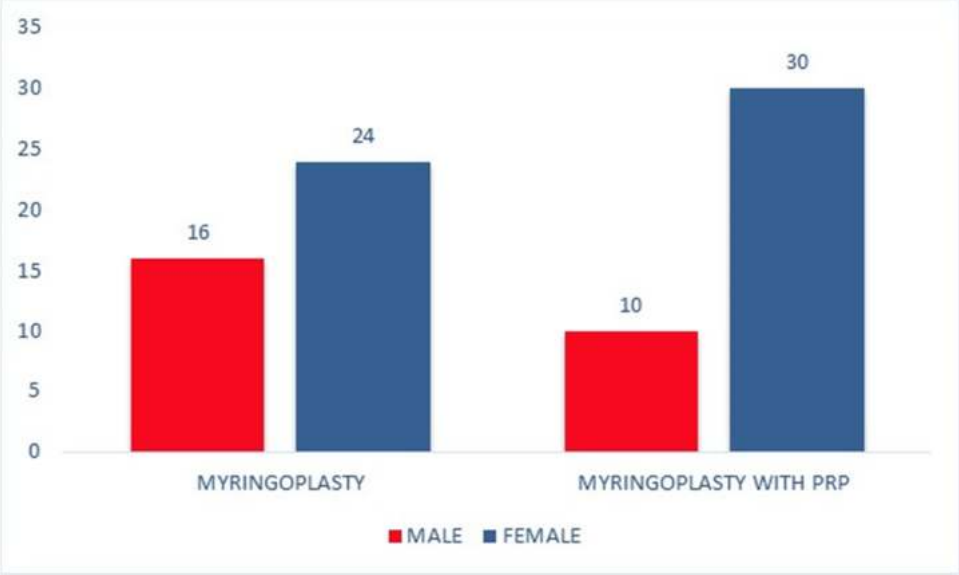


In our study, ages of patients range from 21 to 59 years, with most of patients in the age group of 21-30 years (N=38 , 16 in group A, 22 in group B).(Table 2,figure 19).

TABLE 3 : SEX DISTRIBUTION AND THE TYPE OF PROCEDURE

SEX	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)	TOTAL
MALE	16	10	26(32%)
FEMALE	24	30	54(68%)
CHI SQUARE TEST			
P VALUE - 0.152			
NON SIGNIFICANT			

Fig.20. SEX DISTRIBUTION AND THE TYPE OF PROCEDURE

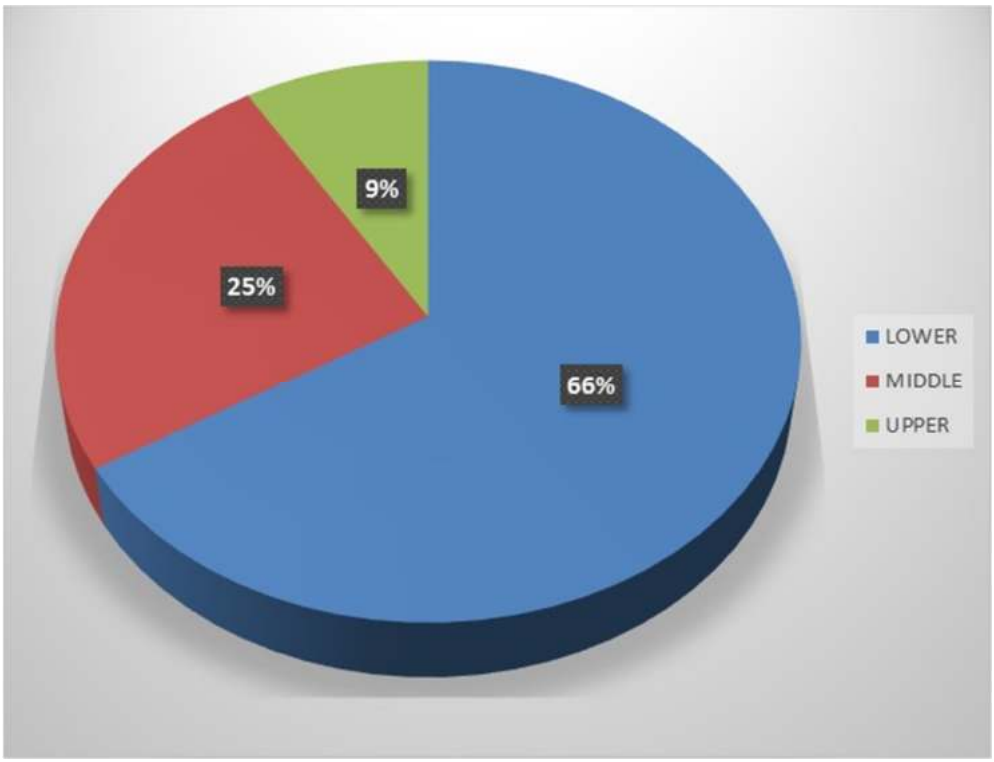


In our study, 68% of the patients are females. (N=54, 24 in group A and 30 in group B) and 32% are males (N=26, 16 in group A and 10 in group B) which was statistically insignificant between the two groups (Table 3, figure 20).

Table 4: SOCIOECONOMIC STATUS

SOCIOECONOMIC STATUS	NO OF PATIENTS	PERCENTAGE
LOWER	53	66%
MIDDLE	20	25%
UPPER	7	9%

Fig.21.SOCIOECONOMIC STATUS

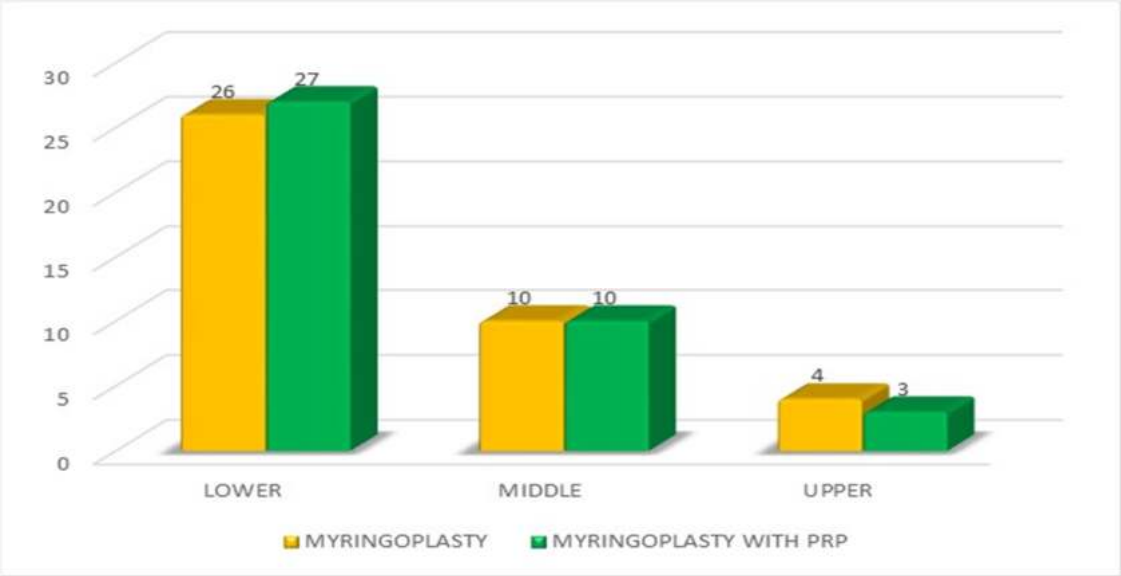


In this study, the majority of people belongs to the lower socioeconomic status.(N=53, 66%)(Table 4,Figue 21).

TABLE 5: SOCIOECONOMIC STATUS AMONG THE TWO GROUPS

SOCIOECONOMIC STATUS	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)	TOTAL
LOWER	26	27	53(66%)
MIDDLE	10	10	20(25%)
UPPER	4	3	7(9%)
CHI SQUARE TEST			
P VALUE - 0.922			
NON SIGNIFICANT			

FIG 22: SOCIOECONOMIC STATUS AMONG THE TWO GROUPS

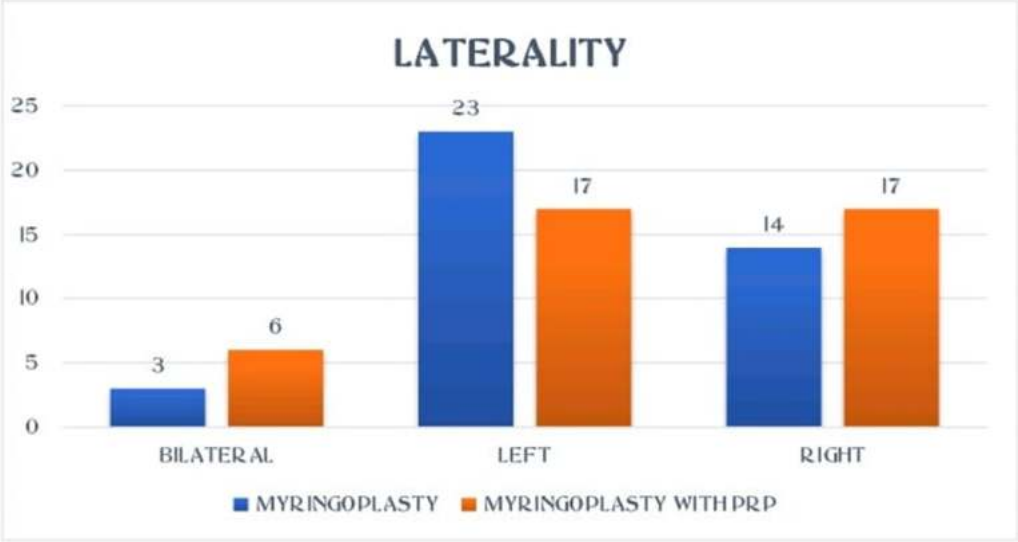


In our study, 66% (N=53, 26 in Group A,27 in Group B) belongs to lower socio economic status, 25%(N=20, 10 in Group A, 10 in Group B) belongs to middle socio economic status and 9%(N=7, 4 in Group A, 3 in Group B) belongs to upper socio economic status, which was statistically insignificant between the two groups.(Table 5, Figure 22)

TABLE 6 : LATERALITY

LATERALITY	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)	TOTAL
BILATERAL	3	6	9(11%)
LEFT	23	17	40(50%)
RIGHT	14	17	31(39%)
CHI SQUARE TEST			
P VALUE - 0.334			
NON SIGNIFICANT			

FIG.23 : LATERALITY



In our study 50% of the cases presented with disease on left side.(N= 40, 23 in group A and 17 in group B), 39% (N=31, 14 in group A and 17 in group B) had disease on the right side and 11% (N= 9, 3 and 6 in group A and group B respectively) had the disease bilaterally. This was statistically insignificant between the two groups (Table 6, Figure 23).

TABLE 7: SIZE OF PERFORATION

SIZE OF PERFORATION	NO OF PATIENTS	PERCENTAGE
LARGE	21	26%
MEDIUM	43	54%
SMALL	16	20%

FIG.24.SIZE OF PERFORATION

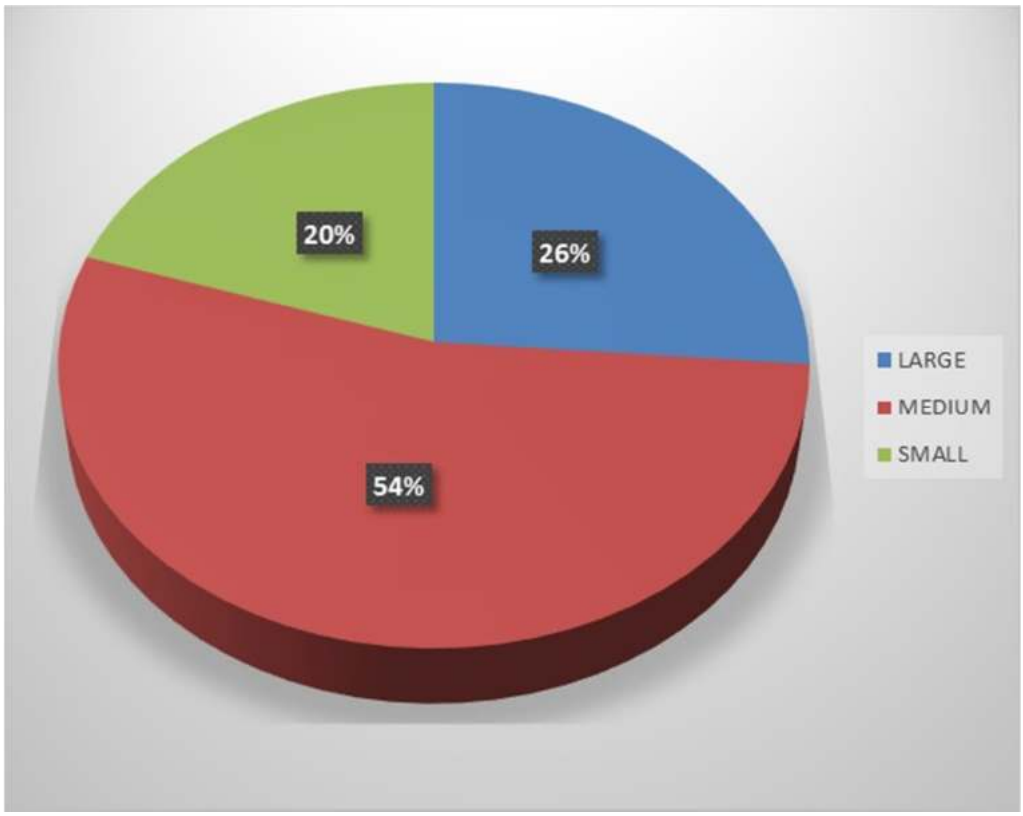
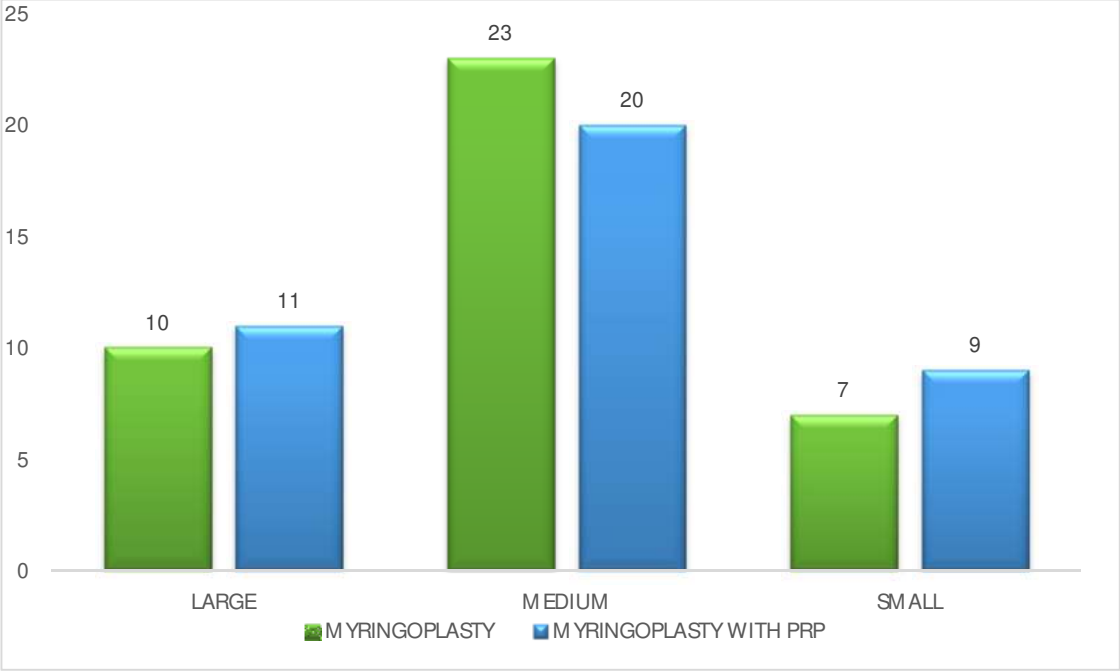


TABLE 8: SIZE OF PERFORATION AMONG THE TWO GROUPS

SIZE OF PERFORATION	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)
LARGE	10	11
MEDIUM	23	20
SMALL	7	9
CHI SQUARE TEST		
P VALUE - 0.776		
NON SIGNIFICANT		

FIGURE 25: SIZE OF PERFORATION AMONG THE TWO GROUPS



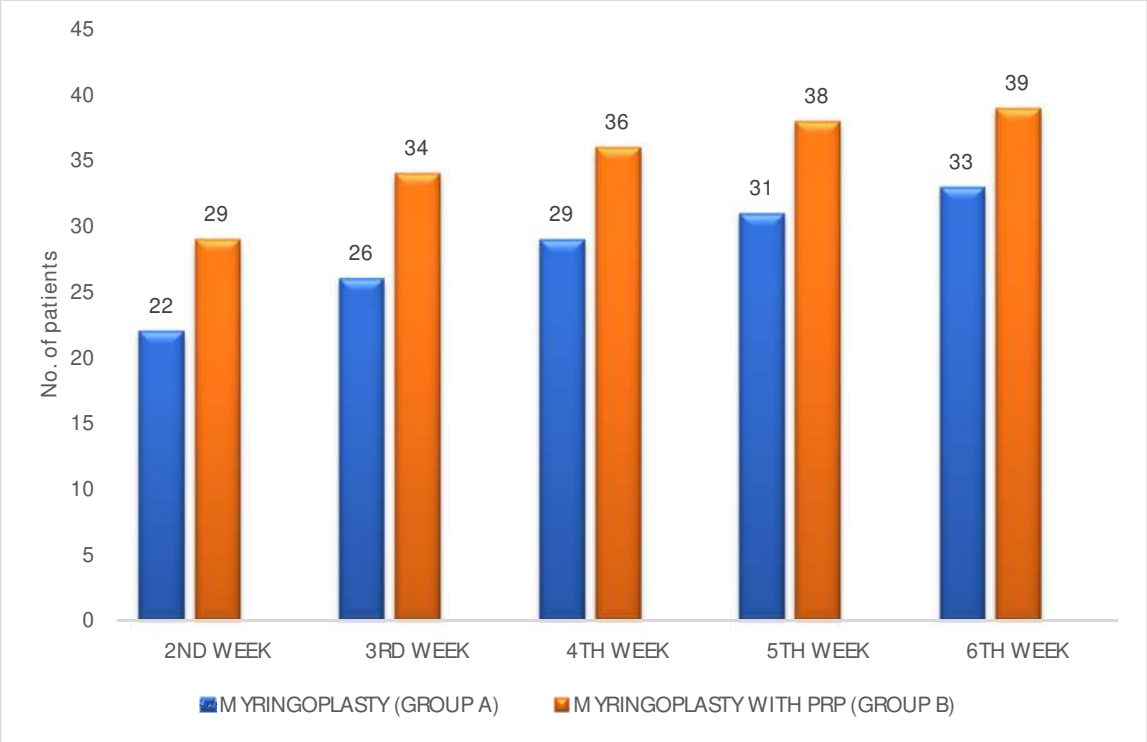
In our study, 54%(N=43, 23 in Group A, 20 in Group B)patients had medium perforation, 26%(N=21, 10 in group A, 11 in group B) had large perforation.20%(N= 16, 7 in group A, 9 in group B) had small perforation, which was statistically insignificant between the two groups (Table 8,figure 25).

TABLE 9: COMPARISION OF GRAFT UPTAKE OVER TIMELINE

BETWEEN THE TWO GROUPS

GRAFT UPTAKE	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)
2ND WEEK	22(55%)	29(72%)
3RD WEEK	26(64%)	34(85%)
4TH WEEK	29(72%)	36(90%)
5TH WEEK	31(78%)	38(95%)
6TH WEEK	33(83%)	39(98%)
CHI SQUARE TEST		
P VALUE- 0.041		
SIGNIFICANT		

FIG 26: COMPARISION OF GRAFT UPTAKE OVER TIMELINE BETWEEN THE TWO GROUPS

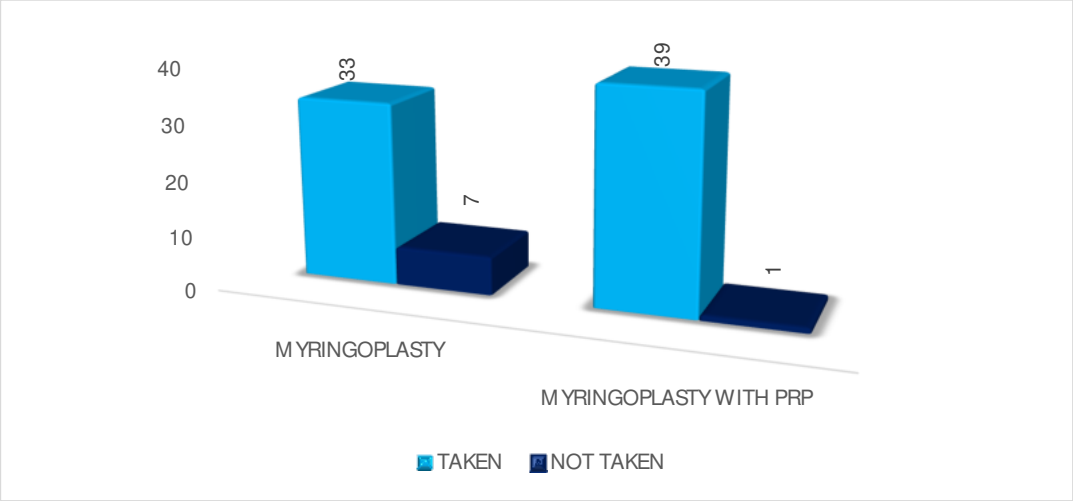


In Group A patients, 55%(N=22) had graft uptake at 2nd week, 64%(N=26) at 3rd week, 72%(N=29) at 4th week, 79%(N=31) at 5th week and 83%(N=33) at 6th week. The graft uptake was faster in Group B patients. 72%(N=29) had graft uptake at 2nd week, 85%(N=34) at 3rd week, 90%(N=36) at 4th week, 95%(N=38) at 5th week and 98%(N=39) at 6th week (Table 9,Figure 26).

TABLE 10: COMPARISON OF GRAFT STATUS BETWEEN THE STUDY GROUPS AFTER 8 WEEKS

GRAFT UPTAKE AT 8TH WEEK	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)	TOTAL
TAKEN	33 (83%)	39 (98%)	72(90%)
NOT TAKEN	7 (17%)	1 (2%)	8(10%)
CHI SQUARE TEST			
P VALUE - 0.025			
SIGNIFICANT			

FIG.27: COMPARISON OF GRAFT STATUS BETWEEN THE STUDY GROUPS AFTER 8 WEEKS

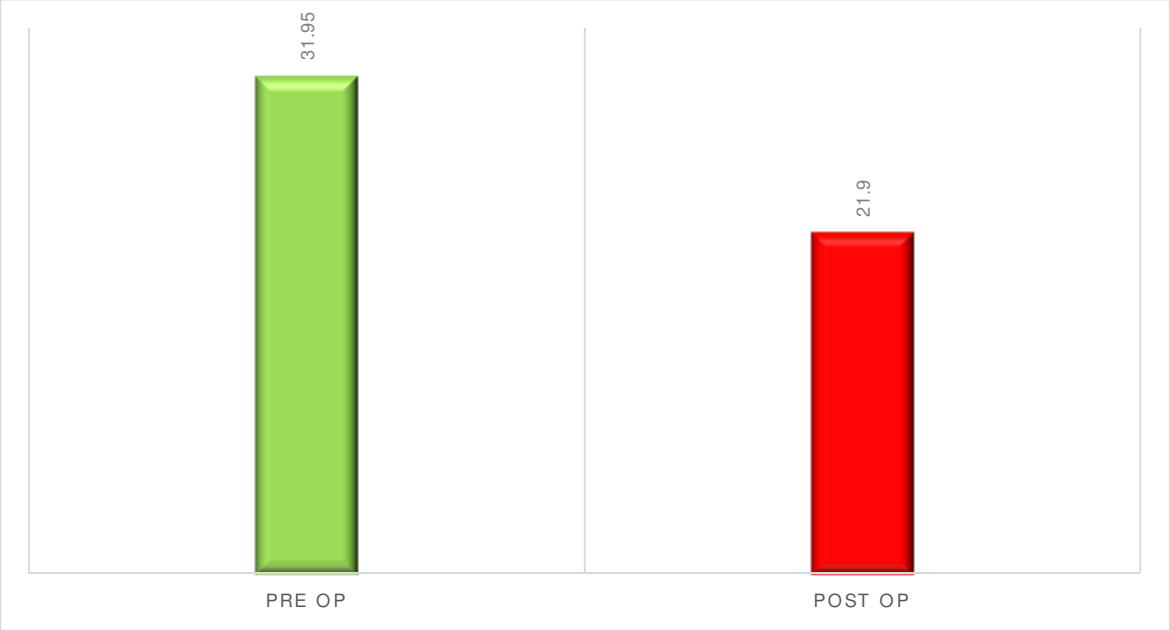


The graft uptake rate in group A (Myringoplasty without PRP) was about 83% with failure rate of about 17% whereas in group B (Myringoplasty with PRP) was about 98% with failure rate of about 2%. In our study, this difference in graft uptake between the study groups by chi square test which was found to be statistically significant (p=0.025) . (Table 10, figure 27).

TABLE 11: MYRINGOPLASTY (GROUP A) – PRE AND POST OP PTA

PTA(DBHL)	MYRINGOPLASTY (GROUP A)	
	PRE OP	POST OP
MEAN	31.95	21.9
SD	5.08	7.46
UNPAIRED T TEST		
P VALUE - 0.001		
SIGNIFICANT		

FIG.28: MYRINGOPLASTY (GROUP A) – PRE AND POST OP PTA

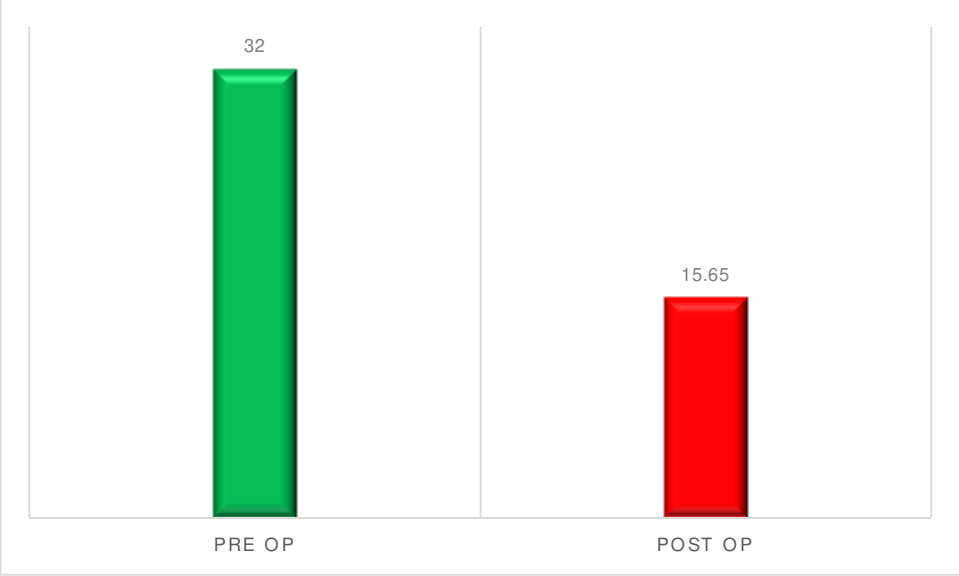


The mean comparison of pre and post-operative PTA among Group A (MYRINGOPLASTY WITHOUT PRP). The table 12 explains that there was significant difference between the pre op 31.95 (SD 5.08) and post op 21.9 (SD 7.46) among group A patients by student t test with p=0.001. (Table 11, Figure 28)

TABLE 12: MYRINGOPLASTY WITH PRP (GROUP B) – PRE AND POST OP

PTA(DBHL)	MYRINGOPLASTY WITH PRP (GROUP B)	
	PRE OP	POST OP
MEAN	32	15.65
SD	5.3	7.46
UNPAIRED T TEST		
P VALUE - 0.001		
SIGNIFICANT		

FIG.29: MYRINGOPLASTY WITH PRP (GROUP B) – PRE AND POST OP

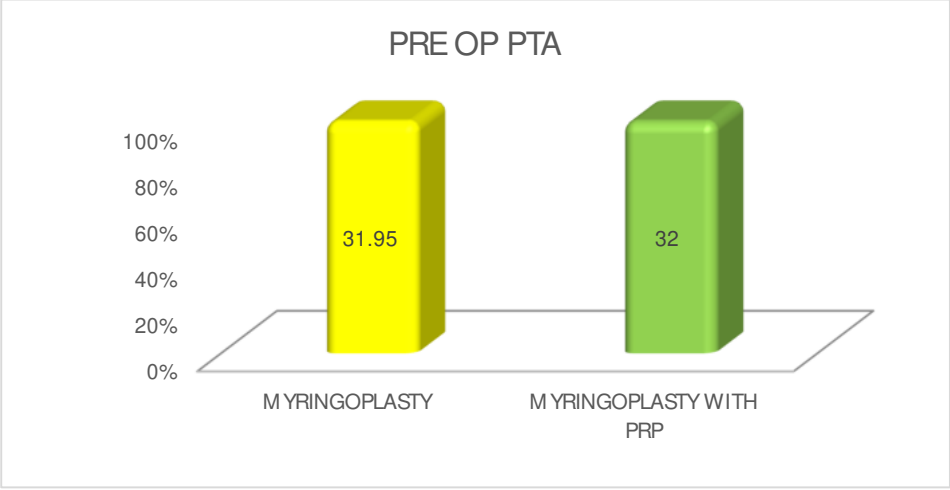


There was significant difference between pre op PTA 32 (SD 5.3) and post op PTA 15.65 (SD 7.46) in group B with p = 0.001. (Table 12, Figure 29)

TABLE 13: PRE OP PURE TONE AUDIOMETRY – COMPARISON

PRE OP PTA	PROCEDURE	
	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)
MEAN	31.95	32
SD	5.08	5.3
UNPAIRED T TEST		
P VALUE - 0.483		
NON SIGNIFICANT		

FIGURE 30: PRE OP PURE TONE AUDIOMETRY – COMPARISON

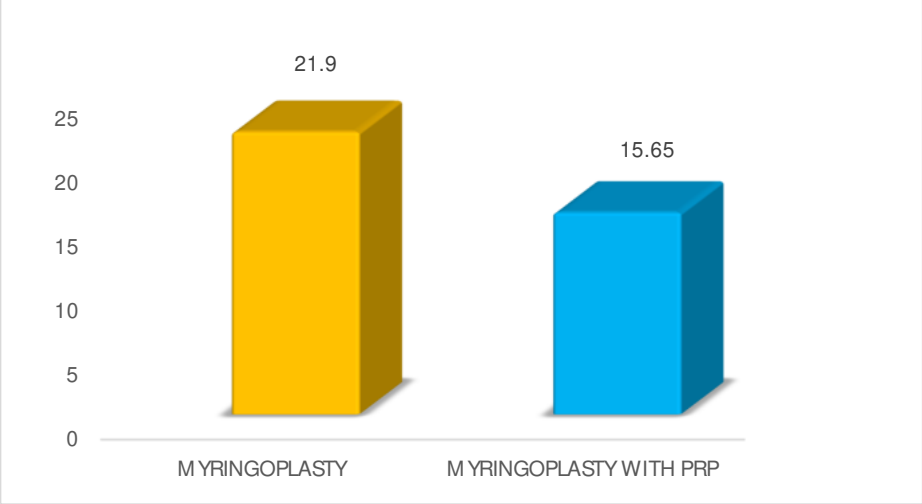


In our study, the pre op PTA average between the two study groups (Group A-31.95 and Group B – 32) was statistically insignificant.(Table 13,Figure 30)

TABLE 14: POST OP PURE TONE AUDIOMETRY – COMPARISON

POST OP PTA	PROCEDURE	
	MYRINGOPLASTY (GROUP A)	MYRINGOPLASTY WITH PRP (GROUP B)
MEAN	21.9	15.65
SD	7.46	5.39
UNPAIRED T TEST		
P VALUE - 0.036		
SIGNIFICANT		

FIG.31: POST OP PURE TONE AUDIOMETRY – COMPARISON

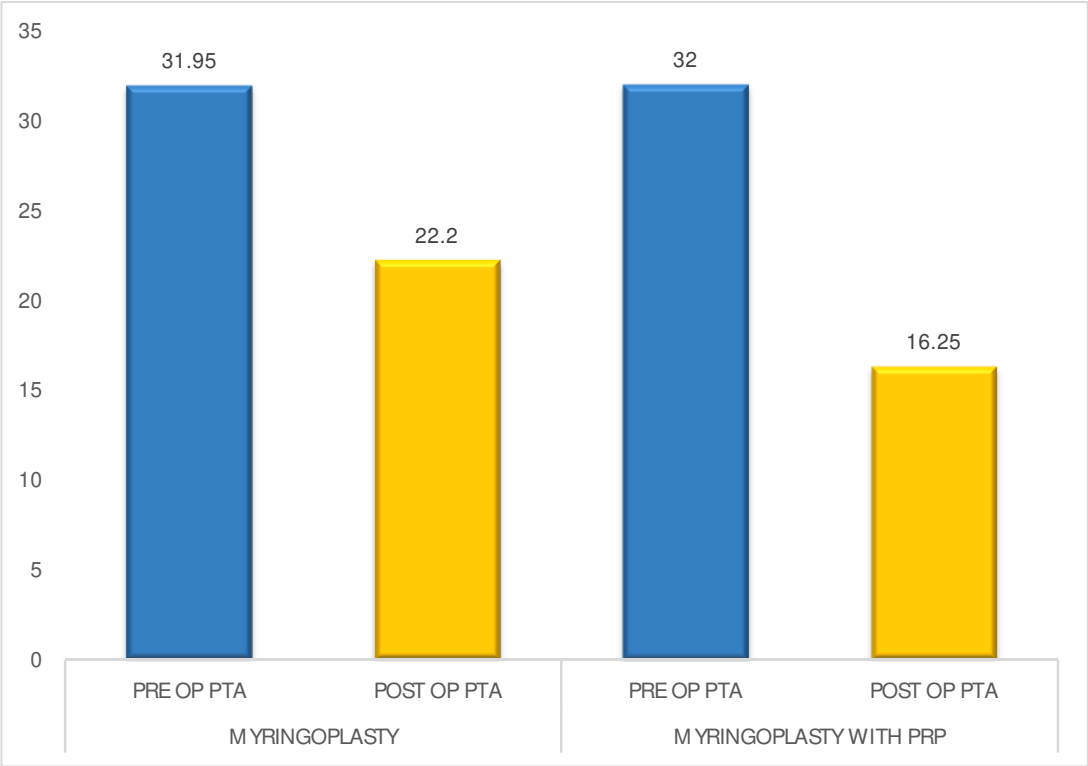


The pure tone average scored between both techniques also showed significant differences between Group A and Group B at post op PTA with p=0.036(Table 14,Figure 31)

TABLE 15: POST OPERATIVE GAIN IN PTA AMONG THE TWO GROUPS

PROCEDURE	PTA	MEAN	SD	P VALUE
MYRINGOPLASTY (GROUP A)	PRE-OP PTA	31.95	5.08	0.001
	POST OP PTA	22.2	7.16	
MYRINGOPLASTY WITH PRP (GROUP B)	PRE-OP PTA	32	5.3	0.001
	POST OP PTA	16.25	6.12	

FIG 32: POST OPERATIVE GAIN IN PTA AMONG THE TWO GROUPS



In our study, the mean preoperative PTA in Group A was 31.95 and group B was 32, which were comparable statistically and it was statistically insignificant. The PTA average at 2 months post operative was 22.2 dB for the Group A, as compared to 16.25 dB for the Group B. This difference in hearing improvement in the two groups was statistically significant.(Table 15, figure 32)

DISCUSSION

The term myringoplasty is reserved for the simple repair of a tympanic membrane in which no ossicular reconstruction is involved[35.] Various materials have been utilised for myringoplasty for grafting. The most widely used graft material was temporalis fascia, which was quickly followed by cartilage. Alternatives to conventional myringoplasty have been intensively investigated in recent decades, including the use of scaffold materials, bioactive compounds, and cells. These new technologies should, in fact, provide more benefits than conventional myringoplasty. Among them, PRP is said to be effective in wound healing and has a lot of potential for TM repair[1].

PRP is a plasma protein concentrate with a higher concentration of platelets generated from whole blood centrifuged to separate RBCs[6]. Because growth factors are present in higher concentrations in PRP than in whole blood, it has been used to improve the healing response in a variety of specializations, as well as in traumatic injuries[20].

Several growth factors and cytokines are present, which help soft tissue and joint healing. It accelerates epidermal, endothelial, and epithelial regeneration, enhances angiogenesis, increases collagen production and soft tissue repair, reduces skin scarring, and improves hemostatic response to damage. PRP is bactericidal because it has a high concentration of WBCs[21]. PRP

has no side effects and may be obtained using a simple method that does not require the use of any additives[22,23]. PRP offers protection to the operated site and it will keep the graft in position and avert sagging of the posterior wall of the ear canal and also prevents complications associated with an EAC pack[24].

In our study, a maximum number (47%) of patients was seen in the age group of 21–30 years. This is similar to the study by Sankaranarayanan G et al[1], which also had the maximum number of cases in the age group between 21-30, but in contrast to the study by Anwar FM et al. [4], which included the maximum number of cases in the age group between 31-40.

In our study, 68% of the patients are females. (N=54, 24 in group A and 30 in group B) and 32% are males (N=26, 16 in group A and 10 in group B) which is similar to the study by Sankaranarayanan G et al[1], where the majority of the cases were females (60%). This is also similar to the study by P K Purushothaman et al[2] which had the majority of cases as females.

According to socio economic status, majority of cases(66%) belong to lower socio economic status (N=53, 26 in Group A, 27 in Group B) which is similar to the study by Sankaranarayanan G et al[1] The increased incidence of this disease in this lower class is due to overcrowding, poor sanitation, poor nutrition and illiteracy.

About 89 percent (71 patients) of people in the study population had unilateral ear disease whereas remaining 11 percent (9 patients) had bilateral disease. In group A 37 patients had unilateral disease and 3 patients had bilateral disease. In group B 34 patients had unilateral disease whereas 6 patients had bilateral disease. Among the unilateral disease in Group A, 14 patients had right ear disease whereas 23 patients had left ear disease. Among Group B, 17 patients had right ear disease and 17 patients had left ear disease. The presence of bilateral ear disease at the time of myringoplasty did not seem to have any influence on the graft uptake. In addition, in our study, there was no statistically significant difference (P = 0.334) for the success rate based on laterality. Bilateral disease is commonly due to bilateral Eustachian tube dysfunction.

In our study, majority of patients (54%) had medium sized perforations (N=43, 20 in Group A, 23 in Group B). This is in similar to the study by Anwar FM et al[4] , which also showed that majority of patients had medium sized perforation(47%). But this is in contrast to the study by Sankaranarayanan G et al[1], which showed that large and subtotal perforation is very common in comparison to other perforations.

In our study , The graft uptake rate in group A (Myringoplasty without PRP) was about 83% with failure rate of about 17% whereas in group B (Myringoplasty with PRP) was about 98% with failure rate of about 2%.In our

study, this difference in graft uptake between the study groups by chi square test which was found to be statistically significant (p=0.025) .

This is similar to the study by El Anwar et al[11] in 2015 who conducted a randomized controlled trial among 64 patients. They were randomized into case group of 32 subjects for autologous PRP usage in Myringoplasty and control group of 32 subjects for only myringoplasty. In this study, age and sex of both groups were statistically matched and the graft uptake in cases (100%) were significantly more than in control group (81.25%) which was statistically significant.

This is also similar to Yadav et al[40] study that included 40 patients. Autologous platelet-rich plasma was applied in-between temporalis fascia graft and tympanic membrane remnant during underlay myringoplasty in group 1 (n = 20). The outcome was evaluated after three months and compared to group 2 (n = 20 control group) that underwent routine underlay myringoplasty without PRP. Results of this study showed that after three months follow up, graft uptake was 95 per cent in group 1 and 85 per cent in group 2 ($p < 0.03$), which was statistically significant.

This is also in similar to the study by Bajpai et al[41] which had Graft uptake in case group (myringoplasty with PRP) was 88.57% and graft uptake in the control group (myringoplasty without PRP) was 77.1%. According to Maria

Luisa Navarrete Alvaro[15] use of platelet rich plasma during myringoplasty will prevent graft displacement, which is also similar to our study.

This is also similar to Saeedi et al[43] who used PRP enriched gelfoam to evaluate the effect on the healing of chronic TM perforation in comparison with gelfoam alone. In their study, complete TM healing was seen in 66.67% patients of intervention group and in 25% patients of control group three months after intervention. So, this study concluded that addition of PRP to conventional gelfoams used in TM perforation repair increased the complete healing rate of TM perforation with less morbidity and complications.

In our study, The PTA average at 2 months post operative was 22.2 dB for the Group A, as compared to 16.25 dB for the Group B. This difference in hearing improvement in the two groups was statistically significant. This is similar to the study by El Anwar et al[11], where pure tone average (PTA) was statistically highly significant at 6 months postoperatively in group with myringoplasty with PRP.In Yadav et al study[40], Mean hearing threshold gain in PTA average was 18.62 dB in group 1 and 13.15 dB in group 2. This difference was statistically significant ($p < 0.01$), which is similar to our study.

This is contrast to the study by Bajpai et al[41], where Success in terms of hearing gain was achieved in 21 patients (65.6%) in case group and 11 patients (34.4%) in control group with statistically nonsignificant difference (P = 0.079). Our study is also in contrast to the study by Anwar FM et al[4], which showed that audiological improvement was seen in 31 cases (88.57%); whereas in the control group, only 27 (77.1%) had audiological benefits, and it is not statistically significant.

CONCLUSION

When autologous platelet rich plasma is administered in myringoplasty, it accelerates epithelialization over the graft, resulting in faster graft uptake. Because it has a high concentration of platelets, it reduces graft displacement. Since platelet rich plasma is derived from the patient's own blood, it has no risk of transmitting HIV, Hepatitis B, or other blood-borne infections from others. Since it is cost - effective and easy to produce, it should be utilized during myringoplasty to improve the success rate.

This is to conclude from our study that there is a definite benefit by using PRP in myringoplasty. As the PRP can be easily prepared, myringoplasty with PRP can be routinely performed. The overall graft uptake rate appeared to be better with myringoplasty with PRP with significant results.

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STUDY PROFORMA

Name: Age: Sex:

IP/OP.No:

Address:

Occupation:

Presenting complaints :

	Side	**Duration**
Ear discharge		
Hard of Hearing		
Ear pain		
Tinnitus		
Giddiness		

History of presenting illness

Ear discharge – Side

Duration

Onset

Type

Quantity

Continuous / Intermittent

Aggrevating / Relieving factor

Hard of hearing

Site

Duration

Onset

Progression

Ear pain

Site

Duration

Intensity

Aggravating/Relieving Factors

Nasal Complaints

Nasal Block

Nasal Discharge

Headache

Throat Complaints

Throat Pain

Difficulty in swallowing

Past History

Any previous of Surgery

Any H/o DM /Hypertension /TB/Asthma/CAD/Epilepsy

Any H/o Drug Allergy/Bleeding Diathesis.

Family History:

Any similar illness in the family .

General Physical Examination:

Built /Nutrition /Febrile/Anemia/Jaundice/Cyanosis/generalized lymphadenopathy.

Systemic Examination –CVS/RS/PA/CNS

ENT Examination

Examination of the Ear	**Right**	**Left**
Preauricular Region		
Pinna		
Postauricular Region		
External Auditory Canal		
Tympanic Membrane		
Middle Ear Status		

Tuning Fork tests

Rinne

Weber

Absolute bone conduction test

Tragus sign

Fistula test

Three point Mastoid tenderness

Facial Nerve Examination

Examination Of Nose

External Nose

Dorsum

Ala

Columella

Anterior Rhinoscopy Right Left

Septum

Inferior Turbinate

Inferior Meatus

Middle Turbinate

Middle Meatus

Cottles Test

Cold spatula Test

Cotton Wool test

Paranasal Sinus Tenderness

Examination of Throat

Oral cavity:

Lips /teeth /gums/anterior 2/3rd Tongue /Hard Palate /RMT

Oropharynx:

Soft palate/Uvula/Tonsil/Anterior and Posterior Pillar /Posterior pharyngeal Wall .

INFORMED CONSENT FORM

Title of the study: "**COMPARATIVE STUDY ON OUTCOMES OF MYRINGOPLASTY WITH AND WITHOUT PLATELET RICH PLASMA''** at Chengalpattu Medical College &Hospital, Chengalpattu.

Name of the participant:

Name of the Investigator: Dr.K.GOKUL

Name of the Institution: Chengalpattu Medical College& Hospital

Documentation of the informed consent.

I _____have read the information in this form (or it has been read to me).I was free to ask any questions and they have been answered. I am over years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in I have read and understood this consent form and the information provided to me.

- I have had the consent document explained to me.
- I have been explained about the nature of the study.
- I have been explained about my rights and responsibilities by the investigator.
- I have been informed the investigator of all the treatments I am taking or have taken in the past including any native (alternative) treatment.

- I have been advised about the risks associated with my participation in this study.
- I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
- I have not participated in any research study within the past_____.
- I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.
- I hereby give permission to the investigators to use the data obtained from me to the sponsors, regulatory authorities, Government Agencies and IEC.
- I have understood that my identity will be kept confidential at all points of time.
- I have had my questions answered to my satisfaction.
- I have decided to take part in the research
- I am aware that if I have any question during this study, I should contact the Investigator (7418387756).By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

Signature of the Participant Signature of the Investigator

Date :

Place:

ஒப்புதல் படிவம்

செங்கல்பட்டு அரசு மருத்துவ கல்லூரி மருத்துவமனை காது மூக்கு தொண்டை பிரிவில் செவிப்பறை ஒட்டறுவை சிகிச்சை தொடர்பாக ஆய்வு மேற்கொள்ளப்படுகிறது. இந்த ஆய்வில் பங்குபெற என் முழு மனதுடன் சம்மதிக்கிறேன். இந்த ஆய்வின் தகவல்கள் மற்றும் முழு விவரங்கள் எனக்கு தெரிவிக்கப்பட்டுள்ளது.

1. இந்த ஆய்வின் போது எனக்கு இருக்கும் உரிமைகளும், பொறுப்புகளும் எனக்கு விளக்கப்பட்டுள்ளது. இந்த ஆய்வின் தன்மைகள் விளக்கப்பட்டன.

2. இந்த ஆய்வில் பங்கு கொள்ளும்போது ஏற்படும் நன்மை தீமைகளை மருத்துவர் விளக்க நான் புரிந்துகொண்டேன்.

3. நான் இதற்கு ஒப்புக்கொண்டு ஒத்துழைப்பேன் மற்றும் ஏதேனும் வழக்கத்திற்கு மாறான உடல் உபாதைகள் ஏற்படின் உடனடியாக மருத்துவரின் ஆலோசனையையும், உதவியையும் நாடுவேன்.

4. மேலும் இந்த ஆய்விலிருந்து எப்போது வேண்டுமானாலும் விலகிக் கொள்ள எனக்கு முழு சுதந்திரம் உள்ளது என அறிந்துகொண்டேன். அதனால் என் சிகிச்சை பாதிக்கபடாது என்பதையும் புரிந்துக்கொண்டேன்.

5. எங்கள் அடையாளம் இந்த ஆய்வின் போது பாதுகாக்கப்படும் என்பதையும் அறிந்துகொண்டேன்.

6. நான் இந்த ஆய்வில் பங்குபெற முழு மனதுடன் சம்மதிக்கிறேன்.

7. இந்த ஆய்விற்கு ஒத்துழைத்து, இந்த ஆய்வின் போது ஏதேனும் அறிகுறிகள் தென்பட்டால் உடனடியாக மருத்துவரிடம் (7418387756) தெரிவிப்பேன் என்று சம்மதிக்கிறேன்.

இந்த ஆய்வில் ஏதேனும் சந்தேகங்கள் ஏற்பட்டால் உடனடியாக மருத்துவரை (7418387756)இந்த தொலைபேசி மூலம் அணுகுவேன். நான் கையெழுத்துயிடுவதன் மூலம் அதிலுள்ள தகவல்கள் எனக்கு புரியும் வகையில் விளக்கமாகவும் தெளிவாகவும் அதில் தெரிவிக்கப்பட்டிருந்தது. மேலும் இந்த படிவத்தின் ஒரு பகுதி எனக்கு அளிக்கப்பட்டது.

நோயாளியின்கையொப்பம்

KEY TO MASTER CHART

M - MALE

F - FEMALE

PRP - PLATELET RICH PLASMA

PRE OP PTA- PRE OPERATIVE PURE TONE AUDIOMETRY

POST OP PTA- POST OPERATIVE PURE TONE AUDIOMETRY

dBHL – DECIBEL HEARING LOSS

GA - GENERAL ANAESTHESIA

LA - LOCAL ANAESTHESIA

T - GRAFT UPTAKEN

NT - GRAFT NOT UPTAKEN

MASTER CHART

S.NO	NAME	AGE	SEX	SOCIO ECONOMIC STATUS	LATERALITY	SIZE OF PERFORATION	PRE OP PTA (IN DbHL)	PROCEDURE	GRAFT UPTAKE IN 8TH WEEK	POST OP PTA (in dBHL)
1	KOWSALYA	21	F	LOWER	RIGHT	SMALL	25	MYRINGOPLASTY WITH PRP	T	15
2	ETTIYAMMAL	36	F	MIDDLE	LEFT	MEDIUM	33	MYRINGOPLASTY WITH PRP	T	18
3	JAYALAKSHMI	45	F	LOWER	RIGHT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	16
4	EZHIL	21	F	UPPER	RIGHT	LARGE	38	MYRINGOPLASTY WITH PRP	T	20
5	UMA	29	F	LOWER	LEFT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	17
6	SUGANYA	26	F	LOWER	BILATERAL	SMALL	21	MYRINGOPLASTY WITH PRP	T	15
7	JENNIFER	21	F	MIDDLE	LEFT	LARGE	38	MYRINGOPLASTY WITH PRP	T	25
8	MANJULA	48	F	LOWER	LEFT	MEDIUM	32	MYRINGOPLASTY WITH PRP	T	18
9	JOTHI	48	F	UPPER	RIGHT	MEDIUM	35	MYRINGOPLASTY WITH PRP	T	21
10	GOKULRAJA	22	M	LOWER	RIGHT	MEDIUM	33	MYRINGOPLASTY WITH PRP	T	17
11	SELVI	40	F	LOWER	RIGHT	LARGE	39	MYRINGOPLASTY WITH PRP	T	25
12	SATHISH	22	M	LOWER	LEFT	MEDIUM	29	MYRINGOPLASTY WITH PRP	T	16
13	ELANGO	23	M	MIDDLE	LEFT	SMALL	22	MYRINGOPLASTY WITH PRP	T	14
14	SARAVANAN	37	M	LOWER	RIGHT	LARGE	39	MYRINGOPLASTY WITH PRP	NT	39
15	GAJALAKSHMI	37	F	LOWER	BILATERAL	MEDIUM	32	MYRINGOPLASTY WITH PRP	T	19
16	VENNILA	45	F	MIDDLE	BILATERAL	MEDIUM	33	MYRINGOPLASTY WITH PRP	T	18

17	VELANKANNI	41	F	LOWER	LEFT	MEDIUM	34	MYRINGOPLASTY WITH PRP	T	18
18	KALAIVANI	34	F	LOWER	LEFT	SMALL	25	MYRINGOPLASTY WITH PRP	T	16
19	VAITHEESHWARAN	29	M	MIDDLE	RIGHT	LARGE	38	MYRINGOPLASTY WITH PRP	T	22
20	ABINA	21	F	LOWER	LEFT	MEDIUM	32	MYRINGOPLASTY WITH PRP	T	21
21	BHUVANESHWARI	27	F	LOWER	RIGHT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	18
22	SUNDARAVADHANAN	21	M	UPPER	LEFT	SMALL	24	MYRINGOPLASTY WITH PRP	T	15
23	SAROJA	38	F	MIDDLE	RIGHT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	15
24	YASODHA	58	F	LOWER	RIGHT	LARGE	39	MYRINGOPLASTY WITH PRP	T	23
25	KATHIRESAN	21	M	LOWER	BILATERAL	MEDIUM	30	MYRINGOPLASTY WITH PRP	T	17
26	VIGNESH	32	M	LOWER	RIGHT	SMALL	24	MYRINGOPLASTY WITH PRP	T	16
27	MENAGA	31	F	MIDDLE	LEFT	MEDIUM	29	MYRINGOPLASTY WITH PRP	T	19
28	NITHISH	25	M	LOWER	LEFT	MEDIUM	28	MYRINGOPLASTY WITH PRP	T	16
29	PUSHPA	36	F	LOWER	LEFT	LARGE	39	MYRINGOPLASTY WITH PRP	T	26
30	UMA	28	F	LOWER	LEFT	MEDIUM	30	MYRINGOPLASTY WITH PRP	T	19
31	KAVITHA	31	F	MIDDLE	BILATERAL	MEDIUM	29	MYRINGOPLASTY WITH PRP	T	18
32	SULAIKA BANU	26	F	LOWER	RIGHT	LARGE	37	MYRINGOPLASTY WITH PRP	NT	37
33	YUVARAJ	32	M	LOWER	RIGHT	MEDIUM	32	MYRINGOPLASTY WITH PRP	T	14
34	GOWRI	36	F	UPPER	LEFT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	16

35	SOWMIYA	24	F	LOWER	LEFT	LARGE	39	MYRINGOPLASTY WITH PRP	T	22
36	KEERTHANA	26	F	LOWER	RIGHT	MEDIUM	32	MYRINGOPLASTY WITH PRP	T	20
37	AMMU	26	F	MIDDLE	LEFT	SMALL	26	MYRINGOPLASTY WITH PRP	T	18
38	DIVYA	21	F	LOWER	BILATERAL	LARGE	39	MYRINGOPLASTY WITH PRP	T	26
39	MANJU	27	F	LOWER	RIGHT	MEDIUM	31	MYRINGOPLASTY WITH PRP	T	18
40	MOHANAPRIYA	23	F	MIDDLE	RIGHT	MEDIUM	37	MYRINGOPLASTY WITH PRP	T	15
41	SUDHA	34	F	LOWER	RIGHT	LARGE	38	MYRINGOPLASTY	T	23
42	SUMUTHA	32	F	LOWER	LEFT	MEDIUM	31	MYRINGOPLASTY	T	18
43	VANITHA	27	F	MIDDLE	LEFT	MEDIUM	30	MYRINGOPLASTY	T	16
44	ANBARASI	35	F	LOWER	LEFT	MEDIUM	29	MYRINGOPLASTY	T	16
45	DHANALAKSHMI	38	F	LOWER	RIGHT	MEDIUM	34	MYRINGOPLASTY	T	18
46	RAMESH	38	M	LOWER	LEFT	MEDIUM	33	MYRINGOPLASTY	T	19
47	USHA	37	F	MIDDLE	RIGHT	LARGE	38	MYRINGOPLASTY	NT	38
48	AFRIN ZAHARA	23	F	LOWER	RIGHT	MEDIUM	34	MYRINGOPLASTY	T	22
49	DESIGAN	30	M	LOWER	LEFT	SMALL	22	MYRINGOPLASTY	T	16
50	ANJALAKSHI	55	F	LOWER	RIGHT	LARGE	39	MYRINGOPLASTY	T	19
51	KARTHIK	25	M	LOWER	RIGHT	SMALL	26	MYRINGOPLASTY	T	15
52	AKASH	29	M	MIDDLE	RIGHT	MEDIUM	33	MYRINGOPLASTY	T	15

53	BHUVANESHWARI	27	F	LOWER	LEFT	LARGE	38	MYRINGOPLASTY	T	23
54	NIRMALA	51	F	LOWER	LEFT	SMALL	25	MYRINGOPLASTY	T	14
55	VIJAYA	40	F	UPPER	LEFT	MEDIUM	35	MYRINGOPLASTY	T	20
56	JAYANTHI	47	F	LOWER	LEFT	LARGE	38	MYRINGOPLASTY	T	24
57	NALINI	35	F	LOWER	BILATERAL	MEDIUM	33	MYRINGOPLASTY	T	18
58	SARAVANAN	41	M	LOWER	LEFT	MEDIUM	34	MYRINGOPLASTY	NT	36
59	VASANTHI	45	F	LOWER	LEFT	MEDIUM	30	MYRINGOPLASTY	T	17
60	KARTHIKEYAN	26	M	LOWER	LEFT	LARGE	38	MYRINGOPLASTY	T	22
61	VASANTHI	45	F	LOWER	LEFT	SMALL	21	MYRINGOPLASTY	T	15
62	INDHIRA	35	F	LOWER	BILATERAL	LARGE	39	MYRINGOPLASTY	NT	39
63	SURESH	25	M	LOWER	LEFT	SMALL	27	MYRINGOPLASTY	T	16
64	JOTHILAKSHMI	24	F	UPPER	LEFT	MEDIUM	33	MYRINGOPLASTY	NT	33
65	SENTHIL	36	M	LOWER	RIGHT	MEDIUM	32	MYRINGOPLASTY	T	18
66	PADAYANDI	37	M	LOWER	LEFT	LARGE	37	MYRINGOPLASTY	T	21
67	VEDHAGIRI	29	M	MIDDLE	RIGHT	SMALL	24	MYRINGOPLASTY	T	14
68	ALAMELU	36	F	LOWER	LEFT	MEDIUM	31	MYRINGOPLASTY	T	16
69	SATHISH	28	M	MIDDLE	LEFT	MEDIUM	36	MYRINGOPLASTY	T	20
70	MUNUSAMY	59	M	MIDDLE	LEFT	MEDIUM	33	MYRINGOPLASTY	T	19

71	JAGADEESAN	49	M	LOWER	RIGHT	SMALL	25	MYRINGOPLASTY	T	16
72	BHAVANA	25	F	MIDDLE	RIGHT	LARGE	39	MYRINGOPLASTY	NT	39
73	SUBASH	27	M	LOWER	LEFT	MEDIUM	31	MYRINGOPLASTY	T	17
74	SHARMILA	29	F	MIDDLE	LEFT	LARGE	38	MYRINGOPLASTY	NT	38
75	LAKSHMI	40	F	LOWER	RIGHT	SMALL	24	MYRINGOPLASTY	T	17
76	MURUGAN	45	M	LOWER	RIGHT	MEDIUM	32	MYRINGOPLASTY	T	18
77	DINESH	27	M	MIDDLE	BILATERAL	MEDIUM	28	MYRINGOPLASTY	T	17
78	ELLAMMAL	36	F	LOWER	RIGHT	MEDIUM	29	MYRINGOPLASTY	T	15
79	INDHUMATHI	24	F	UPPER	LEFT	LARGE	39	MYRINGOPLASTY	T	24
80	VALARMATHI	51	F	MIDDLE	LEFT	SMALL	24	MYRINGOPLASTY	T	15

ETHICAL COMMITTEE CERTIFICATE

INSTITUTIONAL ETHICAL COMMITTEE
CHENGALPATTU MEDICAL COLLEGE, CHENGALPATTU
CDSCO Reg. No: ECR/774/INST/TN/2015

No. IEC-CMC/Approval/5945/2020 Dated: 29.03.2020

Protocol No: CMCH – 19 – PR - 034

Title of Work	:	Comparative study on outcomes of myringoplasty with and without platelet rich plasma
Principal Investigator	:	Dr.Gokul.K
Designation	:	1st Year PG
Co-Investigators	:	Dr.D.Senthamarai Kannan, MS., DNB., Associate Professor Department of Otorhinolaryngology Dr.S.Ravi, MD., Professor and HOD Department of Pathology Chengalpattu Medical College Chengalpattu
Department	:	Otorhinolaryngology

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 19.03.2020 at the Medical Education Unit, Chengalpattu Government Medical College, Chengalpattu at 11.00 AM for the IEC - Chengalpattu Medical College members.

The Members of the committee, the Secretary and the Chairperson are pleased to inform you that your proposed project mentioned above is **Approved** in its presented form.

1. You should inform the IEC in case of any changes in study procedure, methodology, sample size investigation, investigator or guide or any other changes.
2. You should not deviate from the area of work for which you had applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions, if encountered during from study.
4. You should abide to the rules and regulations of the institution(s).
5. You should complete the work within the specific period and if any extension is required, you should apply for the permission again for extension period.
6. You should submit a copy of the trial work to the ethical committee on completion of the study.

31/3/2020

MEMBER SECRETARY
INSTITUTIONAL ETHICAL COMMITTEE
CMCH, CHENGALPATTU

PLAGIARISM CERTIFICATE

Curiginal

Document Information

Analyzed document	GOKUL THESIS WORD DOCUMENT.docx (D123331455)
Submitted	2021-12-21T10:01:00.0000000
Submitted by	K. GOKUL
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Similarity	9%
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Sources included in the report

W	URL: https://www.thieme-connect.de/products/ejournals/abstract/10.1055/s-0039-1700235?lang=en Fetched: 2021-12-21T10:02:08.3870000	2
SA	**Tamil Nadu Dr. M.G.R. Medical University / A STUDY OF HEARING OUTCOMES OF CARTILAGE TYMPANOPLASTY AND OSSICULOPLASTY IN PATIENTS UNDERGOING MIDDLE EAR RECONSTRUCTING SURGERIES IN TERTIARY CARE CENTRE.pdf** Document A STUDY OF HEARING OUTCOMES OF CARTILAGE TYMPANOPLASTY AND OSSICULOPLASTY IN PATIENTS UNDERGOING MIDDLE EAR RECONSTRUCTING SURGERIES IN TERTIARY CARE CENTRE.pdf (D123031867) Submitted by: skpharitha@gmail.com Receiver: skpharitha.mgrmu@analysis.urkund.com	1