CLINICAL OUTCOME AFTER TYMPANOPLASTY WITH USE OF AUTOLOGUS PLATELET RICH PLASMA IN CASES OF TYMPANIC MEMBRANE PERFORATION: A ONE YEAR OBSERVATIONAL STUDY.

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LIST OF ABBREVIATIONS

• CSOM	Chronic Suppurative Otitis Media
• PRP	Platelet Rich Plasma
• PTA	Pure Tone Audiometry
• EAC	External Auditory Canal
• TM	Tympanic Membrane
• ME	Middle Ear
• CHL	Conductive Hearing Loss
• SNHL	SensorineuralHearing Loss
• COM	Chronic Otitis Media
• et al	et alii (Latin; ‘and others’)

ABSTRACT

Background: In cases of Chronic Suppurative Otitis Media (CSOM), the conductive deafness which is most commonly caused is due to the tympanic membrane perforations. Surgical treatment option which is tympanoplasty serves as a better option for the reconstruction and repair of these perforated tympanic membrane and improvement of hearing. For the better healing of these surgically repaired tympanic membranes, biotechnologicalmethods such as gelfoam impregnatedwith platelet rich plasma (PRP) placed over the graft materials gives a better result in formation of neotympanum.

Objectives: The aim of this study is to evaluate the success rate of type 1 tympanoplasty with use of autologous PRP.

Material and methods: This observational study was conducted in the department of Otorhinolaryngology and Head and Neck Surgery of KAHER's Jawaharlal Nehru Medical College and KLES Dr.Prabhakar Kore Hospital and Medical Research Center, Belagavi from January 2019 to December 2019.

Each patient consistent with the signs and symptoms of chronic otitis media withwere assessed for any perforation in the tympanic membrane, followed by which tuning fork tests and Pure Tone Audiometry (PTA) was done. Each of the patients were examined for general physicalconditions followed by which they were planned for the operation type 1 tympanoplasty along with usage of autologous PRPand then the healing of the tympanic membrane was assessed and its assessment was done by PTA before performing the surgery and after 1week, 3week and 3months in the post-operative period.

Post-operative otoendoscopic analysis was done for all the patients to find out the graft uptake.

Result: -Out of 42 patients, 28 were males (66.67%) and 14 were females (33.33%). Maximum patients, 30 patients (71.43%) came with complains of ear discharge and ear ache. Patients who presented with moderate degree hearing loss were 28 patients (66.66%). Most of them were in the age group of 31-40years (28.57%) and all of them underwent type 1 tympanoplasty except 5 patients (11.90%) in whom cortical mastoidectomy was planned based on per operative findings and for all the patients autologous PRP was used. Post operatively, when the patients were examined after 3 weeks, in 85% (36 patients), the External Auditory Canal(EAC) appeared normal with minimal amount of gel foam in the EACwith no pain or inflammation. While in 14.29% (6patients) the EAC appeared slight unhealthy because of either presence of granulation or sticky ear discharge(? gel foam).At the end of 6weeks, except for 1patient who had minimal ear discharge which was non foul smelling and mucoid, all the patients were normal.At the end of 3months follow up period, in 41 patients (97.62%) the graft uptake was well but 1 patient still had minimal mucoid discharge in the EAC.In conclusion, use of PRP was found to be feasible for the tympanic membrane perforations.

Conclusion: -In the present study, a success rate of 97.62% was achieved and thus, we found the use of autologous PRP was very effective in the cases of type 1 tympanoplasty irrespective of the graft material used.

Key words- CSOM, Type 1 Tympanoplasty, PRP

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INTRODUCTION

The current advancement in otological surgeries have emerged over a period of time. Hearing improvement and drum closure was the foremost concern which was achieved by the provision ofdry ear. The advancement in tympanoplasty approaches were driven by coincidental and inspirational inputs from specialist over the world.[1]The revelations of usefulness of the tympanic membrane (TM) and ossicles in hearing as well as advent of antimicrobial buttress up to upgraded understanding appertaining to the condition as well as their recovery subsequently.

First true tympanoplasty is documented to be undertaken by Berthold in 1878. The surgeon de-epithelialized the remnant TM by administering plaster over it for a period duration of 3 days. Then doffing it near the underlying epithelium, and when the defect is created, placing a skin graft onto this defect.[2]

Tympanoplasty is now an established surgery for perforations of TM and is being carried out routinely by otologists. Autologous graft materials such as, fascia lata, tragal perichondrium, temporalis fascia, cartilage and fat graft have stood the test of time in repairing TM perforations. Abundance of such autologous materials implies that there is no such thing as supreme graft material and the choice of it greatly depends on individual surgeon's preference.[3]

Biological interventions such asPRPserves as an arising technology in the field of science in cellular therapy. Speeding up of bone growth and tissue healing facilitated by PRP has been very well documented. Autologous blood, after centrifugation harvests a product which is safe and free from deadly diseases. With legitimate preparation, considerable amount of platelets in the PRP are activated generating hefty concentration of growth factors which triggers soft tissue growth and angiogenesis.[4]

OBJECTIVES

The aim of this study is to evaluate the success rate of type 1 tympanoplasty with use of autologous Platelet Rich Plasma.

REVIEW OF LITERATURE

CSOM is described aschronic middle ear (ME) disease and is described as "chronic inflammation of the ME and mastoid cavity, which presents with recurrent ear discharge or otorrhoea through a tympanic membrane perforation".[5] As multiple factors are responsible for the disease causation, it is said to result from sequential interaction between- host, environment, bacterial and geneticrisk factors.[6,7]

The ubiquitous sequelae of CSOM is hearing impairment.[8] Hearing loss due to CSOM can be both- conductive hearing loss (CHL) and sensorineural hearing loss (SNHL). CHLemanates from the interference in the conduction of sound waves from the structures of ear- "middle ear to the inner ear". CSOM is pervaded by the presence of perforation in the TM, impeding the sound transmission to ear. Damage to the architecture of the ear can have a direct proportional relation to the forfeiture of hearing. The magnitude of compromised hearing has manifested to be directly commensurable to the impairment generated to the anatomy of the ME.[9]

RELEVANT ANATOMY:

The tympanic membrane:

Formation of the lateral embankment of the tympanic cavity is by TM. Construct of TM is imperceptibly oval, silhouetting slant of about 55° with the flooring of the EAC. The protracted width is 9-10 mm which runs from posterosuperior to anteroinferior while shortest is 8-9 mm. Superior limit of sulcus, known as the tympanic annulus forms a fibrous hoop which strides towards the center asmalleolar folds, anterior and posterior folding up till the processuslateralis of malleus. Leaving a small, triangular zone of TM atop the malleolar folds, called the

pars flaccida and there at the periphery is the absence of tympanic annulus. Pars tensa forming a considerable part of the TM points towards the ear canal. The handle of malleus attaches at the centre of TM, recognised as umbo.

Entire part of TM is triple layered-

- Outer epidermal layer
- Fibrous middle layer and lamina propria
- Inner mucosal layer which is in perpetuation with the tympanic cavity lining.

Fibres of lamina propria in pars tensa are aligned radially in the external layers and in the deeper layers, fashioned in circular, parabolic as well as transverse manner.[10]

Arterial supply of TM is catered by branches delivering to the EAC as well as the ME. Both of these sources are interconnected through an extensive anastomosis within layers of the lamina.

- Maxillary artery- deep auricular branch gives off epidermal vessels
- Maxillary artery- anterior tympanic branches gives off mucosal vessels branch
- Posterior auricular artery- gives off the stylomastoid branch
- Vagus nerve- auricular branch
- Glossopharyngeal nerve- tympanic branches.[10]

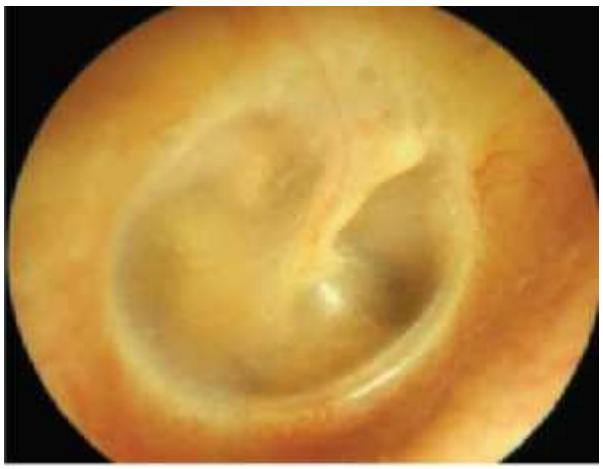


Fig:1-Tympanic Membrane[10]

The tympanic cavity:

There are three compartments a tympanic cavity has:

Epitympanum (upper)- lies at a level above the malleolar folds

Mesotympanum (middle)- lies at a level below that of the tympanic sulcus

Hypotympanum (lower)- It lies below an imaginary horizontal line, from thefibrous annulus to the cochlear promontory.

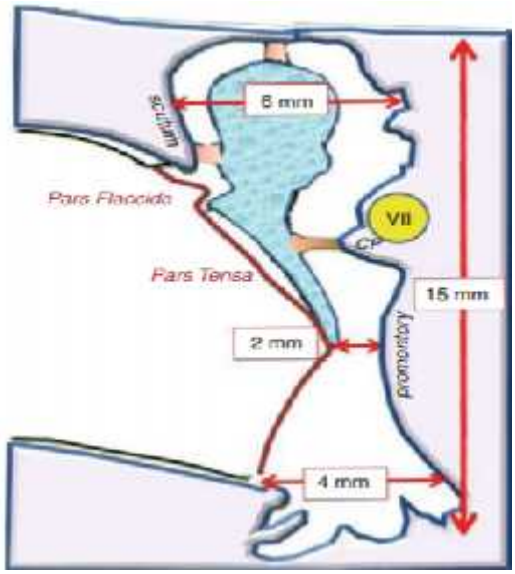


Fig:2- Tympanic Cavity[11]

The lateral wall:

Is formed by-

- Superior- epitympanic bony wall noted as outer attic wall or scutum
- Central- the TM
- Inferior- hypotympanic bony wall.[10,11]

The roof:

Tegmen tympani forms the epitympanic roof. This roof forms a thin plate of bone which separates the middle cranial fossa from ME. Any defect if present then, may yield path for infection access in children, from ear into the extradural space.[10,11]

The floor:

The floor forms a partition between the jugular bulb dome and hypotympanum and has a differing density and ranges accordingly correlated with thestature of the jugular fossa. When there is insufficiency of floor then the jugular bulb is concealed by only a fibrous tissue over it. In such cases, the tympanomeatal flap should be raised carefully.[10,11]

The anterior wall:

Superior and inferior caroticotympanic nerves perforate the anterior wall of tympanic cavity.[10,11]

The medial wall:

Distinction between the internal ear and the ME cavity are by this medial wall. Promontory forms an elevation on this medial wall and occupies a greater part of the

central portion of the medial wall. This elevation is due to the basal coil of cochlea. Inclination of the promontory forwards, merges the anterior wall of the tympanic cavity in the protympanum. The oval window is present behind and above the promontory. This is an approximately "kidney-shaped opening". It connects the cavity of the ME to the vestibule and is closed by the stapes footplate and its annular ligament. The oval window is systematized in a depression of differing width. This depends on the anatomy,

Superiorly: the facial nerve

Inferiorly: the promontory

Round window niche: located below and behind the oval window niche. Is triangular in shape. The shape of round window is approximately oval. The Fallopian canal, facial nerve canal lies over the promontory as well as the oval window and runs in anteroposterior direction.

Anteriorly: the processuscochleariformis, a curvy projection of bone, dwelling the tensor tympani muscle and tendon which then turns laterally and goes to attach to the handle of malleus.[10,11]

The posterior wall:

In the upper part- irregular opening is present called aditusadantrum. This joins mastoid antrum with the epitympanic space. Below aditus- the fossa incudes is present. It holds incus short process with the suspensory ligament. There is presence of pyramid- below the fossa incudis. The stapedial muscle tendon inserts onto the head of stapes.[10,11]

The contents of the tympanic cavity:

Tympanic cavity contains-

- Bones- malleus, incus and stapes
- Muscles- tensor tympani and stapedius
- Nerve- Chorda tympani
- Tympanic plexus.

Most laterally lies malleus which attaches to TM, while the footplate of stapes attaches to the oval window.[10,11]

The mucosa:

Respiratory mucosa with nerves which secretes mucous.[10,11]

Blood supply:

Internal and External carotid arteries.[10,11]

EFFECTS OF PERFORATION:

As said by Mawson et al. "that ruination of TM is associated with auditory function impairment. The degree of impairment not only depends upon the size but also depends on the site of the perforation".[12]

According to Thorburn et al. "the average loss of hearing for frequencies 500, 1000, 2000 Hz varied between 20 and 45 dB which is in proportion to different sizes perforation. It tends to be a little less with anterior perforations while a little more with posterior ones due to loss of round window sound preservation mechanism".[13]

Antony and Harrison et al. in their study on audiological assessment of 103 patients with simple perforations and all subjected to myringoplasty noted that- "all of them had normal hearing after myringoplasty and thus having no other cause of hearing loss. Loss for frequencies from 250 to 4000 Hz were studied. Average of all the types of perforations demonstrated the maximum loss of 25 dB at 250 Hz, gradually decreasing to 13 dB at 4000 Hz. The average hearing loss in all types of perforations of less than 2 mm diameter (12 cases) was between 19 to 8 dB, the higher loss being up to 1000 Hz, and the smallest at 2 and 4 kHz. The average loss in all types of perforation of more than 2 mm diameter (91 cases) also showed the same trend of being more at low frequencies but was greater in magnitude than the smaller perforations the maximum being 27 dB (at 250 and 500 Hz) and minimum 13 dB at 4 kHz. Also, they worked on the site of perforations and compared the central ones with the peripheral. In the group of small central perforations (up to 2 mm diameter) the level of loss of hearing (7 cases) was more in the mid frequencies 500–2000 Hz, whereas, in the peripheral ones (5 cases) the hearing was well reversed, the maximum (25 dB) being for 250 Hz. After comparing the average of all perforations of anterior inferior quadrant with those of postero-inferior quadrant they concluded that the loss in former was 16 dB less than that in the later at 250 Hz but 2–4 dB more at mid frequencies (equal to 4000 Hz)".[14]

Glasscock and Shambaugh stated that ''even if there are identical sizes of perforations but their locations are different, they produce significant hearing loss".[15]

MANAGEMENT:

Any antimicrobial therapy is started after knowing the reports of the pus culture and sensitivity of ear discharge. Common bacteria in Chronic Otitis Media(COM) are anaerobes, proteus, pseudomonas aeruginosa and staphylococcus aureus. Importance of audiological evaluation holds a place in assessing and documenting the type and degree of hearing loss. These patients mainly manifest with CHL.

X-ray Schuller's view of bilateral mastoids is a useful tool for comparing the mastoid cellularity. In such cases, the main aim to treat a patient is to eradicate the middle ear disease and prevent further infection as well as to restore the hearing.[16] To achieve these aims, various surgical and non-surgical treatment modalities have been applied.

Non-surgical approaches are-

- Aural toileting
- Topical and systemic antibiotics.

If recurrence of otorrhea is there or the otorrhea persists despite the medical line of management or if the patient gets compromised hearing, surgical line of management should be taken into consideration.

Ideally, the surgical procedure, tympanoplasty should be done, once-

- infection has been controlled in decent amount

-achieving a healthy ME mucosa

After such conditioning, chances of the tympanoplasty to become successful becomes relatively high.

Perforations of TM is closed by procedures known as myringoplasty, this when combined with disease clearance from the ME along with hearing improvement is termed as tympanoplasty.

Cases that become resistant and are unmanageable by medical management, tympanoplasty combined with cortical mastoidectomy are performed. Wherein, in such procedures, we:

-perform the aeration of the mastoid and ME

- remove the unhealthy tissue

-repair the TM and perform ossiculoplasty if needed.

SURGICAL MANAGEMENT:

Repair of the TM by undertaking tympanoplasty might lead to substantial degree of benefit to patients with TM perforations. These benefits include-

-prevention of ear infections

-prevention of aural discharge,

-improvement in hearing,

-ease of hearing aid usage and

-elimination of the need to take precautions from water while showering and swimming.[17]

Tympanoplasty is said to protect against longstanding damage to the ME by impeding advancement of ossicular pathology. It prevents the migration of squamous epithelium around the margins of the perforation, thus preventing the possible consequences such as formation of cholesteatoma.

The notion of a surgical repair of the TM with a skin graft is usually credited to Berthold in 1878. The following is a description of the operation: "The first step is to freshen the margins around the perforation and the lip-shaped epithelisation of the margins of the perforation from the epithelium in order to change (render) these parts into a wound which enables the healing of a freshly excised piece of skin. For that purpose a court-plaster was glued over the site of perforation so that the eardrum is covered by it still several millimetres distant from the perforation. After three days, this plaster was removed. Harvesting the piece of skin from the forearm and was introduced to the skin into the external ear canal and press it with its wounded surface over the margin of the perforation".[18]

Tympanoplasty includes disease clearance from the ME and the surgically reconstruct a perforated TM. This procedure restores the hearing mechanism and protects the middle ear against infections.[19]

“Tympanoplasty was first described by Berthold and Wullstein”.

The technique was then modified by Zollner.[19-21]

Common approaches to tympanoplasty include-

-endaural

-endomeatal

-postauricular route.

The size or site of the perforation decides the outcomes of a surgical approach even the placement of graft over or under the remnant TM is a deciding factor.[19,22] Most routinely performed technique in a graft placement isgraft positioning under the remnant TM. This method is called as the "underlay" technique.[19,20,23]

To repair the perforated TM, various types of graft materials are present were described by Yegin et al. in 2016 were "temporalis fascia, cartilage, perichondrium, periosteum, vein, fat, skin".[24]

Among all the graft materials described, the autologous "temporalis fascia" graft is commonly used by the surgeons as it is easy to harvest, low metabolic rate and close to the operative field.

Reilly et al. in 2016 suggested- "some surgeons also prefer to use the loose areolar fascia of the temporalis muscle in the patients who have been planned for revision cases". In revision cases, cartilage grafts are the choice for majority of the surgeons. These grafts can be harvested from the tragal perichondrium or conchal perichondrium. These grafts have both durability and strength, but still the functionality of this graft is of utmost importance.[25]

"There are two popular grafting techniques- underlay and overlay technique".

- Underlay technique: after freshening of the margins of the perforation, placement of graft is medial to the remnant TM and handle of malleus.
- Overlay technique: placement of graft is lateral to the malleus and medial to remnant TM or annulus.[26]

In our study we performed underlay tympanoplasty for all the patients.

Failure rates do occur following this procedure due to displacement of graft and improper closure leading to residual perforation but those are minimally reported.

In order to improve the take up of the graft material, various biomaterials or biological tissues have been used such as- "autologous serum, autologous PRP, epidermal growth factor, alloderm, merogel, embryonic stem cell, chitosan patch, silk patch is used during myringoplasty with varying results". In our study, we used autologous PRP for all the patients undergoing type 1 tympanoplasty.

PLATELET RICH PLASMA (PRP):

Procurement of PRP and its use on human body is easy. Due to its autologous nature, there are almost no reported side effects. Centrifugation of blood separates the plasma which is made up mainly of proteins and water. This allows the blood cells- RBC, WBC and platelets to easily circulate in the body.

Thrombocytes conventionally function as blood clotting agent. At the site of injury, there is release of growth factors which promotes healing and repair of the tissue. PRP provides growth factors in a condensed form at the site of injury.

Thus, PRP can be defined as that amount of plasma, fortified with growth factors and platelets. "Four categories of PRP on the basis of leukocytes and fibrin contents have been classified:

(1) leukocyte rich PRP

(2) leukocyte reduced PRP

(3) leukocyte platelet rich fibrin

(4) pure platelet rich fibrin".

"Tissue healing is enhanced by platelets and growth factors and cytokines". Bioactive agents which are secreted by platelets are also involved in proliferation and differentiation of cells. These bioactive molecules are-serotonin, dopamine, adenosine and calcium. They enhance cell permeability as well as facilitate tissue repair.

The growth factor and cytokines are:

- Platelet-derived growth factor.
- Transforming growth factor beta.
- Fibroblast growth factor.
- Insulin-like growth factor 1.
- Insulin-like growth factor 2.
- Vascular endothelial growth factor.
- Epidermal growth factor.
- Interleukin 8.
- Keratinocyte growth factor.
- Connective tissue growth factor.[27]

MATERIALS AND METHODS

Source of data:

All the patients above 10 years of age with CSOM and TM perforation attending the Out Patient Department of ENT, KLES Dr. Prabhakar Kore Hospital between January 2019 to December 2019.

Study setting:

Hospital Based study

Study design:

Observational study

Study population:

The Hospital statistics show prevalence of CSOM with perforation to be around 40 cases on an average of per year as per the last 3 years stastistical study. Considering 95% confidence interval and 1% permissible error, the sample size of 42 is obtained.

Study period:

1year

Ethical clearance:

Ethical clearance was obtained from the Institution’s Ethical Clearance Committee

Ref: dated: 24/11/18 - MDC/DOME/60

Inclusion criteria:

All the patients above the age group of 10 years, having good general physical condition were included in the study. No evidence of active infection in the nose, throat or PNS. Central Perforation of the Pars Tensa of the TM with dry ear for a minimum period of 3 weeks before the day of operation.

Exclusion criteria:

Patient not willing for surgery.

Patients having sensorineural or mixed hearing loss.

Patients with atticoantral disease

Patients with tympanosclerosis.

Methodology:

Tympanoplasty under general anesthesia/local anesthesia was done after working up the patient for anesthesia.

Repeat PTA was done 3 months after the surgery to evaluate the outcome of surgery.

Autologous Platelet Rich Plasma- Preparation:

5ml of venous blood will be obtained from antecubital vein using 18-gauge needle.Blood was collected in a specific tube without anticoagulant. The collected blood will be centrifuged at 3,200 rpm for 12 minutes. The centrifugation will lead to separation of the blood into the three different density layers. In the tube, bottom layer will consist of RBS, middle layer will consist of PRP (about 1.5 ml^3) which contains platelets and WBC (buffy coat). Top most layer contains platelet-poor

plasma. The PRP is extracted via a pipette and will be extracted just before application into the ear canal. Via a transcanal approach, the PRP mixed with gel foam was inserted into the EAC over the graft material. The ear canal was then packed with gelfoam and mastoid dressing was applied. This mastoid dressing was removed after 7th post-operative day and was examined for the post aural/end-aural sutures. After observing that the inscision site was healthy, the sutures were removed. Post-operatively, the patient was given antibiotic course, analgesic and antihistaminics.[28]

Follow up period:

Repeat PTA was done till 3 months after the surgery.

RESULTS

For all the patients in the present study, routine investigations and pre anaesthetic check-up was done and was found to be normal.

As per the preference of the patients, in about 90.48% (38 patients) local anaesthesia was given whereas in 9.52%(4 patients) general anaesthesia was given.

A total of 42 patients were taken for our study. Table-1 & Fig.1 shows the distribution of gender in the study which shows that there were 28 male patients and 14 female patients and hence the Male: Female ratio was 2: 1.

Table 1: Gender wise distribution of patients

Gender	No of patients	% of patients
Male	28	66.67
Female	14	33.33
Total	42	100.00

Figure 1: Gender wise distribution of patients

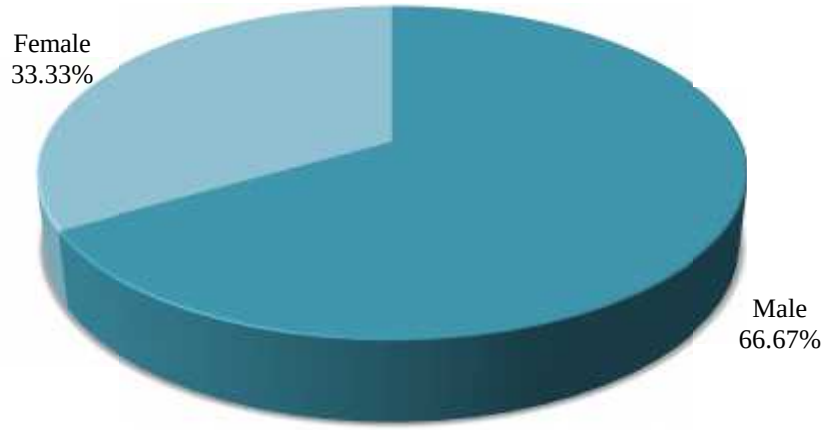


Table-2 & Fig.2 shows the age wise distribution of patients in our study which shows that maximum number of patients, 28.57% (12 patients) belonged to the age group of 31-40years and minimum number of patients, 21.43% (9 patients) belonged to age group of 51-59years who underwent surgical management for CSOM in our study.

Table 2: Age wise distribution of patients

Age groups	No of patients	% of patients
<=30yrs	11	26.19
31-40yrs	12	28.57
41-50yrs	10	23.81
51-59yrs	9	21.43
Total	42	100.00
Mean age	39.26	
SD age	11.74	

Figure 2: Age wise distribution of patients

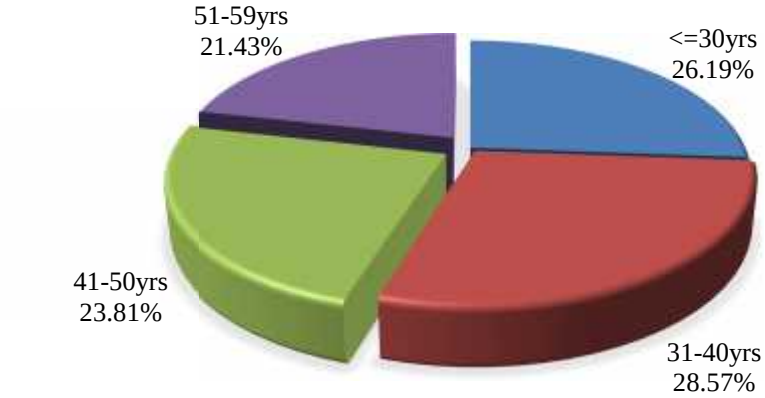


Table-3 & Fig.3 shows the complaint wise distribution of the patients which shows that the commonest complaint of the patients was ear ache and ear discharge and maximum patients 71.43% (30 patients) belonged to that group. 19.05% (8 patients) presented with ear ache, ear discharge & decreased hearing and 9.52% (4 patients) presented with ear ache, ear discharge & tinnitus.

Table 3: Complaints wise distribution of patients

Complaints	No of patients	% of patients
Ear ache & ear discharge	30	71.43
Ear ache, ear discharge & tinnitus	4	9.52
Ear ache, ear discharge & decreased hearing	8	19.05
Total	42	100.00

Figure 3: Complaints wise distribution of patients

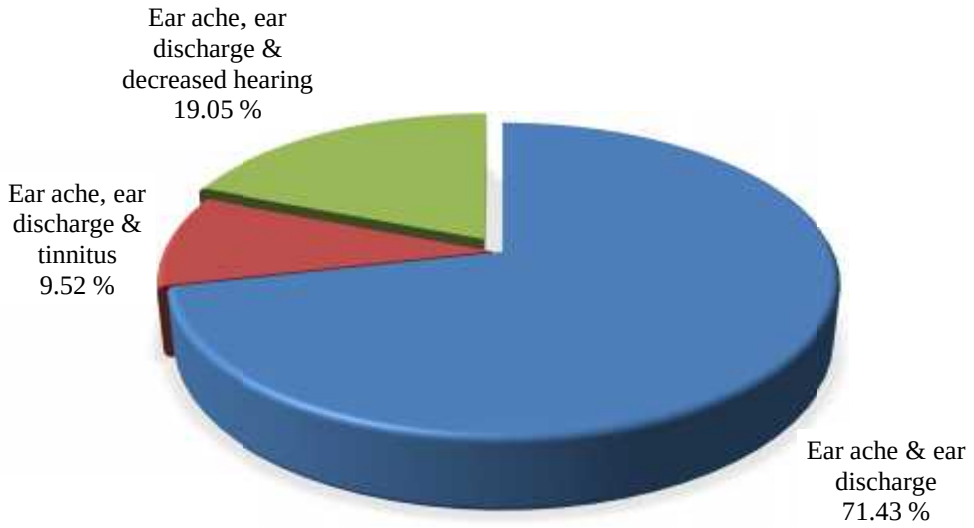


Table-4 & Fig.4 shows the site of perforation wise distribution of patients and it was noted that both the anterior and posterior quadrant involvement was equal in 35.71% (15 patients) whereas the patients in which all the quadrants were involved constituted 28.57% (12 patients).

Table 4: Site of perforation wise distribution of patients

Site of perforation	No of patients	% of patients
Anterior quadrant	15	35.71
Posterior quadrant	15	35.71
All quadrants	12	28.57
Total	42	100.00

Figure 4:Site of perforation wise distribution of patients

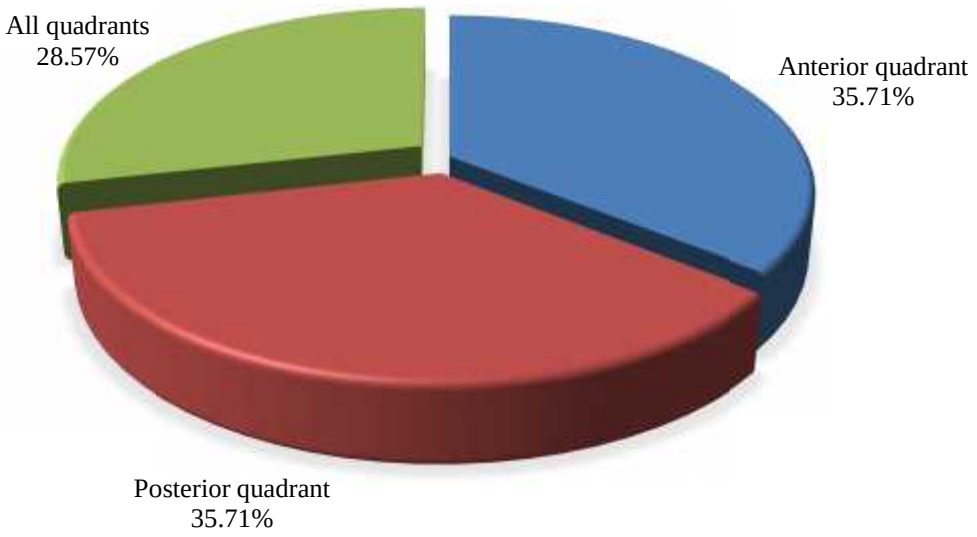


Table-5 shows the involvement of the side of the ear. In our study the commonest affected side was right ear which was 54.76% (23 patients) and involvement of left ear was in 45.24% (19 patients).

Table-5: Ear involved wise distribution of patients

Ear involved	No of patients	% of patients
Left ear	19	45.24
Right ear	23	54.76
Total	42	100.00

Table-6 & Fig-5 shows the level of pre-operative hearing loss in the patients based on audiometric evaluation. Maximum patients 66.66% (28 patients) presented with moderate degree hearing loss, 28.57% (12 patients) presented with mild degree hearing loss and minimum number of patients, 4.76% (2 patients) had severe degree hearing loss.

Table-6: level of hearing loss on pre-operative evaluation

Degree of hearing loss	Pre-operative evaluation	Percentage
mild	12	28.57%
moderate	28	66.66%
severe	2	4.76%
Total	42	100%

Figure 5 : Level of hearing loss

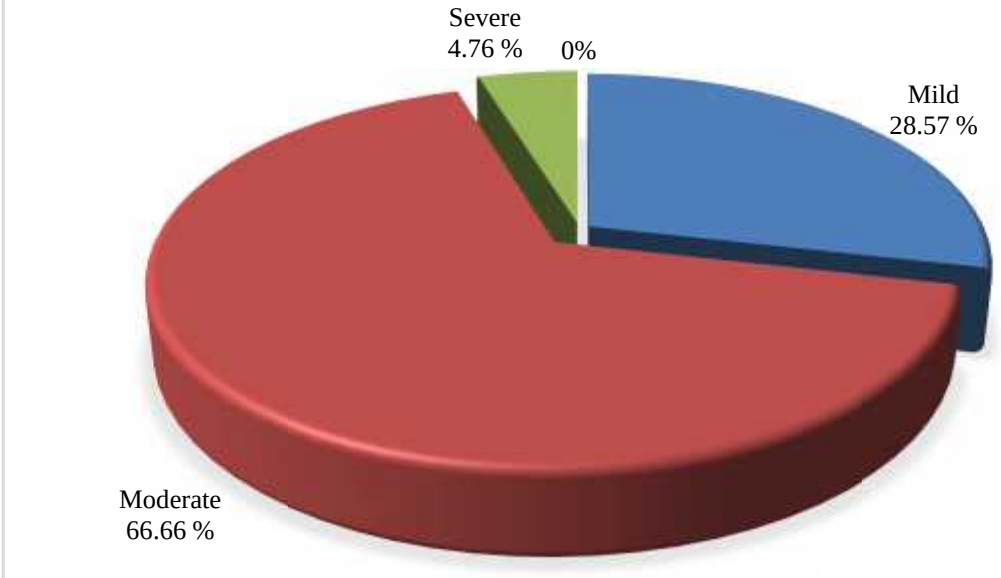


Table-7 shows the status of dry ear before operating which shows that 97.62%(41patients) had dry ear before operating and 2.38% (1patient) had wet ear in the form of non-foul smelling, non-blood tinged mucoid discharge even after antibiotic coverage.

Table 7: Status of dry ear before operating of patients

Dry ear before operating	No of patients	% of patients
No	1	2.38
Yes	41	97.62
Total	42	100.00

For all the patients we performed type 1 tympanoplasty with use of autologous PRP. In 5 patients we had to undertake cortical mastoidectomy based on their intra-operative findings. Table-8 Fig.6 shows the status of operation performed in which 88.10% (37 patients) underwent type 1 tympanoplasty and rest 11.90% (5patients) underwent type 1 tympanoplasty with cortical mastoidectomy.

Table-8: Status of operation performed

Operation performed	No of patients	% of patients
Type 1 tympanoplasty with cortical mastoidectomy	5	11.90
Type 1 tympanoplasty	37	88.10
Total	42	100.00

Figure-6: Status of operation performed

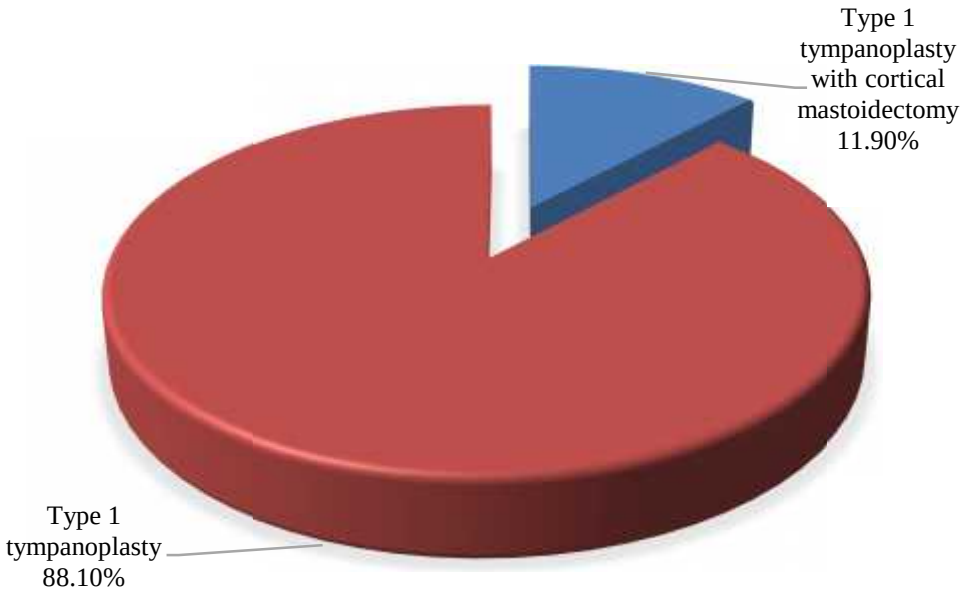
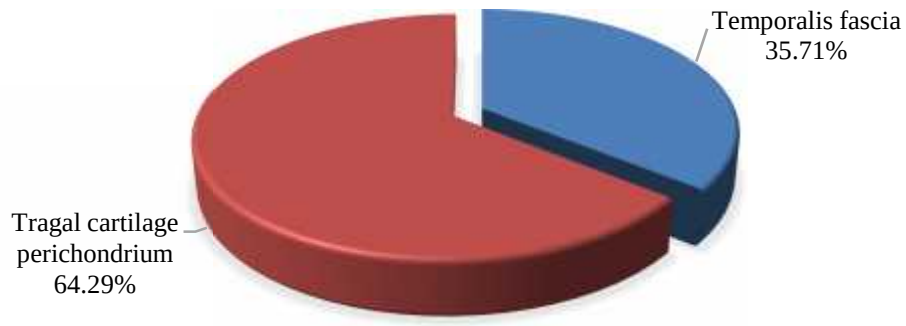


Table-9 Fig.7 shows the distribution of type of graft material used among the patients based on the patient's preference which shows usage of tragal cartilage perichondrium in 64.29% (27patients) and usage of temporalis fascia graft in 35.71% (15 patients).

Table-9: Type of graft used among patients

Type of graft	No of patients	% of patients
Temporalis fascia	15	35.71
Tragal cartilage perichondrium	27	64.29
Total	42	100.00

Figure-7: Type of graft used among patients



There were no intra-operative complications noted in any of the patients.

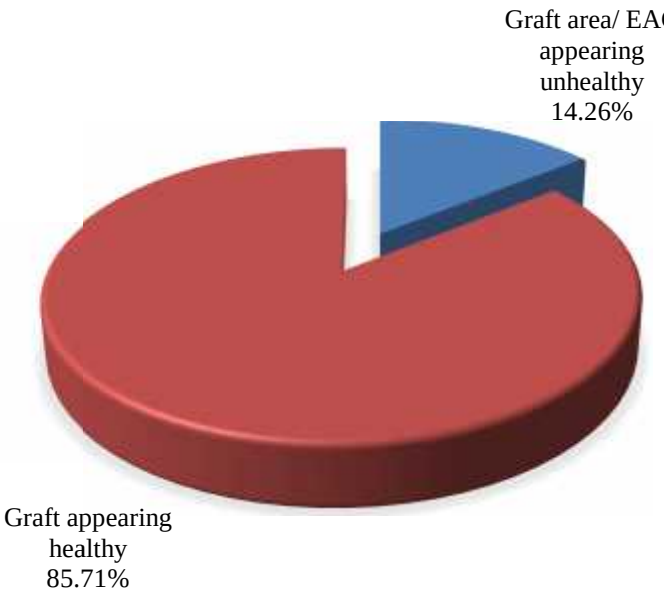
PTA was not done for any of the patient at 1week post-operatively as gel foam was present in EAC in order to avoid the confounding factors. On post-operative 1 week, the post aural wound was found healthy, sutures were in place and no gaping at the incision site was noted and the post aural/ end aural sutures were removed.

Table-10 shows, at the end of 3 weeks of follow up, the incision site healed very well for all the patients. In 85.71% (36 patients), the EAC appeared normal with minimal amount of gel foam in the EAC with no pain or inflammation. While in 14.29%(6patients) the EAC appeared slight unhealthy because of either presence of granulation or sticky ear discharge (? gel foam).

Table-10: Follow up 3 weeks outcome wise distribution of patients-otoendoscopic evaluation.

3 weeks follow up outcome	No of patients	% of patients
Graft area/ EAC appearing unhealthy	6	14.29
Graft appearing healthy	36	85.71
Total	42	100.00

Figure-8: 3 week follow up outcome wise distribution of patients



- At the end of 3weeks, we found that the post aural wound and the EAC was healthy in 36 patients.
- At the end of 6weeks, except for 1patient who had minimal ear discharge which was non foul smelling and mucoid, all the patients were normal.
- At the end of 3months follow up period, in 41 patients the graft uptake was well but 1 patient still had minimal mucoid discharge in the EAC.

DISCUSSION

"The leading causes of CHL is CSOM where perforation of TM is present". In such cases the integrity of the TM must be re-established quickly-

- to preserve the hearing
- to protect the structures of the ear from external insults.[29]

Normally wound healing includes-

-epithelial migration

-increased fibroblastic reaction

-vascular proliferation

-tissue remodelling.

In contrast to this, healing of TM begins with-"bridging of the squamous epithelial layer, followed by regeneration of the fibrous layer. TM perforations may heal either spontaneously and completely, heal with a thin membrane, or persist unhealed".[30]

"Acceleration of perforation of TM and healing follows two main strategies:

(1) stromal support to the regenerating tissue;

(2) cellular regeneration".

Freshening of the edges of TM perforations or cauterisation with chemicals such as- silver nitrate and trichloroacetic acid have very limited success. Results of various studies done on growth factors- concluded that the growth factors function as

"promoters of cellular regeneration and mobilisation". A recent technique of using PRP has been used to accelerateTM perforation healing.[31]

So, we have undertaken this study to determine the effectiveness and observe the results of use of autologous PRP in type 1 tympanoplasty.

Type 1 tympanoplasty is one of the most commonly performed procedures in otology. With advanced microsurgical techniques and equipment, the graft uptake success rates of 96.6% according to Faramarzi et al.[32]In a study conducted by Indorewala et al. temporalis fascia achieved graft success of 95% for large and 83% for subtotal perforations, while fascia lata achieved graft success of 98% for large and 95% for subtotal perforations[33] have been reported. There are various factors influencing the success rate of tympanoplasty. The present study was conducted in the Department of ENT, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi (Karnataka) with the objective to assess the use of autologous PRP to improve the success rate of Tympanoplasty. Total 42 patients were taken in the study who underwent type 1 tympanoplasty with autologous PRP and then its effect was noted on the reconstructed TM.

Demographic profile

In the present study we observed that the mean age group of the patients who presented with CSOM and underwent type 1 tympanoplasty with autologous PRP was 39.26 years. The patients in the age group 31-40yrs comprised of the largest group containing 12 patients which accounted upto 28.57% of our total study population. Nagle et al. observed that majority of the cases were in the second decade of life.[34]Thakur et al. revealed that an age group of 21-30 years had the highest CSOM presentation.[35] Sandhu et al. in 2019 concluded that this early presentation may be due

to health issues and difficulty in hearing affecting the work efficiency, leading patients to seek early medical intervention.[36]

Size of perforation

In 2016, Alsarhan et al. concluded that the severity of hearing loss intensifies with the increase in perforation size. Larger the perforation, greater the hearing loss.[37]Maharjan et al. in 2009 from their study concluded that perforation site in TM and duration of ear discharge significantly affect the intensity of hearing. For example, "posterior quadrant perforations are having poorer hearing than the anterior ones, because there is direct exposure of the round window to sound".[38] However, according to the works of Ibekwe et al. they acknowledged- "there is no significant effect associated with location of the perforation".[39] Also, In the year 2014, Ribeiro et al. from their study concluded thatthere was no correlation between the size of TM perforations and hearing loss[40] and similar results were found in our study.

Site of perforation

On the basis of site of involvement, perforation is divided into- anterior quadrant, posterior quadrant and all quadrant involvement. In the present study, there is no significance noted on the basis of site of perforation and it was comparable to the works of S. E. Voss et al. done in the year 2001, who by their work concluded that- "hearing loss does not depend on the location of perforation"[41] which was in favour of our study. Also, Mehta et al. in 2006 by their work stated that- "hearing loss does not vary substantially with location of the perforation".[42]

Effects of dry ear

Even after medical line of management with antibiotics after pus culture and sensitivity, in the present study, 1patient (2.38%) out of 42 patients undergoing type 1 tympanoplasty with use of autologous PRP had wet ear which can be possibly due to persistent mucosal disease whereas 97.62% of the patients had dry ear and there was no significant failure of the graft was noted with wet ear. Nagle et al. in 2009 "examined the results of type 1 tympanoplasty in 100 wet eared and dry eared patients with perforated TM. They also compared the aural status and closing of the membrane perforation in the two groups".[34] Naderpour et al. in 2006 concluded that- "graft incorporation rate in dry-eared patients was higher (96.7%)" than aforementioned study.[43] Vijendra et al. in 2007 performed histopathological examinations on the remnant TM of the patients. They observed that- "in completely dry and atrophic membranes blood vessels are quite marginalized, while the membranes were either absent or as small as possible". Contrary to Vijendra's results, "the graft incorporation rate in dry eared patients was better than that of wet eared ones (96.7% compared to 93.3%)".[44] However, this difference was not significant statistically.[44]

Table-11: Graft uptake rate in dry ear

Study	Graft uptake rate
Present study	85.7%
Deosthale et al.[45]	86.95%
Dhar et al.[46]	95%

Graft material

Since a very long time, the temporalis fascia graft has long been considered as an ideal graft material for TM repair. However, in the post-operative period due to negative ME pressure, temporalis fascia may not withstand the negative pressure in ME. Tragal cartilage perichondrium proves to be a better graft than temporalis fascia graft material with considerably good amount of hearing outcomes. Graft material is obtained as per patient's preference for scar less surgery. On basis of patient's preference to have scar less surgery, we used tragal perichondrium graft for 27 and for 15 patients, temporalis fascia was used and it was noted that the success rate of tragal perichondrium graft was more than the temporalis fascia graft. The poor performance rate of tragal perichondrium was only 2.3% whereas the poor performance rate of temporalis fascia graft was 11.9%. The incorporated cartilage gave the necessary stiffness to the reconstructed TM and provided mechanical stability to avoid retraction. This is facilitated by- a lower metabolic rate and good compliance in middle ear. Sunita et at.[47] concluded that- "tragal perichondrium cartilage as suitable alternative to temporalis fascia. The key seems to be the use of cartilage of appropriate thickness. This would not hamper conduction of sound while protecting from retraction or reperforation of the neo tympanum. Perichondrium is a tough graft material showing good revascularization".[47] Cavaliere et at. concluded that- "cartilage is a good grafting material, in fact it is easily accessible, easy to fashion, resistant to negative middle ear pressures, stable (particularly in cases lacking fibrous annulus), sufficiently elastic for good sound conduction, well tolerated, resistant to resorption and, above all, it does not involve additional costs".[48]

Cortical mastoidectomy in type 1 tympanoplasty

"Mastoidectomy is not necessary for successful repair of simple TM perforations". Adding cortical mastoidectomy to tympanoplasty improvement in the clinical course in those patients who have received it by reducing the number of patients requiring future procedures and reducing disease progression. Combining mastoidectomy with tympanoplasty during repair of simple perforations in patients with no active evidence of infection remains an appropriate option and may be valuable in reducing progression of disease and the need for future surgery".[49] We undertook cortical mastoidectomy for 5 patients (11.9%) out of 42 patients and the decision for doing cortical mastoidectomy was purely based on the intra-operative findings such as presence of unhealthy ME mucosa. Anjana et al. in 2017 concluded that "mastoidectomy gives no statistically significant benefit over tympanoplasty in tubotympanic type of CSOM as regards to graft success rate and hearing gain. If ME mucosa is not healthy then mastoidectomy can be considered as a good practice, to open the mastoid antrum and air cells and if ME mucosa is healthy tympanoplasty alone is sufficient.[50]

Autologous platelet rich plasma

In the present study there was usage of autologous PRP for all the patients and noted that in 85.71% of the patients, graft uptake was present whereas the rest 14.29% the graft area appeared unhealthy at the end of 3 weeks but at the end of 3 months in only one patient, the graft uptake was questionable as there was presence of minimal amount of discharge in the EAC. Erkilet et al. from his study, suggested- "autologous PRP is effective in accelerating TM perforation healing in rats. This encourages us to try it in myringoplasty in large TM perforation in human, particularly as it is an

autologous material".[51] A study conducted by El-Anwar et al. the rate of graft uptake with PRP was 100%. In all the cases rate of uptake of the graft was significantly higher than those without PRP. No reported significant complications such as infections were reported.[52]

PRP, being newer biotechnology has demonstrated effects in accelerating and stimulating tissue healing. Efficacy of the treatment with PRP is due to its "local delivery of a wide range of growth factors and proteins which support physiologic wound healing".[53]

With this study it is suggested that the Autologous PRP augments wound healing in chronic perforations of TM and also avoids infection.

CONCLUSION

In our study, we achieved a success rate of 97.62% which was much better than using a graft material without use of autologous PRP in type 1 tympanoplasty. Autologous PRP is a newer biotechnological preparation which facilitates the stimulation and acceleration of wound healing. The improved efficacy of PRP in healing and repair process of a tissue is because of local delivery of proteinsand growth factors. Therefore, application of autologous PRP has been now drawn-out to different fields of medicine.

A complex inflammatory response evident within a wound bed, impacts the level of bacterial burden as well as the extent of wound healing which is due to critical interactions between bacteria and host organism.[54] In the PRP there is presence of platelets, leukocytes and monocytes which combat infections. Even in our study, there was no significant number of postoperative infections or complications noted in type 1 tympanoplasty with use of autologous PRP because of its immunogenic potential, thereby considering it safe for use. There were no untoward reactions noted in our study.

The procedure for production of autologous PRP is simple, cheap, safe and easy and the chances of uptake of graft material are better when aided with autologous PRP.

SUMMARY

In the present study, a success rate of 97.62% was achieved and thus, we found the use of autologous PRP was very effective in the cases of type 1 tympanoplasty irrespective of the graft material used. The reason for this can possibly be-

- PRP is cost effective, safe and easy to procure platelet concentrate along with enriched growth factors. It accelerates the healing process of a perforated TM following tympanoplasty.
- As it contains growth factors, PRP has the ability to accelerate the regenerative capacity of endothelium, epithelium as well as the epidermis. It triggers angiogenesis and collagen synthesis, thereby causing soft-tissue healing. It curbs down dermal scarring as well as promotes haemostatic responses to injury.
- Autologous PRP can be easily preparedfrom patient's own blood.
- There is presence of high concentration of leukocytes in PRP. This plays a convincing role in preventing infections. This was also noted in the present studyas only 2.38% (1 patient) had presence of minimal sticky discharge at the end of follow upperiod. Moreover, since PRP is autologous and contains no additives like anticoagulants, this ensures the absence of any anaphylactic reactions. Thus, it improves graft placement and also improves the overall success rate of tympanoplasty.

The demographic factors- including age and gender as well as the status of the mastoid did not seem to have any effect on hearing improvementpostoperatively, while the size and site of the perforation were correlated with the level of hearing gain.

In the present study, all the patients underwent endoscopic assisted microscopic tympanoplasty except for 5 patients in which we had to do cortical mastoidectomy because we found granulation/congestion in the middle ear perioperatively. Even in these patients who underwent cortical mastoidectomy, we did not find any disease in the mastoid.

We recommend a study with a bigger sample size or a multicentric study to prove and confirm the effectiveness of PRP.

In conclusion, theuse of PRP in our study was found to be feasible for TM perforations.It is expected that this work may also inspire many others to use the same in order to achieve successful tympanoplasty.

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 60 **Date: 24/11/2018**

To.

REG. NO. – BE0118005
PG student in Otorhinolaryngology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A STUDY OF CLINICAL OUTCOME WITH USE OF AUTOLOGOUS PLATELET RICH PLASMA IN TYPE 1 TYMPANOPLASTY: AN OBSERVATIONAL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

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ANNEXURE II

INFORMED CONSENT

REG. NO. – BE0118005, PG, Department of ENT Head and Neck Surgery conducting a research work for Award of MS Degree in ENT Head and Neck Surgery.

The Topic for the Study:

CLINICAL OUTCOME AFTER TYMPANOPLASTY WITH USE OF AUTOLOGUS PLATELET RICH PLASMA IN CASES OF TYMPANIC MEMBRANE PERFORATION: A ONE YEAR OBSERVATIONAL STUDY.

Objectives: The aim of this study was to assess the topical use of autologous Platelet Rich Plasma (PRP) to improve the success rate of Tympanoplasty.

I hereby state that the study procedures in details were explained and all questions were fully and clearly answered to the participant / his/her relative.

Investigators Signature:

Date:

Place:

Contact Address:

REG. NO. – BE0118005

Department of ENT Head and Neck Surgery

KLES, Dr. Prabhakar Kore Hospital, Belagavi

I ____have been explained in a language that I understand _____about the study. I have been told that this is study is for academic purpose, that my participation is voluntary and I reserve the full right to withdraw from the study at my own initiative at any time, without having to give any reason and that right to participate or withdraw from the study at any stage will not prejudice my rights and welfare. Confidentiality will be maintained and only be shared for academic purposes.

I hereby give consent to participate in the above study. I am also aware that I can withdraw this consent at any later date if I wish to. This consent form being signed voluntarily indicating my agreement to participate in the study until I decide otherwise. I understood that I will receive a signed and dated copy of this form.

I have signed this consent form before my participation in this study.

Signature / thumb impression of the research subject:

Date:

Place:

Signature of the witness

Procedure involved:

Each patient will be required to fill out a questionnaire addressing the presence of chronic otitis media symptoms and signs consistent with the major and minor symptoms and signs defined for chronic suppurative otitis media, followed by a the operation tympanoplasty along with autologous PRP and then the healing of the tympanic membrane and its assessment by PTA after 3 months of the tympanoplasty.

This study would help to correlate the use of autologous PRP on healing process of the tympanoplasty.

Risks:- Minimal discomfort during test and examination

Alternatives:

Long term medical therapy may be offered to you. The length and cost of medical therapy will differ with different condition and severity of disease. In case you decide to opt of the surgery you will be explained the merits and demerits of alternative treatment. In case you opt out of the study, it will not affect your relationship with KLES Dr. Prabhakar Kore Hospital.

Privacy and Confidentiality:

All information collected from you during the course of the study will be kept confidential to the extent permitted by law. Study records and the information from this study may be published but your identity will be kept confidential.

Institutional policy:

In the event of injury, related to the study, treatment will be made available at KLES Hospital & Medical Research Centre, Belgaum, no reimbursement, compensation or free medical care will be given, by law. If you are injured, you may contact **REG. NO. – BE0118005**at Department of ENT, Head & Neck surgery, KLE's Hospital & Medical Research Centre,

Withdrawal: Participation in this study is voluntary. If you don't wish to participate in this study; you will not lose benefits to which you are entitled. After starting the study, at any time during the study if you feel to withdraw from the study, you are free to do so.

Cost of Participation: The cost of the investigations, surgery which are a part of the study, will be borne by the participant.

Payment of Participation: No incentive will be paid to you for participating in this study.

Legal Rights: By signing this consent form, you are not waiving any of your legal rights.

Publication Rights: This result of the study will be used for teaching and medical publication; however the patient's identity will be kept confidential.

Queries and contacts:

If you have any queries, in future or in case of study related injury or illness, you may contact **REG. NO. – BE0118005**at Department of ENT, Head & Neck surgery KLE's Hospital & Medical Research Centre.

Alternatively you may also contact, Dr. _____, Professor, Dept. of ENT and HNS, JNMC, Belgaum.

1) If you have any queries about your rights as a study subject, you may contact Dr.ROOPA BELLAD**M.D.DCH**, Professor of Pediatrics, Chairman of JNMC Institutional Ethics, Committee on Human Subjects Research, J N Medical College, Belagavi.

ASSENT STATEMENT TO PARTICIPATE IN A RESEARCH STUDY

I,Mr./Mrs.._____ Parent/Guardian of _____ voluntarily agree to let my child/ ward participate in this study, by signing this consent form I am not giving up my legal rights. I may withdraw my child at any time from the study. I am signing after having read, or been read to me in the vernacular language including risks and the benefits and having all queries cleared.

Signature of the parent/ guardian/legally authorized

representative_____

Name of Study patient_____

Sign Of The Patient:_____

Relationship with the patient_____

Name and Signature of Witness_____

_____

Name and signature of investigator_____

_____

DATE:_____ PLACE: _____

ANNEXURE III

PROFORMA FOR DATA COLLECTION

S.No-

NAME:

AGE/SEX:

OP/ IP.NO:

OCCUPATION:

ADDRESS:

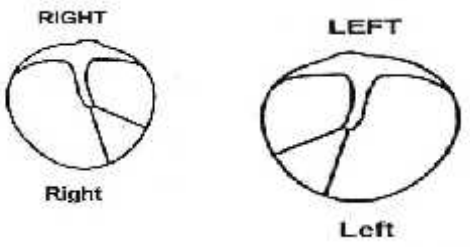
COMPLAINTS:

- Ear ache
  - Onset
  - Duration
- Ear discharge
  - Onset
  - Duration
  - Frequency
  - Consistency
- H/O hearing loss
- H/O headache, vertigo, tinnitus, neck stiffness, swelling around the ear
- PAST HISTORY:
- Hypertension
- Diabetes
- Tuberculosis

- Bronchial asthma
- Ischemic heart disease

GENERAL PHYSICAL EXAMINATION:

- Pulse rate:
- Blood pressure:
- Pallor
- Icterus
- Cyanosis
- Clubbing
- Pedal edema
- Lymphadenopathy
- SYSTEMIC EXAMINATION:
- CVS:
- RS:
- CNS:
- PA:
- LOCAL EXAMINATION:
- (i) EAR

		Right	Left
Pinna			
Pre auricular area			
Post auricular area			
Tragus			
EAC			
TM			
Tuning fork test	Rinne test 256Hz 512Hz 1024Hz		
	Weber		
	ABC		
Vestibular functions	nystagmus		
	Fistula test		

INVESTIGATIONS:

(A) PTA

(B) Blood investigation

- Hb
- TLC
- DLC
- Platelet count
- RBS
- BT
- CT
- Serum urea
- Serum creatinine
- HIV
- HBsAg

(C) Routine urine examination

(D) Chest x ray

(E) ECG

(F) X ray mastoid bone

ANNEXURE IV

PHOTOGRAPHS

PREOPERATIVE PICTURES

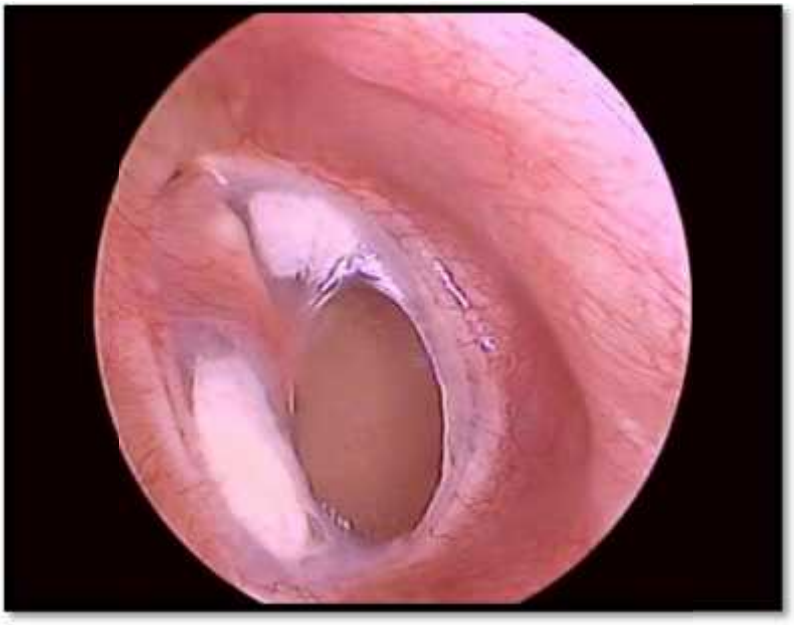


IMAGE- 1: TYMPANIC MEMBRANE PERFORATION

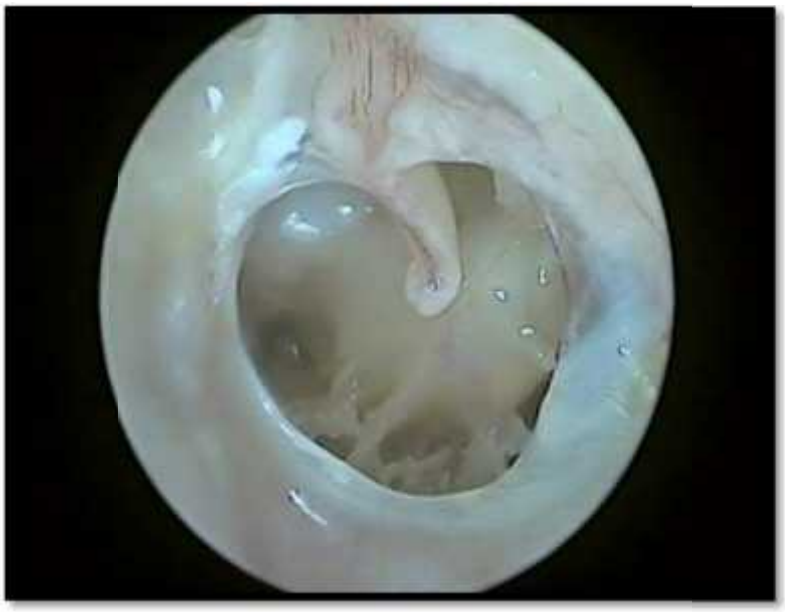


IMAGE-2: TYMPANIC MEMBRANE PERFORATION

PERIOPERATIVE PICTURES:

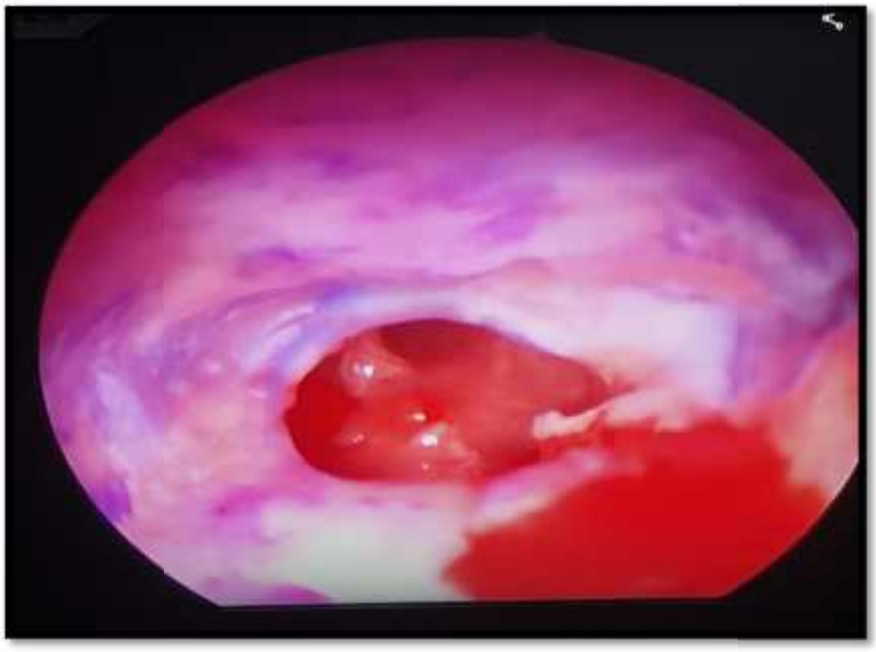


IMAGE 3-PERIOPERATIVE IMAGE OF PERFORATED TM

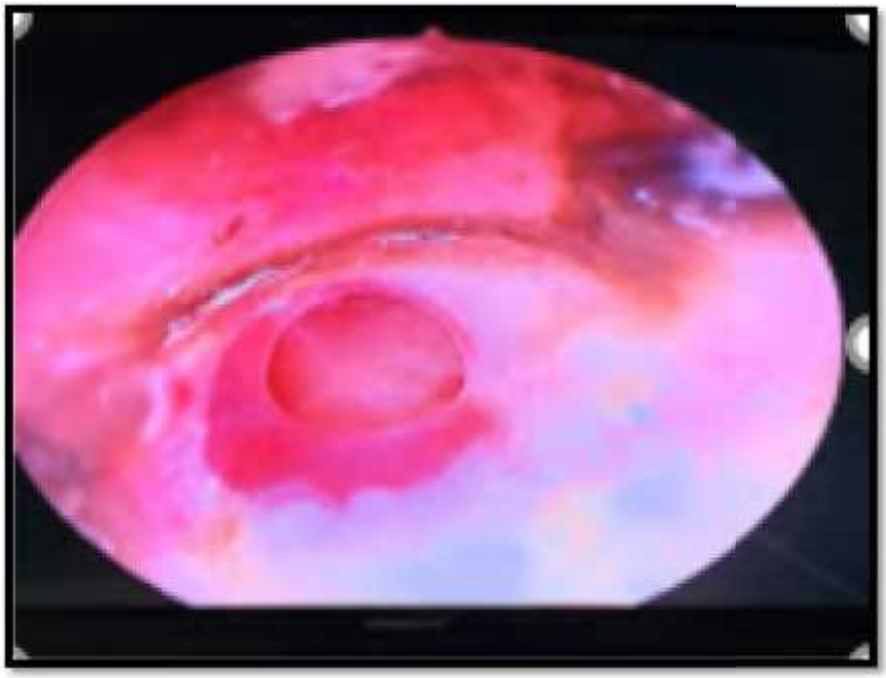


IMAGE 4- PERIOPERATIVE IMAGE OF ELEVATED TYMPANOMEATEAL FLAP

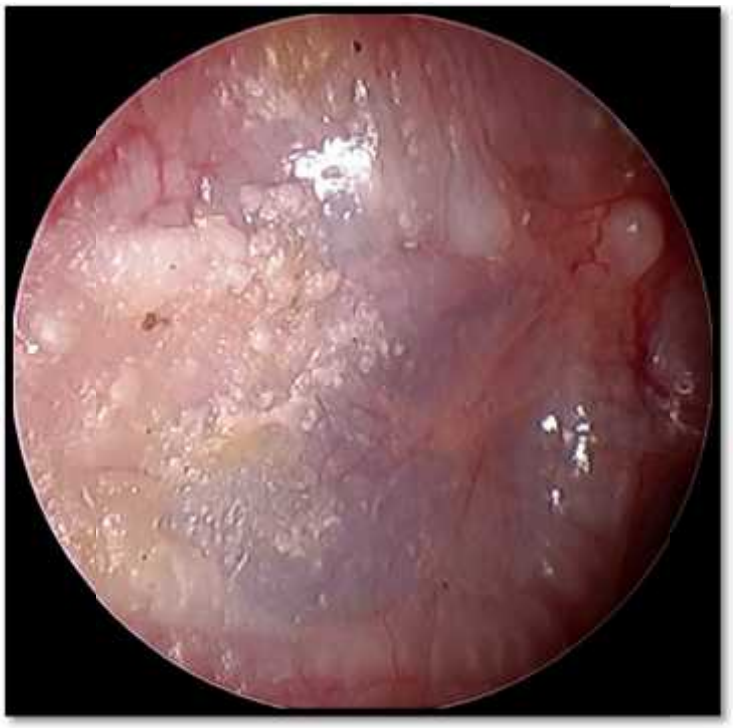


IMAGE-5: POST OPERATIVE APPEARANCE OF HEALED TM

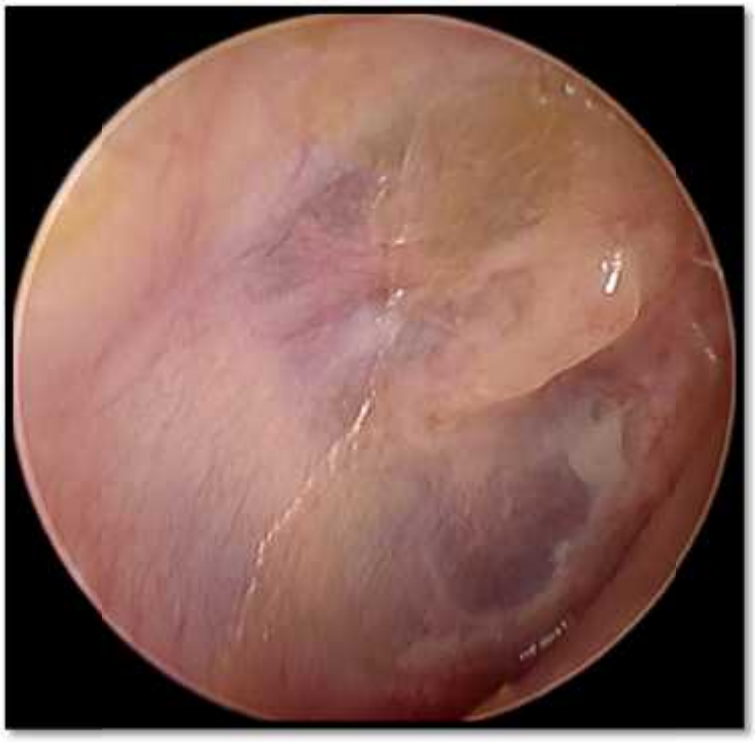


IMAGE-6: POST OPERATIVE APPEARANCE OF HEALED TM

IMAGE-7: CENTRIFUGATION MACHINE

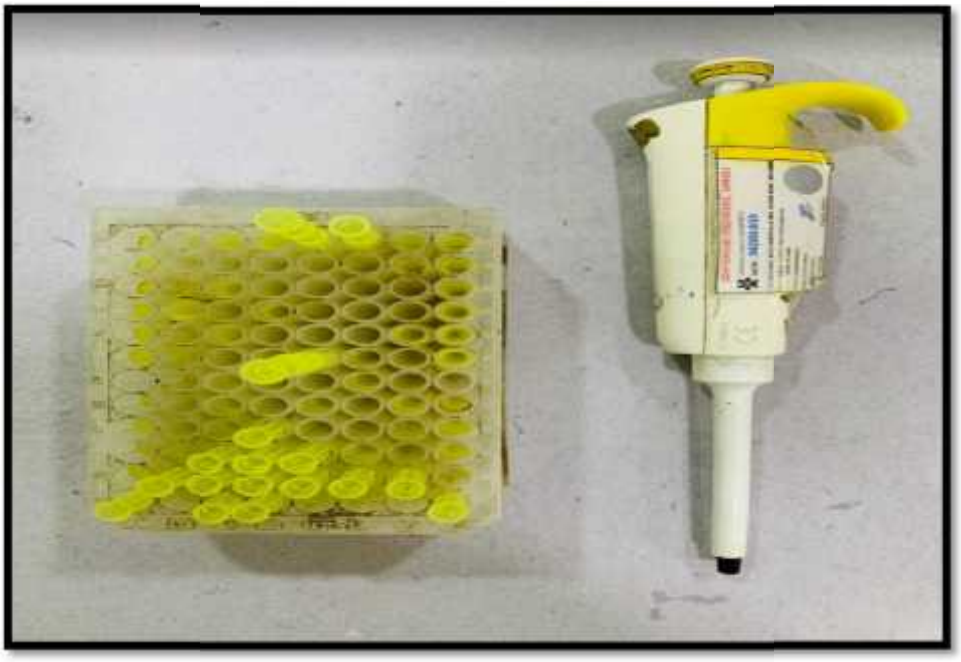


IMAGE-8: PIPETTE

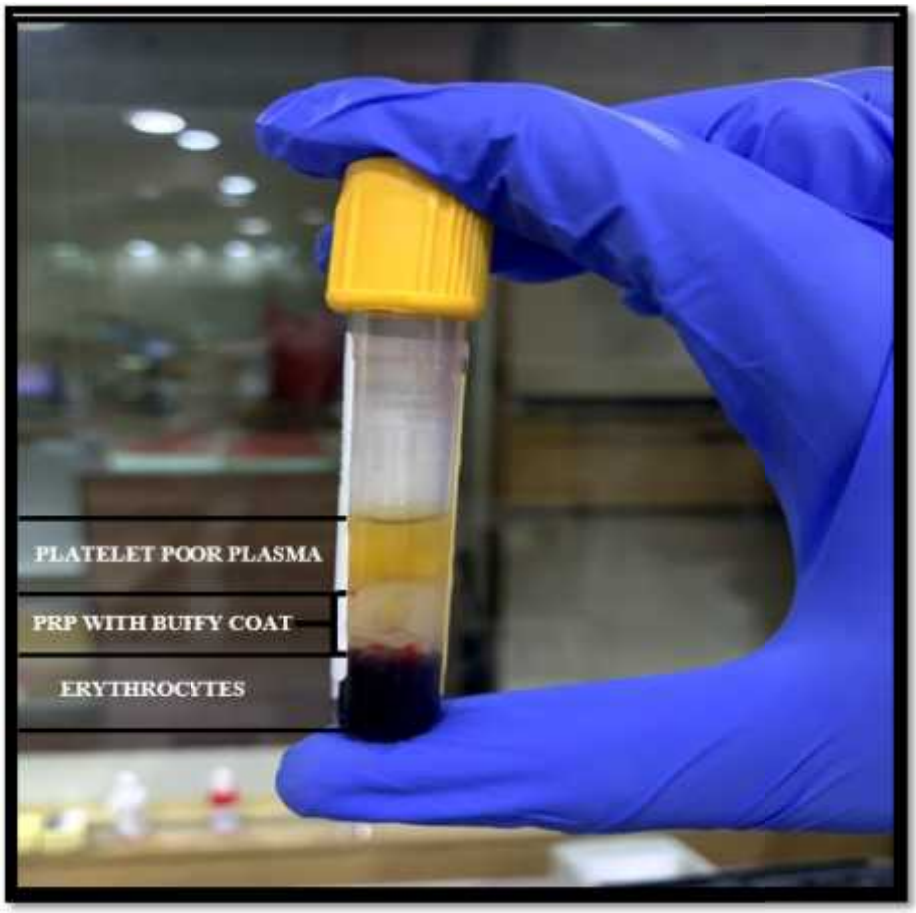


IMAGE-9: PRP WITH BUFFY COAT

ANNEXURE V

KEY TO MASTER CHART

• CSOM	Chronic Suppurative Otitis Media
• F	Female
• GA	General Anesthesia
• I P	Intra Operative
• LA	Local Anesthesia
• LCP	Large Central Perforation
• M	Male
• MCP	Medium Central Perforation
• P O	Pre Operative
• PRP	Plate Rich Plasma
• SCP	Small Central Perforation
• WLN	Within Normal Limits
• y	Years

SERIAL NO.	AGE	GENDER	COMPLAINTS	SIZE OF PERFORATION	SITE OF PERFORATION	EAR INVOLVED	DIAGNOSIS	DRY EAR BEFORE OPERATING	OPERATION PERFORMED	PRP USED	ROUTINE INVESTIGATIONS	ANAESTHESIA	TYPE OF GRAFT USED	I P COMPLICATIONS	P O HEARING LEVEL	FOLLOW-UP: 1 WEEK	FOLLOW UP AT 3WEEKS	FOLLOW UP AT 6 WEEKS	FOLLOW UP AT 3 MONTHS
1	30y	F	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	42.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	35.6	35.6
2	19y	M	ear ache, ear discharge decreased hearing	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	GA	TEMPORALIS FASCIA	NO	33.2	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	DISCHARGE PRESENT	MINIMAL MUCOID DISCHARGE
3	17y	M	ear ache & ear discharge	SCP	anterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	GA	TRAGAL CARILAGE	NO	42.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	32.6	32.6
4	41y	F	ear ache & ear discharge	LCP	all quadrants	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	63.7	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	53.2	53.2
5	48y	F	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	42.7	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.6	40.6
6	52y	M	ear ache, ear discharge and tinnitus	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	54.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	45.6	45.6
7	40y	F	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	34.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	32.2	32.2
8	29y	M	ear ache & ear discharge	MCP	anterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	33.4	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	30.6	30.6
9	33y	M	ear ache & ear discharge	MCP	posterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	42.5	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.1	40.1
10	27y	F	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	34.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	31.1	31.1
11	35y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	43	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.1	40.1
12	50y	F	ear ache, ear discharge & decreased hearing	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	45.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	40.2	40.2
13	56y	M	ear ache, ear discharge & tinnitus	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	50.1	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	48.3	48.3
14	51y	M	ear ache & ear discharge	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	33.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	30.1	30.1
15	49y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	54.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	50.2	50.2
16	32Y	M	ear ache & ear discharge	MCP	posterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	65.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	59.8	59.8
17	40Y	M	ear ache, ear discharge & decreased hearing	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	36.8	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	33.4	33.4
18	20Y	M	ear ache & ear discharge	SCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	38.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	36.7	36.7
19	28Y	M	ear ache & ear discharge	MCP	anterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	39.1	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	34.5	34.5
20	18Y	F	ear ache, ear discharge & decreased hearing	MCP	anterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	42.7	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.5	40.5
21	32Y	M	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	NO	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	45.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.5	40.5
22	42Y	M	ear ache & ear discharge	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	51.2	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	49.5	49.5
23	48Y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	41.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	38.9	38.9
24	21Y	M	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	43.2	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.2	40.2
25	42Y	M	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	32.4	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	30.4	30.4
26	40Y	F	ear ache & ear discharge	LCP	all quadrants	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	42.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	38.7	38.7
27	54Y	M	ear ache, ear discharge & tinnitus	MCP	posterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	49.1	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	49.1	49.1
28	27Y	M	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	35	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	32.1	32.1
29	59Y	M	ear ache & ear discharge	SCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	GA	TEMPORALIS FASCIA	NO	52	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	49.7	49.7
30	35Y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	47.8	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	45.3	45.3
31	34Y	M	ear ache & ear discharge	MCP	posterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	44.2	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.8	40.8
32	45Y	F	ear ache & ear discharge	LCP	all quadrants	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	46.2	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	38.2	38.2
33	55Y	F	ear ache, ear discharge & decreased hearing	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	38	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	30.5	30.5
34	39Y	F	ear ache & ear discharge	MCP	anterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	39.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	35.4	35.4
35	38Y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	43.1	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT NOT TAKEN UP WELL	40.3	40.3
36	52Y	F	ear ache & ear discharge	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	GA	TRAGAL CARILAGE	NO	50.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	45.3	45.3
37	58Y	M	ear ache, ear discharge & tinnitus	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	44.8	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	41.3	41.3
38	45Y	F	ear ache & ear discharge	SCP	anterior	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	56.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	50.7	50.7
39	28Y	F	ear ache, ear discharge & decreased hearing	LCP	all quadrants	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	53.8	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	48.9	48.9
40	40Y	M	ear ache & ear discharge	MCP	posterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	47.9	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	40.7	40.7
41	48y	M	ear ache, ear discharge & decreased hearing	MCP	anterior quadrant	left	LEFT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TEMPORALIS FASCIA	NO	55.3	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	55.1	55.1
42	52y	M	ear ache, ear discharge & decreased hearing	LCP	posterior quadrant	right	RIGHT CSOM	YES	TYPE 1 TYMPANOPLASTY	YES	WNL	LA	TRAGAL CARILAGE	NO	60.6	GEL FOAM IN SITU AND POST AURAL WOUND HEALED WELL	GRAFT TAKEN UP WELL	54.9	54.9