



A STUDY ON EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA IN TYPE I TYMPANOPLASTY

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ABSTRACT

Background: A persistent tympanic membrane perforation increases the patient risk of developing recurrent acute otitis media or chronic middle ear disease, These conditions are frequently associated with an unpleasant otorrhea, Type I Tympanoplasty is a surgical procedure that closes a simple perforated tympanic membrane.

Aims: The aim of this procedure is to create an intact tympanic membrane, forming a dry ear and no further need to protect the ear from water after complete healing.

Materials and methods: This study included 50 patients selected from the ENT out-patient clinic of Mediciti Institute of Medical Sciences, presenting with COM Inactive mucosal type divided into 2 groups with 25 patients in each group. All of them underwent type one underlay tympanoplasty were prospectively reviewed. Group 1 patients received fascia graft with PRP. Group 2 patients received fascia graft without PRP. Post-operative evaluation as Clinical follow-up, graft taking, perforation, retraction, lateralization or blunting, for three months post-operatively. Audiological follow-up by pure tone audiometry at three months.

Results: In Group A 21 patients (84%) had healed the tympanic membrane perforation, 4 patients (16 %) had residual tympanic membrane perforation at 3 months followup. No other complications such as lateralization or retraction were noted post-operatively. In Group B 17 patients (68%) had healed tympanic membrane perforation , 8 patients (32%) had residual tympanic membrane perforation at 3 months follow up postoperatively. No other complications such as lateralization or retraction were noted post-operatively.

Conclusions: Our study concludes that Platelet rich plasma is a cheap and cost effective platelet concentrate with enriched growth factors, topical autologous PRP application during Type I Tympanoplasty is safe and highly efficient and successful with no reported complication.

Keywords: Chronic otitis media (COM), Chronic suppurative otitis media(CSOM), Platelet rich plasma(PRP).

INTRODUCTION

Chronic suppurative otitis media is defined as chronic inflammation of the mucoperiosteal lining of the middle ear cleft. It is associated with persistent or intermittent infected discharge through a non-intact tympanic membrane. It is prevalent in developing countries like India and is more common in lower socio economic groups. The incidence is very high among rural population than in urban population. The overall prevalence rate is 46 and 16 persons per thousand in rural and urban population.

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. 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.^{1,2}The diagnosis of chronic otitis media implies that there is permanent abnormality of pars tensa or flaccida which results from previous acute otitis media or negative middle ear pressure or otitis media with effusion. The clinical presentation of chronic otitis media varies with severity of infection, host response, and the time course over which it manifests.³ Hence we study the efficacy of use of autologous platelet rich plasma in closure of tympanic membrane perforation during Type I Tympanoplasty by Preventing the graft displacement. Promoting quicker healing. Improving the overall outcome. To compare graft uptake post operatively following Type-I Tympanoplasty with and without PRP. To compare Pre and Post-operative Audiological benefit.

MATERIALS AND METHODS:

Prospective Comparative study in ENT Dept at MediCiti Institute of Medical Sciences & Hospital, Ghnapur, Medchal during the study period. In 50 Patients in 18 Months, { January 2021 to June 2022}

Inclusion Criteria: Chronic otitis media inactive mucosal disease (central perforation with dry ear) without discharge for at least 6 to 8 weeks

Exclusion Criteria: Active ear disease, atopic ear conditions, diabetes ,mellitus, other systemic illness like autoimmune disease, active neoplastic disease, Patient on immunosuppressant drugs.

A total of 50 patients diagnosed with Chronic Otitis media inactive mucosal type were included in study group divided into two groups of 25 each

Group 1- Odd numbered patients underwent type I tympanoplasty with PRP

Group 2- even numbered patients underwent type I tympanoplasty without PRP23

History taking is very important as this gives valuable information regarding age at onset, predisposing factors, duration of ear discharge & Hearing Impairment, Eustachian tube function, and previous surgery etc. Patient with chronic otitis media mucosal disease were randomly selected from the ENT OPD at our institution. They were first subjected to examination under microscope which is the gold standard for diagnosis of COM (1). It should be accomplished with the patient in the supine position. This allows an assessment of ear canal size in the surgical position, bend of the neck, shoulder elevation, anticipated comfort of the surgeon in a seated surgical position, and patient tolerance for examination. The Normal ear is carefully examined first and serves as a point of reference. The status of the middle ear mucosa in the diseased ear will helps us to decide the usage of Systemic and topical antibiotics. This also facilitates aural toileting which can be done by suction, irrigation, mopping or instrumental removal.

Under microscopic examination all areas can be fully visualized and perforation edges can be clearly seen. Ossicular chain status can be assessed. Findings like presence of granulation, in growth of squamous epithelium from edges of perforation, tympanosclerosis and adhesions can be seen.

Pus was sent for culture and sensitivity. The bacteriological culture is of potential value in starting

specific antibiotics. All the patients with active ear disease were treated upto one month with specific antibiotics.

Diagnostic nasal endoscope was done for all patients. Those who had nasal obstruction and features of chronic sinusitis were subjected to computerized tomography of paranasal sinus. Patients with symptomatic septal deviation and chronic sinusitis initially underwent Functional endoscopic sinus surgery with septal correction.

Pure tone audiogram is done in all patients which is helpful in assessing degree and type of hearing loss. Usually patients will have conductive hearing loss in this type of illness. It also helped us in deciding the ear to be operated first in case of bilateral disease. In case of bilateral disease usually more symptomatic and worse ear is operated first. It is important to assess whether there is any associated sensorineural hearing loss.

After achieving dry ear for six to eight weeks patient is subjected to X-ray of both mastoids – Law's view or lateral oblique view. X-ray Mastoids to rule out Mastoid disease . Depending on patients preference Surgery was done in Local Anaesthesia or General Anaesthesia. Post auricular {William Wildes } incision was given as it provides better overall exposure and allows complete access to the mastoid tip.

In adults, the incision is placed 8 to 10 mm posterior to the post auricular sulcus where it is hidden by the pinna. This incision can be placed more posterior for wider exposure. It should not be placed directly in the post auricular crease, however, because this creates a deep, difficult to clean post auricular furrow.

In children younger than 2 years, the inferior portion of this incision must be placed more posterior than in adults. This is because the tympanic ring in children is underdeveloped, mastoid pneumatization is incomplete, and the stylomastoid foramen is quite shallow ,therefore, the facial nerve is vulnerable to injury. The surgeon should also keep in mind that congenital anomalies of the temporal bone can result in highly variable facial nerve position.

The post auricular incision is first outlined with a marking pen. Infiltration is given with a mixture of local anesthetic 2% lignocaine and adrenaline. The skin and subcutaneous tissues are incised sharply down to the periosteum overlying the mastoid cortex. The ear flap is elevated anteriorly to identify the posterior edge of the external ear canal

TEMPORALIS FASCIA HARVESTING:

The temporalis fascia can be taken from the operative field in both transmeatal and post auricular approach. Incision was extended superiorly and temporalis fascia graft is harvested.

The fascia 1 cm above the supramastoid crest is usually preferred because it is thin and suitable for grafting the tympanic membrane. Fat adhered to the fascia is removed. Smooth muscle side of fascia should be turned inside the middle ear while placing the graft. Before placing the fascia it should be allowed to dry so that it can get adapted better.

The incision is then extended into the subcutaneous tissue. Soft tissue and post auricular muscles are divided. A T-shaped incision is made through the soft tissues and periosteum overlying bone. The superior limb is placed along the inferior temporal line (inferior margin of the temporalis muscle) starting at a point just superior to the anterior- superior ear canal.

This incision extends posterior as far as is needed for adequate exposure. An inferior limb to the T- is fashioned from the mastoid tip to the superior limb just described.

Periosteal elevators are then used to elevate the periosteum of the mastoid cortex toward the posterior margin of the ear canal. Superior to the ear canal, the periosteum should be elevated anteriorly along the zygomatic root. Inferior to the ear canal, the surgeon should elevate periosteum to the anterior margin of the superior aspect of the mastoid tip. Periosteum and meatal skin are elevated. The meatal skin is now incised about 5 to 6 mm from the edge of the tympanic membrane. Edges of the perforation are freshened and tympanomeatal flap is elevated. Ossicular chain status is noted and intact.

UNDERLAY TYPE I TYMPANOPLASTY TECHNIQUE

Skin incision made in post auricular fold or behind the fold. Soft tissues and post aural muscles are cut and periosteum is elevated as described earlier. Tympanomeatal flap is elevated after incision around edge of perforation has been made Ossicular chain status is examined and intact. The fascia is laid in the tympanic membrane from the middle ear side overlapping the perforation on all edges. Tympanomeatal flap is repositioned. Second generation Platelet rich concentrate, the platelet rich fibrin was prepared and it is applied lateral to the graft and ear canal packed with gel foam. The superficial platelet poor plasma layer is removed and the middle layer which is a Buffy coat containing platelet clot is taken out.

All the patients were under antibiotic cover in the postoperative period. Sutures were removed on 7th postoperative day and patients were given oral antibiotics and antihistamines. Patients were on a regular follow up every 15 days for 3 months.

PURE TONE AUDIOMETRY-PROCEDURE

Audiometric assessment was conducted in sound treated room delivering pure tone stimuli to one ear at a time in frequencies of 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz at various selected intensities. The reference intensity level is designated "X" dB at each frequency, is the mean value of minimal audible threshold of pure tones in healthy individuals. Hearing threshold is taken as the least intensity of pure tone that was audible to the subject.

The subject is advised to signal on hearing the least sound of any sort till it ceases. The subject is presented with various selected tones for 1 to 3 seconds and for a minimum gap of 1 to 3 seconds between successive presentations. Air conduction threshold is repeated for 1000Hz to assess the reliability of the procedure. Air conduction thresholds in the right and left ears were marked by 'O' and 'X' respectively. Bone conduction threshold is obtained by using bone vibrator placed on the skin over mastoid process and assessed to a maximum of 4000Hz.

It is represented by symbols "[and]' for right and left bone respectively. Masking is employed when the difference in right and left unmasked air conduction threshold is 40dB or more.

The hearing threshold grading is given by

(WHO)(WORLD HEALTH ORGANISATION GRADING)⁴

- 0-25dB –normal hearing
- 26-40 dB –mild hearing loss
- 41-55dB –moderate hearing loss
- 56-70dB –moderately severe hearing loss
- 71-90dB-severe hearing loss
- >90dB- profound hearing loss.

Data Analysis:

Data collected was imported into MS-Excel (2010), then data was exported to SPSS and analysed. Continuous variables was summarized as mean and standard deviation. Categorical variables was summarized as proportions. Tests of significance for difference in proportions was performed by using Chi-square test. P value less than or equal to 0.05 were considered statistically significant.

RESULTS

Our study population had 50 patients out of which 25 were Group 1 and remaining 25 were Group 2

Table-1: Age distribution of COM patients in the study population

Age(Yrs)	Total Number of Patients	Percentage
13-20	0	0%
21-30	13	26%
31-40	20	40%
41-50	13	26%
51-60	04	08%
>60	0	0%

In our study majority of cases belonged to young adults between 31 to 40 years of age.

Table-2: Distribution of different variables in the study group

Sex	Group 1	Group 2	Percentage	P Value Group 1&2
Male	16	14	60	0.56
Female	09	11	40	
Unilateral vs. bilateral disease				
Unilateral ear disease	19	17	72	0.528
Bilateral ear disease	06	08	28	
Side of Type I Tympanoplasty				
Rt Tympanoplasty	12	12	50	1
Lt Tympanoplasty	13	13	50	

In 50 patients who underwent surgery, 20 were females (40 %) and 30 (60 %) were males . About 72% (36 patients) of people in the study population had unilateral ear disease whereas remaining 28% (14 patients) had bilateral disease. Among Group 1 and Group 2, 24(12+12) underwent Rt tympanoplasty and 26(13+15) underwent Lt tympanoplasty

Table-3: Size of perforation in both groups

Size of perforation	Total Number of Patients	Percentage
Group 1		
Small	2	8
Medium	7	28
Large	6	24
Sub Total	10	40
Group 2		
Small	3	12
Medium	2	8
Large	11	44
Sub Total	9	36

Table-4: Showing degree of hearing loss

Degree	Group 1	Group 2	P value Group 1& 2
Mild	14	9	0.155
Moderate	11	16	
Severe	0	0	

Table-5: Anaesthesia during surgery

	Group 1	Group 2	Total	Percentage	P value Group 1&2

General Anaesthesia	5	4	9	18	0.711
Local Anaesthesia	20	21	41	82	

Figure-1: Graft uptake status

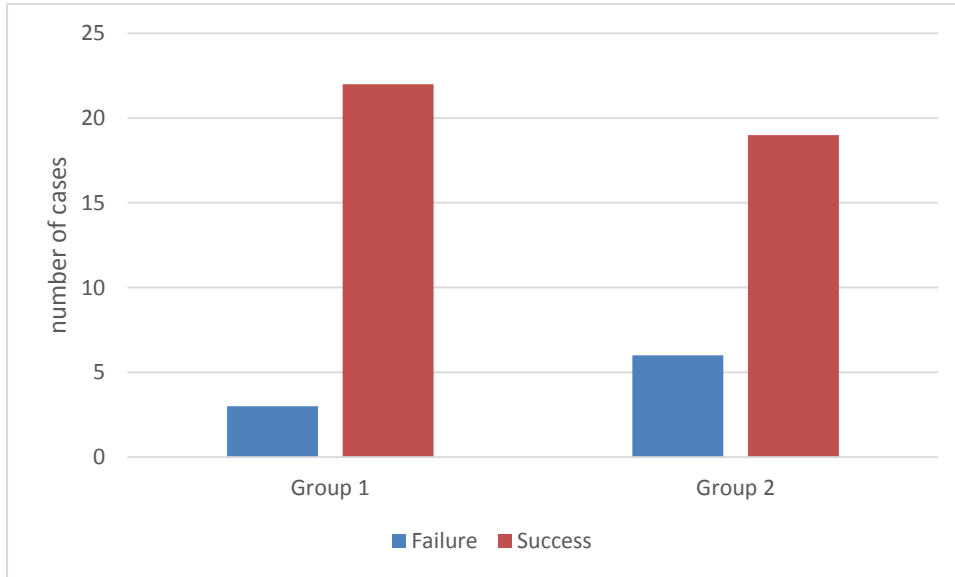


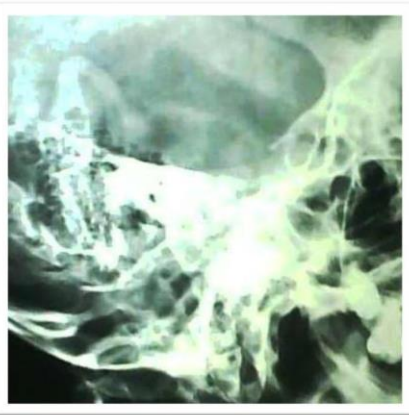
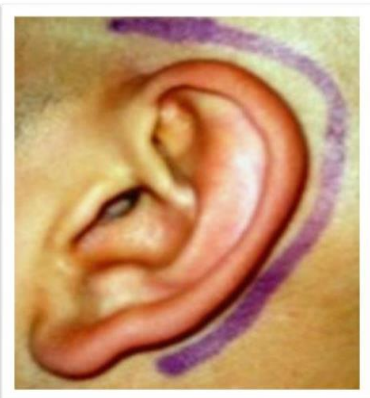
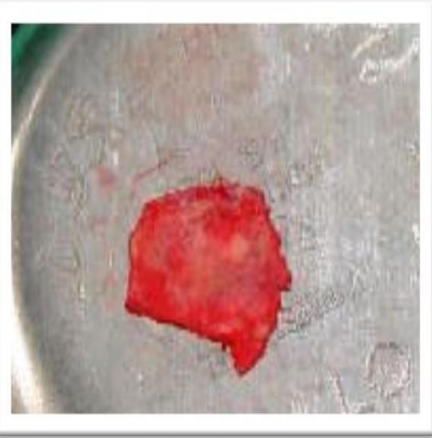



Table-6: Audiological Benefit (≥ 10 db)

Audiological Assessment	Group 1	Group 2	P Value Group 1&2
Absent	3	6	0.27
Present	22	19	

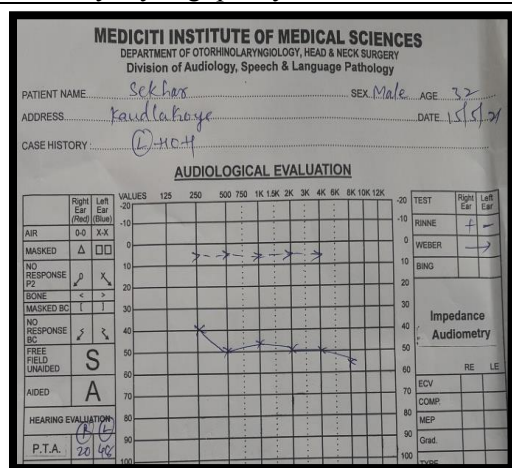
Figure-2: Images in present study

	
Small central perforation	Subtotal perforation
	
cellular mastoids	William Wilde's postaural incision
	
Temporalis fascia graft	Tympanomeatal flap elevation

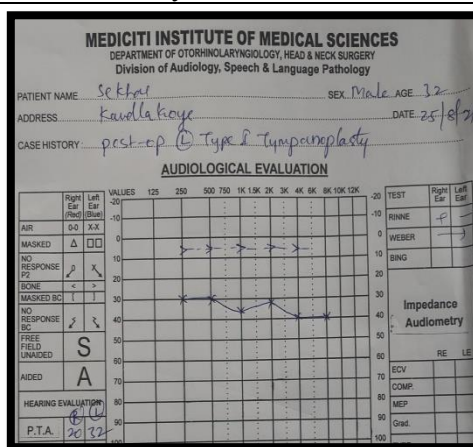


Underlay myringoplasty done

Middle PRF layer



Pure tone audiometry Pre OP



Pure tone audiometry Post OP

DISCUSSION

Chronic otitis media (COM) is defined as a permanent perforation of the tympanic membrane with persistent discharge from the middle ear, lasting more than 6-12 weeks. Chronic suppuration can occur with or without cholesteatoma, and the clinical history of both conditions can be very similar. The treatment plan for cholesteatoma always includes tympanomastoid surgery with medical treatment as an adjunct, tympanic membrane perforation (TMP) is a common otologic problem leading to conductive hearing loss. A persistent TMP increases the patient risk of developing recurrent acute otitis media or chronic middle ear disease, These conditions are frequently associated with an unpleasant otorrhea, Type I Tympanoplasty is a surgical procedure that closes a simple perforated tympanic membrane. The aim of this procedure is to create an intact tympanic membrane, forming a dry ear and no further need to protect the ear from water after complete healing. However, the complications of Type I Tympanoplasty include anterior blunting, tympanic membrane lateralization, stenosis of the external ear canal, delayed healing, epithelial pearls, and a risk of inclusion iatrogenic cholesteatoma

Historically, various grafting materials have been used to reconstruct the tympanic membrane (TM), including skin, fascia, vein, fat, perichondrium, dura mater, and cartilage. Presently, temporalis fascia is the most frequently used grafting material, and most series have reported approximately 90% graft take. Platelet rich plasma (PRP) is an autologous platelet rich concentrate prepared from patients own blood with growth factors up to 8 times that of normal serum and its efficacy when used during Type I

Tympanoplasty is studied.^{5,6}

Application of platelet-rich plasma has been documented in many fields, such as orthopaedics, dentistry, and cosmetic and plastic surgery. In otology, the efficacy of platelet-rich plasma has been demonstrated in tympanoplasty procedures.⁷ Yeo et al.⁸ investigated the effect of platelet-derived growth factor-AA on the healing process of tympanic membrane perforation in rats. The results revealed a speeding up of the healing process of the tympanic membrane defect, an improved rate of healing, and fewer atrophic changes in the healed tympanic membrane. This is explained by the fact that platelet-derived growth factor-AA promotes connective tissue growth. Platelet-rich plasma accelerates the healing of tympanic membrane perforation following myringoplasty. It prevents graft displacement or shrinkage, especially in wet grafts, with its sealant property.⁹ Platelet-rich plasma improves the overall success rate of myringoplasty. Furthermore, it has no noticeable side effects.

In our study out of the 50 patients who underwent surgery, 20 were females (40 %) and 30 (60 %) were males. The age of distribution of chronic otitis media in our study population was compared with the previous data. It shows that the disease is common in 31 to 40 yrs age group in our study population whereas according to UK national study of hearing it is common in 41 to 80 years age group.⁹

This study included 50 patients selected from the ENT out-patient clinic Of Mediciti Institute of Medical Sciences, presenting with COM Inactive mucosal type divided into 2 groups with 25 patients in each group. About 72% (36 patients) of people in the study population had unilateral ear disease whereas remaining 28% (14 patients) had bilateral disease. In Group 1, 19 patients had unilateral disease and 6 patients had bilateral disease. In Group 2, 17 patients had unilateral disease whereas 8 patients had bilateral disease. Among the unilateral disease in Group 1, 10 patients had right ear disease whereas 9 patients had left ear disease. Among Group 2, 9 patients had right ear disease and 8 patients had left ear disease. Bilateral disease is commonly due to bilateral Eustachian tube dysfunction.

In our study large and subtotal perforation is very common in comparison to other perforations. Among Group 1, 2 patients had small perforation, 7 patients had medium, 6 patients had large and 10 patients had subtotal perforation. In Group 2, 3 small, 2 medium, 11 large and 9 subtotal perforations was seen. Out of 9 failures in our study 3 (3 in sub total perforation) occurred in Group 1, and 6 (5 in subtotal perforation, & 1 in large perforation) occurred in Group 2, which similar to the above study.

In our study population most of the patient had mild conductive hearing loss. Among the unilateral disease patients, 29 had mild conductive hearing loss, 11 had moderate conductive hearing loss where as 2 had mixed hearing loss. Among bilateral disease both ears having mild conductive hearing loss was seen in 5 patients. Right ear having mild conductive loss is seen in 1 patient, and left ear having mild loss is seen in 2 patients. Moderate conductive hearing loss was seen in right ear in 2 patients and in left ear in one patient. None of the patient had sensory neural or mixed hearing loss.

X – ray mastoids was done to rule out mastoid disease All patients underwent this investigation after attaining dry ear for 6 to 8 weeks. There is no risk of general anaesthesia complications and no postaural wound or hematoma. Overall there is reduction in post operative morbidity of the patient by this approach. Among Group 1 and Group 2, 24(12+12) underwent Rt tympanoplasty and 26(13+15) underwent Lt tympanoplasty.

Table-7: Graft uptake comparison with other studies

Study	Type I Tympanoplasty With PRP		Type I Tympanoplasty Without PRP	
	Cases	Success(%)	Cases	Success(%)
Mohammed Waheed El-Anwar ¹⁰	32	32 (100%)	32	26(81.25%)
Sankarnaryanan ¹¹	25	24 (96%)	25	20(80%)

Niharika Shetty ¹²	30	29 (96.66%)	30	27(90%)
Our Study	25	22 (88%)	25	19(76%)

In our study among Group 1 patients who underwent Type I tympanoplasty with use of platelet rich plasma, 22 had complete tympanic membrane closure and 3 failures has been noticed. In Group 2, 6 out of 25 patients had failure. At the end of third month follow up, 88% of Group 1 had closure of tympanic membrane, while only 76% of Group 2 had tympanic membrane closure. Thus Our study shows that autologous platelet concentrates accelerates the tympanic membrane closure.

Among Group 1, 88% showed audiological benefit of ≥ 10 db where as in Group 2, 76% persons showed audiological benefit of ≥ 10 db Among Group 1, 3 failures were noted which was due to infection. Among Group 2, 6 failures were noted 5 of them due to graft displacement and 1 due to infection. According to Maria Luisa Navarrete Alvaro use of platelet rich plasma during Type I Tympanoplasty will prevent graft displacement, which is seen in our study also.

Erkilet E et al., studied the effect of PRP in healing of traumatic membrane perforations in 44 rats. They noticed a statistically significant (p-value <0.001) decrease in the mean healing time in the study group compared to the control group. Similar outcome in humans was reported by Habesoglu M et al., with 64.3% closure of perforation in study group compared to 22.2% in control group at the end of one month. Both these studies were on acute or traumatic tympanic membrane perforation whereas the present study was on perforation of chronic middle ear disease. Taneja MK, randomised controlled trial on 82 patients also had a success rate of 95% in PRP group which was comparable to the current study.

Nair NP et al., had a higher success rate of 98% in the study group. The success rate in control group was 80 to 85% in various studies. Sharma D et al., achieved 100% graft uptake rate in small perforation, 92% in medium size and 80% in large perforation.

In our study graft uptake and audiological benefit was seen in more patients of Group 1 when compared to Group 2 but it was statistically not significant with $P=0.27$.

LIMITATIONS

The association of outcome of surgery with other factors like the size and location of perforation and status of middle ear mucosa was not ascertained. Small sample size, hence further studies with larger sample size along with wider coverage of sample should be done.

CONCLUSION

Our study concludes as Platelet rich plasma is a cheap and cost effective platelet concentrate with enriched growth factors. It accelerates the tympanic membrane closure Type I Tympanoplasty. It prevents graft migration, it improves the overall success rate of Type I Tympanoplasty. It has no noticeable side effects.

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