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EFFECT OF PLATELET RICH PLASMA ON OUTCOME OF TYPE 1 TYMPANOPLASTY: A RANDOMIZED CONTROL TRIAL

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Abstract

Aim: To determine the effect of platelet rich plasma among patients undergoing type I tympanoplasty with and without topical use of platelet-rich Plasma (PRP) over the graft.

Materials and Methods: A randomized, prospective, comparative study was conducted among 60 patients divided into two groups: Cases and control consisting of 30 patients each, having inactive mucosal Chronic otitis media who underwent type I tympanoplasty with the use of PRP for enhancing the graft uptake versus patients without use of PRP: 28 (93%) as compared to control 25(83%).

Results: Preoperative and postoperative air-bone gap (A-B gap) was calculated at the end of 3 months and compared, and it was found to be statistically significantly better both in the case and control group ($P < 0.05$) and mean healing time of 4.64+/- 1.57 in cases in comparison to control group with mean healing time of 6.2+/-1.98.

Conclusion: Our study shows that PRP is cheap, easy to prepare, autologous and cost effective. This platelet concentrate is enriched with various growth and healing factors, which helps in faster tympanic membrane closure following tympanoplasty and hence overall improving successful outcomes rate of tympanoplasty by preventing graft migration, with little to no perceivable side effects.

INTRODUCTION

Tympanic membrane(TM) perforation is a common issue in otorhinolaryngology, particularly in developing countries like India, due to inadequate healthcare, infrastructure, education, and socio-economic status[1]. This can result in chronic infection to the middle ear cleft, leading to TM perforation[2]. Middle ear infections can be acute or chronic, active or inactive. Acute otitis media

can resolve spontaneously, while chronic otitis media may present with chronic ear discharge, earache, conductive hearing loss, and associated symptoms.

Tympanoplasty involves using various graft materials to maintain the integrity of the tympanic membrane. The success rate of graft uptake after tympanoplasty ranges from 70 to 90%, depending on factors such as the type of graft used, technique, material, patient age, and post-operative care[3]. Graft migration is the most common post-operative complication of tympanoplasty[4]. To improve the success rate of graft uptake, newer materials have been explored, including platelet rich plasma (PRP), fibroblast growth factor, heparin, epidermal growth factor, platelet rich plasma, and transforming growth factor[5].

PRP is well known for its clot-forming property and is rich in growth factors that promote healing and migration of fibroblasts. It has additional benefits such as being autologous, easy to prepare, available, cheap, and rich in growth factors. PRP is further divided into four categories based on leukocyte and fibrin contents: leukocyte rich PRP, leukocyte reduced PRP, leukocyte platelet rich fibrin, and pure platelet rich fibrin[5].

These growth factors help in cell proliferation and differentiation, optimizing the tissue environment and favouring the healing process of the body. Other bioactive agents like calcium chloride, serotonin, and adenosine also increase cell permeability, contributing to the healing process.

Aim: To determine the effect of platelet rich plasma (PRP) among patients undergoing type 1 tympanoplasty with and without topical use of platelet-rich Plasma (PRP) over the graft.

MATERIAL AND METHODS

Plan of Study: CTRI registration was done after Institutional ethical committee approval before starting the study. A written consent was obtained from the patients who were selected for the study according to inclusion and exclusion criteria. Detailed history was taken as per the performa. Pure tone audiometry (PTA) was performed on all patients before surgery and after the surgery. All the investigation required for fitness under local anaesthesia were done and under local anaesthesia initial Examination under Microscopy is performed followed by definitive surgery. Allocation of the group was done based on the random table method.

Study Design: Randomized control trial.

Study Setting: The proposed study was carried out in the Department of Otorhinolaryngology and Head & Neck surgery, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh.

Duration of Study: One Year (1st November 2022 to 31st October 2023).

Inclusion Criteria:

- Patients willing to participate in this study.
- Mucosal type of Chronic Otitis Media.
- Patients of both the gender between the age of 18 to 60 years.
- Dry middle ear cavity for 1 month.
- Clinically no active disease of nose and throat.

Exclusion Criteria:

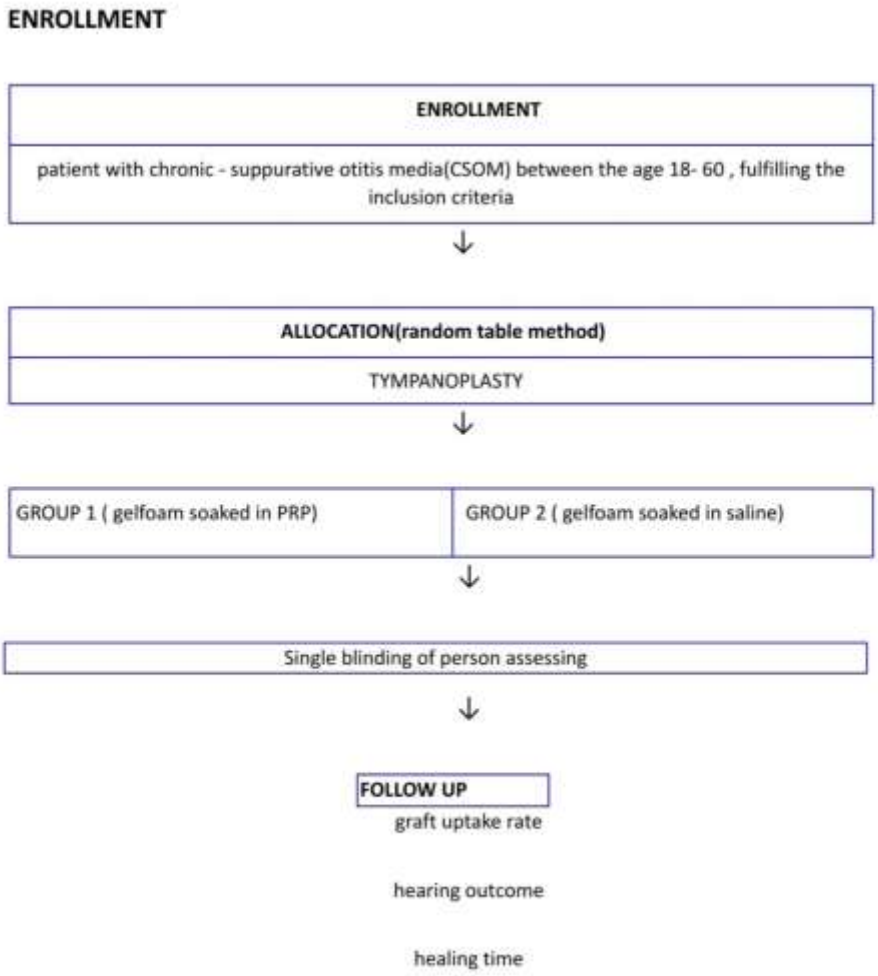
- Patients with platelet dysfunction syndrome and Low platelets count.
- History of previous ear surgery.
- Squamous type of Chronic Otitis Media.
- Cases with ossicular discontinuity.
- Active Rhino sinusitis.
- Patients with hypertension, Diabetes Mellitus.

Sample Size: All patients attending the OPD in ENT and Head and Neck Surgery Department of Rohilkhand Medical College & Hospital (RMCH), Bareilly in the stipulated period fulfilling the Inclusion benchmarks were enrolled for the study till the sample size was reached.

Sample size of 60 was taken, which was calculated by power and sample size calculator (with alpha = 0.05, power =0.9, P_0= 0.45, P_1 =0.85, M =1)72, Total = 60 calculator (with alpha = 0.05, power =0.9, P_0= 0.45, P_1 =0.85, M =1)72, Total = 60 cases .Allocation of the group was done based on the random table method.

Group A: This group included 30 patients that underwent tympanoplasty with PRP.

Group B: This group will include 30 patients that underwent tympanoplasty without PRP.



Tympanoplasty was performed and graft was placed medial to handle of malleus.PRP was applied with a tuberculin syringe over the graft. After flap reposition Abgel soaked in PRP was placed in middle ear.

PRP was extracted by the following method.

Venous blood was with-drawn the patient with the help of 16 to 18 g cannula to avoid any kind of injury to the platelets and in a vial containing anticoagulants to avoid haemolysis followed by centrifugation of blood at automatic centrifuge machine using 1500 rpm for 15 minutes produced two layers, one yellowish and one dark red, and the supernatant plasma was transferred to another sterile tube for hard spin using a sterile pipette. The second centrifugation was performed at 3000 rpm for 15 minutes, and the top supernatant platelet deficient plasma was gently sucked with a

pipette, leaving 1 ml of fluid and pallet in the bottom. With another sterile pipette, carefully mix the pallet into the solution, preserving it for use during surgery.[5]

RESULTS

The study analysed the age distribution of 30 patients in two groups: Group A (PRP) and Group B (without PRP). The majority (56.7%) were aged 18-30 years, while the mean age of patients in Group A was 31.63 ± 9.28 years, while in Group B (without PRP), it was 34.5 ± 9.69 years. No significant difference was found in the average age between the two groups. The majority of patients in Group A were females, while in Group B, there was no significant difference in gender. The graft uptake rate in Group A was 93.3%, with a failure rate of 6.7%. In contrast, in Group B, the graft uptake rate was 83.3% and the failure rate was 16.7%. However, there was no significant difference in the graft uptake and failure rate between the two groups.

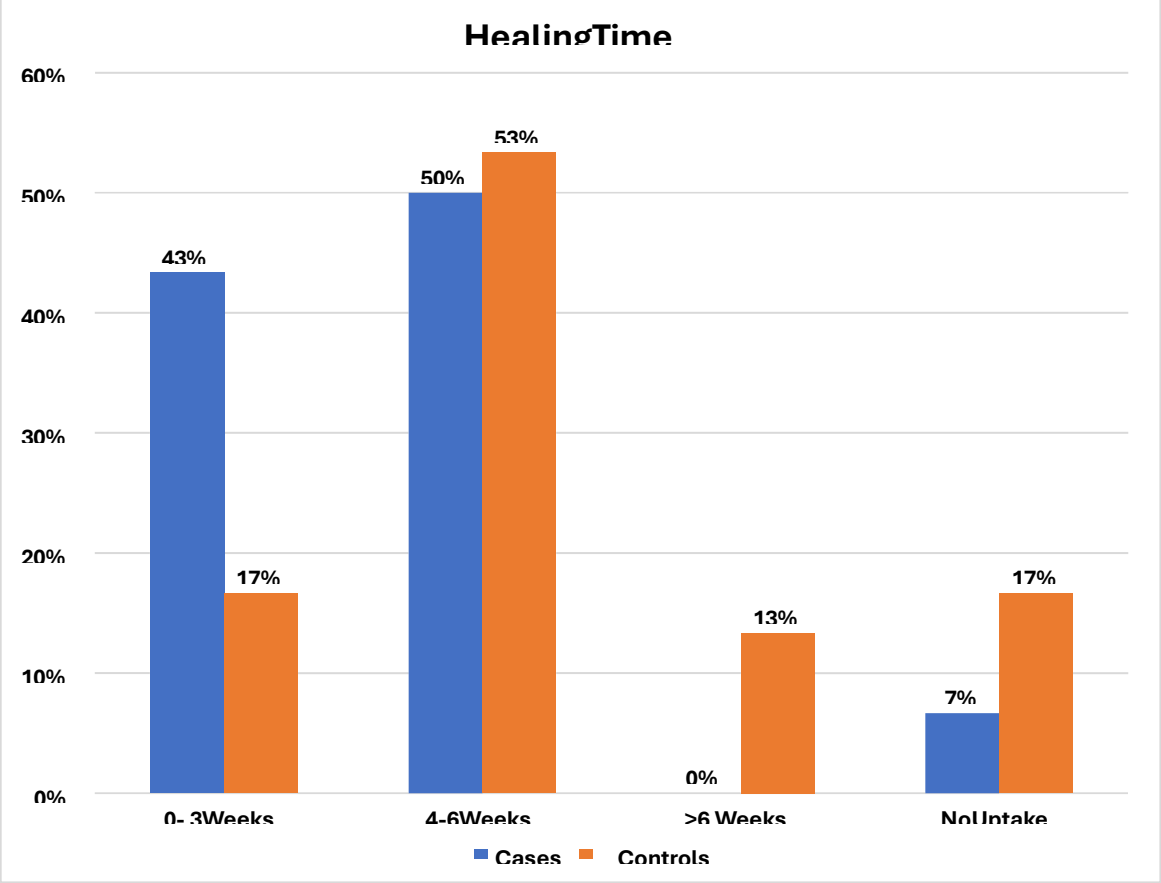
The study found that healing time for patients in Group A (PRP) was 0-3 weeks. In Group B (without PRP), the mean healing time was 6.2 ± 1.98 weeks, with a significant difference between the two groups. In Group A, 43.3% of patients experienced hearing output of 11-12 dB while in Group B it was 13.3% of patients, with a significant difference between the two groups. In Group A, the mean hearing gain was 10.25 ± 1.67 dB, while in Group B, it was 8.8 ± 1.44 db. The study also found a significant difference in the mean hearing gain outcome between the two groups. The results suggest that PRP may be a potential treatment option for patients with hearing loss, but further research is needed to determine the best treatment approach.

Table I- Mean Healing Time in Group A (PRP) & Group B (Without PRP).

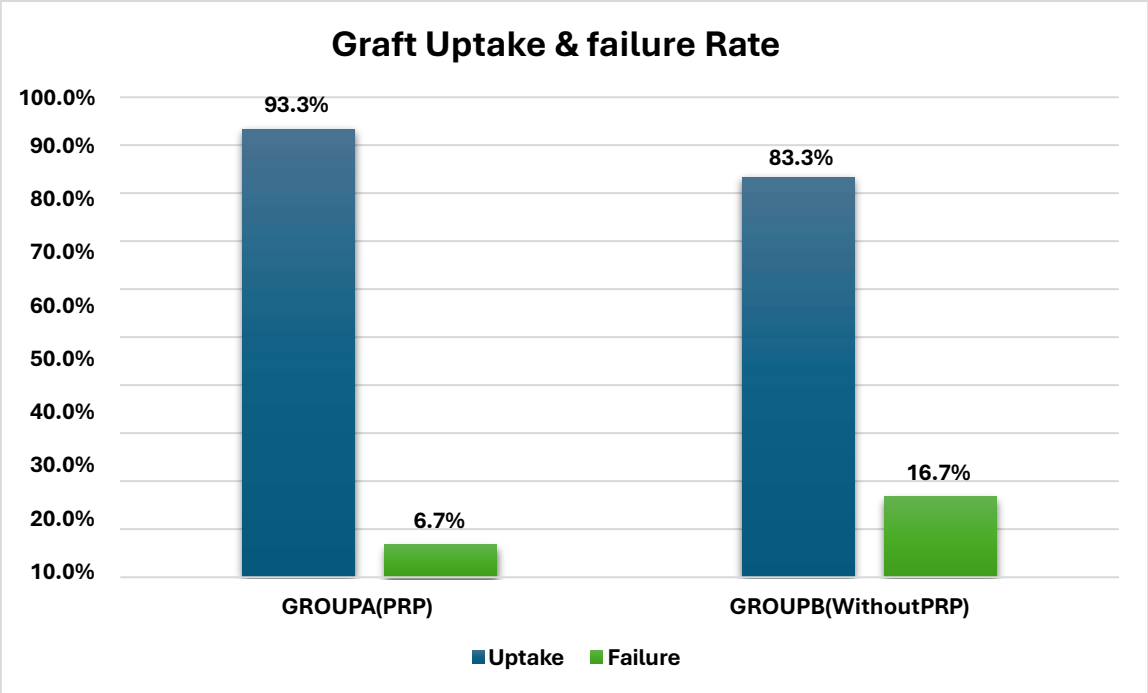
	GROUPA(PRP)	**GROUPB (Without PRP)**	
	Mean±SD	**Mean±SD**	**P-Value**
Healingtime (in weeks)	4.64±1.57	6.2±1.98	0.002

Table II: Gender Distribution In Group A (PRP) & Group B (Without PRP).

	GROUPA(PRP)		GROUPB (Without PRP)		P-Value
GENDER	**Number**	**Percentage %**	**Number**	**Percentage %**	
Male	12	40.0	15	50.0	0.436#
Female	18	60.0	15	50.0	

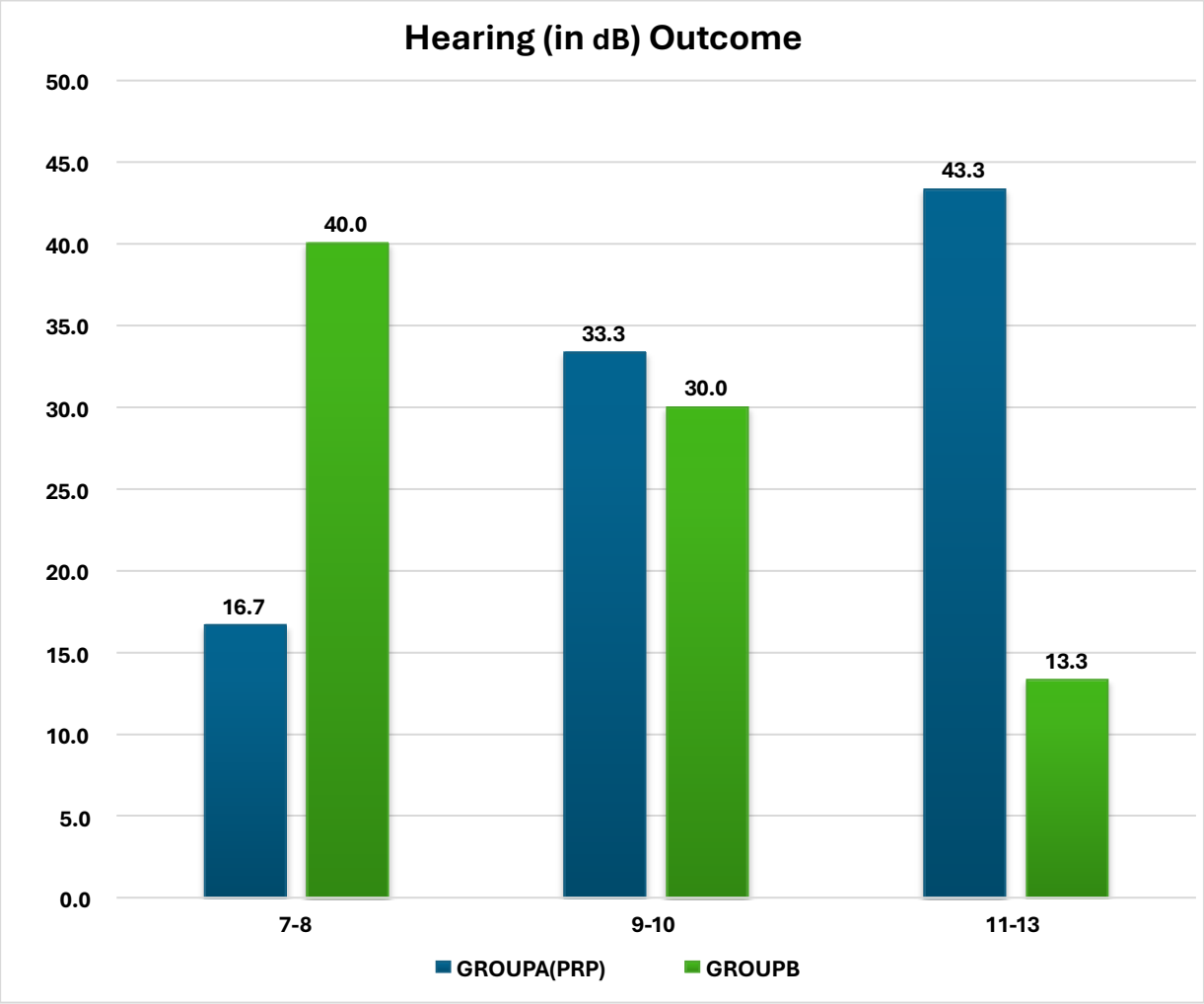


Graph I: Showing healing time in weeks in Group A (Cases; PRP) & Group B (Control; Without PRP).



Graph II: Showing graft uptake rate in Group A (PRP) & Group B (Without PRP).

Graph III: Showing hearing outcome (dB) in Group A (PRP) & Group B (Without PRP).



Picture showing extracted PRP.

DISCUSSION

Tympanic membrane perforation is one of the most commonly encountered problem in otorhinolaryngology in developing countries like India because of inadequate health care, infrastructure, education, low Socio-economic status of people leading to improper care and compliance to the treatment facilities resulting in chronic infections of middle ear cleft leading to tympanic membrane perforation, these perforation when are chronic and non healing are repaired with the help of tympanoplasty.

Tympanoplasty involves the use various grafts material for the sufficient closure of tympanic membrane to maintain the integrity of tympanic membrane. Various graft materials like cartilage, fascia, Dura, vein, fat etc.[6]There has been use of various material as an adjuvant to surgery (Tympanoplasty)to improve the success rate of graft uptake and to provide better prognosis in the surgeries. Newer materials like fibroblast growth factor, heparin, epidermal growth factor, platelet rich plasma, and transforming growth factor have been widely used in surgeries like dental, head and neck, and orthopaedics. PRP, or platelets rich plasma, is rich in growth factors that promote healing and migration of fibroblasts, activating cytokines.[5] It is autologous, easy to prepare, available, and cheap, making it a valuable addition to surgical treatments, so the scope of surgical exploration of PRP is fast, giving in account its only draw back that standardization of PRP is still not something which is yet to brought into practice; to provide uniformity to all studies being conducted using the same.

Our study analysed the hearing outcomes of patients in two groups: Group A (PRP) and Group B (non-PRP). The results showed that the average hearing gain for patients in Group A was 10.25 + 1.67 dB, while Group B had a mean hearing gain of 8.8 ± 1.44 db. The mean hearing gain of patients in Group A was enhanced than that of Group B (without PRP).

Other Research by Huang J et al. showed that the average improvements in hearing after surgery varied from 10.3 dB to 18.62 dB for the PRP treatment groups and from 7.23 - 15.64 dB for the control groups. [7]The PRP groups showed effective improvement rates ranging from 65.6 to 90%, while the control groups showed rates ranging from 40.6 to 77.1%. Using PRP in conjunction with auto grafts may assist in cured mild chronic TM perforations and result in an acceptable restoration of hearing.

Hosam M et al. conducted a study on the effect of topical use of platelet-rich fibrin in repairing central tympanic membrane perforation using the endoscopic inlay butterfly cartilage myringoplasty technique. [8]The study found that postoperative hearing gains were higher in the PRP group. Graft uptake was higher in the PRP group, but there was no significant difference in graft uptake and failure rate between the two groups.

A similar study by Yadav et al. showed that the use of platelet-rich fibrin resulted in a significant improvement in graft uptake, with 93% improvement compared to 73% for the control group.[4]Thus, the study shows that with the use of PRP in type I tympanoplasty, patients observed better healing time and a better hearing outcome compared to without PRP.

Taking in account all the studies and literature available, it can easily be said that PRP is cheap, easy to prepare autologous and cost effective. This platelet concentrate is enriched with various growth and healing factors, which helps in faster tympanic membrane closure following tympanoplasty and hence overall improving successful outcomes rate of tympanoplasty but standardization of it should be brought into practice to promote universally acceptable benchmark for PRP development.

CONCLUSION

In our study we concluded that Platelet rich plasma is cheap, easy to prepare autologous and cost effective. This platelet concentrate is enriched with various growth and healing factors, which helps in faster tympanic membrane closure following tympanoplasty and hence overall improving successful outcomes rate of tympanoplasty by preventing graft migration, with little to no perceivable side effects.

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