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Role of Platelet Rich Fibrin As An Adjunct In The Surgical Outcome Of Type I Tympanoplasty In Mucosal Type Of Chronic Otitis Media: A Randomized Controlled Trial

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ABSTRACT

Objective: To determine the role of Platelet Rich Fibrin as an adjunct to Temporalis fascia in the surgical outcome of Type I tympanoplasty in Mucosal type of Chronic Otitis Media.

Methods: In this Randomised Controlled trial, 90 patients with Chronic Otitis Media of mucosal who have undergone Type I Tympanoplasty were randomly divided into two groups. The Cases group (n=45) were treated with Type I tympanoplasty using Temporalis fascia and Platelet rich fibrin while in controls only temporalis fascia graft was used. At the end of 3 months both groups' patients were compared in terms of in graft uptake and hearing improvement.

Results: At 3 months, the case group showed a reduction in mean Air-Bone Gap (ABG) from 35.63 ± 5.13 dB to 24.45 ± 3.96 dB (ABG closure: 11.18 ± 4.9 dB, $p < 0.0001$). The control group showed a reduction from 35.38 ± 4.84 dB to 24.79 ± 3.83 dB (ABG closure: 10.79 ± 4.54 dB, $p < 0.0001$). Graft uptake was 97.78% in the case group and 91.11% in the control group, with no statistically significant difference ($p > 0.05$).

Conclusion: Although PRF showed promising results in hearing improvement and graft uptake, the difference was not statistically significant. Further studies are needed to establish PRF's role in enhancing tympanoplasty outcomes.

KEYWORDS: Chronic Otitis Media, Platelet Rich Fibrin, Tympanoplasty, Graft uptake, Hearing improvement.

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INTRODUCTION

Chronic Otitis Media (COM) is a persistent infection of the tympanic cavity that leads to the progressive destruction of the middle ear and mastoid processes, often resulting in irreversible alterations. This condition commonly causes perforations in either the Pars Tensa or Pars Flaccida of the tympanic membrane, frequently as a sequelae of previous acute otitis media, negative pressure within the middle ear, or serous otitis media[1-2]. COM represents a significant public health issue due to its association with recurrent purulent discharge through a perforated eardrum[3-4].

The aims of closing chronic tympanic membrane perforation are to improve hearing and prevent middle ear infections [5]. Perichondrium, cartilage, and fascia are commonly used materials for repairing a perforated eardrum. These tissues can be easily harvested from the surgical area and their biological characteristics are useful, especially in the early stage of the healing process. Using autologous grafts, obtained from the patient's own tissues, offers several advantages in terms of biocompatibility and safety compared to materials of animal origin. Various studies have demonstrated experimental usage of bioactive substances such as hyaluronic acid, pentoxifylline and fibroblast growth factors for healing of tympanic membrane perforation [6].

Choukroun et al. first documented the use of Platelet Rich Plasma (PRP) in wound healing in 2001 and in 2007, they reported its use for tympanic membrane perforation[7-8]. Platelet Rich Fibrin (PRF) is an anticoagulant-free, second-generation platelet concentrate made from the patient's own blood. Leukocytes, cytokines, glycoproteins have structural properties, and growth factors such as VEGF, TGF-B, and platelet-derived growth factor (PDGF) are all present in it. PRF functions as a resorbable component that protects the tympanic graft from inflammation and mechanical stress and also hastening matrix remodelling and cell division [7].

This autologous biomaterial can be produced quickly, cheaply, and readily. It additionally serves as safe, biocompatible, and easy to utilize during surgery[9]. Studies have been conducted to examine the impact of PRF, either in isolation or in conjunction with temporalis fascia or tragal cartilage, on the results of tympanoplasty/myringoplasty. To the best of my knowledge, there are, however, few Randomized Controlled studies examining the impact of PRF on Type I Tympanoplasty outcomes.

This study was conducted with the aim to determine the role of Platelet Rich Fibrin as an adjunct to Temporalis fascia in the surgical outcome of Type I tympanoplasty in Mucosal type of Chronic Otitis Media with respect to graft uptake and hearing improvement.

MATERIALS AND METHODS

A hospital-based, two-year Randomized Controlled Trial was conducted in the Department of Otorhinolaryngology at a tertiary healthcare hospital in India (NPK. Salve Institute of Medical Science and Research Centre and LMH, Digdoh Hills, Hingna Road, Nagpur,Maharashtra) after approval from the Institutional Ethics Committee-EC/18/2022, Septeber 28, 2022 (MUHS/PG/E-1/1503/27/2829/17,

Dated-September 28, 2022). Clinically diagnosed patients with mucosal-type of Chronic Otitis Media (COM) undergoing Type I Tympanoplasty during the study period, who met the inclusion criteria, were recruited. Inclusion criteria included patients aged 10 to 60 years of either gender with inactive mucosal-type COM for at least six weeks with pure conductive hearing loss functioning Eustachian tube, and an intact, mobile ossicular chain intraoperatively. Patients undergoing revision surgery were excluded.

After obtaining valid consent, participants were recruited into the study using a convenience sampling method. The sample size was calculated using the formula for comparing two independent proportions:

n per group = p1(1−p1)+p2(1−p2)$p_1(1-p_1) + p_2(1-p_2)$p1 (1−p1)+p2 (1−p2) × (Zα/2 + Zβ)² / ($p_1 - p_2$)²

Based on previously published literature, the expected graft uptake proportions were assumed as $p_1 \approx 0.98$ in the PRF group and $p_2 \approx 0.91$ in the control group. With 95% confidence and 80% power, this yielded a required sample size of 40 subjects per group (80 total). After adjusting for a 10% attrition rate, the final target sample size was 90, with 45 subjects allocated to each group.

Participants were divided into 2 groups by using Block and Randomization as follows-

- Case group- Type I Tympanoplasty was done using Temporalis fascia with autologous Platelet Rich Fibrin.
- Control group- Type I Tympanoplasty was done using Temporalis fascia alone.

Each patient underwent a comprehensive clinical examination of the ENT region. Additionally, an otological examination was performed. Otomicroscopy was utilized to evaluate the characteristics of the eardrum perforation, such as size, location, and the presence of otorrhea or cholesteatoma. Size of perforation was classified as small (less than 50% of the total surface area), medium (50–75% of the total surface area), or large (more than 75% of the total surface area). Audiological assessment, specifically pure-tone audiometry, was conducted to measure the air-bone gap and hearing threshold and Impedance Audiometry to assess the status of Eustachian tube.

Type I tympanoplasty was done under general anaesthesia by inlay technique using Temporalis fascia graft and PRF in Cases and only temporalis fascia in Controls. In the case group, 10 ml of blood was drawn preoperatively, centrifuged at 3000 RPM for 12 minutes, and the Platelet-Rich Fibrin (PRF) clot was carefully extracted (fig.1) and then pressed for 8 min between two glass slides, transforming it into a thin membrane (fig.2). This PRF membrane was subsequently placed over temporalis fascia graft which was placed by the inlay technique, and the tympanomeatal flap was repositioned. Preoperative evaluation and Surgery were performed by a single surgeon while post operative assessment by means of otomicroscopy and Pure Tone audiometry was done by another surgeon without revealing the group to which that patient belongs to.

At the end of 3 month follow up, patients were assessed for graft uptake (Fig. 3) and hearing improvement. Mean ABG closure was calculated by subtracting Mean Postoperative ABG from mean pre-op ABG. For this study, Success criteria for surgery were-

- Successful graft uptake was stable, healed, clinically intact tympanic membrane.
- Graft failure includes residual perforation, reperforation, medialization of graft, and complete graft failure.
- Hearing improvement after surgery was said to be significant when Air Bone Gap Closure (ABGC) was≥ 10dB.

STATISTICAL ANALYSIS

To analyse continuous variables between the two groups and within a group, a t-test and paired t-test were used, respectively. The chi square test was used to compare categorical variables in the two groups. The statistical analyses were performed using SPSS 22.0 software. P-values less than 0.05 were considered statistically significant in all cases.

fig.1. Platelet Rich Fibrin clot

fig.2. Membrane of PRF

fig.3 Graft uptake at the end of 3 months.

RESULTS

Total 90 patients of COM of mucosal type who underwent for Type I Tympanoplasty were included in the study with 45 patients each in the Case (Temporalis Fascia with PRF) group and the Control (Temporalis fascia alone) group. In both the groups, maximum patients were in the age group of 31-40 years**.** Mean age of the Cases group (Temporalis Fascia with PRF) group was 30.5 ±8.84 years and that of the Control group (Temporalis Fascia) was 31.9±7.95 years. Male: Female ratio was 1 :1.36 and 1:1.14 in the case and control groups respectively. No statistical difference was found between the two groups with respect to age and gender distribution (Chi-square test, p>0.05)

In the Case group (Temporalis Fascia with PRF) 13(28.89%) had right ear involved and 24(53.33%) had left ear involved and the Control group (Temporalis Fascia) the distribution of patients was exactly similar with 16(35.56%) having right ear involved and 21(46.67%) having left ear involvement. Bilateral disease was seen in 8 (17.78%) patients

In the Case group, 23(51.1%) had moderate central perforation, followed by 13 (28.9%) with large central perforation and 5 (11.1 %) with subtotal central perforation. In the Control group, maximum i.e. 27 (60%) cases had moderate central perforation, followed by 10 (22.2%) with large central perforation, 4 (8.9%) patients had subtotal and 4(8.9%) patients with small central perforation.

Table No. 1: Comparison between two treatment groups regarding Preoperative Hearing Level

Hearing Level (in dB)	Treatment Groups				Chi Square Test	p value
	Case group (Temporalis Fascia		Case group (Temporalis Fascia)			
	N	%	N	%		
≤25dB	0	0	0	0		

26-40dB	32	71.11	30	66.67		
41-55dB	13	28.89	15	33.33		
TOTAL	45	100	45	100		

As shown in Table No.1, Maximum patients i.e. 32 (71.11%) in the Case group had hearing level in the range of 26-40 dB, followed by 13 (28.89%) in the range of 41-55dB. In Case group (Temporalis Fascia), there were 30 (66.67%) patients with hearing levels in the range of 26-40 dB, followed by 15(33.33%) in the range of 41-55dB. The difference in two groups was statistically insignificant with P-value of 0.67 (P > 0.05) using Pearson's chi-square test.

Table No. 2: Comparison between both groups regarding Graft uptake at the end of 3 months

Graft Uptake	Treatment Groups				Chi Square	p value
	Case group (Temporalis Fascia with PRF) (n=45)		Control group (Temporalis Fascia) (n=45)			
	Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)		
Success	44	97.78	41	91.11	1.41	0.32 (Insignificant difference)
Failure	1	2.22	4	8.89		
Total	45	100	45	100		

Graft uptake was assessed at the end of 3 months. The number of cases in both the treatment groups were observed with the data shown in Table 2. In the Case group (Temporalis Fascia with PRF), 44 (97.78%) patients had successful graft uptake, while in the Control group (Temporalis Fascia) group, 41 (91.11%) had successful graft uptake. The difference of success rates between two groups was statistically insignificant with P-value of 0.32 (P > 0.05) using Pearson's chi-square test as shown in Table No. 2.

Table No. 3: Distribution of patients according to types of graft failure in two treatment groups

Graft Uptake	Treatment Groups				Chi Square	p value
	Case group (Temporalis Fascia with PRF) (n=45)		Control group (Temporalis Fascia) (n=45)			
	Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)		
Medialisation	1	2.22	1	2.22	3.85	0.16 (Insignificant difference)
Residual perforation	0	0	3	6.67		
Total	1	2.22	4	8.89		

Table No. 3 elaborates types of graft failure in both the groups. In the Case group (Temporalis Fascia with PRF) group, there was 1(2.22%) graft failure which had medialisation of graft. In Control group (Temporalis Fascia) group, total 4 patients had graft failure of which 1 (2.22% of patients in this group) had medialisation of graft and 3(6.67% of patients in this group) had residual perforation.

Table No. 4: Comparison between pre and post operative mean Air Bone Gap (ABG) & hearing Gain in two treatment groups

Variables	Air Bone Gap in dB (Mean ± SD)		P value*
	Case group (Temporalis Fascia with PRF)	Control group (Temporalis Fascia)	
Preoperative	24.45 ± 3.96	24.79±3.83	
Postoperative	35.63±5.13	35.38 ± 4.84	
Hearing Gain (ABG Closure)	11.18± 4.95	10.59±4.54	0.67

* t-test was used

As shown in Table No. 4, in the Case group (Temporalis Fascia with PRF), the pre-operative mean ABG was 35.63 ±5.13dB, which was improved to 24.45 ± 3.96 dB post-operatively, and the ABG Closure of 11.18±4.9 dB was statistically significant with P-value < 0.0001 (Paired t-test). While, in the Control group (Temporalis Fascia), the mean ABG before surgery was 35.38 ± 4.84dB which was changed to 24.79 ± 3.83 dB postoperatively with ABG Closure of 10.79 ± 4.54dB (Paired t-test), showing significant hearing improvement, as indicated by P- value < 0.0001 using paired t-test. On comparing the variables between two groups using independent t-test, the difference was statistically insignificant (Table No. 5).

Table No. 5: Comparison between two treatment groups regarding distribution of patients with respect to postoperative hearing improvement.

Hearing improvement (in dB)	Treatment Groups				Chi Square	P Value
	Case group (Temporalis Fascia with PRF)		Control group (Temporalis Fascia)			
	Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)		
Air Bone ≥ 10dB	28	62.2	24	53.3	0.72	0.39 (Insignificant difference)
Air Bone <10 dB	17	37.7	21	46.6		
Total	45	100	45	100		

An Air Bone Gap Closure (ABGC) of 10dB and above was treated as significant improvement in hearing. Accordingly, in the Case group (Temporalis Fascia with PRF), there were 28 (62.2%) cases who showed improvement (≥10dB ABGC), while in the Control group (Temporalis Fascia), there were 24 (53.3%) cases who showed improvement (>=10dB ABGC). The difference in the proportion of cases showing improvement in two groups was statistically insignificant with P-value of 0.3 (P > 0.05) using Pearson's chi-square test as shown in Table No. 5.

Table No. 6: Comparison between two treatment groups regarding hearing gain according to the size of perforation.

Size of central perforation	Hearing Gain in dB (Mean ± SD)		P value*
	Case group (Temporalis Fascia with PRF)	Control group (Temporalis Fascia)	
Small CP	11.32±4.93	10.79±4.61	0.8826
Moderate CP	11.25±4.95	10.15±4.54	0.2749
Large CP	12.10±4.84	12.66±4.64	0.5767
Subtotal CP	11.97±5.02	10.84± 4.70	0.7406

*Independent t- test

From Table No., it is evident that the difference of Hearing gain (mean ABGC) between two groups was statistically insignificant irrespective of size of perforation (P > 0.05) as per t-test for independent samples. Maximum mean ABGC in both groups was in large and subtotal CP as compared to small CP.

DISCUSSION

Traditionally, graft materials such as temporalis fascia and conchal cartilage have been used in tympanoplasty. In recent years, biologically active materials including Platelet-Rich Fibrin (PRF) have gained interest due to their potential role in enhancing tissue healing and regeneration. PRF is a healing biomaterial derived from autologous blood with a high concentration of cytokines, growth factors and cells. It is available as a platelet gel and has been used in conjunction with bone grafts, with reported advantages such as improved wound healing, bone growth, graft stabilisation, haemostasis and better handling characteristics. Choukroun et al. were the first to describe PRF as a second-generation platelet-derived concentrate [8].

Several studies to understand the role of platelet-rich fibrin to improve surgical outcome has been studied extensively. In 2009, Erkilet et al[10] reported that platelet-rich plasma (PRP) is effective in speeding up the healing of perforated TMs in rats and leads to shortening of the healing period. Therefore, they suggested that PRP might be effective in humans as it is an autologous material.

In the present study. The success with respect to graft uptake was reported among 97.78% and 91.11% of the subjects in Temporalis Fascia+ Platelet Rich Fibrin and Temporalis Fascia group respectively with statistically insignificant difference as

p>0.05. Failure was due to medialisation of graft in Temporalis Fascia+ Platelet Rich Fibrin group. In TEMPORALIS FASCIA group, total 4 patients had graft failure of which 1 (2.22% of patients in this group) had medialisation of graft and 3 (6.67% of patients in this group) had residual perforation. In a study by Kütük SG et al [11], the Graft survival rates at 1st, 3rd and 6th month were significantly higher in those Platelet Rich Fibrin as compared to without PRF. (100%, 97.2%, 94.4% vs. 85.5%, 80% and 74.5%). Yadav SP et al[12], noted a graft uptake of 95% in autologous Platelet Rich Plasma (PRP) group vs 85% in control group. El-Anwar et al[13] noted this to be 100% vs. 81.25% at evaluation conducted at 6th month. Sankaranarayanan G et al [14] noted 4% failure rate in graft uptake vs 20% failure rate in control group and concluded that PRF accelerates graft uptake. According to Shetty N et al [15], the success of graft uptake was 96.66% in PRF group. Taneja MK [16] conducted randomised controlled trial on 82 patients and found a success rate of 95% in PRP group which was comparable to the current study. Nair NP et al [17], had a higher success rate of 98% in the PRF group. The success rate in control group was 80 to 85% in various studies whereas it was 91.11% in a study by Shanmugan R et al[18]. In contrast Budhiraja G et al [19] in their study revealed that all patients underwent postauricular underlay Platelet Rich Fibrin grafting, in which the graft take up was seen in 42 cases and so the graft take rate in their study was 84%.

The study of Shindy et al[20] included 50 patients, thee mean air bone gap improved in the platelet rich fibrin-treated group from 18.83±3.99 dB to 3.38±4.13 dB and in the control group from 18.90±3.43 dB to 9.84±8.04 dB. The post-treatment mean air bone gap significantly improved better in the platelet rich fibrin-treated group than in the control group (P 0.004). Hearing gain by >10 dB was obtained in 88% of patients in the platelet rich fibrin group and in 44% of patients in the control group (P 0.001). Our findings were consistent with Shindy et al study.

In this study; an Air Bone Gap Closure (ABGC) of 10 dB and above was treated as significant improvement in hearing. Accordingly, in the Temporalis Fascia + Platelet Rich Fibrin group, there were 28 (62.2%) cases who owed improvement (≥10dB ABGC), while in the Temporalis Fascia group, there were 24 (53.3%) cases who showed improvement (≥10dB ABGC). The difference in the proportion of cases showing improvement in two groups was statistically insignificant with P-value of 0.3 (P > 0.05) using Pearson's chi-square test. Shetty N et al [15] in their study too stated that the postoperative hearing gain among cases shows that 18 cases (60%) had an improvement of >15 dB whereas among controls 12 cases (40%) had hearing improvement of >1dB. The p-value=0.3804 which was statistically not significant. Similar study conducted by Sharma D et al [21], on 100 patients showed significant improvement in air-bone gap at speech frequencies. A similar study by Anwar FM et al [22], with 70 patients showed an audiological improvement of >10 dB in 88.6% of cases and 77% of the controls. According to Budhiraja G et al [19], 46 cases (92%) of the total cases in which graft was taken had PTA average gain of more than 10dB.

A systematic review with meta-analysis was performed by Huang et al. in 2022[23] to evaluate the regeneration of the tympanic membrane utilizing platelet-rich fibrin. Seven of the ten papers eligible for the qualitative evaluation were included in the final quantitative comparison. The study concluded that PRF can lower the occurrence of infections, improve the survival rate of autografts in TM operations, and boost the closure rate of acute perforations, but with no effect on hearing outcomes. The study supported the use of PRF as a healing agent for tympanic membrane surgeries.

CONCLUSION

Although Platelet-Rich Fibrin is an autologous, low-cost biologic adjunct with theoretical regenerative benefits, this study did not demonstrate a statistically significant improvement in graft uptake or hearing gain when compared with temporalis fascia alone. While numerically higher graft uptake and hearing improvement were observed in the PRF group, these differences were not statistically significant. Larger, adequately powered studies are required to determine whether PRF provides a true clinical benefit in Type I tympanoplasty.

LIMITATIONS

This study is limited by its relatively small sample size and short follow-up period of 3 months. Long-term outcomes such as graft stability and hearing preservation was not tested. Future studies with longer follow-up periods are warranted to confirm these findings

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