e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(10); 268-275

Original Research Article

Enhancing Tympanoplasty Outcomes: Evaluating the Effectiveness of Platelet-Rich Plasma in Type 1 Tympanoplasty with Temporalis Fascia Grafts

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Received: 25-07-2024 / Revised: 23-08-2024 / Accepted: 26-09-2024
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Conflict of interest: Nil

Abstract:

Objective: This study evaluated the impact of Platelet-Rich Plasma (PRP) on the outcomes of Type 1 tympanoplasty using temporalis fascia grafts.

Methodology: This study utilized a cohort prospective randomized controlled trial (RCT) design over 24 months at a tertiary care facility in Northern India to assess the effectiveness of Platelet-Rich Plasma (PRP) in Type 1 Tympanoplasty with temporalis fascia grafts. A total of sixty-five patients with chronic otitis media were randomly assigned to either the PRP group (n=32) or the control group (n=33). The randomization process ensured detached group allocation for evaluating the impact of PRP on surgical outcomes.

Result: The study compared demographic and clinical factors in CSOM patients. Group 1 had fewer individuals aged 18-30 and more non-working individuals than Group 2. PRP treatment (Group 2) showed significantly higher graft uptake (90.6% vs. 69.7%, p=0.032). Group A experienced greater hearing improvement (15.06 dB vs. 14.93 dB, p=0.03) and a larger reduction in air-bone gap (24.09 ± 7.54 dB vs. 22.8 ± 8.14 dB). Follow-up attendance was high across both groups, with Group B achieving 100% attendance at all intervals.

Conclusion: In conclusion, Platelet-Rich Plasma (PRP) enhances graft uptake and hearing outcomes in Type 1 tympanoplasty, as indicated by improved air-bone gap and success rates. However, the overall impact on graft uptake remains uncertain, warranting further research with optimized PRP protocols and larger, standardized trials to confirm its effectiveness.

Keywords: Chronic Otitis Media, Hearing Improvement, Platelet-Rich Plasma (PRP), Temporalis Fascia Grafts, Type 1 Tympanoplasty.

Introduction

Chronic otitis media (COM) constitutes a widespread and persistent illness, especially in India, where it has a substantial influence on public health [1]. The issue often results in perforations of the tympanic membrane (TM), which can be worsened by many reasons, such as trauma caused by incorrect ear cleaning [2]. Frequent perforations frequently lead to significant morbidity, characterized by recurring ear drainage, hearing impairment, and tinnitus [3]. These symptoms not only decrease the quality of life but also present significant difficulties in controlling and treating the affected individuals [4]. When tympanic membrane holes continue to exist after the anticipated healing period, surgical intervention becomes necessary [5]. Tympanoplasty has become a surgical treatment used to repair perforations in the eardrum. It is usually suggested for individuals whose perforations do not heal on their own [6]. Conventional tympanoplasty procedures utilize graft materials such as temporalis fascia or cartilage [7]. These approaches have demonstrated efficacy in numerous instances, yet their rates of success in terms of graft integration and overall surgical results might vary considerably [8]. Several factors that impact these results include the patient's general well-being, the dimensions and placement of the perforation, and the biological reaction to the graft material [9]. The spontaneous repair of tympanic membrane perforations is an intricate biological process that involves multiple crucial stages [10]. At first, there is an increase in the growth of epithelial cells to cover the area where the perforation has occurred [11]. Subsequently, there exists a process of cell migration and

fibroblast proliferation, which actively contribute to the development of fresh tissue [12]. Angiogenesis, the physiological process of neovascularization, serves as crucial for the transportation of vital nutrients and oxygen to the regenerating tissue [13]. Ultimately, tissue remodelling guarantees the seamless integration of the newly created tissue with the surrounding structures [14]. If the perforation persists for more than three months, significant issues could arise when the healing process is insufficient or delayed. These problems may involve chronic recurring otitis media and permanent hearing loss, requiring additional surgical procedures and the use of graft materials [15].

Advancements in surgical techniques have recently incorporated Platelet-Rich Plasma (PRP) as a promising addition to tympanoplasty [16]. Platelet-rich plasma (PRP) is a substance made from the patient's blood that has a high concentration of platelets and growth factors, which are known to promote tissue regeneration [17]. The utilization of Platelet-Rich Plasma (PRP) in diverse medical domains, such as Orthopaedics and oral surgery, has exhibited noteworthy advantages. PRP is believed to augment the regenerative mechanisms by stimulating cell proliferation, expediting tissue healing, and diminishing inflammation [18]. The potential of tympanoplasty to enhance transplant integration and overall surgical results is highly encouraging [19].

The incorporation of platelet-rich plasma (PRP) in tympanoplasty has the potential to mitigate several disadvantages commonly associated with conventional grafting methods [20]. Platelet-rich plasma (PRP) has the potential to enhance graft uptake rates by improving the local regeneration environment. This, consequently, increases the chances of effective integration of the graft material with the surrounding tissue [21]. Moreover, the regenerative characteristics of PRP could potentially result in improved closure of the air-bone gap, which is a crucial indicator of surgical success in tympanoplasty [22]. In addition, the utilization of Platelet-Rich Plasma (PRP) has the potential to decrease postoperative problems, such as infection and inflammation, which can have a negative impact on the healing process and overall results [23]. The study assessed the effectiveness and safety of integrating Platelet-Rich Plasma (PRP) into Type I tympanoplasty procedures using temporalis fascia grafts [24]. This study intends to assess whether the use of PRP-enhanced grafts in tympanoplasty operations leads to a notable increase in surgical success rates and a decrease in the requirement for subsequent interventions in comparison to the use of standard temporalis fascia grafts alone.

Methodology

Study design: This study employed a cohort prospective and randomized study-controlled trial (RCT) design to evaluate the effectiveness of Platelet-Rich Plasma (PRP) in enhancing outcomes of Type 1 Tympanoplasty using Temporalis Fascia Grafts. Participants were randomly assigned to either the intervention group receiving PRP or the control group receiving standard care without PRP. Outcome measures included graft uptake rates, hearing improvement, and postoperative complications.

Study area

The study was carried out exclusively within the Department of Otorhinolaryngology at the specified tertiary care hospital located in Northern India.

Study Duration: The study spanned a total duration of 24 months, during which data collection, participant recruitment, interventions, and follow-up assessments were conducted according to the study protocol.

Study Participants: Patients diagnosed with chronic otitis media (COM) mucosal inactive (dry perforation) condition who were attending the Ear, Nose, and Throat (ENT) outpatient department had a comprehensive screening and evaluation to see if they met the requirements for participation. The trial included a group of 65 eligible patients, aged 18-59, who needed Type I tympanoplasty with a temporalis fascia graft and consented to participate. The patients were allocated randomly to two groups: Group 1, consisting of 33 patients, underwent Type I tympanoplasty with a temporalis fascia graft only, whereas Group 2, including 32 patients, received Type I tympanoplasty with both a temporalis fascia graft and platelet-rich plasma (PRP). The exclusion criteria included individuals outside the age range of 18-59, those with active ear infections, individuals with diseases that inhibit healing (such as uncontrolled diabetes, immunocompromised states, and the use of specific drugs), and pregnant women due to potential risks associated with PRP.

Preoperative phase: Before the insertion of the temporalis fascia graft in the tympanic membrane perforation, blood was taken from the PRP group and then spun in a centrifuge to create PRP. This PRP was then applied over the temporalis fascia graft. The control group underwent normal Type 1 tympanoplasty without the use of platelet-rich plasma (PRP). Each individual received a thorough clinical examination, audiological testing, and routine preoperative care.

Preparation of Autologous PRP: A blood sample of 9 ml was collected from each patient and combined with 1 ml of anticoagulant. The sample underwent an initial centrifugation at 1500 rpm for 15

minutes to separate the layers, followed by a subsequent centrifugation at 3000 rpm for 15 minutes to further concentrate the platelets. The platelet-depleted plasma was extracted, and the remaining liquid was combined and stored. During the surgical operation, the platelet-rich plasma (PRP) was activated using calcium gluconate and administered using gel foam. The follow-up and outcome assessment were carried out according to the original plan.

Surgical Procedure: A Type I Tympanoplasty (Myringoplasty) procedure was performed under general anaesthesia. A graft of temporalis fascia was obtained by making a postaural incision. After raising the musculo-periosteal flap, a posterior meatotomy was done, and the edges of the perforation were freshened. The tympano-meatal flap was raised in order to inspect the middle ear cavity and ossicular chain. Temporalis fascia graft was inserted via the underlay technique, and gel foam placed in the middle ear and external auditory canal. Finally, postaural wound was sutured, and mastoid dressing applied.

Postoperative phase: Postoperative treatment immediately after surgery consisted of closely monitoring the patient in the recovery area and administering pain medication and antibiotics as prescribed. Subsequent appointments were made at intervals of 1 week, 1 month, 3 months, and 6 months after the surgery. During each visit, otoscopic examinations and tympanometry were conducted to examine the acceptance and healing of the graft. Additionally, pure-tone audiometry was performed at the 3-month and 6-month marks to assess improvements in hearing. Complications have been closely tracked for indications of infection, graft lateralization, or any other problems.

Follow-Up Assessment: Patients were monitored on the 10th, 30th, and 90th days after the procedure. Tympanoplasty was considered successful if the graft had been properly incorporated and the tympanic membrane healed without any tears, retraction, or lateralization within 90 days. Any of these complications indicated failure.

Ethical considerations: Before their participation, all participants were given detailed information about the purpose of the study, methods, potential risks, and benefits, as outlined in the consent form, to ensure compliance with ethical standards and voluntary participation.

Statistical Analysis: Data was entered into Microsoft Excel and analysed using SPSS version 26. Descriptive statistics were presented as frequencies, percentages, and means ± standard deviations. For inferential statistics, Student's t-test or ANOVA was employed, with a p-value ≤ 0.05 considered statistically significant.

Results

The study examined several demographic and clinical factors in individuals receiving treatment for Chronic Suppurative Otitis Media (CSOM). The following are the comprehensive findings, organized with statistical analysis, tables, and graphical representations.

Patient Demographics analysis: The patient's demographic and clinical features indicate that both groups have similar age distribution, gender, and socioeconomic position (Fig. 1, 2). Group 1 includes a smaller number of individuals aged 18-30 (30.3%) compared to Group 2 (37.5%) and a higher proportion of individuals who are not working (39.4%) compared to Group 2 (31.3%) (Fig. 3). Most participants in both groups are from the middle socioeconomic level. The pattern of disease is nearly identical between the groups, with a slight prevalence of left-sided chronic suppurative otitis media (CSOM) and comparable diameters of perforation (Fig. 4).

Table 1: Clinical and Demographic Characteristics of Patients

Demographic Characteristic	Group 1 (n=33)	Group 2 (n=32)
Age		
18-30 years	10 (30.3%)	12 (37.5%)
31-40 years	11 (33.3%)	8 (25.0%)
41-50 years	7 (21.2%)	6 (18.8%)
51-60 years	5 (15.2%)	6 (18.8%)
Gender		
Male	19 (57.6%)	18 (56.3%)
Female	14 (42.4%)	14 (43.8%)
Socioeconomic Status		
Low	12 (36.4%)	11 (34.4%)
Middle	18 (54.5%)	18 (56.3%)
High	3 (9.1%)	3 (9.4%)
Occupation		
Working	20 (60.6%)	22 (68.8%)
Non-working	13 (39.4%)	10 (31.3%)

Disease Side		
Left CSOM	20 (54.1%)	17 (53.1%)
Right CSOM	13 (45.9%)	15 (46.9%)

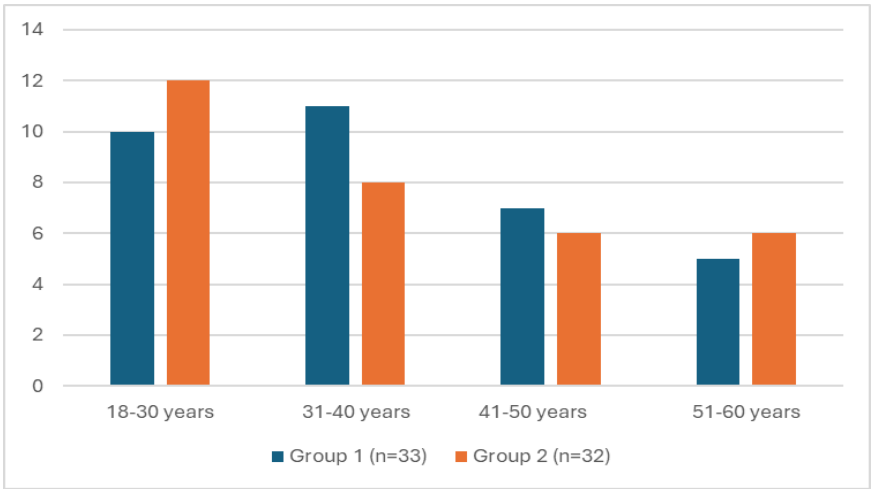

Figure 1: Illustration of Distribution among Age Groups between Groups 1 (n = 33) and 2 (n = 32)

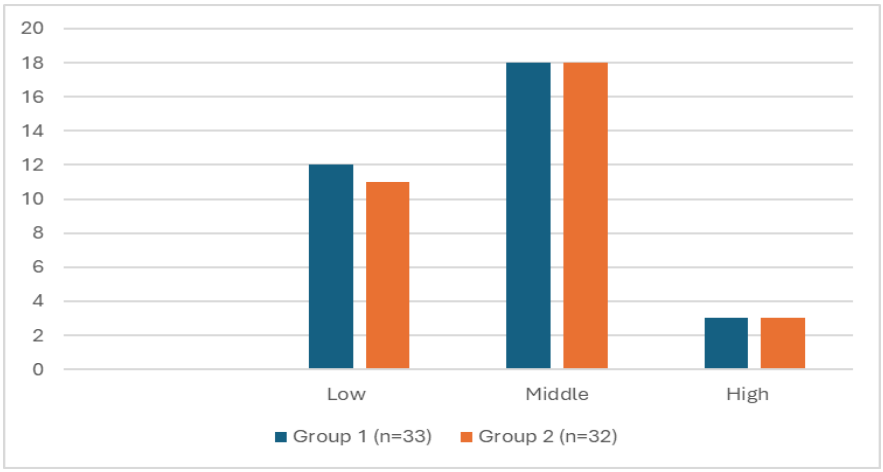

Figure 2: Illustration of Socio-economic Status Distribution between Group 1 (n=33) and Group 2 (n=32)

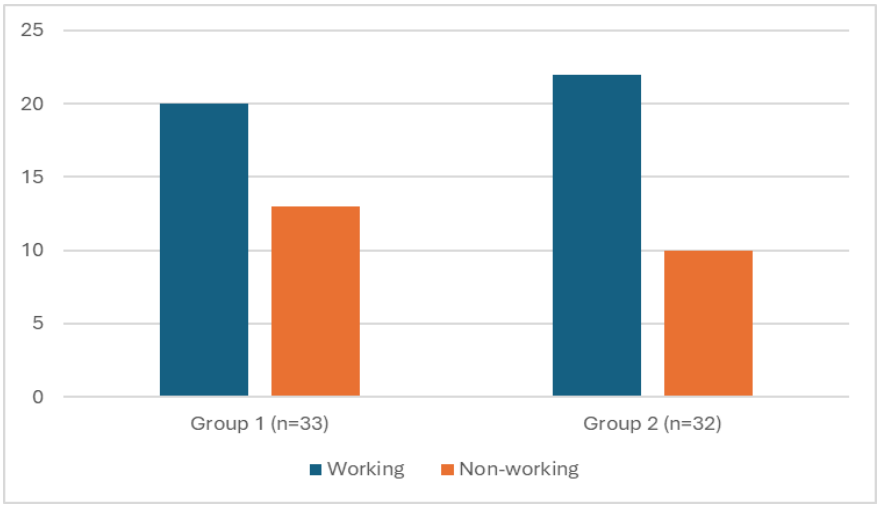

Figure 4: Illustration of Occupation Distribution between Group 1 (n=33) and Group 2 (n=32)

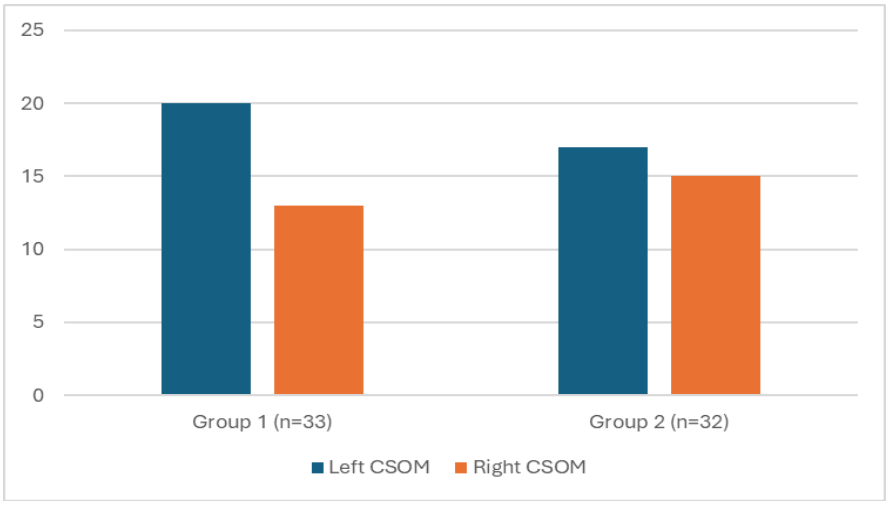

Figure 5: Illustration of Disease Side Distribution between Group 1 (n=33) and Group 2 (n=32)

Preoperative Analysis: Table 2 indicates that the incidence of Subtotal Type Perforation (STP) in the two groups. It was found to be identical in both (36.4%&37.5%), leading to a combined prevalence of 36.9% across both groups. The p-value of 0.74 indicates that there is no statistically significant disparity in the prevalence of STP between the groups.

Table 2: Distribution of Patients with Subtotal Type Perforation (STP) in Group A and Group B

Group	Group A (n = 33)	Group B (n = 32)	Total (n = 65)	p-value
Patients with Subtotal Type Perforation (STP)	12 (36.4%)	12 (37.5%)	24 (36.9%)	0.74

Post-operative analysis

Graft Uptake Status: According to Table 3, the Platelet-Rich Plasma (PRP) group (Group 2) had a significantly higher percentage of successful graft uptake (90.6%) compared to the Control group (Group 1), which had a rate of 85% (p = 0.032). These findings indicate that PRP treatment greatly enhances the probability of effective graft integration in tympanoplasty surgeries.

Table 3: Comparison of Successful Graft Uptake between Control Group and PRP Group

Variable	Group 1 (Control) (n = 33)	Group 2 (PRP) (n = 32)	Total (n = 65)	P Value
Successful Graft Uptake	28 (85%)	29 (90.6%)	57 (87.7%)	0.032
Unsuccessful Graft Uptake	5 (15%)	3 (9.4%)	8 (12.3%)	
Total Patients	33	32	65	

Hearing Gain: According to Table 4, Group A had a higher mean hearing improvement of 15.06 dB compared to Group B, which had an average improvement of 14.93 dB.

Within Group A, a total of 22 people observed an auditory improvement over 10 decibels, but in Group B, only 16 persons achieved a similar level of progress. The hearing gain disparity between the two groups is statistically significant, with a p-value of 0.03, suggesting that Group A observed a significantly greater improvement in hearing compared to Group B.

Table 4: Comparison of Hearing Gains between Group A and Group B

group	Average Hearing Gain (dB)	0-10 dB Gain (n)	>10 dB Gain (n)	p-value
A	15.06	11	22	0.03
B	14.93	16	16	0.9

Correlation of Preoperative and Postoperative Air-Bone Gap (ABG) Measurements: Table 5 demonstrates that both Group A and Group B exhibited substantial enhancements in the air-bone gap (ABG) after undergoing therapy. Group A exhibited a significant decrease in ABG, with the average value dropping from 39.09 ± 6.9 dB to 15 ± 6.65 dB. This corresponds to a mean improvement of 24.09 ± 7.54 dB, which was statistically significant (p = 0.00012). Group B exhibited a decrease from 37.7 ± 6.11 dB to 14.9 ± 9.14 dB, resulting in an average improvement of 22.8 ± 8.14 dB (p = 0.00002). Both groups demonstrated substantial enhancements, with Group B exhibiting an

approximate greater overall improvement, albeit with a more fluctuating final ABG.

Table 5: Correlation and Improvement in Air-Bone Gap (ABG) for Group A and Group B

Group	Initial ABG (Mean ± SD)	Final ABG (Mean ± SD)	Improvement (Mean ± SD)	p-value
A	39.09 ± 6.9 dB	15 ± 6.65 dB	24.09 ± 7.54 dB	0.00012
B	37.7 ± 6.11 dB	14.9 ± 9.14 dB	22.8 ± 8.14 dB	0.00002

Follow-up assessment: Table 6 indicates that the attendance rates for follow-up were high and remained consistent in both Group A and Group B, with a 100% attendance rate at 10 days for both groups (p=1.000). However, Group A exhibited marginally lower attendance rates (94.4%) than Group B (100%) at 1 month and 3 months. However, these disparities were not statistically significant (p=0.160).

This suggests that Group B consistently attended all follow-up sessions, but Group A experienced a tiny reduction in attendance during the subsequent follow-ups. Overall, both groups demonstrated high adherence to the follow-up schedule.

Table 6: Follow-up Attendance Rates and Graft Failure Rates for Groups A and B

Follow-up	Group A (n = 33)	Group B (n = 32)	p-value
10 days	33 (100%)	32 (100%)	1.000
1 month	31 (94.4%)	32 (100%)	0.160
3 months	31 (94.4%)	32 (100%)	0.160

Discussion

Chronic Suppurative Otitis Media (CSOM) has become a significant global health issue, impacting hearing function and overall quality of life, despite developments in medicinal and surgical interventions [25]. Tympanoplasty is the most frequent surgical option given to the patient. The success rates of this procedure have been shown to range from 86% to 100% [26]. Temporalis fascia has been the preferred material for grafting, with success rates of up to 88%, as evidenced by many meta-analyses [27]. Recent improvements suggest that fat grafts provide a viable option by enhancing the creation of new blood vessels, hence minimizing post-surgical shrinking and facilitating the production of replacement tiny blood vessels [28].

The demographic features of the research groups were generally similar in terms of age distribution, gender, and socioeconomic position. The alignment of this study is in line with other research that has also identified no notable demographic biases that impact the results of tympanoplasty. The results of our investigation revealed a marginally reduced proportion of younger persons in Group 1 in comparison to Group 2, which seems consistent with the observations made by Yang et al. (2019) regarding age discrepancies among patient groups undergoing identical procedures [29]. The results of our study found that the incidence of Subtotal Perforation (STP) was similar in both groups, and there was no statistically significant difference. These findings are consistent with the results reported by Alam et al., 2023. The absence of significant discrepancy suggests that the initial characteristics of the perforations were identical, hence reducing possible factors that could influence the evaluation of postoperative outcomes [30]. The results of our study indicate that the PRP group had a considerably greater percentage of effective graft take-up (90.6%) in comparison to the control group (85%). This finding aligns with multiple studies that have emphasized the advantages of PRP in enhancing the integration of grafts and increasing success rates in tympanoplasty. The observed increase in graft acceptance in our PRP group provides evidence to support the idea that the bioactive growth factors included in PRP contribute to improved tissue healing and integration of the graft. In contrast, alternative research conducted by Gunes et al. in 2023 yielded inconclusive findings regarding the influence of PRP on graft acceptance. This suggests that the advantages of PRP could vary based on variables like as the surgical method employed and patient-specific circumstances. This diversity highlights the necessity for additional research to clarify the exact circumstances in which PRP demonstrates its advantageous benefits [31].

Group A demonstrated a statistically significant increase in hearing compared to Group B, with a larger average hearing improvement and a greater number of subjects experiencing increases exceeding 10 dB. This finding aligns with the research conducted by Jayakumar et al. in 2016, which demonstrated that PRP can improve hearing outcomes after tympanoplasty. The enhanced auditory improvement observed in the PRP group can be due to the expedited regeneration of tissues and the decreased inflammation facilitated by PRP [32].

Nevertheless, certain studies, including the ones conducted by Zhu et al. in 2020, have indicated that the improvements in hearing outcomes achieved through PRP are only minimal. This suggests that although PRP may have some benefits, its effect on hearing gain may not be consistently significant and could be influenced by individual patient factors and surgical variables [33]. Both groups had

substantial decreases in the air-bone gap (ABG) after the surgery, with the PRP group displaying a slightly superior enhancement. This is consistent with the results of a prior study conducted by Ebrahim et al., 2018, which indicated that PRP can be effective in enhancing hearing function. The significant enhancement found in our PRP group provides additional evidence that the regenerative characteristics of PRP contribute to improved auditory outcomes by boosting middle ear function and lowering conductive hearing loss [34].

The rates of follow-up attendance were high in both groups, and there was no notable disparity in total adherence. This observation aligns with the research conducted by Ma et al. in 2024, which reported high percentages of successful patient follow-up in individuals who received tympanoplasty.

The marginal decrease in attendance in Group A during subsequent follow-ups, while lacking statistical significance, implies that patient compliance with follow-up could be influenced by variables other than the intervention itself [35].

Conclusion

In conclusion, the administration of Platelet-Rich Plasma (PRP) in Type 1 tympanoplasty with temporalis fascia grafts has demonstrated promising results in enhancing graft uptake and improving hearing outcomes. This is demonstrated by the observed decrease in the air-bone gap and greater success rates observed in the PRP group. Although there are advantages to using PRP, its influence on graft uptake rates continues to be uncertain. Therefore, additional research must be conducted to develop improved PRP protocols and conduct greater standardized studies in order to confirm the effectiveness in enhancing clinical practice.

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