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EFFECT OF INTRA-TYMPANIC PLATELET RICH PLASMA AND STEROID INJECTION ON SENSORINEURAL HEARING LOSS

Original Research

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Acknowledgement: The authors acknowledge the support of Combined Military Hospital, Sialkot, in facilitating this study.

Conflict of Interest: None

Grant Support & Financial Support: None

ABSTRACT

Background: Sensorineural hearing loss (SNHL) is one of the most prevalent forms of hearing impairment worldwide, often resulting from irreversible damage to cochlear structures. Inflammation has been identified as a critical factor in its pathogenesis. While corticosteroids are the conventional therapeutic choice due to their anti-inflammatory effects, platelet-rich plasma (PRP) has recently emerged as a promising alternative because of its regenerative and anti-inflammatory properties.

Objective: To compare the frequency of hearing improvement in patients with SNHL treated with intra-tympanic platelet-rich plasma versus intra-tympanic dexamethasone injection.

Methods: This quasi-experimental study was conducted at Combined Military Hospital, Sialkot, from January to June 2023. Ninety patients aged ≥18 years with documented SNHL and intact tympanic membranes were enrolled and non-randomly allocated into two groups: Group-P (intra-tympanic PRP) and Group-S (intra-tympanic dexamethasone). Each patient received four weekly injections of their assigned treatment. Pure tone audiometry (PTA) was performed at baseline and two weeks after the final injection. Hearing improvement was defined as a ≥10 dB gain in PTA. Data were analyzed using SPSS version 22, with $p \leq 0.05$ considered statistically significant.

Results: The median age was 35.00 (IQR: 11.25) years; 58 (64.4%) were male and 32 (35.6%) were female. Pre-injection PTA values were comparable: 52.00 (7.00) dB in Group-P and 52.00 (7.50) dB in Group-S ($p = 0.721$). Post-injection PTA values showed significant improvement in both groups: 35.00 (16.50) dB in Group-P and 38.00 (6.50) dB in Group-S ($p = 0.023$). Hearing improvement was achieved in 32 (71.11%) patients in Group-P compared to 23 (51.11%) in Group-S ($p = 0.041$).

Conclusion: Intra-tympanic PRP demonstrated superior efficacy compared to dexamethasone in improving hearing outcomes among patients with SNHL.

Keywords: Dexamethasone, Middle Ear, Platelet-Rich Plasma, Sensorineural Hearing Loss, Steroid Therapy, Tympanic Membrane, Tympanic Injection.

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INTRODUCTION

Hearing loss is a widespread and often underestimated health condition, affecting more than 1.5 billion individuals globally—equivalent to nearly one in every five people (1). In the United States alone, approximately 22.2% of the population, or over 72 million individuals, experience some form of hearing impairment (2). This condition extends far beyond auditory limitations, frequently leading to substantial cognitive, behavioral, social, and academic challenges that significantly compromise an individual's quality of life (3,4). Among the various forms of hearing loss, sensorineural hearing loss (SNHL) emerges as the most prevalent type, resulting from damage to the inner ear or auditory nerve pathways (5). The etiopathogenesis of SNHL is multifactorial, encompassing a wide array of triggers including infectious agents, autoimmune conditions, metabolic dysfunctions, traumatic injuries, neurovascular disorders, and ototoxic exposures (6). Owing to this diverse etiology, a comprehensive diagnostic workup is essential for accurate evaluation. Investigative modalities typically include genetic screening, ancillary tests such as electrocardiograms for identifying syndromic associations, imaging techniques like CT and MRI, serological assays for congenital infections like cytomegalovirus, and acoustic reflex evaluations (7). Despite the availability of advanced diagnostics, pure tone audiometry (PTA) remains the gold standard for confirming SNHL (8).

Management strategies for SNHL continue to evolve and include systemic or local administration of corticosteroids, hyperbaric oxygen therapy, and more recently, intra-tympanic delivery of therapeutic agents (9). In this context, platelet-rich plasma (PRP) has garnered attention as a regenerative treatment due to its rich concentration of growth factors that may facilitate cochlear repair. While intra-tympanic corticosteroids, particularly dexamethasone, are well-established in practice, the clinical utility of PRP in this setting is still under exploration (10). The lack of consensus on the comparative efficacy of PRP versus corticosteroids delivered via the intra-tympanic route underscores a critical gap in current otologic therapeutics. To address this, the present study was undertaken with the objective of comparing the frequency of hearing improvement in patients diagnosed with sensorineural hearing loss who were treated with intra-tympanic platelet-rich plasma versus intra-tympanic dexamethasone injection.

METHODS

This quasi-experimental study was conducted at Combined Military Hospital, Sialkot, over a six-month period from January 2023 to June 2023, following approval from the Institutional Ethical Committee. The sample size was calculated using the WHO sample size calculator, considering a level of significance of 5%, power of 80%, and the anticipated post-injection mean pure tone audiometry (PTA) values of 47.31 ± 15.40 dB for the platelet-rich plasma (PRP) group and 38.27 ± 14.91 dB for the dexamethasone group (10). This yielded a sample size of 90 participants, with 45 individuals assigned to each group. Non-probability consecutive sampling was employed for participant recruitment. Male and female patients aged 18 years or older who presented with sensorineural hearing loss (SNHL) and had an intact tympanic membrane were considered eligible. Individuals with comorbidities such as hypertension, ischemic heart disease, or chronic renal failure, those with tympanic membrane perforation or active ear infection, and patients with a history of prior intra-tympanic treatment or ear surgery were excluded from the study. Written informed consent was obtained from all participants after explaining the intra-tympanic drug administration protocol. Baseline clinical characteristics including age, gender, duration and laterality of hearing loss, and pre-injection PTA values were documented. Participants were allocated into two treatment groups based on the phase of study. From January to March 2023, participants received intra-tympanic PRP and were assigned to Group-P, while from April to June 2023, participants received intra-tympanic dexamethasone and were designated as Group-S. To maintain patient blinding, the therapeutic agent was not disclosed to the participants.

Both groups underwent the same standardized intra-tympanic administration procedure. The affected ear was first anesthetized using a cotton pledget soaked in 2% lignocaine solution, which was left in place for 20 minutes. During this time, 0.5 ml of PRP (autologous, freshly prepared) and 2 mg of dexamethasone (0.5 ml of a 4 mg/ml solution) were drawn into sterile 1 cc syringes. The patient was positioned supine with the head turned at a 45-degree angle away from the surgeon. Under direct otoscopic visualization, the designated injection was administered into the postero-inferior quadrant of the tympanic membrane. Following injection, patients remained in the same position for 30 minutes. This procedure was repeated once weekly for four consecutive weeks. All patients received identical post-injection therapy consisting of Flurbiprofen 100 mg twice daily and Cephradine 500 mg twice daily for three days after each injection.

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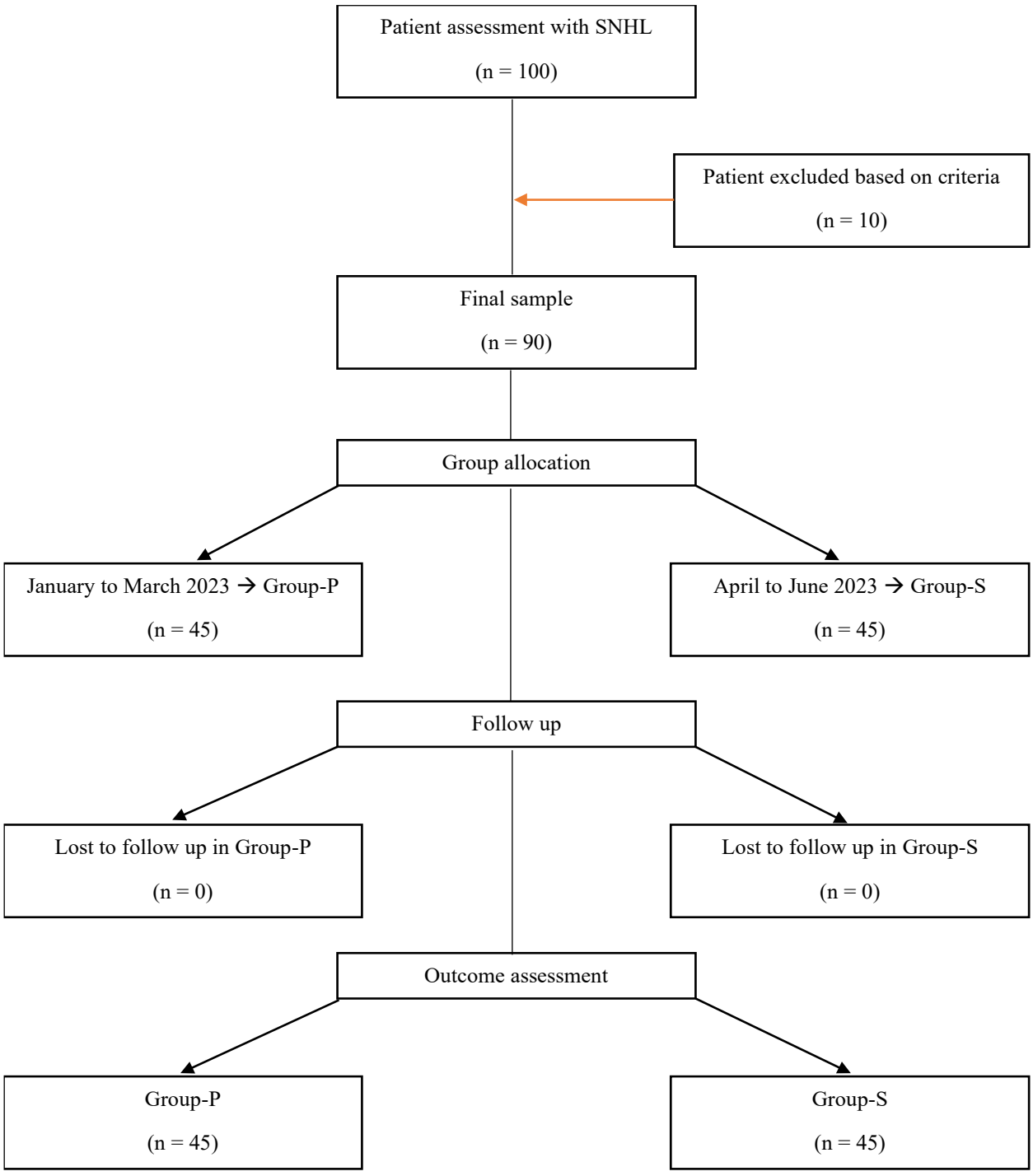
Two weeks after the final injection, PTA was repeated to assess post-treatment hearing thresholds. A hearing improvement was defined as a ≥10 dB gain in PTA compared to baseline. Data were analyzed using SPSS version 22. Normality of quantitative variables was assessed using the Shapiro-Wilk test, which indicated that variables such as age, duration of deafness, and PTA values were not normally distributed. Therefore, these were presented as medians with interquartile ranges (IQR), and comparisons between groups were made using the Mann-Whitney U test. Qualitative variables including gender, laterality of hearing loss, and presence of hearing improvement were reported as frequencies and percentages. Group comparisons for categorical variables were performed using the Chi-square test, except for hearing improvement which was analyzed using Fisher's exact test due to small expected frequencies. Within-group comparisons of pre- and post-injection PTA values were conducted using the Wilcoxon matched-pairs signed-rank test. A p-value of ≤0.05 was considered statistically significant.



CONSORT Patient Flow Diagram

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RESULTS

A total of 90 patients with sensorineural hearing loss were included in the study. The overall median age was 35.00 years with an interquartile range (IQR) of 11.25 years. Out of the total participants, 58 (64.4%) were male and 32 (35.6%) were female. The median duration of deafness was 6.50 months (IQR: 2.00 months). The laterality of hearing loss was evenly distributed, with 44 (48.9%) patients affected in the right ear and 46 (51.1%) in the left ear. The baseline comparison between the two treatment groups showed no statistically significant differences in age (Group-P: 35.00 ± 11.50 years; Group-S: 34.00 ± 11.00 years; $p = 0.418$), gender distribution ($p = 0.378$), duration of deafness (Group-P: 7.00 ± 2.00 months; Group-S: 6.00 ± 2.00 months; $p = 0.533$), or laterality of hearing loss (right vs. left; $p = 1.000$). Similarly, the pre-injection PTA values were comparable between Group-P and Group-S with a median of 52.00 dB in both groups ($p = 0.721$), confirming baseline homogeneity. Post-injection PTA values demonstrated significant improvement in both groups. Group-P exhibited a post-injection PTA median value of 35.00 dB (IQR: 16.50), whereas Group-S showed a median of 38.00 dB (IQR: 6.50), with the inter-group comparison showing statistical significance ($p = 0.023$). Within-group analysis also revealed statistically significant improvements in PTA values in both treatment arms ($p < 0.001$ for both).

When comparing the frequency of hearing improvement—defined as a ≥10 dB gain in PTA—Group-P demonstrated a higher response rate with 32 out of 45 patients (71.11%) showing improvement, compared to 23 out of 45 patients (51.11%) in Group-S. This difference was statistically significant ($p = 0.041$), suggesting superior efficacy of intra-tympanic PRP over dexamethasone in improving auditory outcomes in this cohort. Based on the comparison of hearing improvement between groups, the effect size analysis demonstrated that patients in the PRP group had 2.35 times higher odds of showing hearing improvement compared to those in the dexamethasone group. The 95% confidence interval for the odds ratio ranged from 0.99 to 5.62. In terms of relative risk, the probability of hearing improvement in the PRP group was 1.39 times that of the dexamethasone group, with a 95% confidence interval of 0.99 to 1.96. Although the point estimates suggest a clinically meaningful benefit of PRP over dexamethasone, the lower bounds of both confidence intervals narrowly include 1.00, indicating borderline statistical significance. These findings support a potentially superior therapeutic effect of intra-tympanic PRP in improving hearing thresholds, warranting further investigation with larger sample sizes for more definitive conclusions.

Table 1: Comparison of Pre- Injection Patient Characteristics Between Groups (N = 90)

Parameter	Group-P (n = 45)	Group-S (n = 45)	p-value
Median age	35.00 (11.50) years	34.00 (11.00) years	0.418
Gender			
Male	31 (68.89%)	27 (60.00%)	0.378
Female	14 (31.11%)	18 (40.00%)	
Median duration of deafness	7.00 (2.00) months	6.00 (2.00) months	0.533
Laterality			
Right	23 (51.11%)	23 (51.11%)	1.000
Left	22 (48.89%)	22 (48.89%)	

Table 2: Comparison of Pre-Injection and Post-Injections PTA Values Within and Between Groups (N = 90)

Parameter	Group-P (n = 45)	Group-S (n = 45)	p-value
Pre-injection PTA	52.00 (7.00) dB	35.00 (16.50) dB	0.721 **
Post-injection PTA	52.00 (7.50) dB	38.00 (6.50) dB	0.023 **
	p < 0.001 *	p < 0.001 *	

Table 3: Comparison of Hearing Improvement Between Groups (N = 90)

Hearing improvement	Group-P (n = 45)	Group-S (n = 45)	p-value
Yes	32 (71.11%)	23 (51.11%)	0.041
No	13 (28.89%)	22 (48.89%)	

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Table 4: Effect Size Analysis: PRP vs Dexamethasone

Measure	Value
Odds Ratio (OR)	2.35
95% CI (OR)	0.99 – 5.62
Relative Risk (RR)	1.39
95% CI (RR)	0.99 – 1.96

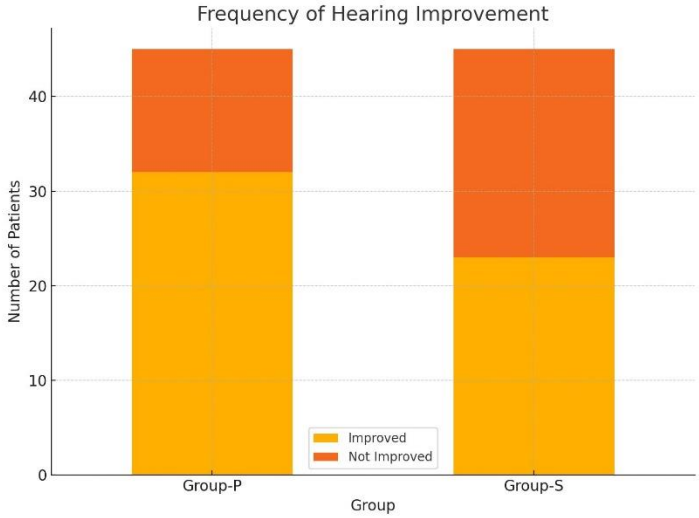

Figure 1 Frequency of Hearing Improvement

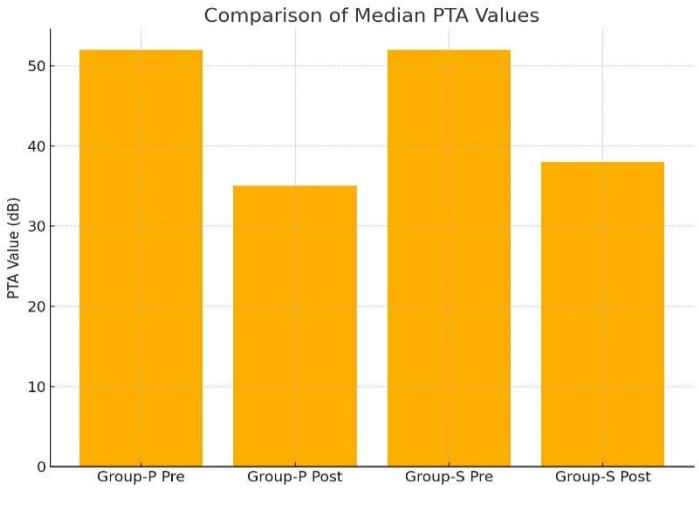

Figure 2 Comparison of Median PTA Values

DISCUSSION

Inflammation has long been established as a principal pathophysiological contributor to the onset and progression of sensorineural hearing loss (SNHL) (11,12). In this context, the therapeutic use of anti-inflammatory agents, particularly corticosteroids, has been extensively explored and integrated into routine clinical practice as a frontline treatment modality for managing SNHL (13,14). In recent years, platelet-rich plasma (PRP) has gained considerable attention for its anti-inflammatory, regenerative, and healing-promoting properties. These unique attributes have led to its experimental use in a variety of inflammatory and degenerative conditions, including otologic disorders (15,16). Building upon this background, the present study was conducted to evaluate whether intra-tympanic PRP offers superior therapeutic outcomes compared to intra-tympanic corticosteroids in patients with SNHL. In the present study, the median age of affected individuals was 35 years, and nearly two-thirds of the participants were male. This finding aligns with previous observations wherein male predominance was noted among patients with SNHL, potentially due to increased occupational and environmental exposure to auditory stressors such as noise pollution, especially in socio-cultural settings where men are more frequently involved in outdoor labor. Conversely, some investigations have reported a higher prevalence of SNHL among females, particularly in specific populations such as COVID-19 patients, indicating that etiological context and population dynamics can influence the gender distribution of SNHL (17-19).

The present findings demonstrated that both PRP and dexamethasone, when administered via the intra-tympanic route, significantly improved hearing thresholds relative to baseline values, indicating their effectiveness in reversing auditory impairment ($p < 0.001$ for both groups). However, the inter-group comparison highlighted the superior efficacy of PRP, as evidenced by significantly lower post-injection PTA values ($p = 0.023$) and a higher frequency of patients achieving clinically meaningful hearing improvement (≥10 dB gain) in the PRP group compared to the steroid group ($p = 0.041$). These outcomes reinforce the therapeutic promise of PRP and are corroborated by previous studies in which intra-tympanic PRP produced significantly better auditory outcomes than corticosteroids (10,20). Nonetheless, a few contradictory findings have emerged in the literature, where no statistically significant differences were observed between the therapeutic outcomes of PRP and steroid injections ($p = 0.852$ and $p = 0.35$, respectively) (21,22). This discrepancy

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may be attributed to variations in study protocols, including the frequency of injections, timing of post-treatment assessment, and patient selection criteria. For instance, studies that reported non-significant results often employed fewer PRP injections compared to the four-dose regimen used in the current study, potentially influencing the magnitude and durability of treatment response.

The strength of the current study lies in its methodical approach, including clearly defined inclusion and exclusion criteria, uniform administration technique, and a robust follow-up schedule. The use of pure tone audiometry as the gold standard assessment tool and strict criteria for defining hearing improvement further enhance the reliability of the findings. However, some limitations must be acknowledged. The study lacked long-term follow-up to assess sustained auditory recovery, and the absence of local comparative studies limited the ability to contextualize results within regional clinical practice. Additionally, the quasi-experimental design, though pragmatic, carries inherent biases related to non-random allocation. Future research should aim to validate these findings through randomized controlled trials with larger sample sizes, longer follow-up durations, and inclusion of functional and quality-of-life outcomes to comprehensively evaluate the clinical utility of PRP. Comparative cost-effectiveness analyses may also be warranted to determine the feasibility of incorporating PRP into mainstream otologic treatment algorithms. Overall, the findings of this study support the preferential use of intra-tympanic PRP over dexamethasone for treating SNHL, positioning it as a potentially more efficacious and biologically restorative intervention in the evolving landscape of auditory therapeutics.

CONCLUSION

In conclusion, the findings of this study highlight that intra-tympanic administration of platelet-rich plasma offers a more effective therapeutic approach than steroids in enhancing hearing outcomes among patients with sensorineural hearing loss. By demonstrating superior clinical improvement, this intervention presents a promising advancement in the non-invasive management of SNHL. Its regenerative potential and favorable safety profile underscore its value as a preferable treatment modality, paving the way for its broader application in clinical practice and encouraging further exploration in future research.

AUTHOR CONTRIBUTION

Author	Contribution
Amna Raza*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Sohail Aslam	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published

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