

Therapeutic Role of Intratympanic Platelet Rich Plasma with Steroid in Sensorineural Hearing Loss and Tinnitus

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ABSTRACT

Objective: To observe the curative effects of intratympanic injection of platelet-rich plasma and steroids on sensorineural hearing loss and tinnitus, in order to achieve audiometric gain and symptomatic relief respectively.

Study Design: Prospective longitudinal study.

Place and Duration of Study: Combined Military Hospital, Hyderabad Pakistan, from Dec 2022 to Dec 2023.

Methodology: A total of 60 patients were selected. One ml of platelet-rich plasma (PRP) with steroid was injected through tympanic membrane. Three sessions were performed 6 weeks apart. Degree of hearing loss and its recovery as complete, partial and no recovery was recorded using pure-tone audiometry before and after the therapy. Similarly, tinnitus handicap inventory questionnaire was filled to observe the grades of tinnitus, handicap levels and improvement of symptoms. Chi square test and Mann-Whitney U-test were applied.

Results: Out of 60 patients, 38(63.3%) were male and 22(36.7%) female. Mean age was 39.18±16.44 years. Median of pretreatment scoring of tinnitus was 37.00 (49.25–18.00) and post treatment 10.50 (22.50–0.00). There was significant difference pre and post treatment as ($p<0.001$). After three sessions of PRP therapy, the distribution of hearing improvement across degrees of hearing loss was statistically significant ($p=0.004$), indicating a meaningful effect of PRP therapy on hearing outcomes.

Conclusion: We concluded that introducing regenerative intratympanic PRP therapy in ENT is highly effective and shows significant improvement in sensorineural hearing loss and tinnitus due to release of growth factors, nerve regeneration and its natural healing process.

Keywords: Platelet-Rich Plasma, Sensorineural Hearing Loss, Tinnitus.

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INTRODUCTION

Sensorineural hearing loss affects around 466 million people worldwide, 90 % of whom reside in low and middle income countries, like Pakistan.¹ It results from either damage to the hair cells within the inner ear, the vestibulocochlear nerve or the brain's central processing centers.²

Sensorineural hearing loss can be associated with tinnitus, which is a subjective sensation of hearing a sound in the absence of external stimulus.³ Tinnitus can be distressing and disabling as a result of which people tend to experience restricted career choices, depression, occupational stress and social isolation.¹

Intratympanic steroid injection for inner ear disorders was first described in the 1990s.⁴ Studies have shown that cochlear perilymph concentrations are about 100 fold higher with intratympanic drug

administration.^{5,6} It ensures minimal systemic absorption and reduces the risk of side effects.⁷

Platelet rich plasma (PRP) therapy is currently being used in diverse medical fields. It is a simple and minimally invasive method that has multiple advantages including its ingenious preparation, minimal infection risk, fewer complications and that it is an autologous product with no known adverse effects, in contrast to the commonly used corticosteroids.⁸⁻¹⁰

Acknowledging the countless healing benefits of PRP, this study aims to also introduce it in the field of ENT, by observing the curative effects of intratympanic injection of platelet-rich plasma and steroids on sensorineural hearing loss and tinnitus, in order to achieve audiometric gain and symptomatic relief respectively.

METHODOLOGY

This prospective longitudinal study was carried out in hospital's outpatient department of ENT at Combined Military Hospital Hyderabad, Pakistan,

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from December 2022 to December 2023 under clinical trial registration number NCT06025097. The study received ethical clearance from the institutional review board (ERC no. 111).

Inclusion Criteria: Patients aged 8 to 70 years, of either gender with normal anatomical ears, sensorineural hearing loss of 25-90dB (mild to severe) due to any cause based on pure tone audiometry, with either unilateral or bilateral ear involvement were included.

Exclusion Criteria: Patients with chronic suppurative otitis media, conductive hearing loss, trauma to ear, and those who could not follow-up for 3 sessions were excluded.

WHO calculator was used to calculate sample size, which came to 60, based on the previous prevalence of sensorineural hearing loss.¹¹ Informed and written consent was taken prior to data collection, and non-probability consecutive sampling was used.

All patients had 3 sessions, 6 weeks apart. Pure tone audiometry was performed before the therapy, dividing hearing loss into mild, moderate, moderately severe and severe according to American speech-hearing-language association's criteria of hearing impairment.¹² Slight, normal and profound cases were not included. Those suffering from tinnitus were asked to fill the questionnaire of Tinnitus Handicap Inventory (THI) before and after the therapy. It is a highly reliable test and can be applied easily due to its clear measurements. It consists of 25 items divided into 3 subscales: functional, emotional and catastrophic.¹³ Patient's handicap is labelled mild, moderate, severe and catastrophic according to the scoring of the questionnaire.

For every patient, fresh platelet-rich plasma (PRP) was prepared in the Rehabilitation Department of Combined Military Hospital, Hyderabad on the day of PRP therapy by withdrawing 5ml of blood collected in a sodium citrate vial. PRP separation from whole blood was achieved using the single-spin method in a centrifuge machine, with centrifugation at 1,720 rpm for 10 minutes.

Zero-point five ml of prepared PRP was mixed with 0.5ml of methylprednisolone solution, which is prepared by diluting 1g of methylprednisolone in 25ml of distilled water (40 mg/ml solution). This mixture was put into 3cc syringe and its needle was replaced with 27-gauge LP needle.

Wax and debris in external auditory canal were removed, after which a pyodine soaked wick was placed for 5 minutes, and lidocaine 10% was applied to anesthetize it. Patient was seated comfortably and then 1ml of mixture was injected using 0-degree endoscope through anteroinferior quadrant of tympanic membrane into the middle ear space until a meniscus of fluid can be seen completely filling the space (**Error! Reference source not found.**). After this the patient was made to lie supine for half an hour to achieve perfusion into round window niche.



Figure-1: Meniscus of Fluid seen filling the Middle Ear Space

PTA was repeated after the therapy was completed. Complete (>20dB), partial (1-20dB) or no recovery was recorded comparing the audiometric gain on PTA. THI scoring was also compared to observe improvement and symptomatic relief.

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 22. Normality of data was checked by Shapiro-Wilk test, which showed that age was normally distributed while duration of tinnitus scores pre- and post-PRP was non-normally distributed. Quantitative data was represented using Mean±SD and median (IQR). Qualitative data was represented using percentage and frequency. Chi square test (for qualitative variables), and Mann-Whitney U-test (for non-normal data) were applied, and a *p*-value of ≤0.05 was considered statistically significant.

RESULTS

Out of 60 patients, 38(63.3%) patients were male and 22(36.7%) female. Mean age was 39.18±16.44 years range from 14 to 82 years. 11 patients had

involvement of unilateral ear [06(10.0%) Right ear, 05(8.3%) Left ear] while 49 (81.7%) patients had bilateral ears involved. 35(58.3%) patients presented in acute phase of disease (≤ 3 months) while rest 25(41.7%) were in chronic phase (>3 months). However, 46 patients (76.7%) had tinnitus associated with sensorineural hearing loss. According to American speech-language-hearing association's criteria of hearing impairment, 21(35.0%) cases had mild hearing loss (26-40dB), 19(31.7%) had moderate hearing loss (41-55dB), 13(21.7%) had moderately severe hearing loss (56-70dB) and 7(11.7%) had severe hearing loss (71-90). Slight (<25 dB) and profound (>91 dB) cases were not included. Demographic and clinical characteristics of study participants shown in Table-I. Median of pretreatment scoring of tinnitus was 37.00 (49.25–18.00) and posttreatment 10.50 (22.50–0.00). There was statistically significant difference pre and post treatment as p -value <0.001 shown in Table-II.

Table-I: Demographic and Clinical Characteristics of Study Participants (n=60)

Study Parameters	Values
Age (Mean \pm SD)	39.18 \pm 16.44 years (Range: 14-82 years)
Gender	
Male	38(63.3%)
Female	22(36.7%)
Laterality	
Both Ears	49(81.7%)
Left Ear	05(8.3%)
Right Ear	06(10.0%)
Duration	
Acute (≤ 3 months)	35(58.3%)
Chronic (> 3 months)	25(41.7%)
Tinnitus	
Only Sensorineural Hearing Loss	14(23.3%)
Tinnitus With Sensorineural Hearing Loss	46(76.7%)
Hearing loss	
Mild	21(35.0%)
Moderate	19(31.7%)
Moderate Severe	13(21.7%)
Severe	7(11.7%)

Table-II: Comparison of Pre and Post Platelet-Rich Plasma Tinnitus scores (n=60)

	Pre-therapy Scores Median (IQR)	Post-therapy Scores Median (IQR)	p -value
Tinnitus scores	37.00 (49.25–18.00)	10.50 (22.50–0.00)	<0.001

However, Before PRP treatment, the majority of patients had moderate handicap (35.0%), followed by mild handicap (26.7%), no or slight handicap (23.3%), severe handicap (13.3%), and a small proportion with catastrophic handicap (1.7%). Following PRP therapy,

there was a marked shift toward lower grades of tinnitus handicap. The proportion of patients with no or slight handicap increased substantially from 23.3% to 63.3%. Moderate handicap showed a notable reduction from 35.0% before treatment to 10.0% after treatment. Severe and catastrophic handicap, which together accounted for 15.0% of patients pre-PRP, were completely absent post-PRP. The proportion of patients with mild handicap remained unchanged at 26.7% shown in Figure-2. Furthermore, after three sessions of PRP therapy, improvement in hearing thresholds was observed across different degrees of hearing loss shown in Table-III.

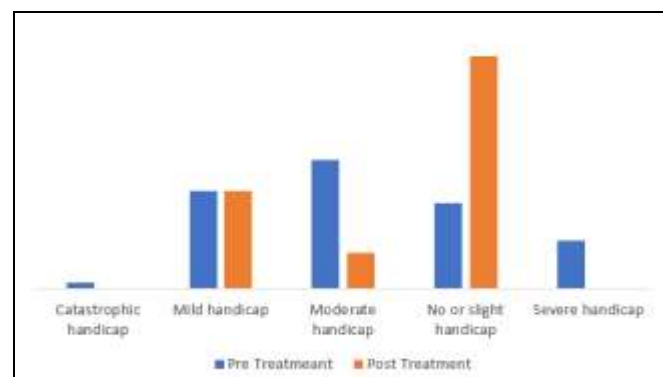


Figure-2: Improvement in Grades of Tinnitus before and after Platelet-Rich Plasma with respect to Tinnitus Handicap Inventory (n=60)

Table-III: Improvement in Degree of Hearing Loss after Three Sessions of Platelet-Rich Plasma Therapy (n=60)

PTA done after 3 sessions of PRP	Degree of hearing loss				Total	p -value
	Mild (n=21) n(%)	Moderate (n=19) n(%)	Moderately Severe (n=13) n(%)	Severe (n=7) n(%)		
Complete recovery (>20 dB)	16(76.2%)	10(52.6%)	1(7.7%)	2(28.6%)	29(48.3%)	0.004
Partial recovery (1-20dB)	5(23.8%)	6(31.6%)	10(76.9%)	3(42.9%)	24(40.0%)	
No recovery (0dB)	0(0.0%)	3(15.8%)	2(15.4%)	2(28.6%)	7(11.7%)	

Complete recovery (>20 dB improvement) was most frequent in patients with mild hearing loss (76.2%), followed by those with moderate loss (52.6%), while it was less common in moderately severe (7.7%) and severe hearing loss (28.6%). Partial recovery (1–20 dB improvement) was predominantly seen in patients with moderately severe hearing loss (76.9%), whereas no recovery was mainly observed in patients with moderate to severe hearing loss. Overall, the distribution of hearing improvement across degrees of hearing loss was statistically significant ($p=0.004$), indicating a meaningful effect of PRP therapy on hearing outcomes.

DISCUSSION

To the best of our knowledge no previous study has been conducted in Pakistan using same protocols used in current study for the management of sensorineural hearing loss and tinnitus.

PRP preparations have gained increasing popularity as it harnesses and amplifies the autologous growth factors produced by platelet degranulation which helps to heal the damaged tissues.⁹

Wang *et al.*, conducted a study which showed PRP has a role in promoting nerve recovery and describes it as neuroprotective and neurogenic. This study was limited to few nerves but it encourages future clinical trials and studies of PRP for nerve repair.¹⁴ Therefore, we can assume that it has therapeutic effects on vestibulocochlear nerve, hair cells and cochlea which in return improves hearing impairment. This growth factor mixture has also shown analgesic abilities which makes post procedure recovery quicker.¹⁴

The mechanism behind idiopathic sensorineural hearing loss can be multifactorial.¹⁵ However, there is an increasing suggestion that it involves proinflammatory cytokines in the inner ear along with tumor necrosis factor, causing a reduction in cochlear blood flow. For that reason, steroids have been mainstay of treatment due to their anti-inflammatory actions for decades.¹⁶ Based on previous studies we know that intratympanic steroids have a positive effect on hearing.¹⁷ Bhandari *et al.*, conducted a study on the role of intratympanic methylprednisolone injection within 4 days of sudden sensorineural hearing loss. A gain of 15 dB or more was seen in 78% of patients at the low hearing frequency, 72% at medium and 56.67% at high hearing frequency.¹⁸ In our study, by augmenting steroids with platelet rich plasma we achieved audiometric gain of up to 20 dB in 67% patients, with improvement in pure tone audiometry (PTA) average after the treatment. Complete recovery of around 85.7% in mild cases, 63.1% in moderate, 38.4% in moderately severe and 28.5% in severe cases was seen. Ruchika *et al.*, conducted a study on the role of PRP in sensorineural hearing loss, and their results are in accordance with our study. Seventy patients showed complete recovery of 70.8% in mild cases, 25% in moderate cases, 66.7% in moderately severe and 42.9% in severe, with a hearing gain of more than 10dB. It showed better recovery in severe cases as compared to moderate

cases.¹⁹ This was in contrast to our study, which showed better gain at low to moderate frequencies.

This study also evaluated significant improvement in quality of life of those suffering from tinnitus. Previously, there was a lack of convincing proof about the effects of intratympanic steroids on tinnitus. Yener *et al.*, conducted a study on 107 patients with tinnitus in which dexamethasone injections were administered to 60 patients and intratympanic saline to 47 in the control group. THI was performed before and after the treatment. In the study group, post-treatment THI scores were significantly better, showing intratympanic dexamethasone was effective in the treatment of subjective tinnitus.³ Whereas, in a study conducted by Araújo *et al.*, there was no advantage of intratympanic dexamethasone over saline in the treatment of severe disabling tinnitus; both solutions produced a placebo like improvement.²⁰ Our study shows improvement in symptoms with better average THI scores post-treatment. Sixty percent were left with no or slight handicap and no case of severe handicap was recorded after the treatment. The few patients who reported low mood and depressive episodes in the questionnaire also showed improvement. In one disabling case, tinnitus did not resolve but the patient's mental and physical health improved.

Although previous studies show injection of steroids through the tympanic membrane comes with some associated risk such as residual perforation or increased susceptibility to infections, but our patients did not experience any such symptoms except a few felt transient vertigo/vasovagal episode, nausea and mild pain.⁵

LIMITATIONS OF STUDY

Our study limitation is that it could have been conducted on a bigger sample size with a control group who were injected just platelet rich plasma to deduce the role of PRP in comparison to steroids. It could not be done in our setup as patients came from far areas of interior Sindh especially for PRP therapy and there was loss to follow up in many patients and they had to be excluded from the study. This study can be a base of future prospective studies.

CONCLUSION

This study highlights the regenerative potential of platelet rich plasma in achieving audiometric gain in hearing loss and improved quality of life in patients suffering from tinnitus. It has shown to enhance the effects of steroid therapy and promote natural healing and nerve repair.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MI & FA: Data acquisition, data analysis, critical review, approval of the final version to be published.

NK & UY: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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