



Research Article

Efficacy of Autologous Intratympanic Platelet-Rich Plasma in the Management of Sensorineural Hearing Loss

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ABSTRACT

BACKGROUND: Hearing loss is one of the major causes of disability. SNHL leads to communication difficulties, cognitive decline, social isolation and impaired quality of life. Hearing aids and cochlear implantation may not be suitable for all patients. Intratympanic or intravenous steroids have been used with variable efficacy. Recently PRP injections have shown some promising results in regeneration of hair cells and auditory nerve fibers. Hence PRP may pave way for novel approach for patients with SNHL. The present study was conducted to assess the effectiveness of intra tympanic PRP in improving the Pure Tone Average of hearing threshold. and to analyze the efficacy of intra tympanic PRP based on the duration of hearing loss. **MATERIALS AND METHODS:** This prospective cohort study was conducted at a tertiary care hospital in South India from August 2022 to July 2023 after obtaining ethical clearance. Thirty patients aged ≥ 7 years with sensorineural hearing loss (SNHL) confirmed by pure tone audiometry (PTA) and intact tympanic membranes were included by purposive sampling. Exclusion criteria were age < 7 years, conductive/mixed hearing loss, tympanic membrane perforation, ear pain/discharge, and prior ear surgery. After informed consent, 5 ml venous blood was collected, and platelet-rich plasma (PRP) was prepared by double centrifugation. Baseline PTA was done before treatment. Following topical lignocaine spray, 0.5 ml autologous PRP was injected intratympanically weekly for 3 weeks. PTA was repeated 6 months after the first injection. Data were analyzed using SPSS Version 17. **RESULTS :** Most of the patients were males ($n=18$) than females ($n=12$) and belonging to 71-80 age group ($n=7$) and 41-50 age group ($n=6$). Majority of patients presented within 6-24 months of onset of hearing loss ($n=9$). 15 patients had unilateral hearing loss (right>left) and 15 patients had bilateral hearing loss. Mean pure tone audiogram showed significant improvement after PRP injections with p value of <0.001 . On comparing degree of hearing loss with recovery, 91.11% of patients had recovery and 8.89 % did not have any recovery. On comparing duration of hearing loss with recovery, patients presented with less than 5 years duration had significant recovery. **CONCLUSION:** Sensorineural hearing loss is an emerging problem in the younger age groups due to changes in lifestyle. PRP being safe, minimally invasive and feasible on an outpatient basis has shown promising results in this domain. In conclusion, our study shows that PRP can be used as a viable treatment modality for the management of SNHL especially in younger age group patients and patients with mild to moderate hearing loss with minimal complications.

Keywords: Platelet-rich plasma, Sensorineural Hearing loss, Intratympanic, Pure Tone Average, Hearing Improvement, Hearing threshold.

INTRODUCTION:

Hearing loss is the third leading cause of disability worldwide as estimated by Global Burden of Disease study[1]. According to the WHO, approximately 6.1 percent of the global population suffers from disabling hearing loss. Sensorineural hearing loss (SNHL) is a type of hearing loss resulting from damage to cochlea, vestibulocochlear nerve or central auditory processing pathway. It may arise due to various etiological factors such as genetic (syndromic or non-syndromic), perinatal causes, age-related, noise-induced, ototoxicity, traumatic, Ménière's disease, infective, immunologic, vascular or idiopathic causes [2].

SNHL leads to communication difficulties, cognitive decline, social isolation and impaired quality of life [1,3]. It may also lead to high levels of depression and anxiety in patients with severe to profound hearing loss [4]. Current treatment options are limited and focus on symptom management rather than restoration of hearing[5]. Hearing aid and Cochlear Implantation remains the mainstay of management but may not be ideal for all individuals due to social, cultural or personal reasons. Hearing aids can also be cumbersome for older patients.

Intratympanic or Intravenous steroids have also been used with various efficacies, especially in sudden SNHL but only when administered early. Thus, research continues to focus on restorative options. PRP contains growth factors such as Platelet derived growth factors, Transforming growth factor beta, vascular endothelial growth factor and Epithelial growth factor⁵ and cytokines apart from platelets[6]. Hence, it has gained attention as a regeneration therapy. It has been applied successfully in Sports Medicine, Dermatology, Orthopedics, Dentistry and more recently considered for Otology[7]. PRP may help regenerate cochlear hair cells and auditory nerve fibers offering a novel approach for patients with SNHL.

This study evaluates the efficacy of Intratympanic PRP in restoring hearing and reducing disability in patients with SNHL. This study was conducted to assess the effectiveness of intra tympanic PRP in improving the Pure Tone Average of hearing threshold and to analyze the efficacy of intra tympanic PRP based on the duration of hearing loss.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective cohort study conducted at a tertiary care hospital in South India from August 2022 to July 2023 (12 months). Institutional ethical committee approval [PMCHRI-IHEC-066/12.08/2022] was obtained.

Study Population and Sampling

A total of 30 patients were selected by purposive sampling based on predefined inclusion and exclusion criteria.

Inclusion and Exclusion Criteria

- Inclusion: Patients aged ≥ 7 years with SNHL diagnosed by pure tone audiometry (PTA) and intact tympanic membrane on otoscopy.
- Exclusion: Age < 7 years, conductive/mixed hearing loss on PTA, tympanic membrane perforation, ear pain/discharge, or prior ear surgery.

Preparation of Platelet-Rich Plasma (PRP):

After informed consent, 5 ml venous blood was collected in a citrate vial and processed using double centrifugation (hard and soft spin) in the Transfusion Medicine department.

Procedure

Baseline PTA was done. Hearing threshold > 30 dB with air-bone gap < 10 dB was considered SNHL. Patients were positioned supine with the affected ear upwards. After topical 10% lignocaine spray, 0.5 ml of autologous PRP was injected intratympanically near the round window niche. Patients maintained position for 10 minutes to allow diffusion. In bilateral cases, the other ear was injected after 10 minutes. Patients were observed for 1 hour for adverse effects. The procedure was repeated weekly for 3 weeks.

Outcome Assessment

PTA was repeated 6 months after the first injection. Recovery was defined as:

- Partial: improvement of 1–10 dB
- Complete: improvement of > 10 Db

All procedures were performed by a single surgeon, and PTA was conducted by a blinded audiologist.

Statistical Analysis: Data were entered in Microsoft Excel and analyzed using SPSS Version 17. Descriptive statistics were expressed as frequency and percentage for categorical variables and as mean \pm standard deviation for continuous variables. Paired t-test was used for continuous variables and Chi-square test for categorical variables. A p-value < 0.001 was considered statistically significant.

RESULTS:

In this study 60% of the patients were males (n=18) and 40% were females (n=12). 50% of patients (n=15) had unilateral hearing loss (right>left) and 50% (n=15) had bilateral hearing loss. Most of the patients were belonging to 71-80 age group (n=7) and 41-50 age group (n=6)[Table1].

Table 1. Distribution by age group

Age group (years)	Number of patients	Percentage (%)
0 – 10	1	3.3
11 – 20	3	10.0
21 – 30	1	3.3
31 – 40	2	6.7
41 – 50	6	20.0
51 – 60	4	13.3
61 – 70	5	16.7
71 – 80	7	23.4
81 – 90	1	3.3
Total	30	100

Majority of patients presented within 6-24 months of onset of hearing loss (n=9)[Table 2].

Table 2: Degree of hearing loss

Degree of hearing loss	Number of patients	Percentage (%)
Mild	12	26.66
Moderate	9	20.00
Moderately severe	8	17.77
Severe	8	17.77
Profound	8	17.77
Total	45	100

Based on the severity of hearing loss 12 cases had mild, 9 cases had moderate 8 cases had moderately severe, 8 cases had severe and 8 cases had profound hearing loss [Table 3].

Table 3: Duration of hearing loss

Duration of hearing loss	Number of patients	Percentage (%)
< 6 months	1	3.3
6 – 24 months	9	30.0
2 – 3.5 years	8	26.7
3.6 – 5 years	4	13.3
> 5 years	8	26.7
Total	30	100

The mean PTA for right ear and left ear before the procedure were 61.33dB (+/-22.79) and 66.29dB (+/- 24.22) respectively. The mean PTA for right ear and left ear after the procedure were 51.13dB (+/- 26.47) and 56.85 dB (26.38) respectively with significant p value of <0.001 [Table 4].

Table 4: Comparison of Pure Tone Audiometry readings before and after procedure

Pure Tone Audiometry	Ear	Number of patients	Mean	Standard Deviation	p value
Before Procedure	Right	24	61.33	22.79	<0.001
After Procedure		24	51.13	26.47	
Before Procedure	Left	21	66.29	24.22	<0.001

Pure Tone Audiometry	Ear	Number of patients	Mean	Standard Deviation	p value
After Procedure		21	56.85	26.38	

Recovery varied with severity of hearing loss. In mild cases, 5 patients (11.11%) had complete and 7 (15.55%) partial recovery. Moderate cases showed 5 (11.11%) complete and 4 (8.89%) partial recovery, while moderately severe cases had 4 (8.89%) each with complete and partial recovery. In severe cases, 2 (4.44%) had complete and 6 (13.33%) partial recovery. Profound loss showed only partial recovery in 4 (8.89%) and no recovery in 4 (8.89%). The association was statistically significant ($p < 0.001$) [Table 5].

Table 5: Comparison between degree of hearing loss and recovery

Severity (Degree of Hearing loss)	Complete recovery N (%)	Partial recovery N (%)	No recovery N (%)	p value
Mild	5 (11.11)	7 (15.55)	0	<0.001
Moderate	5 (11.11)	4 (8.89)	0	<0.001
Moderately Severe	4 (8.89)	4 (8.89)	0	<0.001
Severe	2 (4.44)	6 (13.33)	0	<0.001
Profound	0	4 (8.89)	4 (8.89)	<0.001
Total	16 (35.55)	25 (55.55)	4 (8.89)	

Recovery was better with shorter duration of hearing loss. Complete recovery occurred in 1 patient (2.22%) with <6 months duration, 8 (17.78%) with 6 months–2 years, 4 (8.89%) with 2.1–3.5 years, 1 (2.22%) with 3.6–5 years, and 1 (2.22%) with >5 years. Partial recovery was highest in patients with 2.1–3.5 years (17.78%) and >5 years (17.78%) duration. No recovery was observed only in patients with >5 years duration (8.89%). The association was statistically significant ($p < 0.001$) [Table 6].

Table 6: Comparison between duration of hearing loss and recovery

Duration of Hearing Loss	Complete recovery N (%)	Partial recovery N (%)	No recovery N (%)	p value
< 6 months	1 (2.22)	0	0	<0.001
6 months – 2 years	8 (17.78)	5 (11.11)	0	<0.001
2.1 – 3.5 years	4 (8.89)	8 (17.78)	0	<0.001
3.6 – 5.0 years	1 (2.22)	5 (11.11)	0	<0.001
> 5 years	1 (2.22)	8 (17.78)	4 (8.89)	<0.001
Total	15 (33.33)	26 (57.78)	4 (8.89)	–

DISCUSSION:

PRP is a safe, easily obtainable biologically active blood derivative. It doesn't cause hypersensitivity or transfusion-related reactions. Activated PRP remains viable for approximately 8 hours. It can be administered easily on an outpatient basis and does not require overnight hospital admission. The growth factors present in PRP help in repairing and regenerating damaged hair cells of cochlea and the auditory nerve, however its efficacy of PRP may vary depending on the duration of hearing loss, age of onset, etiology and the site of lesion.

SNHL is a major cause of hearing impairment in adults[8]. Various treatment options are available for SNHL but several studies on PRP injections have shown better results. A study conducted by Tom S M et al., showed that PRP had 8 times better hearing improvement when compared to Dexamethasone[9]. This study aims to know the potential of PRP in the management of SNHL. In our study most of the patients were males (60%), mean age group was between 41-50 years which is similar to the study done by Savariya et al[10].

Study conducted by Ruchika et al. and Tyagi et al., showed SNHL to be more unilateral than bilateral[11,12]. In our study there was no difference in laterality. Most of the patients presented with mild to moderate hearing loss which was similar to a study done by Ruchika et al [11]. The mean PTA after PRP injections showed significant improvement in hearing threshold in 91.11% of cases and no improvement in 8.89%. The above results were found to be significant and similar to a study conducted by Qian et al[13]. Out of 45 total cases, 25 cases (55.55%) had partial recovery, 6 cases (25.55%) had complete recovery and 4 cases (8.89%) had no recovery.

On comparing degree of hearing loss with recovery after PRP injection, 4 patients (8.89%) who did not show any recovery had profound hearing loss. This shows that, patients with profound hearing loss either have partial recovery or no recovery. Thus PRP will be helpful in those who present earlier or who have mild to moderate degree of hearing loss. These findings were similar to the study done by Savariya et al and Ruchika et al [10,11].

A study by Tom SM et al suggested that single dose of intratympanic PRP is having better results in hearing improvement [9]. Similar results were found in a study done by BBPS Tyagi et al [14].

In our study, we found that most of our observations and results coincide with other similar studies. PRP being an autologous injection has a very low risk of immune reaction. Its easy availability and low cost will be advantageous to the patients.

Our study had several limitations. We had a relatively small sample size of 30 patients. We had a relatively short follow up period of 6 months, thus limiting the generalizability and long term assessment of the treatment effects. We did not evaluate subjective symptom improvement after each injection and long term safety outcomes could not be determined.

CONCLUSION: Sensorineural hearing loss, which was once a common disability in elderly individuals, has now become an emerging problem in the younger age groups due to changes in lifestyle. Most treatments aim at providing supplements for nerve regeneration or assisted hearing devices. PRP being safe, minimally invasive and feasible on an outpatient basis has shown promising results in this domain. In conclusion, our study shows that PRP can be used as a viable treatment modality for the management of SNHL especially in younger age group patients and patients with mild to moderate hearing loss with minimal complications.

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