

Original Research Article

Clinicoaudiological evaluation of hearing improvement in patients with sensorineural hearing loss using intratympanic platelet rich plasma versus steroid injection

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ABSTRACT

Background: SNHL is a heterogenous disorder, which can arise due to damage to pathway for sound impulses from the hair cells of inner ear to auditory nerve. This study is to evaluate and compare the effect of intratympanic instillation of PRP in patients having sensorineural hearing loss with steroid therapy.

Methods: A prospective observational study carried out in the department of ENT, NSCB medical college Jabalpur. The cases were selected who presented with sensorineural hearing loss and mixed hearing loss with intact TM. Total of 54 cases were enrolled in the study from 1 March, 2020 to 31 August 2021. Preoperative PTA was recorded. 0.5 ml of intratympanic platelet rich plasma and 0.5 ml of steroid dexamethasone administered. Postoperative PTA was done after 15 days of intratympanic injection and results recorded.

Results: In our study the mean age of the participants was 40.4 years. Bilateral and gradual hearing loss were common in the present study. The improvement from baseline to follow up period was higher in PRP group compared to DEXA group. It is statistically significant ($p=0.001$). The improvement in hearing loss is decreasing with the increase in age. The study revealed that hearing improvement with PRP is better than steroid.

Conclusions: The study concluded that the hearing improvement was more with single injection of PRP than dexamethasone.

Keywords: Sensorineural hearing loss, Intratympanic, Platelet rich plasma, Steroid

INTRODUCTION

According to the most recent estimates of the world health organization, 360 million people, or approximately 5.3% of the world's population, live with disabling hearing loss.¹ Hearing loss has repeatedly been demonstrated to affect their academic, behavioral and cognitive development as well as overall quality of life in children.^{2,3} It causes poor overall physical functioning and social interactions. Overall quality of life is decrease.⁴ The most common form of hearing loss

worldwide is sensorineural hearing loss (SNHL).⁵ SNHL is a heterogenous disorder, which can arise due to damage to pathway for sound impulses from the hair cells of inner ear to auditory nerve.⁶ The treatment for SNHL has been proven challenging. A number of treatments have been reported, such as vasoactive substances, hyperbaric oxygen, antivirals and vitamins.^{7,8} Each approach has, however, been debated with no standard protocol universally accepted until the introduction of steroid therapy. Administration of steroids, systemically or intratympanically, alone or in combination, is

considered to be the mainstay of treatment for SSNHL.^{9,10} The use of intratympanic steroid injections for inner ear disorders was described in the mid-1990s for use in patients with Menier's disease, autoimmune inner ear disease and sudden sensorineural deafness.¹¹ The most common treatment of SSNHL is oral corticosteroids. Although no clear side effects of steroids used in SSNHL was reported in cochrane review, the side effects of long term use of systemic steroids include fluid and electrolyte abnormalities, hypertension, hyperglycemia, increased susceptibility to infection, osteoporosis, myopathy, behavioral disturbances, cataracts, growth arrest, fat redistribution, striae and ecchymosis.¹³ Minimal systemic absorption of intratympanic steroids has been reported and the risk of systemic side effects is minimized.¹⁴ Studies have shown that cochlear perilymph concentrations are on the order of 100 fold higher with intratympanic administration of steroids vs. IV or oral. Platelet-rich plasma (PRP) is an autologous concentration of human platelet to supra-physiologic levels. Platelets are non-nucleated cytoplasmic bodies with irregular shape derived from fragmentation of megakaryocyte precursors. They circulate in the blood of mammals expressing glycoproteins on their cell membranes and play a pivotal role in hemostasis and wound healing via the formation of fibrin clots.^{15,16} At baseline levels, platelets function as a natural reservoir for growth factors including platelet-derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor-beta (TGF-B1), Vascular endothelial growth factor (VEGF), basic fibroblast growth factor (FGF), hepatocyte growth factor (HGF), and insulin like growth factor (IGF-1). The alpha granules of activated platelets release this growth factors and are involved in important cellular processes including mitogenesis, chemotaxis, differentiation, and metabolism.¹⁷⁻²¹ PRP injection is a new technique which is on the path of trial. This study is to evaluate and compare the effect of intratympanic instillation of PRP in patients having sensorineural hearing loss with steroid therapy.

METHODS

Study type, place and location

Current study is a prospective observational study conducted at department of ENT, NSCB medical college Jabalpur from 1 March, 2020 to 31 August 2021.

Selection criteria

The cases were selected from in and out patients of the department, who presents with sensorineural hearing loss and mixed hearing loss with intact TM. Total of 54 cases were enrolled in the study.

Procedure

The patients undergone a thorough history taking and clinical examination, the findings of which were recorded

in a structured proforma. Preoperative PTA was done and recorded. 0.5 ml of intratympanic platelet rich plasma was injected in the selected patients. 0.5 ml of Intratympanic administration of steroid dexamethasone done. These patients were followed up after the procedure. Post-operative PTA was done after 15 days of intratympanic injection and results recorded.

Statistical analysis

The data of the present study recorded into the computer and after its proper validation, coding & decoding compiled and analysed with the help of SPSS 20 software for windows. Appropriate univariate and bivariate analysis and the descriptive statistics was carried out. Other statistical tests such as Student's t-test for continuous data and Fishers Exact Test or χ^2 test for categorical data will also be applied if the necessity felt to support the hypothesis if the necessity felt to support the hypothesis. Sensitivity, specificity positive predictive and negative predictive value will also be measured. All means are expressed as mean \pm standard deviation and the proportion as in percentage (%). The critical value for the significance of the results will be considered at 0.05 level.

RESULTS

In current study, the mean age of the participants was 40.41 \pm 13.21. Out of 54 patients, 4 (7.4%) patients in the age group of less than 20, 11 (20.4%) patients in the age group of 20-30, 14 (25.9%) patients in the age group of 30-40, 12 (22.2%) patients in the age group of 40-50, 9 (16.7%) patients in the age group of 50-60, and 4 (7.4%) patients in the age group of more than 60.

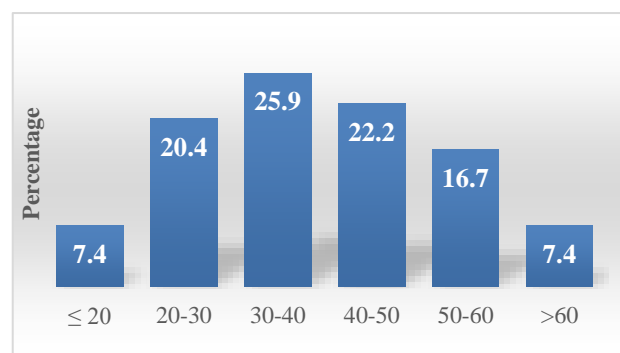


Figure 1: Age distribution of study participants.

In current study 46 (85.2%) had Gradual hearing loss and 8 (14.8%) had sudden hearing loss. Out of 54 participants, 5 (9.3%) patients have etiology, 8 (14.8%) patients have tinnitus, 1 (1.9%) patient have vertigo and 1 (1.9%) patient have significant past history. Out 54 participants, 23 (42.6%) patients received platelet rich plasma and 31 (57.4%) received DEXA. The table shows the comparison of PTA value between pre-operative and post-operative of both PRP group and Dexa group. The table reveals that mean baseline PTA value was higher in

PRP treatment 56.80 ± 15.88 compared to DEXA 39.51 ± 15.14 , it is statistically significant ($p < 0.001$). The post op mean PTA value was 47.31 ± 15.40 in PRP group and it was 38.27 ± 14.91 in DEXA group and the difference is statistically significant ($p = 0.039$).

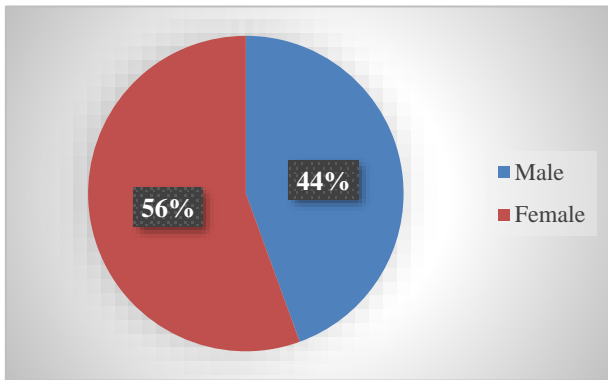


Figure 2: Sex distribution of study participants.

Table 1: Distribution of duration of hearing loss in months.

Duration in months	N	%
0-6	26	48.1
6-12	23	42.6
>12	5	9.3
Total	54	100.0

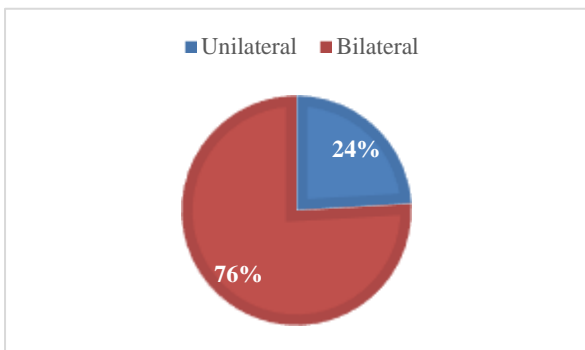


Figure 3: Distribution of unilateral and bilateral hearing loss.

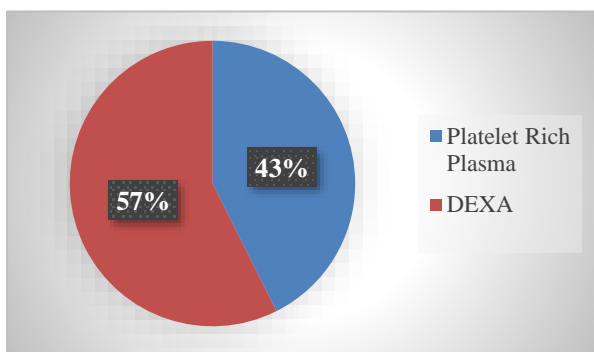


Figure 4: Distribution of treatment.

The improvement from baseline to follow up period was higher in PRP group 10.21 ± 10.45 compared to DEXA group 1.24 ± 1.34 . It is statistically significant ($p = 0.001$). The correlation between improvement of post procedure hearing outcome with Age, Sex, duration of hearing loss, Hb, TLC and PLT were analysed. Only age is correlated with improvement in hearing loss. There is significant moderate negative correlation between age and improvement of hearing loss ($r = -0.301$, $p = 0.030$). It indicates that the improvement in hearing loss is decreasing with the increase in age. There is no correlation between onset of treatment and duration of hearing loss.

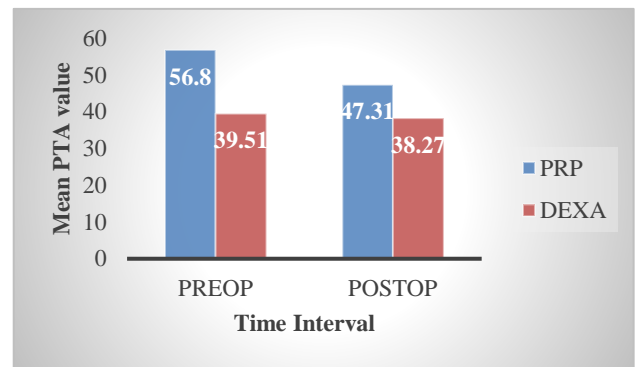


Figure 5: Comparison of PTA value between PRP and DEXA groups.

DISCUSSION

Sensorineural hearing loss is a major cause of hearing loss in adults. It results from damage to the hair cells within the inner ear, vestibulocochlear nerve or the brain's central processing centers. Steroids in moderate doses have become the most widely accepted treatment option for idiopathic sudden SNHL. Wilson and associates performed a double-blind randomized trial of steroids versus placebo for idiopathic sudden SNHL.²² Their active drug group was treated with either a 10- or 12-day course of orally administered dexamethasone or methyl-prednisolone at tapering doses. They found that all patients with midfrequency losses had a complete recovery regardless of treatment. They noted that among patients with losses greater than 90 dB HL at all frequencies, no difference in recovery was reported between the steroid versus placebo groups. Among the remaining patients, a significant increase in recovery was reported in the steroid group. Of patients in the steroid-treated group, 78% experienced complete or partial recovery compared with 38% in the placebo-treated group.

In a similar study, Moskowitz and colleagues confirmed a significantly improved recovery rate in a steroid-treated group compared with a nontreated control group.²³ Direct steroid treatment to the inner ear via middle ear instillation or round window microcatheter has seen increasing use on an empiric basis.

Table 2: Comparison of PTA value between PRP and DEXA.

Treatment	N	PTA		Mean difference	t value	P value
		Mean	SD			
Pre-operative						
PRP	23	56.80	15.88	17.29	4.07	<0.001
DEXA	31	39.51	15.14			
Post-operative						
PRP	21	47.31	15.40	9.04	2.12	0.039
DEXA	31	38.27	14.91			
Improvement from pre-operative to post-operative (Mann Whitney U Value)						
PRP	21	10.21	10.45	8.97	74.50	<0.001
DEXA	31	1.24	1.34			

This treatment has the potential advantage of very high steroid concentrations within the inner ear without the associated systemic side effects. Anecdotal reports indicate that this treatment may be more effective than orally administered steroids and that local complications are infrequent. A single randomised, placebo controlled, triple blind study comparing intratympanic steroids to a placebo therapy was found.²⁴ It consisted of 50 patients with moderate unilateral ISSHL. 25 received intratympanic prednisolone once a day for 3 consecutive days. The control group consisted of the other 25 patients. They received saline injections for 3 consecutive days. Another approach to SNHL was primary intratympanic steroid treatment with or without systemic steroids versus systemic steroid treatment alone. A study was conducted in Turkey in 2013 in which 79 patients compared oral steroid therapy vs. 4 intratympanic injections of methylprednisolone plus oral steroid therapy.²⁵ They had an improvement of 44 dB in the intratympanic plus oral group pure tone average vs. a 26 dB improvement in the group with oral steroids only. The results were statistically the same for patients with an initial pure tone average of less than 70. The study concluded that the combination therapy, oral plus intratympanic steroids, can be used as a primary treatment of ISSHL. Another study with 158 patients out of Turkey compared systemic steroids alone vs systemic steroids in combination with intratympanic methylprednisolone was analysed.²⁶ It showed an improvement of 13 dB in the systemic steroid only group compared to 20 dB in the combination group. This was statistically significant and this group similarly recommended combination therapy as a primary treatment for ISSHL.

The release of bioactive molecules stored in alpha granules of platelets after its activation with the activating factor causes the potential effects of PRP.^{27,28} Platelet-derived growth factor (PDGF), transforming growth factor (TGF- β), epidermal growth factor (EGF), insulin-like growth factor (IGF-1), hepatocyte growth factor (HGF), basic fibroblasts growth factor (FGF) and vascular endothelial growth factor (VEGF) are some of the key proteins associated with the acceleration of

healing process.²⁷ The elements found in platelet granules act under normal physiological conditions on local cells to promote wound healing. On the other hand, plasma activation also promotes the polymerization of fibrinogen into a three-dimensional fibrin scaffold and it keeps the bioactive mediators trapped through fibrin heparin sulfate binding domains.²⁸ This biocompatible and biodegradable scaffold are responsible for cell proliferation, differentiation, migration and correct orientation in the nascent tissue.²⁹ A gradual, sustained release of GF and other biomolecules occurs when fibrinolysis begins. Thus, this technology provides a fibrin scaffold as a controlled drug delivery system of GF suitable for regenerative medicine.³⁰ A small volume of venous blood is withdrawn in tubes containing anticoagulant. These are centrifuged so that it can be separated into the blood components. The plasma fraction just above the red blood cells is collected.

Thrombin or calcium is added to activate PRP to promote platelet degranulation and exocytosis of GF. This liquid formulation is administered as PRP injections. As PRP is autologous in nature and relatively noninvasive collection technique, the risks of injection or immune rejection associated with PRP are less. Thus, this strategy has been employed as a biological adjuvant in peripheral nerve injuries and neuropathies.³¹ The PRP bioactive proteins initiate and control the healing of nerve fibers. Increasing the concentration of TGF- β , PDGF and IGF-1 could accelerate healing of the regenerating nerve fibers.³² Studies conducted in rabbits after implantation of PRP together with Schwann cells reported beneficial effects on axonal counts, myelination and electrophysiological parameters.³³ Cho et al. observed considerably increased expression of neurotrophic factors such as BDNF, NGF, FGF and Glial cell-derived neurotrophic factor (GDNF) after PRP injection in guinea pigs with facial nerve transection. It means PRP and MSCs act as a source of neurotrophic factors. They also could prove an enhancement of axon counts and myelination in the groups treated with PRP.³⁴ In the study conducted in Ghaziabad, Out of 200 patients with injection PRP intratympanic, 172 patients were having improvement in hearing after 5 times of repeated injections and 28 patients didn't show any improvement in hearing.⁶ In this

study we compared improvement in hearing outcomes in terms of PTA in patients with sensorineural hearing loss after intratympanic administration of platelet rich plasma and dexamethasone. In our study the mean age of the participants was 40.4 years. Out of 54 participants, 24 (44.4%) were male and 30 (55.6%) were female. In our study the incidence of SNHL is more in females. In this study, 48.1% patients had duration of hearing loss 0-6 months and 42.6 % had 6-12 months and 9.3% had more than 12 months. Most of the patients had hearing loss of 0-6 months. 75.9% patients had Bilateral hearing loss and 24.1% had Unilateral hearing loss. 85.2% had Gradual hearing loss and 14.8% had Sudden hearing loss. Bilateral and gradual hearing loss were common in the present study. Out of 54 participants, 5 (9.3%) patients have history of trauma, 8 (14.8%) patients have Tinnitus, 1 (1.9%) patient have Vertigo. There was no significant risk factor found in this study. Out of 54 participants, 23 patients received Platelet Rich Plasma and 31 received DEXA. The mean baseline PTA value was higher in PRP treatment group compared to DEXA, it was statistically significant ($p < 0.001$). The post op mean PTA value was 47.31 in PRP group and it was 38.27 in DEXA group and the difference is statistically significant ($p = 0.039$). The improvement from baseline to follow up period was higher in PRP group compared to DEXA group It is statistically significant ($p = 0.001$). Hence in my study single dose of intratympanic PRP administration is superior to single dose of dexamethasone administration. The hearing improvement with PRP is 8 times better than Dexamethasone. Only age is correlated with improvement in hearing loss. There is significant moderate negative correlation between age and improvement of hearing loss ($r = -0.301$, $p = 0.030$). It indicates that the improvement in hearing loss is decreasing with the increase in age of the patient. There were no complications associated with PRP. Hearing improvement more in young than aged. There was no direct correlation established between nature of onset of hearing loss with hearing improvement. The study revealed that there is no correlation between onset of hearing loss and improvement in hearing after intratympanic injections. There is no statistically significant difference in improvement in males and females. In current study, we found that single dose of intratympanic PRP injection is having better results than dexamethasone in terms of hearing improvement. These findings are similar to that of the study of BBPS Tyagi and Rani.⁶ They concluded that platelet rich plasma is a better modality of treatment of SNHL. The role of PRP in SNHL is in the path of research. PRP is an autologous product and hence the risk of immune reaction is very low. It is easily available and low cost of production. PRP is rich in growth factors and helps in nerve regeneration. So PRP can be used as an effective treatment of SNHL.

Limitations

The limitations of study were small sample size. The causes of hearing loss were not evaluated in the study.

Hence the causal relationship with hearing improvement could not be studied. The study needs to be validated by conducting large multicenter trials in resource limited setting with long term follow-up.

CONCLUSION

Sensorineural hearing loss is a type of hearing loss due to pathology in the inner ear or the auditory nerve. There a lot of trials have been conducted regarding improvement of SNHL. Steroids play a major role in the treatment of SNHL until now. The role of Platelet rich plasma is being studied in every field. As it is an autologous product, there is minimal risk of immune rejection. Hence it was tried as an treatment for SNHL. NGF, BDNF and PDGF are some of the components in PRP that can improve nerve regeneration. The study concluded that the hearing improvement was more with single injection of PRP than dexamethasone. There were no complications associated with PRP. Hearing improvement more in young than aged. There was no direct correlation established between nature of onset of hearing loss with hearing improvement. PRP can be used as an effective mode of treatment for SNHL.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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