Original Research Paper

Volume - 13 | Issue - 03 | March - 2023 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

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COMBINED INTRATYMPANIC AND SYSTEMIC STEROID FOR THE TREATMENT OF IDIOPATHIC SUDDEN SENSORINEURAL HEARING LOSS- A COMPARATIVE STUDY

Dr Kanishka Chowdhury* Assistant Professor, Department of ENT, N.R.S Medical College, Kolkata, West Bengal, India.*Corresponding Author

Dr. Anirban Ghosh Consultant ENT surgeon, Hope Nursing Home, Raniganj, West Bengal, India

Dr. Sutirtha Saha 3rd Year ENT Resident, Department of ENT, N.R.S Medical College, Kolkata, West Bengal, India.

Dr Sudipta Pal Consultant ENT surgeon, Sushrut Nursing Home, Kalayani, West Bengal, India

ABSTRACT **Objectives-** Idiopathic Sudden Sensorineural Hearing Loss (SSNHL) is a medical emergency where hearing preservation is possible in 40-70% of cases. A novel technique of combined intratympanic and systemic steroid for SSNHL is described in this case series. **Methods-** 41 cases of SSNHL has been divided into two groups- one received combined intratympanic steroid (ITS) along with oral steroid in tapered doses and another group received only systemic steroid. Pre and post treatment audiometry were documented. **Results-** Combined intratympanic and systemic steroid group provides better hearing outcome than systemic steroid alone (76.1% vs 45%), 38 % patients in this group reached normal hearing (less than 20dB). **Conclusion**- Combined intratympanic and systemic steroid is a novel effective first line treatment option in cases of idiopathic SSNHL if medically not contraindicated.

KEYWORDS : Sudden sensorineural hearing loss, intratympanic steroid, combined intratympanic and oral steroid

Introduction:

Sudden sensory-neural hearing loss (SSNHL) is defined as decrease of 30dB or more in Air Conduction threshold in 3 or more consecutive frequencies in less than 3 days. Only 5-10% cases have identifiable causes; all other cases are Idiopathic SSNHL. Different causes have been postulated for Idiopathic SSNHL including viral, vascular, immunologic, viral cause being most likely. Treatment options include steroid, Hyperbaric O2, antiviral drugs. New drug delivery by intratympanic steroid (ITS) injection has been used in salvage therapy or where systemic steroid is contraindicated. Combined ITS with oral tapering steroid can be tried as initial therapy for Idiopathic SSNHL. This prospective randomized control trial was carried out to compare combined ITS and oral steroid therapy with oral steroid therapy alone for treatment of Idiopathic SSNHL.

Material and method:

Patients attending with sudden sensorineural hearing loss for less than 2 weeks were included in this study. Patients with contraindication for systemic steroid therapy eg, diabetes, hypertension, asthma, cataract were excluded from the study. Each patient underwent detailed otorhinological examination with Pure tone audiometry (PTA) and speech audiometry with Speech Reception Threshold (SRT) and Speech Discrimination Score (SDS). Routine blood examination and screening MRI brain were done. Then they are divided into two groups randomly. Group A containing 21 patients received intratympanic dexamethasone 0.5ml on first day, third day and seventh day; along with oral Prednisolone (1mg/kg body weight maximum 60md/day) for 10 days then taper by 10 mg for 3 days. Group B consisting 20 patients, received only oral Prednisolone 1 mg/kg/day for 10 days then taper by 10 mg per 3 days. Post treatment PTA and SDS, SRT done at 1 month after the completion of the treatment. Pre and post treatment audiometry were plotted and statistical significance was calculated. Statistical analysis was done by SPSS software (version 17) (IBM, USA).

Results:

Total 41 patients were included in the study. Mean age of the patients was 41.97 (range 67-23), male: female ratio was 4.15:1. Pre-treatment average PTA in group A was 81.79dB (85±12.7), post-treatment average PTA 32.62dB (25.6±11.3), Pre-treatment average PTA in group B was 83.9dB (84.85±9.09), post-treatment average PTA 37.79 (33.55±12.44). According to the guidelines drawn by American Association of Otolaryngologists and Head- Neck Surgery (AAOHNS) complete recovery (CR) was defined by pure tone average within 10 dB of pre-treatment audiogram level as seen in the opposite ear. If follow-up PTA is improved to within 50% of pre-treatment hearing level, it is called partial recovery (PR). No recovery (NR) was defined as less than 10 dB improvement of pre-treatment hearing threshold (1). It was also noticed that subjective feeling of better hearing was noticed only when air conduction threshold is within 30dB or within 15dB of contralateral ear. Associated symptoms like vertigo, nausea, tinnitus, aural fullness was also noted. In group A (combined therapy) 16/21(76.1%) patients showed complete response, 2/21 (9.5%) patients showed no response, rest of patients had partial recovery. In group B (only oral steroid group) 9/20 (45%) patients had complete response, 3/20 (15%) showed no recovery and rest 8/20 (40%) patients showed partial recovery. One interesting fact was in group A (combined therapy) 8/21(38%) patients showed normal post treatment hearing after combined intratympanic and oral steroid therapy, whereas none showed normal (i.e. less than 20dB hearing) post treatment hearing in group B (oral steroid group) (Table 1).

Table 1: Master Chart of patients on Combined Intratympanic steroid (ICS) + oral steroid (Group A)

Serial no.	Age	Sex	Side	Associated symptoms	Pretreatment ACT	Post-treatment ACT	Response-CR/PR/NR	% of improvement
1	43	M	R	Vertigo, Tinnitus	75dB	20db	CR	73.33
2	46	M	R	Vertigo	90dB	88dB	NR	2.22
3	30	M	L	Aural fullness	85dB	11.6dB	CR	86.35
4	26	M	L	Vertigo	95dB	25.6 dB	CR	73.05
5	51	F	L		100dB	20dB	CR	80
6	26	F	L	Tinnitus	70dB	13.3 dB	CR	81
7	31	M	R		90dB	28.3 dB	CR	68.56
8	31	M	L	Tinnitus	63.3dB	11.6dB	CR	81.67
9	38	M	R	Tinnitus	88.6dB	38.8dB	CR	56.2
10	38	M	L	Vertigo	90dB	35dB	CR	61.11
11	43	M	R	Vertigo	100 dB	38 dB	CR	62
12	60	F	R	Tinnitus	103 dB	39.8 dB	PR	61.36
13	40	M		Vertigo	71dB	28dB	CR	60.56
14	38	F	L	Aural fullness	74dB	15.6 dB	CR	78.92
15	34	M	R	Vertigo	88 dB	24.6 dB	CR	72.05
16	48	M	R	Tinnitus, vertigo	65.5 dB	11.3 dB	CR	82.75
17	47	M	R		87.9 dB	77 dB	NR	12.4
18	44	M	L	Vertigo	78.6 dB	28.6dB	PR	63.61

19	56	M	R	Aural fullness	58.6dB	13.8 dB	CR	76.45
20	43	M	R	Tinnitus	66.6 dB	54.8 dB	NR	17.72
21	49	M	L	Tinnitus	77.6 dB	11.8 dB	CR	73.33

ACT – Air Conduction Threshold, CR-Complete Response, PR-Partial Response, NR-No Response

In group A, 9/21 had vertigo, 8/21 had tinnitus, and 3/21 had aural fullness as associated symptoms. Among the patients of group A who had vertigo as associated symptoms, 6/9 (66.6%) had complete recovery, 2/9 (22.2%) had partial recovery and 1/9 (11.1%) showed no response. In group B, 10/20 had vertigo, 10/20 had tinnitus, and 2/20 had aural fullness as associated symptoms. Among the patients of group B who had vertigo as associated symptoms, 6/10 (60%) had complete recovery, 2/10(20%) had partial recovery and 2/10 (20%) showed no response (Table 2).

Table 2: Master chart of patients on Oral steroid only (Group B)

Serial no.	Age	Sex	Side	Ass symptoms	Pretreatment ACT	Post-treatment ACT	Response - CR/PR/NR	% of improvement
1	42	M	R	Tinnitus	82.6dB	50db	PR	39.47
2	56	M	R	Vertigo	92dB	38dB	CR	58.69
3	33	M	L	Tinnitus	85.8dB	41.6dB	PR	51.51
4	33	M	R	Tinnitus, Vertigo	95dB	25.6 dB	CR	73.05
5	23	F	R	Tinnitus	100dB	43.3dB	PR	56.7
6	29	F	L	Tinnitus	74dB	23.3 dB	CR	68.51
7	38	M	R	Vertigo	90.8dB	38.3 dB	CR	57.82
8	37	M	L	Tinnitus	73.3dB	31.6dB	PR	56.89
9	34	M	R	Vertigo	87.6dB	68.8dB	NR	21.46
10	44	M	L	Tinnitus	96dB	45dB	PR	53.12
11	43	M	R	Vertigo	95.5 dB	28 dB	CR	70.68
12	66	F	R	Tinnitus	87.6dB	29.8 dB	CR	65.98
13	46	M	L	Vertigo, aural fullness	71.8dB	22.8 dB	CR	68.24
14	48	F	R	Aural fullness	72.2dB	25.6 dB	CR	64.54
15	54	M	R	Vertigo	80.6 dB	28.6 dB	CR	64.52
16	38	M	L	Tinnitus, vertigo	75.5 dB	33.3 dB	PR	55.89
17	67	M	R		83.9 dB	57 dB	NR	32.06
18	34	M	R	Vertigo	68.6 dB	32.6dB	PR	52.48
19	46	M	L	Tinnitus	78.6dB	33.8 dB	PR	57
20	48	M	R		86.6 dB	58.8 dB	NR	32.1

ACT – Air Conduction Threshold, CR-Complete Response, PR-Partial Response, NR-No Response

On statistical analysis, mean hearing improvement in Group A was 62.5655 with a standard deviation of 24.07513 and standard error of mean being 5.38336. For Group B, mean came as 56.0355 with a Standard Deviation of 13.96106 and standard error of 3.12179. Tests for significance was done using Paired Samples T test which showed a p value of 0.145 that is the difference in outcomes in the two groups was not statistically significant. However, the point to be noted here is that this study was made with a relatively small sample size and the percentage of patients having complete recovery after combined therapy [Group A] is much greater than that of the patients of Group B in absolute terms. Moreover 8 patients of Group A had normal hearing after completion of treatment whereas none of the patients in Group B had normal hearing post treatment.

DISCUSSION:

Sudden Sensorineural Hearing Loss (SSNHL) is a medical emergency. There is sudden 30 dB or more decrease in air conduction threshold in three or more consecutive frequencies in a very short period of time (72 hrs.)[1]. Mostly SSNHL are idiopathic, only 5-10% will have identifiable causes. Regarding Idiopathic SSNHL, different theories of causation have been postulated. Various viruses like EBV, Herpes family, Influenza B, Mumps, Rubella, CMV have been proposed as increased seroconversion for these viruses have been found[2]. Butt evidence is conflicting as in some studies fail to show higher titre of seroconversion or higher incidence of SSNHL in Herpes patients[3]. Though temporal bone studies in patients with Idiopathic SSNHL showed greater loss of neurons in apical spiral ganglion compared to basal region without corresponding loss of hair cells and dendrites. This evidence again establishes viral aetiology as other causes like presbyacusis, noise induced hearing loss, acoustic trauma, hypoxia cause more injury to the basal spiral ganglion[3,4]. Other causes include vascular, autoimmune, Meniere's disease and intra-cochlear membrane rupture. End-Artery of Cochlea, increased viscosity leading to cochlear ischaemia leading to vascular cause, though evidences are contradictory[5]. Immunological theory postulates that IgG is found in Perilymph and Endolymphatic Sac is likely site for immune processing and SSNHL is also seen in Immunological disorders like Wegener's' Granulomatosis, Sjogren's Syndrome, Rheumatoid Arthritis, etc.

Diagnosis is simple and based on Pure Tone Audiometry and Speech Audiometry. Contrast enhanced MRI Brain with special emphasis on the Cerebello-Pontine Angle should be done to rule out Acoustic Neuroma as 10-12% of Acoustic Neuroma patients present with SSNHL. Other investigations like CBC, VDRL, Serology for Lyme's Disease, electrolytes, lipid profile, Auto-Antibodies (ANA, anti-cardiolipin Antibody, Lupus Anticoagulant, ANCA) etc. done to identify the cause.

Though 28-50% patients recover spontaneously, some poor prognostic factors have been identified; they are – time between start of treatment and the onset of SSNHL, Age >60 years, Profound SNHL or Right sloping Curve in Audiogram and Presence of Vertigo along with Deafness.

Different treatment options like Steroids, volume expanders, anti-virals have been tried. Steroids act by their anti-Inflammatory, membrane stabilizing and ion balancing action, though exact mechanism is not known. Gluco-corticoid and Mineralocorticoid receptors are present in the inner ear[6]. In this way they can modulate gene expression, mediate vasculitis by inhibiting cytokine secretion[2].

Aquaporins (AQP) is seen in the inner ear and is important in water and ion balance maintenance in inner ear[7]. Thus, IT Steroid will modulate the inner ear environment via AQP pathway to restore Stria Vascularis morphology & restoring ion balance[7].

Though Cinamon et at[8], Nosati-Zarence et al[9] failed to show any significant benefit of steroid therapy in case of SSNHL. Whereas other studies[10, 11, 12, 13, 14] showed early cortico-steroid therapy within first 2 weeks is associated with greatest hearing outcome with minimal benefit after 4-6 weeks. Dosing of systemic Prednisolone is based on the fact that maximum adrenal output of cortisol is 200-300 mg/day and Prednisolone is 4 times more powerful than cortisol. So, dosing will be 1mg/kg/day (maximum daily dose 60 mg for 10-14 days). With the advent of newer drug delivery techniques, ITS therapy now plays an important role. ITS has 2 major advantages, namely fewer side effects as labyrinth- blood barrier does not allow drugs to enter systemic circulation and higher steroid concentration in inner ear.

One large series consisting of 250patients in 16 centers showed that ITS & oral steroids have similar effect on hearing if promptly (within 2 weeks) administered and equivalently dosed[15]. Filipo et at[16] investigated IT steroid as sole therapy and found improvement in hearing in 31 out of 34 patients. Battaglia also supported this view where 14 out of 16 patients showed complete/partial hearing recovery in combination therapy of IT & Oral steroids[17]. Three randomized Controlled Trials[18, 19, 20] have failed to demonstrate any significant benefit by adding IT'S to oral steroid, however, there is trend towards greater improvements with combination therapy. Lim et al[21] in their study found similar efficacy of oral steroid, ITS and ITS+ oral steroid groups.

The results of different studies comparing ITS, Oral Steroid and combination therapy of ITS & oral steroid for ISSNHL is conflicting. In view of these reports, we undertook this prospective study to compare oral steroid therapy alone with combined IT & Oral steroid therapy in cases of Idiopathic SSNHL. In this study, patients who presented with Idiopathic SSNHL within 2 weeks of onset were included to abolish this important confounding factor (duration between onset of disease to starting of treatment).

In this prospective randomized study, we found that combined intratympanic and oral steroid therapy is better than only oral steroid therapy as in combined therapy 76.1 % patients had complete recovery and 14.4% had partial recovery. Whereas in oral steroid group 45% had complete recovery and 40% had partial recovery. One interesting fact that was found in this study that 38 % of Combined therapy patients reached normal (less than 20dB) hearing after treatment. Another interesting fact was that 84.4% of patients with vertigo as associated symptoms showed favorable outcome (complete and partial recovery). Thus, from this study, we did not find vertigo as a poor prognostic factor in regard to hearing outcome.

CONCLUSION:

In this prospective randomized study, we found that statistically there was no significant difference in outcomes between the two groups of patients. However, the tests of significance consider only the mean hearing improvements between the two groups. But the present study clearly demonstrated that combined intratympanic and oral steroid therapy is better than oral steroid therapy as more patients had complete and partial recovery after combined therapy when absolute number of patients was considered. More number of patients achieved normal or near normal hearing after combined therapy. We recommend a larger Randomized Controlled Trial comparing these two treatment protocols along with the use of combined intratympanic and oral steroid therapy for Idiopathic SSNHL patients as a primary treatment option if not medically contraindicated.

Conflict of Interest - None

Financial Disclosure – This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Ethical Standards - The authors assert that all procedures contributing to this work comply with the ethical standards of the institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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