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Intratympanic steroids versus oral steroids in idiopathic sudden sensorineural hearing loss, hospital-based study

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ABSTRACT

Introduction: Idiopathic sudden sensorineural hearing loss (ISSHL) is defined as a hearing loss of 30 dB or more, affecting at least 3 consecutive frequencies, occurring within 3 days without any identifiable cause. To find the effectiveness of intratympanic steroid injection (ITS) for hearing recovery and comparing the results with oral steroids therapy.

Methods: This prospective study was done in the department of ENT, Govt medical college, Srinagar, over a period of two years. A total 60 patients of ISSHL was selected for the study. Through examination, otoscopy and pure tone audiometry (PTA) was done for all the cases before initiation of therapy. Thirty patients received and thirty patients received oral prednisolone for a protocol-based dose and duration. PTA was repeated every two weeks over duration of two months for documentation of improvement of hearing on pure tone four frequency averages.

Results: Chances of recovery were more with middle ear injection group in 18 patients (60%) in comparison to oral steroids in 14 patients (46.66%). Complete recovery was found in six cases (20%) in injection group and four cases (13.33%) in oral steroid group. The ITS group showed a better control of associated symptoms like dizziness, tinnitus and vertigo are controlled better with ITS (73.33%) than oral steroid group (56.66%). The ITS group showed faster recovery also with lower side effects.

Conclusion: Intratympanic dexamethasone injection is more effective in comparison to oral prednisolone for the management of ISSHL, however larger studies may be required.

Keywords: ISSHL, Intra tympanic steroids, Pure tune audiogram

INTRODUCTION

Nearly 60 years after the first report of idiopathic sudden sensorineural hearing loss (ISSHL), otologists are still looking for answers to the aetiology, physiopathology and therapeutic management of this disorder. Idiopathic sudden sensorineural hearing loss (ISSHL) is a clinical diagnosis characterized by a sudden deafness of cochlear or retro-cochlear origin, in the absence of a clear precipitating cause. The most common theories of the aetiology of ISSHL include viral infection, vascular disturbances, occlusion with microcirculatory immunologic diseases, and intralabyrinthine membrane breaks.2-6 ISSHL usually presents as an acute unilateral deafness of more than 30 dB hearing loss involving three

contiguous frequencies, with an abrupt onset, generally within three days or less.

Sudden sensorineural hearing loss affects 5 to 20 per 100,000 populations, with about 4000 new cases per year in the United States. 7.8 The management of this disorder poses a challenge. Normally, steroids are delivered systemically either orally or parenterally. Though the systemic delivery of medication promises a favourable outcome, it has several drawbacks, such as variable access to the inner ear due to the blood cochlea barrier and potential systemic side effects.

Several drugs with different dose and duration have been tried with unsatisfactory results. None of these

conventional management options have shown better result than placebo. So, there is a search and need for newer methods. Intratympanic steroid (ITS) injection is new in this field. Many advantages of this procedure explain the enthusiasm for ITS. It can be done under local anaesthesia at the office setting with relatively low cost, exerts its effect only at the affected ear, and bypasses systemic side effects of steroid. The technique is minimally invasive, easily to perform, and well tolerated by patients. Furthermore, through the animal study, it was proven that the peri lymphatic concentration of corticosteroid is much higher when the medications were administered through a trans tympanic route compared with systemic administration.^{9,10}

Aims and objectives

To find the effectiveness of intratympanic dexamethasone injection (IDI) for recovery of hearing and associated symptoms. Comparing the results with the patients using oral steroids therapy.

METHODS

This prospective study was done in the department of ENT, H&NS Govt medical college, Srinagar, over a period of two from January 2017 to December 2019 after ethical clearance from local ethical committee. Patients presenting with chief complain of sudden hearing loss in our outpatient department were thoroughly examined and enrolled for this study.

Inclusion criteria

The patients presenting with 30 dB or more hearing loss on three or more contiguous frequency developed within 72 hours were included in this study. The patients presenting within one month of initiation of symptoms were included. They were age 20 years or older.

Exclusion criteria

Infective changes in ear, any identifiable etiology, medically unfit candidate. Unwilling for injection in ear. The cases with delayed presentation i.e. after one month of initiation of symptoms were not included. Oncologic history with recent chemotherapy or radiation therapy, autoimmune diseases, congenital cochlear malformations, Meniere's disease, acute or subacute otitis media with abnormal tympanometry, neurological disorders, recent use of ototoxic medications, severe liver or renal dysfunction, pregnancy, recent trauma.

Out of 60 patients of ISSHL selected for the study, 30 patients consented for injection of steroids into middle ear and adhered to follow-up. Other 30 patients were shifted

to oral steroid group. Antivirals were not prescribed to any patient.

Table 1: Number of cases as per delay in presentation.

Groups	Delay in presentation	Number of cases	
1	0 to 7 days	17	
2	8 to 14 days	23	
3	15 to 21 days	11	
4	22 to 30 days	9	

Table 2: Incidence of associated symptoms (n=40).

S.no.	Associated Symptoms	Number of cases	
1.	Dizziness	9	
2.	Vertigo	5	
3.	Tinnitus	3	
4.	Combinations of above	23	

Through examination, otoscopy and pure tone audiometry was done for all the cases before initiation of therapy. Four contiguous frequency average of hearing threshold was noted on 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Any associated symptoms like tinnitus, dizziness and vertigo were noted also.

Initially, intratympanic dexamethasone injection was started on thirty patients. Dexamethasone injection preparation with 2 mg/ml was taken. 0.5 ml of this preparation was loaded in a 2.5 ml injection syringe. 24 gm intravenous cannula needle was fitted with the syringe. Ear canal was thoroughly cleaned, and 10% xylocaine sprayed on tympanic membrane for local anesthesia. The tympanic membrane was examined under microscope; the needle was inserted in middle ear through postero-inferior quadrant and dexamethasone injection given to fill the middle ear. Head was tilted to ipsilateral side immediately and the position was maintained for 15 minutes. Patient was asked not to swallow for that time. It helps for longer duration stay of injected steroids in the middle ear.

The intratympanic injection was repeated every 7th day and four injection given in this way. Repeat pure tone audiometry was done within seven days of second and fourth last injection. PTA was done every two weeks up to two months from the day of presentation. Four frequency hearing thresh hold average was noted for each patient again. Patient was thoroughly examined before each injection. Patients were monitored for associated symptoms i.e. tinnitus vertigo and dizziness. Exact date of subjective improvement of hearing loss and associated symptoms.

Table 3: Hearing outcome after treatment of ISSHL

Group	Total no of cases	Complete recovery	Partial recovery	No of cases no hearing improvement	Recovery of associated symptoms	Mean time for recovery
Middle ear injection	30	6	12	12	22 (73.33%)	21 days
Oral steroid	30	4	10	16	17 (56.66%)	45 days

Thirty (30) patients received oral prednisolone for a protocol-based dose and duration. Prednisolone tablet was given per oral 1 mg/kg body weight for first seven days. It was reduced by half strength weekly and continued for four weeks.

Pure tone audiometry was done on third and fifth week for this group also. Pure tone audiometry was repeated every two weeks up to two months for documentation of hearing improvement on pure tone four frequency averages.

RESULTS

This study was conducted on sixty cases of ISSHL, out of which, 30 patients received intratympanic injection and 30 patients received oral steroids. Their age ranges from 20 to 50 years. There was no sex predilection as male to female ratio is one.

The interval between the sudden hearing loss and start of treatment, which is a known variable to affect recovery, varied from days to months among the studies. Many studies reported better results when initial or salvage treatment was started within 2 weeks from the onset.

The cases were divided in four groups according to the delay in presentation i.e. first week, second week, third week and fourth week groups.

Hearing loss was associated with other symptoms like dizziness, tinnitus and vertigo in descending order of incidence seen in 40 patients. Only 20 cases presented with pure hearing loss without any associated symptoms. The ITS group showed a better control of associated symptoms like dizziness, tinnitus and vertigo are controlled better with ITS (73.33%) than oral steroid group (56.66%).

Chances of recovery were more with middle ear injection group in 18 patients (60%) in comparison to oral steroids in 14 patients (46.66%). Here improvement is defined as 20 dB improvement in PTA. Complete recovery was found in six cases (20%) in injection group and four cases (13.33%) in oral steroid group. Complete recovery is defined as pure tone average of 25 dB or better.

Morbidities

Intratympanic injection group showed fewer incidences of side effects. No complications were found in follow up. Tympanic membrane was thoroughly examined before

each injection under microscope. No perforation observed. Only few patients' complaint of dizziness after injection that persisted for five to ten minutes and did not required any extra medications. No antibiotics or analgesic were required also. But the 30% patients of oral steroid group complaint side effects of steroid like dyspepsia, hot sensation and rise of blood pressure, palpitation.

DISCUSSION

The effectiveness of steroids in the treatment of ISSHL remains unproven. Furthermore, the natural history of ISSHL is highly variable, probably because its pathogenesis is multi factorial. Because spontaneous improvement frequently occurs early after the onset of the hearing loss; the prognosis is worse if the symptoms persist longer. Therefore, prospective randomized controlled trials might be biased and prone to interpretive error, because not all patients can be seen at the same stage of the disease. Further bias could also result from a self-selection process, whereby those who recover quickly do not seek medical care.

Different authors have defined ISSHL differently. The definition given by Wilson et al is most widely accepted and we also followed it in our study. ¹¹ Kronenberg et al defined ISSHL as ≥20 dB sensorineural hearing impairment occurring abruptly or within seven days. ¹⁴

This is a very frightening disease as the patient suddenly feels handicapped and often associated with dizziness, tinnitus and vertigo. At present no monotherapy or combination therapy has shown proven cent percent recovery. So many drugs and treatment modalities are tried for this disease. Unfortunately, no one proved a better result than placebo 15 which showed 50% spontaneous recovery rate.

Agents used for the management of ISSHL includes steroids, vasoactive agents, vitamins and antioxidants, drugs to improve inner ear blood circulation, anti-viral drugs and others.

Dose frequency of ITS varies with different authors. Sugihara et al found no difference in outcome of hearing with dose frequency. ¹⁶ They have tried dose frequency every 1-4 days, 5-10 days and 11-30 days in different groups. We have used frequency of every 7 days.

The use of intratympanic steroids (ITS) by the otolaryngologist varies in different region. The current frequency of use is not clear. In a survey in Europe Sutton et al showed that it is being used by 49.1% otolaryngologist for the management of ISSHL. 17 20.6% use ITS along with oral steroids. We have used it as the monotherapy.

Evidence based medicine shown 50 % recovery by the oral steroids and placebo.¹⁵ In our study, we have found 46.66% recovery with oral steroids. But the ITS group showed 60% recovery in our study. The ITS group showed a better control of associated symptoms like dizziness, tinnitus and vertigo are controlled better with ITS (73.33%) than oral steroid group (56.66%). Mean time taken for recovery of hearing is 21 days 45 days with ITS and oral steroid group respectively.

CONCLUSION

Intratympanic dexamethasone injection is more effective in comparison to oral prednisolone for the management of ISSHL. In our initial study we have found a better result in respect of recovery rate, control of associated symptoms, side effects and mean time duration for recovery. It is an emerging therapy for the management of ISSHL.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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