



EFFECTIVENESS OF COMBINED INTRA-TYMPANIC STEROIDS AND SYSTEMIC STEROIDS IN THE MANAGEMENT OF IDIOPATHIC SUDDEN SENSORI NEURAL HEARING LOSS(ISSNHL)

ENT

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ABSTRACT

OBJECTIVE:To compare hearing results in Idiopathic sudden sensori neural hearing loss patients treated with systemic steroids alone or combined intra tympanic and systemic steroids.

STUDY DESIGN: Prospective

SETTING: Government Dharmapuri Medical College Hospital, Dharmapuri.

PATIENTS: In this study, 50 eligible patients with ISSNHL were allocated into 2 groups. Patients in the control group were treated with systemic prednisolone alone. Patients of the combined group received additionally 3 intra tympanic dexamethasone injection within 5 days.

MAIN OUTCOME MEASURES: The main outcome measures used were the differences between pretreatment and post treatment pure tone audiometry (PTA) averages. The assessment of hearing was performed on 5th, 10th and 15th days of treatment.

RESULTS: Significant hearing recovery was observed in 20(80%) of 25 combined treatment cases and in 16(64%) of 25 control patients.

CONCLUSION: The addition of intra tympanic steroids to the conventional systemic steroid therapy may provide a safe and potentially effective therapeutic option in patients with mild to severe ISSNHL.

KEYWORDS

Dexamethasone-ISSNHL-Intratympanic steroids-PTA-Prednisolone.

INTRODUCTION

ISSNHL is a rare ENT problem encountered and it is widely defined as a hearing loss of greater than 30 dB in at least 3 contiguous frequencies, occurring within 3 days(1). Profound hearing loss, vestibular symptoms, prolonged time from onset to treatment and down sloping audiogram are considered as negative prognostic variables(2). Currently systemic steroids are considered to be the most effective and commonly accepted treatment for ISSNHL. Their efficacy was initially established by Wilson et al(3). Nevertheless, the systemic administration of corticosteroids is associated with side effects and is contraindicated in certain pathological conditions(4). To address this problem, intratympanic steroid delivery treatment has been developed. This treatment reduces systemic steroid toxicity and offers significantly high drug levels to the inner ear. Because of these 2 key advantages of intra tympanic steroids, their popularity has increased.

Intratympanic steroids were first used as salvage therapy in refractory cases of ISSNHL. Their promising results have made some authors promote their use as first-line therapeutic option in patients with contraindication to systemic steroids(5). Additionally, intratympanic steroid administration has been applied as an adjunctive treatment given concomitantly with systemic steroids.

The main objective of the current study is to investigate whether intratympanic steroid injections in combination with systemic steroids give an additional advantage over standard therapy with systemic steroids alone in patients with ISSNHL.

MATERIALS AND METHODS:

The study was conducted at the Department of ENT, Government Dharmapuri Medical College hospital, Dharmapuri and the duration of study is from September 2015 to August 2017. Inclusion criteria for the study was an ISSNHL of unknown cause greater than 30 dB in 3 contiguous audiometric frequencies developing within 3 days. Patients with history, symptoms or findings of acoustic trauma or barotraumas, Menieres disease or other peripheral vertigo, tumours, autoimmune disease, coagulopathy or small vessel disease, syphilis, hypothyroidism, and ototoxic drug use were excluded from the study. Patients with a contraindication to use systemic steroids, such as uncontrolled diabetes mellitus and hypertension or cardiovascular disease, also were left out of the study.

Patients were allocated to 2 groups on a 1:1 basis, depending on the odd or even number of presentation. The control group received consecutive administration of 100 mg intravenous methylprednisolone in the first day, 80 mg/day oral prednisolone in 3 divided doses for the next 2 days, and continued with oral administration of steroids by tapering the dose 20 mg in every 2 days. The patients in the combined

treatment group received intratympanic injection of dexamethasone(4 mg/ml) on the first, third and fifth day in addition to the treatment given to the control group. Before the treatment is initiated all the patients underwent a thorough ENT and audiological evaluation.

After confirmation of an intact tympanic membrane, with the guidance of an otoendoscope with monitor control, patient in the supine position and the head turned to the healthy side, under endoscopic guidance, intra tympanic injections are given without any topical anaesthetic agent. Using an insulin syringe with a 25 gauge spinal needle, 0.4 to 0.6 ml of dexamethasone (4mg/ml) was instilled slowly through the posterior-inferior quadrant of the tympanic membrane. The patient was then asked to refrain from swallowing and remain still in the supine position for 20 minutes to create the optimal conditions for the solution to continuously fill the round window niche.

Hearing assessment of the patients was based on pure tone audiometry. Pure tone average was measured by taking the average of the threshold values at 0.5, 1, 2 and 4 kHz. Pure tone audiogram was performed before the beginning of the treatment and at 5th, 10th, and 15th days of treatment. The hearing results were classified as "failed"(hearing gain, <10dB) or "improved"(hearing gain, >10 dB)

RESULTS

Seventeen(68%) of the control group and fifteen(60%) of the combined group were male subjects. Eight(32%) of the control group and Ten(40%) of the combined group were female subjects. The sex distribution between groups was not statistically significant. (table 1)

Table1: Sex distribution

Gender	Control group	Combined group
Male	17	15
Female	8	10
Total	25	25

Table 2: Duration of symptoms before treatment.

	Control group	Combined group
1-7 DAYS	14	17
8-15 DAYS	5	6
16-23 DAYS	5	1
24-30 DAYS	1	1
TOTAL	25	25

The distribution of patients according to duration of their symptoms before treatment is shown in Table 2.

The baseline characteristics of patients are given in Table3. There were not any significant difference according to presence of tinnitus,vestibular symptoms and history of upper respiratory tract infection.

Table3: Baseline characteristics of patients.

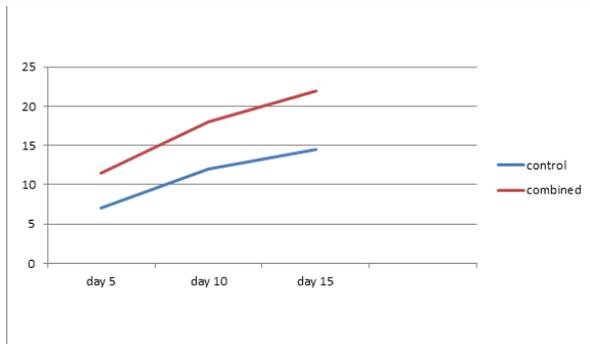
	Control group	Combined group
No of patients	25	25
Tinnitus positive	18	20
Vestibular symptoms present	10	19
URI	12	11

The mean PTA gains of the control group were 7dB at 5th day,12dB at 10th day,and 14.5 dB at 15th day .Whereas the mean PTA gains for the combined group were 11.5dB ,18db and 22dB respectively.The mean PTA gains were statistically significant.(table4,fig1)

Table 4:PTA gain

	Control group	Combined group
PTA gain,5 th day	7	11.5
PTA gain,10 th day	12	18
PTA gain,15 th day	14.5	22

According to improved hearing results(>10 dB gain)there were statistically significant difference between the control and combined group at 5th, 10th and 15th days(fig1)



DISCUSSION

Different modalities have been used for the treatment of ISSNHL, which include steroids, histamine, carbogen, heparin, antivirals, calcium channel blockers,triiodobenzoic acid derivatives, diuretics, piracetam, caroverine,magnesium sulphate etc(6,7,8).Currently systemic steroid therapy is the most commonly used modality for treatment of ISSNHL(9,10).The effect of steroids in treatment of ISSNHL is thought to originate from its anti-inflammatory activity and its ability to increase cochlear blood flow(11).Systemic steroids treatment is ideally begin within 7 days for better results(12).

Intratympanic steroid may be applied to the tympanic cavity by direct injection,by placing a round window pledget,or by pumping through a special sustained-release catheter(13,14).Intratympanic use of steroids have very important advantages, namely, the inner ear can be targeted directly,a higher concentration of steroids in the perilymph can be obtained(15) and the well known systemic side effects of steroids are prevented.The applied steroid uses the following routes to enter the inner ear:the round window membrane,annular ligament of the oval window, vasculature, and lymphatics(16).

The optimal corticosteroid for intratympanic therapy remains a matter of debate.Dexamethasone is the most common steroid applied followed by methylprednisolone In current study ,dexamethasone is used. The selection is based on a combination of facts and consideration. First,dexamethasone has a greater anti-inflammatory effect than methylprednisolone.Regarding the preparation of two therapeutic agents ,methylprednisolone solution usually prepared from a sterile powder immediately before giving it to the patient,

whereas dexamethasone is supplied as sterile pharmaceutically stable solution. Additionally, some patients do not tolerate the burning discomfort in ear or throat associated with methylprednisolone.Finally according to a pharmacokinetic animal study,intratympanically injected dexamethasone travels rapidly from middle ear to the inner ear, converts to its active form.(17)A similar study has not been performed for methylprednisolone.

CONCLUSION

The results of the present study suggest that intratympanic dexamethason in conjunction with systemic prednisalone provides good hearing improvement in significant cases of ISSNHL.

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