

A Study on Intra Tympanic Dexamethasone for Sudden Idiopathic Sensori Neural Hearing Loss

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Abstract

To evaluate intra tympanic injection of steroids as a primary mode of treatment in patients whom steroids are contra indicated and patients who presented after 7 days of onset of symptom. To compare the outcome between patients who received 3 weeks dose and 4 weeks dose of intra tympanic steroid injection. Role of intra tympanic steroid as salvage therapy for patients whom systemic steroids have failed.

Introduction

Idiopathic sudden sensory neural hearing loss (SNHL) is defined as a decline in hearing less than or equal to 3 days, affecting 3 or more frequencies by 30 dB or greater with no identifiable aetiology [1]. This kind of sudden idiopathic hearing loss is usually unilateral, sometimes the patient may also complain of other symptoms such as aural fullness, tinnitus.

This sudden idiopathic sensory neural hearing loss is a real medical emergency. The treatment of this entity is a subject of debate for many years. Also it is believed that, the patients from this idiopathic SNHL also recover spontaneously. There is no specific protocol proposed for this aetiology. Steroids, antiviral agents, anti-coagulants, anti-inflammatory drugs are all proposed to be of therapeutic importance in treatment of sudden SNHL [2, 3]. There are controversies regarding treatment of sudden idiopathic SNHL with oral steroids. There are also studies strongly supporting the use of oral steroids [4].

There is one more therapeutic approach for this SNHL. It is the use of intra tympanic steroid injection that will directly act in the inner ear with high concentration. There are several studies supporting the use of intra tympanic steroids as a method of treatment in SNHL. In this study intra tympanic injection of steroid was done in patients that presented to our department with either, (1) completion of oral steroid therapy with no improvement, (2) patients who were contra indicated for oral steroid therapy because of systemic disorders like Diabetes, (3) patients who presented after 7 days after the onset of hearing loss. This total population was classified into two groups, patients who had received steroid therapy and patients who present after 7 days after onset of symptom. In this second group they were randomly chosen for an intra-tympanic steroidal therapy for 3 weeks duration as well as 4 weeks duration and these results are studied.

Materials and Methods

The study was conducted in a tertiary care hospital. The study period was from august 2013- august 2015. Patients attending ENT outdoor with clinically suggestive sudden SNHL of unknown aetiology were taken into consideration. An ethical committee clearance was obtained. Informed consent was taken from each participant after they were explained about the procedure, prognosis. The outcome report was also consulted and then taken up for study. In 15 patients who did not respond to oral steroids, salvage therapy with intra tympanic injection was planned (study category 1). Patients who presented for the first time with SNHL after a time period of about 7 days and lesser than 120 days, as well as who were not fit for systemic steroids were taken into study category 2. In this category there were a total number

of 30 patients who were sampled randomly into two groups - Group 3 and group 4. Intra tympanic injection of 3 weeks duration was carried out in Group 3 and with group 4, therapy was given for 4 weeks.

Dexamethasone was selected for giving intra tympanic injection. On basis of patient` response and audiometric review the correct ear was selected for therapy. Lignocaine 4% was used for topical anaesthesia; the head is placed in position 45° toward the unaffected ear in supine position. The dexamethasone solution of 40mg/mL is checked and warmed to body temperature before injection. Before each procedure, the patient is counselled regarding the risks and expectations of the procedure and informed consent obtained. Approximately 0.3 to 0.5 mL of the solution is injected into the middle ear under microscopic guidance, after this procedure the head is turned toward the affected side and then back to the original position, so that maximum exposure is given over the round window membrane. This procedure is repeated in the same ear at one week interval for consecutive 3 weeks if the subjects were belonging to group 3, and 4 weeks if the subjects were belonging to group 4. In case of salvage therapy we gave intra tympanic injections once weekly for consecutive 4 weeks. Exclusion criteria from this group were those patients` incomplete records, inadequate follow up, or inadequate audiometric analysis, patients with fluctuating HL or Meniere disease. These exclusions left a total of 45 patients with idiopathic sudden SNHL who underwent intratympanic dexamethasone Injection. 15 belonged to salvage therapy, remaining 30 were divided to group 3 and group 4 as described earlier. In this study we made the criteria for improvement as, if the PTA readings after the course of treatment if found to be improved by 20 dB, then it was taken as significant improvement.

Results

Among the salvage therapy group, out of a total of 15 patients 9 patients were male and 6 were female. Among group 3, 2 patients were

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female and 13 patients were male. In group 4 6 patients were female and 9 patients were male (Chart 1).

In the salvage therapy group it was found that after a course of oral steroids there was no improvement in hearing, these patients were 15 in number among them 7 patients presented within 30 days of duration and remaining 8 patients after a time period of 30 days to less than 120 days. In this group who presented early hearing improvement was seen in 6 patients, and only one patient who presented greater than 30 days had hearing improvement. Thus nearly 90% of the population who had presented within a time period of 30 days there was 90% improvement in hearing. The average improvement in hearing was found to be 33 dB.

In respect to group 3, only 2 patients were female and 13 patients were male. In this group 12 patients presented within 30 days of duration and 3 patients presented at a later date 30 to 120 days. In this group less than 30 days 8 patient had improvement in hearing only 4 patients had no improvement. Among the patient who presented greater than 30 days, there was no improvement in hearing in any of the patient. The average hearing outcome in the group 3 was around 33.3 dB improvement (Chart 2).

In respect to group 4, 6 patients were female and 9 patients were male. They were given intra tympanic injection for 4 weeks duration. Among this group 11 patients presented less than 30 days duration and 4 patients presented with greater than 30 days of duration. Among these 11 patients 7 patients had statistically significant improvement, 4 patients had no improvement. Patients who presented after 30 days also had no significant improvement in hearing. The average hearing improvement in the study group was about 28.8dB.

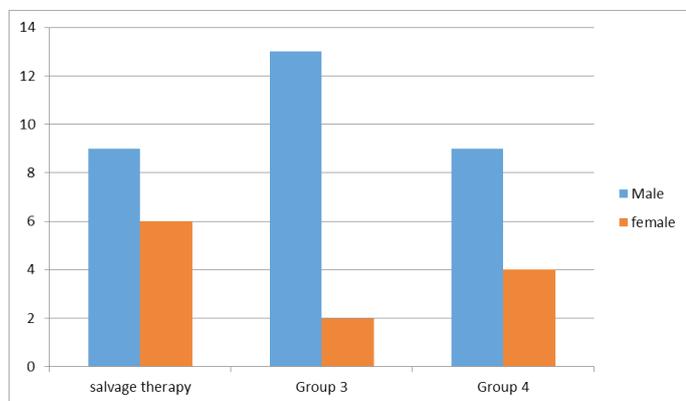


Chart 1: Sex distribution among three groups.

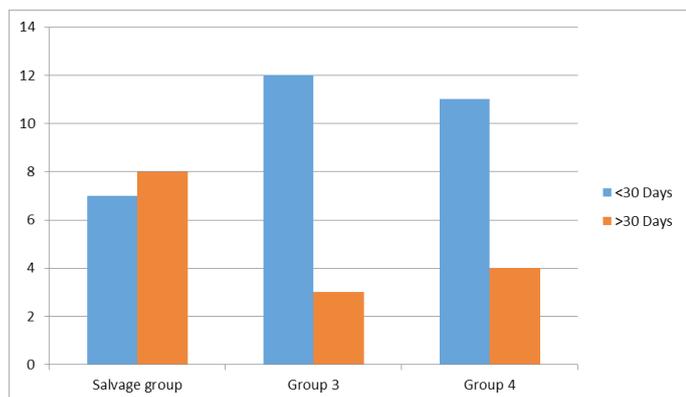


Chart 2: Distribution of study population according to Duration of Deafness.

On assessing chi square test, on comparing the patients of both group 3 and group 4, when patients are presenting at the earliest of less than 30 days duration, the improvement in hearing was found to be statistically significant, compared to late clinical presentation.

On comparing the outcomes between group 3 and group 4, there was no statistically significant difference is noted. Comparatively the hearing outcome average of group 3 was comparatively more compared to group 4.

On comparing the hearing outcome in the salvage therapy groups between patients presenting at an earlier dates with late presentation, results were found to be statistically significant.

Discussion

Itoh was the first to report on the use of intratympanic steroids for inner ear disease when he treated patients for Meniere disease in 1991 [5]. The first report on the use of intratympanic steroids for sudden SNHL was by Silverstein in 1996 [6]. There are various advantages of intra tympanic steroid administration. Advantages are it is an Office-based procedure, we can Easily administer, Relatively painless, Use in patients in which systemic steroids may be, contraindicated (example: immunocompromised patients, HIV, tuberculosis, diabetes), Ability to direct therapy to the affected ear, A high concentration of medication can be delivered directly to the (affected) ear, Side effects/complications are uncommon [7]. All these advantages make intra tympanic injection safer and comparatively give a better outcome. Intra tympanic steroid injection use in SNHL is mainly used as three conditions as follows,

As an initial or primary treatment for sudden SNHL without systemic steroids; as adjunctive treatment given concomitantly with systemic steroids for sudden SNHL; as “salvage therapy” after failure of systemic steroids for sudden SNHL [8].

In this study we have tried to add one more condition like when the patient is presenting to the opd after 7 days of onset of symptom instead of oral steroids we prefer using intra tympanic steroids. 30 patients were selected in this study and these patients were divided into 2 more groups as group 3 and group 4 [9]. Group 3 one injection was given a week for a consecutive 3 weeks and in group 4 one injection per week was given consecutively for 4 weeks and the outcomes were analysed.

Comparison of Outcomes from Various Literature Available Online

Thus it is very clearly evident from this study that patients who are presenting at an earlier stage of less than 4 weeks duration, has a significant improvement in hearing. There was a gain in hearing of nearly 20 dB.

Also we can see in this study that patients in whom oral steroids have failed to give considerable improvement; salvage therapy with intra tympanic injection was given. And in this category patient who presented at an earlier date that is within 4 weeks’ time duration about 85.7% improvement in hearing was noted. Also it was found to be statistically significant value. $P=0.004574$ [10].

There is no definite protocol for administering the certain dose or its duration. Different studies follow their own institutional protocol. In our study also we formulated and followed our institutional protocol by administering dexamethasone approximately 40mg/ml loaded. We administer only 0.3-0.5 ml of the drug into the middle ear, focussing more on the round window membrane region, so that local site of

action is more and also more amount of drug is delivered to the inner ear, reaches maximum concentration.

In many studies the same drug is administered for a period of once weekly for four weeks. Some study also suggests three weeks is sufficient [11]. In our study we made a comparative analysis by selecting two separate groups. Group 3 and group 4. A group 3 injection was given for 3 weeks and in group 4 injections was given for four weeks. It was found that analysis of outcome by chi square test was found to be statistically insignificant. P= 1.2. Hence it is very clearly evident from this study that, there is no significant difference in the two groups. Hence 3 doses of intratympanic injection will be sufficient and gives a better outcome compared to 4 doses. Because the average hearing gain in group 3 was found to be 33 dB, but in case of group 4 it was found to be around 27 dB. Hence once weekly intra tympanic injection for three consecutive weeks is a better treatment regimen (Table 1 and Figure 1).

Conclusion

Though there are lots of debate regarding management of idiopathic sudden SNHL, intra tympanic steroid injection have shown to give a better result in comparatively many studies. In our study also an average of nearly 70% patient showed improvement in hearing of nearly 20 dB if the patient presented within a time period of 30 days. In salvage therapy group (patients were oral steroidal therapy failed), intra tympanic steroids gave a better result if given within a time period of 30 days. Thus intra tympanic steroids can be considered as a better alternative form of treatment, if the patients are presenting at an earlier time period of <30 days. Also intra tympanic steroid treatment regimen of instilling 40mg/ml dexamethasone of about 0.3 ml to 0.5ml for a consecutive three weeks once weekly will give a better result compared to 4 weeks regimen.

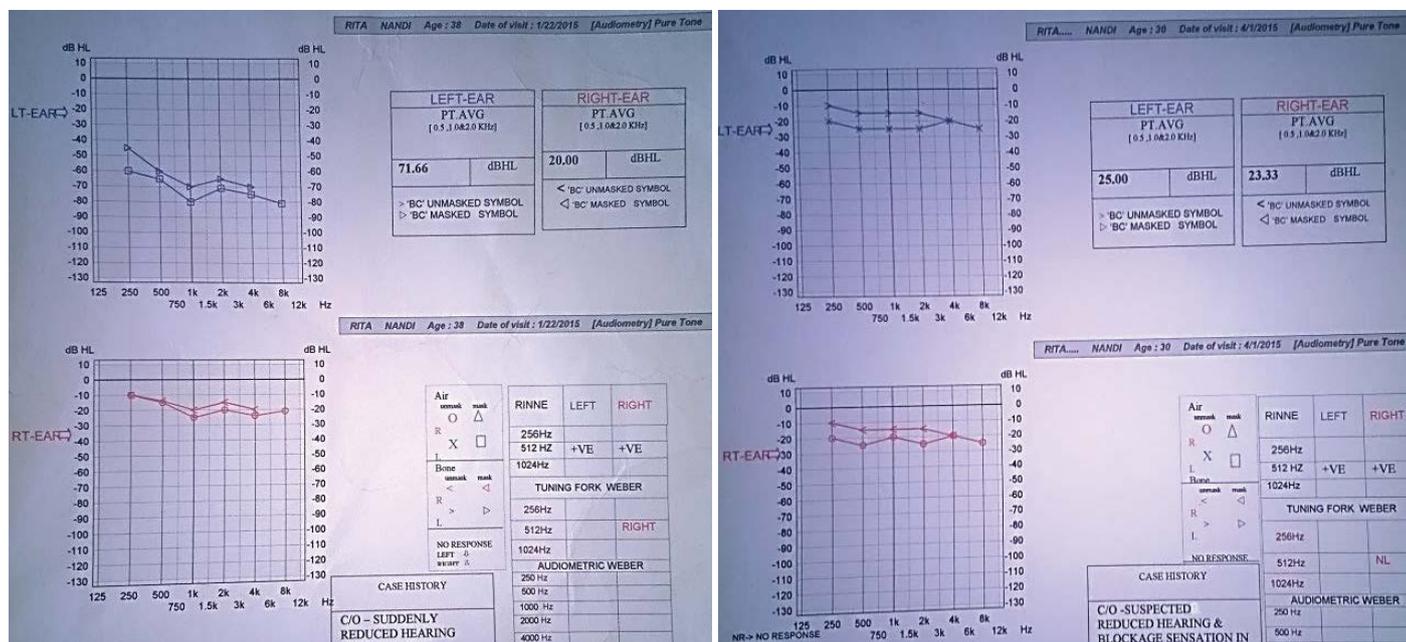


Figure 1: PTA report of a patient before and after intra tympanic steroid injection.

Table 1: Average Improvement in Hearing in 3 Groups.

| Group | Average improvement of hearing (dB) |
|-----------------------|-------------------------------------|
| Salvage therapy Group | 33 |
| Group 3 | 33.3 |
| Group 4 | 28.8 |

Table 2: Chi square test results.

| Groups Comparison | Chi Square results (p value) | Statistically significant |
|--|------------------------------|---------------------------|
| Group3 and Group 4 comparison between hearing outcome in earlier presentation (<30 days) with late presentation (>30 days) | 0.001237 | P value <0.05 YES |
| Salvage therapy groups comparison between hearing outcome in earlier presentation (<30 days) with late presentation (>30 days) | 0.004574 | P value <0.05 YES |
| Comparison in hearing outcome between group 3 and group 4 | 1.2 | P value >0.05 NO |

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