

Original Research Article

A study on efficacy of injection of intratympanic dexamethasone in treatment of sudden sensorineural hearing loss

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ABSTRACT

Background: Sudden sensorineural hearing loss is a common otologic emergency which occurs due to various etiologies affecting the inner ear. Majority of treatment protocols are focussed on glucocorticoids either systemically or through intratympanic route due to their antioxidant and anti-inflammatory properties.

Methods: This was a pre and post observational clinical study conducted in patients visiting Rajarajeswari medical college between December 2015 to December 2016 with a history of sudden hearing loss (30 patients). 6 of these patients presented with bilateral hearing loss, and we considered each ear as a separate case, giving us a total of 36 cases. A diagnosis of idiopathic sudden sensorineural hearing loss was made based on the patient's history and audiological evaluation. All the patients were treated with 3 doses of Intratympanic injections of Dexamethasone (4 mg/ml), on alternate days. Pure tone audiometry (PTA) and brain stem evoked response audiometry (BERA) was done pre-treatment, at 1 and 6 months after treatment.

Results: Mean age of our patients was 44.8. 80% of our patients were male. The average PTA gain, 1 month after treatment was 27.917 and 6 months after treatment was 29.639 with a p value of <0.001, which correlated with BERA. At the end of 6 months after treatment, 15 cases had complete recovery (41.7%), 9 cases showed slight recovery (25%), 6 cases had marked recovery and 6 cases (16.7%) had no recovery.

Conclusions: Intratympanic dexamethasone injections can be used as the first line of treatment with minimal side effects.

Keywords: Intratympanic injection, Dexamethasone, Sudden sensorineural hearing loss

INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is a common otologic emergency, presenting mostly as an acute unilateral deafness, with an abrupt onset (generally within 3 days), of more than 30 dB hearing loss at three consecutive frequencies. 15,000 new cases are reported annually worldwide accounting for approximately 1% of all cases of sensorineural hearing loss.¹ SSNHL can occur due to various causes such as viral infection of the labyrinth or cochlear nerve, labyrinthine membrane

rupture, perilymphatic hypoxia, vascular incident, inflammatory and autoimmune disorders. The etiology and pathogenesis of SSNHL are still unclear, and its treatment is still controversial.

Spontaneous recovery occurs in approximately 30% of cases and recovery occurs usually within the first 2 weeks after onset.² Many factors affect the recovery; the degree of hearing loss, the audiogram, presence of vertigo and the time between the onset of SSNHL and treatment probably being the most important.

For many years, corticosteroids have been used to treat a various inner ear disorders and they have multiple mechanisms of action such as immunosuppression, anti-inflammatory action, ion balance regulation, increased perfusion, membrane stabilization. Recently, various reports have suggested that transtympanic steroid perfusion offers many advantages over oral or intravenous steroid delivery to treat inner ear disease. The advantages of transtympanic steroid delivery include higher steroid concentration can be delivered to inner ear compared to other routes of delivery; can be used as office-based procedure; systemic adverse effects of steroid use can be avoided; ability to direct therapy to the affected ear.

The objective of this study was to study the efficacy of intratympanic injection of dexamethasone in the treatment of sudden sensorineural hearing loss.

METHODS

This was a pre and post observational clinical study conducted in patients visiting Rajarajeswari Medical College between December 2015 and December 2016.

All patients who visited Rajarajeswari Medical College with a history of sudden hearing loss, (a total of 30 patients) were included in the study. 6 of these patients presented with bilateral hearing loss, and we considered each ear as a separate case, giving us a total of 36 cases. A diagnosis of idiopathic sudden sensorineural hearing loss was made based on the patient’s history and audiological evaluation

Inclusion criteria

All cases of sudden sensorineural hearing loss of all age groups, as determined by history and pure tone audiometry (PTA) were included.

Exclusion criteria

Patients not consenting to the study, patients with middle ear disease, patients with hearing loss of more than three months duration, patients who have been treated previously for the same complaints were excluded.

All the patients were treated with 3 doses of Intratympanic injections of dexamethasone (4 mg/ml), on alternate days.

Pure tone audiograms were recorded (using ELKON eda 3N 3 MULTI audiometer) before the first dose of ITD, 1 month after the first dose of ITD and 6 months after. Frequencies of 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz, 8 kHz were tested and average of 500 Hz, 1 kHz and 2 kHz were taken as the pure tone average

Brain evoked response audiometry (BERA) was also performed on the same days. Threshold estimation was

done using BERA (Biologic navigator pro). The intensities were varied from 90 dBnHL and reduced by 10 dBnHL until 30 dBnHL. The minimum intensity at which 5th wave is obtained was considered as the threshold.

Procedure

The procedure was performed under Omega Serwell operating microscope in the outpatient department. Patient was made to lie in supine position, with the head turned 45° away from the direction of the affected ear. 10% xylocaine spray was used as a local anaesthetic, and the external auditory canal was filled with the drug 5 minutes prior to the procedure. The anaesthetic spray was suctioned out just before administering the injection.

Inj. dexona (4 mg/ml) was taken in a 2-cc syringe, and a 26×1 1/2-inch needle was used to administer the injection. Aural speculum was used in the external auditory canal, and tympanic membrane was visualized. Dexamethasone injection (0.4 to 0.5 ml) was injected in the postero-inferior quadrant of the tympanic membrane, the area overlying the round window niche (Figure 1).

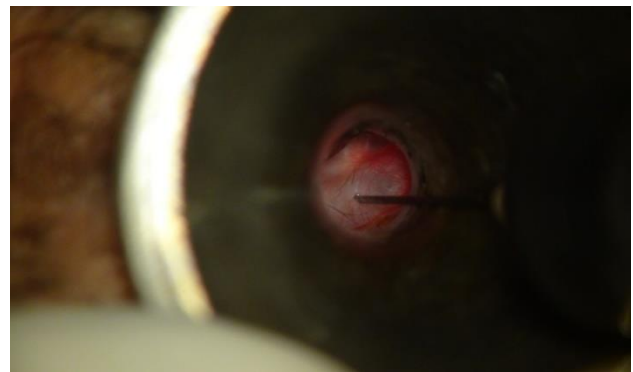


Figure 1: The needle piercing the postero-inferior quadrant of the tympanic membrane.

The patient was made to lie down in the same position for 30 minutes to allow the drug to percolate through the round window. The patient was asked not to speak or swallow during this period, in order to prevent the drug from draining through the Eustachian tube.

The injection was repeated on alternate days for 3 days. Hearing loss was classified as per WHO guidelines (Table 1).⁹

Table 1: Hearing loss.

Hearing (dB) in PTA	Degree of loss
0-25	Normal
26 to 40	Mild
41 to 55	Moderate
71 to 91	Moderately severe
>91	Profound

The criteria for audiological improvement were based on that used by Furuhashi et al who classified the outcomes as complete recovery, marked improvement, partial improvement, or no recovery.⁴

Statistical methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD (min-max) and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Analysis of variance has been used to find the significance of study parameters between three or more groups of patients. Chi-square or Fisher exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting for qualitative data analysis.

Statistical analysis

The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver. 2.11.1 were used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables etc. P value <0.05 considered as statistically significant.

RESULTS

During the period of study, 30 patients presented to us with sudden sensorineural hearing loss, out of which 6 patients had bilateral hearing loss. The age of our patients varied from 12 years to 69 years. Majority of the cases were in the age group between 61 and 70 years (9 patients), with the next major group being between 31 and 40 years of age. The mean age of our patients was 44.8 with a standard deviation of 17 years. 24 out of the 30 patients (80%) of the patients in our study were males. Our study showed that the left ear and right ear were almost equally affected, with 55.6% cases involving the right ear and 44.4% of the cases involving the left ear.

Table 2: Criteria for hearing improvement.

Hearing improvement (in dB)	Grade of recovery
PTA <25	Complete recovery
PTA improvement >30	Marked improvement
PTA improvement of 10-30	Slight improvement
PTA improvement <10	No recovery

13 out of 30 patients (36.1%) had severe hearing loss at the time of presentation. 7 (19.4%) patients had moderately severe hearing loss. There were 6 (16.7%) patients each who had moderate and profound hearing

loss and 4 (11.1%) patients presented with mild degree of hearing loss.

The average PTA gain, 1 month after treatment was 27.917, which was statistically significant with a p value of <0.001. The average PTA gain, 6 months after treatment was 29.639, which was also significant, with a P value of <0.001 (Table 3). There was no significant change in hearing between 1 month and 6-month PTA reading.

Table 3: Comparison of hearing loss (PTA) and improvement after treatment.

	Min-max	Mean ± SD
Hearing loss	28.30-108.30	69.28±20.97
PTA 1 month	11.60-95.00	41.37±22.46
PTA 6 months	11.60-95.00	39.64±22.17
Difference		
Hearing loss-PTA 1 month	27.917	
Hearing loss-PTA 6 months	29.639	
PTA 1 month- PTA 6 months	1.722	
P value		
Hearing loss-PTA 1 month	<0.001**	
Hearing loss-PTA 6 months	<0.001**	
PTA 1 month- PTA 6 months	0.203	

**Strongly significant (p value: p≤0.01).

Before treatment, 13 out of 36 cases had hearing thresholds of 41-71 dBHL 10 cases (27.8%) had hearing thresholds of 71-99 dBHL, 9 patients had thresholds of 0-25, while 4 patients (11.1%) had thresholds of 26-40 dBHL. In the hearing threshold estimation (as calculated by BERA) after 1-month post-treatment, 14 cases (38.9%) had hearing thresholds between 41-71 dBHL. 12 (33.3%) cases had thresholds of 26-40 dBHL. 7 patients (19.4%) had thresholds between 0-25 dBHL. 3 cases had thresholds of 71-99 dBHL. In the 6 month post-treatment BERA results, 13 patients (36.1%) had hearing thresholds of 26-40 dBHL, 13 (36.1%) had thresholds of 41-71 dBHL, 7 cases (19.4%) had thresholds of 0-25 dBHL and 3 cases (8.3%) had thresholds between 71 and 99 dBHL.

At the end of 6 months after treatment, 15 cases had complete recovery (41.7%), 9 cases showed slight recovery (25%), 6 cases had marked recovery and 6 cases (16.7%) had no recovery. There were no complications reported in our study, related to the administering of intratympanic dexamethasone injection.

DISCUSSION

According to our study, intra-tympanic injections of inj. dexamethasone is effective as the only mode of treatment of sudden sensorineural hearing loss.

According to a study conducted by Megighian et al, the peak age of patients who have SSNHL is between 30 and 60 years.⁴ Our study showed similar results; the mean age of our patients was 44.8 with a standard deviation of 17 years. However, in our study, patients between the ages of 61 and 70 constituted the largest number of cases (9 patients). Various studies have shown a slight male preponderance for this condition similar to our study.²

Oh et al conducted a study which showed that bilateral SSNHL was rare and was seen in 4.9% of the patients.⁵ In our study, the incidence was a little higher (20%). However, the study conducted by Oh et al was a retrospective study and had a larger sample size of 344 patients.⁵ Our study showed that the left ear and right ear were almost equally affected, with 55.6% cases involving the right ear and 44.4% of the cases involving the left ear.

In our study, the average PTA gain, 1 month after treatment was 27.917, which was statistically significant with a p value of <0.001. This is consistent with other similar studies conducted, such as the study by Rauch et al which showed a PTA gain of 28.7dB following treatment with ITD.⁶ A study conducted by Tsai et al showed an average PTA improvement of 31.1dB.⁷ The average PTA gain, 6 months after treatment was 29.639, which was also significant, with a p value of <0.001. There was an average difference of 1.722 dBs between the hearing 1 month post-treatment, and 6 months post-treatment, which was not significant, implying that intratympanic injections act immediately, and the hearing remains the same after the initial action and there is minimal long-term action of the drug. The study conducted by Rauch et al also showed that there was no significant change in pure tone averages between 2 months and 6 months post-treatment.

We also performed a BERA on all the patients before treatment, 1 month post-treatment and 6 months post-treatment. BERA was done in order to have an objective test for calculating hearing, along with the subjective test PTA. Our BERA findings co-related with the PTA findings. According to most of the studies, the hearing thresholds obtained from BERA are on average 10-15 dB more than the Pure tone averages. A study conducted by Van der Drift, showed that the hearing thresholds of BERA, on average, are 11dB higher than Pure tone average.⁸

Although most studies done so far have only used intratympanic steroid injections in sudden sensorineural hearing loss as a treatment modality in refractory cases which do not respond to other first line modalities, according to our study, there was a significant improvement in hearing in our patients who received Intratympanic dexamethasone injections as the first line of treatment. Intratympanic injections have various advantages such as increased localised action, safety in diabetic patients and that it is an office based procedure.

CONCLUSION

Early diagnosis and management of idiopathic sudden sensorineural hearing loss is of utmost importance and the condition should be treated as an emergency. Intratympanic dexamethasone injections can be used as the first line of treatment with minimal side effects.

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