Effectiveness of Intratympanic Dexamethasone Injection in Sudden sensory neural hearing loss

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Abstract: Abstract: Objective: To compare outcomes in two groups of patients with idiopathic sudden sensor neural hearing loss (ISSNHL). Group I treated with oral methylprednisolone at 1 mg/kg/day and Group II treated with intratympanic (IT) dexamethasone (DEX) at 24 mg/mL. **Study Design:** prospective clinical trial. **Setting:** Tertiary referral center at Al Azhar University, Faculty of Medicine for girls, Al Zahraa University Hospital & National institute of Hearing and Speech, Cairo, Egypt. **Patients:** Forty adults with ISSNHL divided into 2 groups. **Interventions:** Group I received oral methylprednisolone at 1mg/kg/day over 9 days; tapered over 6 days, Group II patients received a series of IT DEX injections for 3 weeks with 24 mg/mL. **Main Outcome Measure:** Greater than 30-dB improvement in pure-tone average (PTA). **Results:** Baseline characteristics were similar between groups. Mean follow-up was 24 weeks. Sixteen (80%) of 20 patients treated with 24 mg/mL had greater than 30-dB improvement in PTA compared with eight (40%) of 20 treated with oral methylprednisolone ($p = 0.022$, Fisher's exact test). There was a trend toward improved word recognition score outcome with 24 mg/mL. Change in PTA was not significantly affected by age, sex, pretreatment hearing levels. **Conclusion:** To our knowledge, this is the first demonstration of superiority of IT DEX at 24 mg/mL for the treatment of ISSNHL in Egypt, with significantly better and safer recovery of PTA. Our data suggest that treatment should be initiated as soon as possible.

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Key Words: Idiopathic sudden sensor neural hearing loss-Intratympanic dexamethasone 24mg/mL-oral methylprednisolone- PTA (pure tone audiometry) - word recognition score – dB (decibel).

1. Introduction:

Idiopathic sudden sensor neural hearing loss (ISSNHL) is defined as a decline in hearing over 3 days or less affecting 3 or more frequencies by 30 dB or greater with no identifiable etiology**. (1)**

Many different therapies have been used to treat ISSNHL, including vasodilators, antiviral agents, anticoagulants, and hyperbaric oxygen (HBO). However, corticosteroids havebecome the most frequently used treatment. **(2)**

In the 1990s, the intratympanic (IT) route of administration of corticosteroids for ISSNHL was introduced, with the goal of minimizing systemic side effects while allowing achievement of a higher drug concentration in the inner ear. **(3)**

To date, no published study has focused on defining the optimal dose of IT corticosteroids for hearing recovery after ISSNHL.

The purpose of this study is to prospectively compare the effect of two different modalities of treatment, oral methylprednisolone versus IT DEX 24mg/mL for primary treatment of ISSNHL.

2. Methods:

This study was approved by the University of Al Azhar ethical committee on May 2013.

The study was made at Al Zahraa University hospital and The National Institute of Hearing and Speech during the period from May 2013 to May 2016.

The study sample was 40 patients (14 females & 26 males) and their ages ranged between 18 - 67 years old. All these patients were suffering from unilateral idiopathic sudden sensorineural hearing loss. (Written informed consent was taken from the patients).

Inclusion criteria: Idiopathic sudden sensory neural hearing loss, Unilateral mild, moderate, severe and profound hearing loss, No history of other otological problems, Normally appearing tympanic membrane, With or without previous treatment to the SSHL, Both sexes, Adult patients (18 years and older).

Exclusion criteria: Associated vertigo, nystagmus, Associated focal neurological lesions, Pregnancy, Abnormal color of tympanic membrane.

All selected candidates were evaluated as regard:

Patient history, physical examination and otorhinolaryngological examination, Assessment with tuning fork tests, Audiometric confirmation of

idiopathic sensorineural hearing loss (ISSNHL), Evaluation of patients with ISSNHL for retrocochlear pathology (Pure-tone audiometry, auditory evoked brainstem response [ABR], tympanometry, speech response testing) and magnetic resonance imaging (MRI) of temporal bone will be performed only if a retrocochlear lesion is suspected by means of ABR.

After evaluation all patients were randomly allocated into 2 groups

Group I

Twenty patients received oral steroid (methyl-prednisolone, 1 mg/kg per day divided in 2 doses in the initial 9 days, followed by tapering to 10 mg/day for another 5 days).

Group II

Twenty patients received intra-tympanic dexamethasone sodium phosphate (24 mg/mL) injection once a week for 3 consecutive weeks.

The intra-tympanic injection was through the tympanic membrane into the middle ear, using an operating microscope.

Anesthesia was obtained with topical lidocaine 4 mg applied 30 minutes before injection.

Patients were positioned supine and were instructed to avoid swallowing during injection and to tilt their head 30 to 40 degrees to the healthy side so that the round window membrane would be bathed for 30 minutes.

Myringotomy was performed with a 22-gauge spinal needle under microscopy at the junction between the poster inferior and poster superior quadrants, and dexamethasone (24 mg/ mL) was injected undiluted.

After injection, patients will be observed for 30minutes before being discharged.

Intra-tympanic dexamethasone injection was performed once a week for 3 consecutive weeks.

The study included 6 visits:

A screening visit; a baseline visit to obtain informed consent, enroll, randomize, and initiate treatment; 3 additional safety monitoring visits during the 3-week treatment interval; an immediate post treatment follow-up visit (primary), and a 6-month (extended) follow-up visit to assess hearing and safety outcomes.

Adverse events and serious adverse events were assessed at all study visits.

Successful treatment is defined as complete recovery or an improvement of hearing in the six-frequencies (250,500, 1,000, 2,000, 4,000, and 8,000 Hz) with pure-tone average (PTA) of 30 dB or more.

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 22.

The comparison between two groups with qualitative data was done by using Chi-square test and/or Fisher exact test was used instead of Chi-square test when the expected count in any cell was found less than 5.

The comparison between two independent groups with quantitative data was and parametric distribution was done by using Independent 2-sided t-test.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered ± significant as the following:

P > 0.05: Not significant

P < 0.05: Significant

P < 0.01: Highly significant.

3. Results:

This study included 40 patients (17 females & 23 males) divided into two study groups.

Group I included 20 patients (10 male & 10 female); with (mean age & SD) (48.15±10.27) range: 29- 63 years.

Group II included 20patients (13 male & 7 female); with (mean age & SD) (41.35±12.86) range: 22- 65 years.

Table (1): Characteristics of the study population.

Age in years	
Mean ±SD	44.75 ±11.99
Mode	29, 38, 41, 50
Range	33
Gender	
Male	23
female	17
Duration of SSNHL in weeks	
Mean ±SD	8.42 ±3.18
Range	13
Side of SSNHL	
Right	14
Left	26
Level of HL in dB	
Mean ±SD	80.38 ±12.00

A clinically significant improvement in PTA (definedas >30 dB) was attained 16 of 20 patients in the 24-mg/mLgroup compared with only 8 of 20 patients in the oral methylprednisolone group (p = 0.022, Fisher's exact test).

Table (2): Comparison between the outcomes of intervention in group I and group II.

Outcomes	Group I		Group II		Fisher's exact test
Improved	8	40%	16	80%	P value = 0.022
Not improved	12	60%	4	20%	

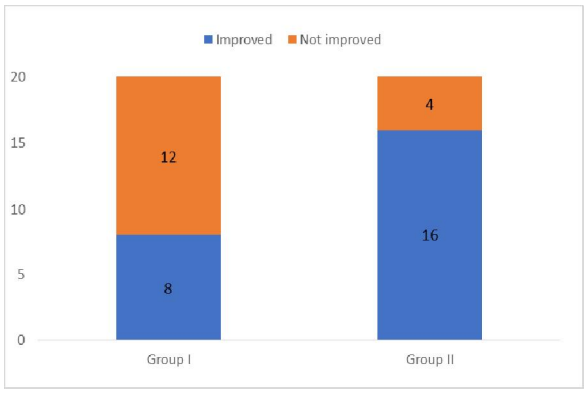

Figure (1): Comparison of the outcomes of intervention between the study groups.

There was a trend toward greater mean improvement in PTA in the 24-mg/mL group compared with the oral methylprednisolone group.

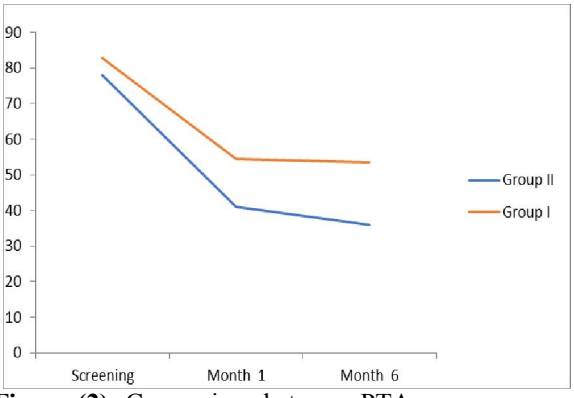

Figure (2): Comparison between PTA average means at screening, month 1and month 6 between the study groups.

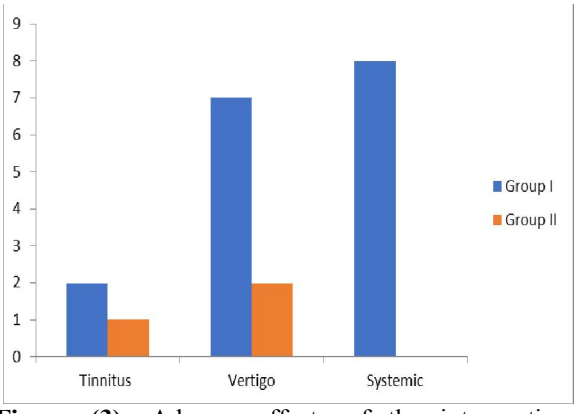

Figure (3): Adverse effects of the interventions between the study groups.

IT DEX injections were well tolerated at each dose. A total of two patients were noted to have tinnitus and one patient suffered vertigo.

No patients were noted to have any of the systemic adverse effects of corticosteroids.

Whereas the oral methylprednisolone group had eight patients with systemic adverse effects of corticosteroids with seven patients suffered from tinnitus and two patients had vertigo.

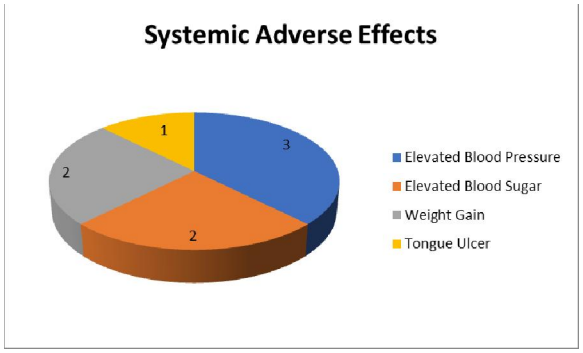

Figure (4): Systemic adverse effects of corticosteroids in group I

4. Discussion:

Silverstein in 1996 was the first to apply the intratympanic steroid injection as a treatment of SSNHL, followed by several studies since the initial report.

Most of the studies showed the efficacy of intratympanic steroids as an initial treatment for SSHNL patients (intratympanic injection only or combination with systemic steroids) or a salvage treatment for the refractory SSNHL patients, i.e. those who had insufficient recovery after initial systemic steroids therapy. (4)

The aim of the current study is to evaluate the effectiveness of intratympanic injection of dexamethasone 24 mg/ml in the treatment of cases with idiopathic sudden sensorineural hearing loss.

The present study included 40 patients (17 females & 23males) with the mean age of (44.75 ±11.99). The distribution of cases according to their sex and age revealed no significant statistical difference (P>0.05).

Alexander Thomas H. (2015) found that sex and age at the time of onset of hearing loss had no impact on post injection hearing results. (5)

In the present study, the mean level of hearing loss in group I is 78 ±13.61dB, meanwhile the mean level of hearing loss in group II is 82.75 ±11.86 dB, although the span of hearing loss is wider in group II, there is no significant difference between the two groups (P>0.05).

In the present study, group I shows improvement of more than 30 dB in 20% of patients between screening and 1 month assessment of hearing levels, there is no significant difference between the two assessments (P>0.05).

Assessment at 6 months shows improvement of more than 30 dB in 40% of patients of group I, compared to the assessment at 1 month, there is no significant difference between the two assessments (P>0.05).

Chen-Lin Liu (2014) found that after 6 months, the average absolute recovery rate was 74% in patients who received full dose prednisolone which was statistically significant than control group. (6)

The assessment of hearing level in group II shows improvement of more than 30 dB in 70% of patients between screening and 1 month assessment of hearing levels, there is a significant difference between the two assessments (P<0.05).

Assessment at 6 months shows improvement of more than 30 dB in 80% of patients of group II, compared to the assessment at 1 month, there is no significant difference between the two assessments (P>0.05).

The comparison of the outcome of the intervention between group I and group II as regard the improvement of hearing levels of more than 30 dB is statically significant (P<0.05).

Dan Zhao (2016) found that Local steroid therapy appears to generate higher rate of complete hearing recovery than systemic steroid treatment as an initial treatment for sudden sensorineural hearing loss, which may be especially useful for patients in whom systemic steroids are contraindicated. (7)

Alexander Thomas H. (2015) in his study about the dose effect of intratympanic dexamethasone for idiopathic sudden sensorineural hearing loss showed the superiority of intratympanic dexamethasone 24mg/ml injection in the improvement of hearing levels over dexamethasone 10mg/ml injection.

In the present study, group I shows significant difference in the number of patients with adverse effects of systemic steroids post treatment including 3 patients with elevated blood pressure levels, 2 patients with elevated blood sugar levels, 2 patients with weight gain and one patient with tongue ulcer.

This result is in agreement with Dan Zhao (2016) who concluded that adverse reactions of systemic steroids use were cardiovascular, gastrointestinal, neurologic, and endocrine problems.

Group II shows no adverse effects of systemic steroids.

Up to the moment, many attempts have been made to investigate the most effective treatment for idiopathic sudden sensorineural hearing loss. For the same purpose, we describe our experience of using intratympanic dexamethasone 24mg/ml as a primary treatment for idiopathic sudden sensorineural hearing loss.

5. Conclusion:

We conclude from our data that intratympanic dexamethasone at 24mg/ml injection is more safe and more effective than oral steroids in the primary management of idiopathic sudden sensorineural hearing loss.

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