

The Effect of Intratympanic Injection of Dexamethasone for the Treatment of Sudden Sensorineural Hearing Loss

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Abstract

Background: Steroids remain the treatment of choice for sudden hearing loss regardless the cause. With the adverse effects of systemic corticosteroids, Intratympanic injection of steroids appears to be an attractive method of management of Idiopathic Sudden Sensorineural Hearing Loss (ISSHL) in patients with contraindication for systemic steroids.

Patients and Methods: 40 patients, presented with moderate to severe and severe SSNHL were enrolled in the study. Patients were randomly allocated in one of two groups: (Group I) received intratympanic injection of dexamethasone 4mg for 5 times over 4 weeks and (Group II) received systemic steroid 1mg/kg for one week and tapering the dose for two weeks. Pure Tone Audiogram (PTA) and Speech Discrimination (SD) were used for assessment pre and post-treatment in the two groups.

Results: Group I treated with intratympanic injection of dexamethasone showed hearing improvement in 45% of patients (9 patients) and no improvement in 55% of patients (11 patients), while Group II treated with systemic corticosteroids showed hearing improvement in 60% of patients (12 patients) and no improvement in 40% of patients (8 patients). The degree of improvement showed no statistically difference between both groups.

Conclusions: The intratympanic injection of dexamethasone is an effective alternative to systemic steroids in treatment of ISSNHL as a primary therapy.

Key Words: Intratympanic dexamethasone injection – Sudden deafness – Steroid.

Introduction

SUDDEN Sensorineural Hearing Loss (SSNHL) is defined as a rapid onset, occurring over a 72-hour period, of a subjective sensation of hearing impairment in one or both ears. Sudden Sensorineural Hearing Loss (SSNHL) meets certain audiometric criteria. (A) Sensorineural hearing loss indicates an abnormality of the cochlea, audi-

tory nerve, or higher aspects of central auditory perception or processing. (B) The most frequently used audiometric criterion is a decrease in hearing of ≥ 30 decibels (dB), affecting at least 3 consecutive frequencies. Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL) is defined as SSNHL with no identifiable cause despite adequate investigation [1].

Corticosteroids may act in the inner ear to affect hearing not only by their anti-inflammatory effects but also by altering the inner ear's fluid and electrolyte balance, thus affecting endocochlear potential. Because of the blood-labyrinthine barrier, systemic steroids have a limited ability to reach the inner ear. Intratympanic corticosteroid therapy may potentially provide organ-specific treatment, with high doses applied over the round window membrane, thereby avoiding the adverse effects of systemic corticosteroid therapy [2].

Intratympanic steroids are used in one of three manners: As salvage therapy after failure of initial systemic steroids, in combination with systemic steroids as initial treatment, and alone as an initial treatment when systemic steroids or their side effects are not tolerated [3].

The aim of the work is to study the efficacy of intratympanic injection of dexamethasone for the treatment of idiopathic sudden sensorineural hearing loss, and compare between efficacy of Intratympanic injection of dexamethasone and administration of systemic corticosteroids.

Patients and Methods

This prospective case series study was carried out at ENT Department, Tanta University Hospitals from December 2015 to September 2017 on 40 patients with unilateral idiopathic moderate-severe

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and severe sudden sensorineural hearing loss within the first month of presentation after approval of the local ethical committee (approval code: 30585/11/15). Written informed consent was taken from parents of 40 patients 18 years old or older (to sign the written consent). Any sudden hearing loss with identified cause was excluded from the study. Patients were allocated to 2 groups. The treatment group (Group I) consisted of 20 patients with contraindication to systemic corticosteroids. They received intratympanic injection of dexamethasone 4mg. The control group (Group II) received oral prednisolone. Patients in Group I received five intratympanic injection of dexamethasone 4mg about 0.4-0.6ml each time. Cotton soaked with lidocaine spray applied to tympanic membrane for 10 minutes for surface anesthesia. 25-gauge spinal needle was introduced into the anterior superior portion of the tympanic membrane to allow air escape, and then the needle was reinserted in the posterior inferior portion of the tympanic membrane and injection of dexamethasone inside the tympanic cavity. The patient was asked to lay in supine position and his head was tilted to the other side and to remain in this position for 30 minutes after injection. The patient was asked not to swallow and to remain in this position for 30min after injection.

Patients in Group II received systemic steroids in the form of oral prednisolone. They started with the 1mg/kg for one week and tapering the dose for two weeks.

Hearing recovery was measured with Siegel's criteria [4]. According to this classification, type I (complete recovery) included patients whose final hearing level was better than 25 dB regardless of the size of the gain. Type II (partial recovery) included patients who showed more than 15 dB of gain and whose final hearing level was between 25 and 45 dB. Type III (slight recovery) included patients who showed more than 15 dB of gain and whose final hearing level was poorer than 45 dB; and type IV (no improvement) included patients who showed less than 15 dB of gain. Pure-Tone Audiometry (PTA) was performed on the initial day and the second week and after treatment and one month after-treatment.

Results

Regarding the demographic data as age and sex, in Group I, the age ranged from 26 years to 64 years with a mean age of 43.95 ± 13.21 years. In Group II, the age ranged from 19 years to 60

years with mean age of 39.45 ± 12.47 years. In Group I there were 13 males (65 percent) and 7 females (35 percent). In Group II, there were 11 males (55 percent) and 9 females (45 percent). There was no statistically significant difference between the two groups in these variables. There is no correlation between age or gender of patients and improvement in hearing ($p=0.275$) and ($p=0.475$) in that order. Table (1).

There were forty patients in this study. Twenty one patients (52.5%) showed hearing improvement, and divided according to Siegel's criteria to complete recovery was in five patients (12.5%), partial recovery was in 10 patients (25%), and slight improvement in 6 patients (15%). No improvement was noticed in 19 patients (47.5%). Table (2).

Comparing the two groups, Group I treated with ITI of dexamethasone showed hearing improvement in 45% of patients (9 patients) and no improvement in 55% of patients (11 patients), while Group II treated with systemic corticosteroids showed hearing improvement in 60% of patients (12 patients) and no improvement in 40% of patients (8 patients). The degree of improvement showed no statistically difference between two groups. ($p=0.720$). Table (3).

There were no significant difference between the both groups before and after-treatment. The mean PTA in-Group I and Group II before-treatment was 74.38 ± 16.99 and 66.47 ± 21.84 respectively with no significant difference. And after-treatment, The average PTA in Group I and Group II was 56.33 ± 21.46 and 45.83 ± 20.63 respectively with no significant difference ($p=.123$). Figs. (1,2).

The speech discrimination in-Group I before and after-treatment with ITI of dexamethasone was 25.20 ± 30.73 and 44.50 ± 36.01 respectively with improvement about 19.30% which was a highly significant difference ($p=0.004^*$). In-Group II before and after-treatment with ITI of dexamethasone was 37.40 ± 33.27 and 68.20 ± 22.50 respectively with improvement about 30.80% which was a highly significant difference ($p=0.001^*$). Fig. (3).

Eight patients complained of vertigo immediately after injection, and all of these patients recovered within 10 minutes. Otalgia occurred in 2 patients after injection, which was relieved after 30 minutes. No cases of residual tympanic membrane perforation or otitis media was noted. No long term complications resulted from intratympanic steroid injection in any of the patients.

Table (1): Relation between age and gender and degree of improvement.

	Degree of improvement						χ^2	<i>p</i>		
	Complete recovery		Partial recovery		Slight improvement				No improvement	
	N.	% N.	N.	% N.	N.	% N.			N.	% N.
<i>Age intervals:</i>										
<20	0	0	0	0	0	0	1	5.3	4.385	0.275
21-40	3	60	3	30	2	33.3	10	52.6		
41-60	2	40	6	60	3	50	6	31.6		
>.60	0	0	1	10	1	16.7	2	10.5		
<i>Gender:</i>										
Male	2	40	3	50	11	57.9	2.785	0.475		
Female	3	60	2	20	3	50	8	42.1		

Table (2): Degree of improvement in the whole study patients.

Degree of improvement	All study patients (n=40)	
	N.	%
Complete recovery	5	12.5
Partial recovery	10	25
Slight improvement	6	15
No improvement	19	47.5

Table (3): Degree of Improvement according to treatment type.

Degree of improvement	Group I (n=20)		Group II (n=20)		χ^2	<i>p</i>
	N.	%	N.	%		
Complete recovery	2	10	3	15	1.340	0.720
Partial recovery	5	25	5	25		
Slight improvement	2	10	4	20		
No improvement	11	55	8	40		

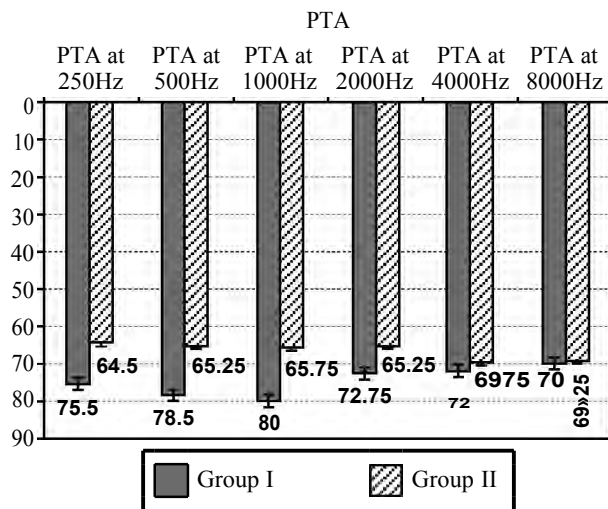


Fig. (1): Description of Pure Tone Audiometry (PTA) before treatment.

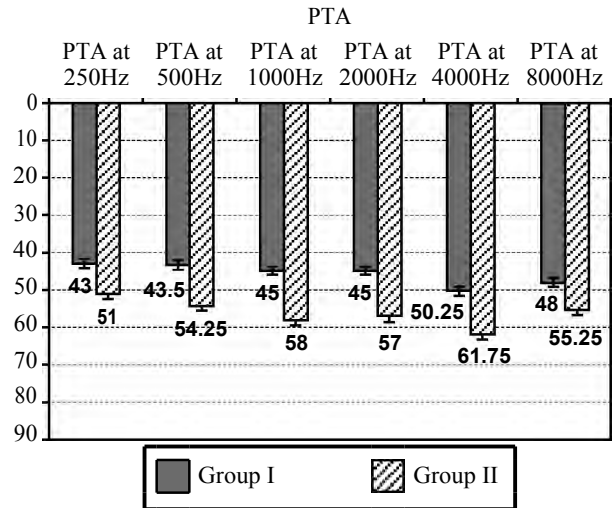


Fig. (2): Pure Tone Audiometry (PTA) after treatment in both groups.

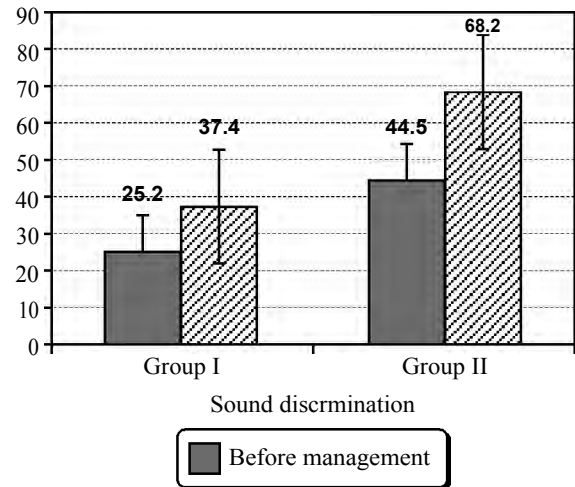


Fig. (3): Comparison of sound discrimination before and after treatment in both group.

Discussion

Sudden Sensorineural Hearing Loss (SSNHL) is an otologic emergency, and it is defined as 30dB or greater shift in bone conduction thresholds in three consecutive frequencies occurring within 72 hours or less [5].

There are many advantages of ITI use. The main advantage is the possibility to treat all patients presenting with SSNHL avoiding systemic effects of steroids and thus treating those patients in which systemic steroids are contraindicated (i.e., immunocompromised patients, diabetics, tuberculosis, HIV). High dose regimen of steroids may expose patients (elder ones in particular) to various adverse effects: Glucose intolerance, avascular necrosis of the hip, insomnia, irritability, gastritis, and osteoporosis. Other advantages are: It is an office-based procedure, reduction in delay of start of

treatment after diagnosis and to treat only the affected side and the possibility to combine ITSI with other systemic drugs without dangerous pharmacological interactions. Local administration of steroids via the middle ear cavity may act directly on the inner ear at a higher concentration [6,7].

The study included forty patients, 24 patients (60%) were males and 16 patients (40) were females with a ratio 1.5:1 with no statistically significant difference in incidence of SSNHL or improvement of hearing after treatment ($p=0.475$). Our study agreed with Byl et al., [8], Cinamon et al., [9], that sex is not a prognostic factor in SSNHL. On the other hand, only Samim et al., [10] have shown that female patients had a better prognosis where the ratio between male:female 2.3:1 ($p<0.05$).

In this study, the age of patients ranged from 19 to 64 years with mean age 41.5 ± 22.5 . In the ITI group, the age ranged from 26 years to 64 years with a mean age of 43.95 ± 13.21 years. In systemic steroid group, the age ranged from 19 years to 60 years with mean age of 39.45 ± 12.47 years. There were no correlation between age of the patients and hearing improvement ($p=0.275$). Incidence of SSNHL increased with age in the present study, with maximum number around 41 years, then the incidence decline after the age of 60 years. Byl et al., [8] also found increasing incidence with increasing age, with a peak incidence of 47 per 100,000 in patients 65 years and older. Teranishi et al., [11] reported a peak annual incidence of 58 per 100,000 in patients aged 60 to 64 in Japan, with a steep decline in incidence with increasing age above 65 years. Klemm et al., [12] reported bimodal peaks at 40 to 49 years and 60 to 69 years in Germany.

In this study, intratympanic injection of dexamethasone results in improvement of PTA about 18.049 dB and improvement in speech discrimination about 18.25 ± 24.19 . Both results was statistically significant. The percentage of subjects improved was 45%. Parnes et al., [13] reported mean improvement of PTA about 62 dB and the percentage of subjects improved was 46%. Banerjee and Parnes [14] in another study reported mean improvement of PTA about 23 dB and the percentage of subjects improved was 50%. Battisa et al., [15] reported mean improvement of PTA about 17 dB and the percentage of subjects improved was 12%, although they used a larger concentration of dexamethasone 24mg. All previously mentioned studies were prospective with no comparator group.

In our study, the comparator group that received oral corticosteroid treatment showed mean PTA

improvement about 20.64 dB. This is comparable with the 61% reported by Wilson et al., [16]. The improvement in sound discrimination in this group was 31.40 ± 23.20 . The percentage of subjects improved 60%. There is no significant difference in PTA improvement and sound discrimination between ITI group and oral corticosteroid group.

In 2011, Rauch et al., [17] conducted a multi-center prospective randomized controlled trial comparing the outcomes of primary treatment with oral prednisone and intratympanic methylprednisolone (40mg/ml). They observed a mean Pure Tone Average (PTA) improvement of 30.7 dB in the oral prednisone group compared with 28.7-dB improvement in the intratympanic group, and were able to reject null hypothesis of inferiority of intratympanic administration.

Battaglia et al., [18] observed superior hearing outcomes with the use of intratympanic 12mg/ml dexamethasone alone compared with oral prednisone alone. Similarly, in a prospective, nonrandomized study, Kara et al., [19] also found superior hearing outcomes with intratympanic dexamethasone compared with oral methylprednisolone. Neither of these outcomes achieved statistical significance. No study has reported treatment with intratympanic steroids, alone or combination with systemic steroids, to be less effective than systemic steroids alone [3].

Conclusion:

From the results of the present study we concluded that The intratympanic injection of dexamethasone is effective in treatment of ISSNHL as a primary therapy. There is no statistically significant difference between treatment with intratympanic injection of dexamethasone and treatment with oral prednisone. Intratympanic dexamethasone injection is a suitable alternative if there are medical contraindications to systemic steroids.

Limitations:

The superiority of ITI in comparison to systemic steroids still needs to be reproduced in level I studies, before they can replace them as the mainstay treatment modality of this condition, and a universal treatment protocol for ISSNHL has to be further evaluated. A larger study group, a later time of presentation, and a longer follow-up periods are recommended for further studies.

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Conflicts of interest:

No conflicts of interest declared.

Authors' contributions:

All authors had equal role in design, work, statistical analysis and manuscript writing.

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تأثير حقن مادة الديكساميثازون داخل تجويف الأذن الوسطى في علاج فقدان السمع الحسى العصبى المفاجئ

مقدمة: الستيرويدات تبقى العلاج المفضل لفقدان السمع المفاجئ بغض النظر عن السبب. مع الآثار السلبية من الستيرويدات النظامية، يكون الحقن الموضعي للستيرويد داخل تجويف الأذن الوسطى علاج بديل لحالات فقدان السمع الحسى العصبى المفاجئ المجهولة السبب فى المرضى الذين يعانون من موانع للإستيرويدات النظامية.

المرضى وطريقة البحث: تشمل هذه الدراسة أربعين مريضا يعانون من فقدان سمعى حسى عصبى مفاجئ مجهول السبب. ويقسم المرضى إلى مجموعتين: المجموعة الأولى تشمل عشرين مريضا لديهم موانع مرضية لتلقى الستيرويدات النظامية ويتم حقن 0.5 مل من مادة الديكساميثازون 4 ملجم داخل تجويف الأذن الوسطى لمدة خمس مرات أسبوعيا، والمجموعة الثانية تشمل عشرين مريضا يتلقون الستيرويدات النظامية بجرعة 1 ملجم/كج لمدة أسبوع ويتم تقليل الجرعة على مدار أسبوعين. يتم عمل رسم سمع وإختبار تمييز الكلام قبل وبعد العلاج.

النتائج: أظهرت المجموعة الأولى تحسنا فى السمع فى 45% من المرضى (9 مرضى) وعدم تحسن فى 55% من المرضى (11 مريضا)، فى حين أن المجموعة الثانية أظهرت تحسن السمع فى 60% من المرضى (12 مريضا) وعدم تحسن فى 40% من المرضى (8 مرضى). أظهرت درجة التحسن عدم وجود فرق إحصائى بين المجموعتين.

الإستنتاج: حقن الديكساميثازون داخل تجويف الأذن الوسطى فى حالات فقدان السمع الحسى العصبى المفاجئ هو بديل فعال للإستيرويدات النظامية فى حالة وجود موانع لتناولها.