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The Outcomes in Patients Treated With Intratympanic and Systemic Steroids for Sudden Hearing Loss and Prognostic Factors

ABSTRACT

Objective: Steroid therapy is the gold standard in treating sudden sensorineural hearing loss (SSNHL). This study aimed to compare the results of the systemic and intratympanic administration of steroids used to treat patients with SSNHL.

Methods: A retrospective analysis was performed with 90 patients treated for SSNHL in our clinic between 2014 and 2017. Intratympanic steroid (ITS) was administered to 44 patients and systemic administration (intravenous or oral) to 46. Pure-tone average (PTA) values were recorded before treatment and at the first and third months post-treatment. Hearing improvement was evaluated according to the Furahashi criteria.

Results: The pre-treatment PTA values were 68.9 ± 25.9 dB in the systemic steroid-treated group and 79.0 ± 22.6 dB in the intratympanic steroid-treated group, with no statistically significant difference determined ($P = .07$). After 1 month of treatment, the PTA median value was 6.0 (from −23.0 to −65.0) dB in the systemic group; and the median was 7.5 dB (from −13.0 to −84.0) in the intratympanic group. No statistically significant difference was determined between the groups in terms of regression in pure-tone median values after treatment ($P = .90$). According to the Furahashi criteria, in the evaluations between the 2 groups, those with complete improvement and significant improvement were compared together, and those with mild improvement and those without improvement were compared separately. There was no statistically significant difference in the distribution with respect to healing, between the groups ($P = .692$).

Conclusion: Although steroids−−which are the only treatment with proven efficacy in sudden idiopathic hearing loss−−are effective in the improvement of hearing, the methods of administration showed no differences in terms of effectiveness.

Keywords: Sudden hearing loss, steroid, intratympanic, Furahashi criteria, prognostic factors

INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is defined as a sensorineural hearing loss of at least 30 dB in 3 consecutive frequencies developing over 72 hours or less.[1]

SSNHL occurs unilaterally in 90% of cases. Bilateral involvement is uncommon, and has a poor prognosis. The incidence of SSNHL is 5-20/100 000, and accounts for approximately 1% of all patients with sensorineural hearing loss.[2] Many factors are involved in the etiology, which could be of viral, vascular, autoimmune, tumoral (acoustic neurinoma), perilymph fistula, acoustic trauma, trauma, or psychogenic origin. A specific etiological factor can be detected in only 10% of cases, and the rest are considered sudden idiopathic hearing loss.[3,4]

Although many treatment methods have been applied in SSNHL treatment, following a study by Wilson et al.[5] in 1980, corticosteroids became accepted as the primary treatment. The spontaneous recovery rate of sudden idiopathic hearing loss has been reported as 32-65% in different studies, and with steroid treatment, the rate rises to 49-89%.[5,6]

Due to the side effects of systemic steroids, the administration of intratympanic steroid (ITS) in the treatment of SSNHL, which creates a high perilymphatic drug concentration, has become popular. In intratympanic administration, a chemical substance passes into

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the middle ear through the annular ligament of the round window and the oval window, through the vascular and lymphatic structures.[7,8]

In intratympanic applications, the drug administered to the middle ear is absorbed through the round window by diffusion and passes to the inner ear; therefore, the desired doses in the inner ear fluids can be reached easily in a short time. Studies have indicated that steroids administered systemically should be given at a very high dose to be able to reach a sufficient concentration in the inner ear fluids, whereas the drug administered through the transtympanic route can easily reach the desired level in the inner ear.[4]

This study aimed to compare the effectiveness or treatment with systemic steroid and ITS in patients followed up with SSNHL.

METHODS

A retrospective analysis was performed with the files of 90 patients diagnosed with sudden hearing loss, who were examined and treated between 2014 and 2017 in Ondokuz Mayıs University Department of Otorhinolaryngology. Written consent was obtained from all patients included in the study. This study was performed with the ethics committee's approval (Approval No. 2020/433).

Patient information such as age, gender, time since the onset of SSNHL, affected ear, and patient history (chronic diseases, previous hearing loss) were recorded.

The routine otolaryngological examination of patients was evaluated. The complete blood count, complete biochemistry, thyroid function tests, autoimmune markers, audiological tests, temporal CT, and/or MRI were assessed for etiological evaluation. Patients who had sensorineural hearing loss of 30 dB and above at 3 consecutive frequencies within 3 days were determined as matching the diagnostic criteria. In addition, the degrees of hearing loss, audiogram type, and time to treatment onset were recorded.

The hearing losses were classified as 26-40 dB = mild, 41-70 dB = moderate, 71-90 dB = severe, and 91 dB and above = very severe/total. The rate of recovery and the recovery status with different degrees of hearing loss were compared, according to the clinical practice guideline.

MAIN POINTS

- Steroid therapy is the gold standard in the treatment of sudden hearing loss.
- Treatment options for sudden hearing loss include systemic and topical steroids.
- Intratympanic steroid (ITS) administration has many advantages over systemic steroid treatment.
- Steroids, the only treatment with proven efficacy in sudden idiopathic hearing loss, show no difference in efficacy with respect to the different methods of administration.

The correlation between treatment initiation time and treatment success was calculated, and the effect of early treatment on hearing gain was examined. The time to treatment initiation was grouped as 1-15 days, 15 days to 1 month, and 1 month and later.

The effect of distinctly retained frequencies on prognosis was investigated. Additionally the hearing gain in terms of degree of gain, method of treatment, the type of audiogram, and the status of improvement relative to the type of audiogram (bowl, ascending, flat, and descending type audiograms) were compared.

All patients were given detailed information about different treatment methods. Only ITS injection was applied to some patients, especially for those with diabetes mellitus, other comorbid diseases, or those with systemic side effects to corticosteroids. Before ITS treatment was performed, all patients were given detailed information about the application with an explanation of the risks, and an informed consent form was signed.

Of the 90 patients evaluated, 44 received ITS (group 1), and 46 received systemic steroid therapy (group 2). In the study, of the 44 patients who received ITS treatment in group 1, 29 patients were administered ITS because systemic steroid use was contraindicated, while 15 patients did not recover despite systemic therapy, and ITS therapy was used as salvage therapy.

Forty-six patients received systemic steroid treatment in group 2, and 33 of them were patients who received systemic steroid treatment for the first time. Thirteen of them did not fully apply and did not respond to the first dose of systemic steroid treatment administered at another center, and to a second additional dose as salvage therapy.

The patients in group 2 were administered 1 mg/kg of methylprednisolone systemically, (which was then tapered and discontinued), rheomacrodex 500 cm^3 (6 h IV infusion), gastroprotective medication, and a salt-free diet. For ITS application, the patient was placed in a supine position with the head rotated 45° toward the right ear. Following topical anesthesia of the outer ear canal under otomicroscopic vision, 1 mL of methylprednisolone (Depomedrol®) was applied with a 27-gauge dental injector from the posteroinferior quadrant of the affected side. To avoid vestibular irritation, the drug was kept at body temperature for 15-30 minutes before application. After the application, patients were told not to swallow and to remain in the same position for 30 minutes, for the drug to remain in the middle ear for a longer time. A total of 4 doses were applied 2 days a week for 2 weeks. In the audiological examinations, tympanometry and pure-tone audiometry were performed. Pure-tone average (PTA) at 500, 1000, 2000, 4000, and 8000 Hz was recorded before the treatment and at the first and third months post-treatment. The audiological improvement criteria defined by Furahashi were used to determine the response to treatment (Table 1).[9] Of the 92 patients initially included in the study, 64 underwent MR imaging, of which 62 were reported as normal, and schwannoma was determined on the images of 2 patients. These 2 patients with schwannoma were excluded from the study, and the final evaluation was made of 90 patients (53 males and 37 females), all aged >18 years.

Table 1. Audiological Improvement Criteria Defined by Furahashi

Improvement	Audiological Value
Complete Recovery	PTA ≤25 dB
Significant improvement	PTA improvement >30 dB
Mild improvement	PTA improvement between 10 dB and 30 dB
No improvement	PTA improvement between 0 dB and 10 dB

Statistical Analysis

Data obtained in the research were analyzed statistically using Statistical Package for the Social Sciences (SPSS) version 22.0 (IBM SPSS Corp.; Armonk, NY, USA). The continuous variables were presented as mean ± standard deviation or median (range: min-max) values, and the numerical data as number (*n*) and percentage (%). The conformity of the data to normal distribution was evaluated with the Shapiro–Wilk's test. Pearson's chi-square test and Fisher's exact test were used to compare the frequency data. Continuous variables were evaluated using the Mann–Whitney *U*-test, as they did not conform to normal distribution. A value of $P < .05$ was accepted as statistically significant.

RESULTS

The 90 patients included in the study consisted of 53 (58.8%) males and 37 (41.1%) females with a mean age of 46.7 years (18-79). The mean age of patients in group 1 was 47.9 years, and it was 45.6 years for those in group 2. Hearing loss was unilateral in all patients. The right ear was affected in 47 patients and the left ear in 43 patients, with no statistically significant difference determined with respect to the affected side (Table 2). None of the patients had audiograms before SSNHL. The information obtained from the anamnesis was compared with the other ear, and the hearing had been similar to the opposite ear before SSNHL.

Table 2. Descriptive Statistics of the Groups

	Systemic Steroid	Intratympanic Steroid
Age (years)	47.9	45.6
Gender		
Male	17	20
Female	29	24
Side		
Right	21	26
Left	25	18

While the duration of stay in the hospital was 11.3 ± 11.1 days in group 1, it was 6.2 ± 7.6 days in group 2, and a statistically significant difference was found between the groups in terms of hospitalization times ($P = .007$). The time to treatment initiation was between the first and the 14th days in 68 patients (75.6%), between the 15th and 29th days in 15 patients, (16.7%), and in the range of 1 month and later in 7 patients (7.8%). When the treatment success was analyzed according to the patients' time to treatment initiation, it was observed that only 1 patient (14.3%) in the group who started treatment after 1 month had a slight recovery ($P > .05$).

When the audiograms at the first admission were examined, 10 patients (11.1%) had mild hearing loss, 29 patients (32.2%) had moderate hearing loss, 24 patients (26.7%) had severe hearing loss, and 27 patients (30%) had total hearing loss. The recovery status according to the degree of hearing loss was evaluated, and it was observed that there was complete recovery in 10 (11.1%) patients. The rates of complete recovery were 30% for mild hearing loss, 17.2% for moderate, 4.2% for severe and 3.7% for total hearing loss (Table 3).

When the audiogram type was examined, it was observed that 13 (14.4%) patients had a descending type, 16 (17.8%) had an ascending type, 13 (14.4%) had a bowl type, and 48 (53.4%) had a flat type audiogram for hearing loss. The treatment success of the patients according to the audiogram type at the first admission was evaluated, and it was determined that while there was no patient with complete recovery in the descending audiogram type, complete recovery was found in 14.6% of the flat type and 12.5% of the ascending type (Table 4).

When the improvement in hearing level was examined according to the Furahashi criteria, 4 (9.1%) of 44 patients who underwent intratympanic treatment showed complete improvement, 8 (18.2%) showed significant improvement, 12 (27.3%) showed mild improvement, and in 20 patients (45.5%), no improvement was observed. There was a complete improvement in 6 (13%) of the 46 patients who underwent systemic steroid treatment, significant improvement in 5 (10.9%), mild improvement in 10 (21.7%), and no improvement in 25 (54.3%). The ITS and systemic steroid treatment groups were compared with respect to complete and significant improvement, mild improvement, and no improvement. No statistically significant difference was determined between the groups in terms of the levels of improvement ($P = .692$) (Table 5).

Table 3.

	Improvement Status				
Degree of hearing loss	No Improvement	Mild Improvement	Significant Improvement	Complete Improvement	*P*
Mild	5 (50.0)	2(20.0)	0 (0.0)	3(30.0)	.11
Severe	12 (50.0)	5 (20.8)	6 (25.0)	1 (4.2)	
Moderate	16 (55.2)	7 (24.1)	1 (3.4)	5 (17.2)	
Total	12 (44.4)	8 (29.6)	6 (22.2)	1 (3.7)	
Total	45	22	13	10	

Table 4.

	Improvement Status				
	No Improvement	**Mild Improvement**	**Significant Improvement**	**Complete Improvement**	***P***
Audiogram types					
Bowl	3 (23.1)	3 (23.1)	6 (46.2)	1 (7.7)	.07
Ascending	9 (56.3)	4 (25.0)	1 (6.3)	2 (12.5)	
Flat	24 (50.0)	12 (25.0)	5 (10.4)	7 (14.6)	
Descending	9 (69.2)	3 (23.1)	1 (7.7)	0 (0.0)	
	45	22	13	10	

Table 5. Improvement Status of the Groups According to the Furahashi Criteria

	Systemic Steroid Group	**Intratympanic Steroid Group**
Complete-significant improvement	23.9%, *n* = 11	27.3%, *n* = 12
Mild improvement	21.7%, *n* = 10	27.3%, *n* = 12
No improvement	54.3%, *n* = 25	45.5%, *n* = 20

The patients in group 1 who received treatment as primary treatment ($n=29$), and those who received treatment as salvage treatment ($n=15$), were examined according to the Furahashi criteria, and no statistically significant difference was determined in the levels of improvement ($P=.268$). Similarly, the patients in group 2 who received systemic steroid treatment as primary treatment ($n=33$) and those who received the systemic steroid treatment for the second time as salvage treatment ($n=13$) were compared, and no statistically significant difference was determined in terms of the levels of improvement ($P=.336$) (Table 5).

DISCUSSION

SSNHL is an otological emergency that requires prompt treatment. It is thought that the sooner the treatment is started, the better the prognosis of the disease.[1,10] The efficacy of corticosteroids has been demonstrated in many studies.[1-3] The treatment options include systemic and topical steroids, antiviral agents, vasoactive and hemodilution treatments, hyperbaric oxygen therapy, other medical treatments, surgical fistula repair, and observation only.[1,3,10]

The etiology of SSNHL includes vascular, viral, traumatic, and immune theories. The administration of systemic steroids to patients with SSNHL aims to suppress inflammation and autoimmune damage, reduce edema, and regulate microcirculation.[1] Recent studies have stated systemic stress and chronic inflammation to be responsible in SSNHL. Chronic inflammation disrupts blood flow in the inner ear, with endothelial damage, forms atherosclerosis, and then triggers microvascular damage in the stria vascularis, increasing the risk of ischemia. When the relationship between SSNHL and inflammation is evaluated, the importance of systemic steroid treatment with anti-inflammatory properties and the rapid response of patients can be clearly understood. However, the chronic use of systemic steroids can lead to severe side effects, but as steroid treatment for SSNHL is recommended for a short period of 10-14 days, as these side effects are uncommon and can be managed.[1,2]

Several factors, such as the type and intensity of hearing loss, the time between the onset of symptoms and beginning of treatment, the duration of treatment, the route of administration of the steroid, the tinnitus and/or vertigo accompanying hearing loss, systemic diseases, advanced age (or a very young age), and a descending curve in the audiogram affect the prognosis.[5,11]

Müderris et al.,[12] in their analysis of 73 cases, found that the mean gain was 57 dB in patients admitted within the first week and 16 dB in patients admitted after the third week. Hughes[13] stated that the prognosis is better in cases with early treatment, which had recovery within the first 2 weeks, moderate and low-frequency hearing loss, and no vertigo. Considering that this period was 11.3 ± 11.1 days in group 1 in our study, we determined it as a poor prognostic factor. We observed that 17 patients in group 1 and 15 patients in group 2 had at least 1 or several systemic diseases, and hypertension and diabetes were the most common comorbidities.

The treatment of inner ear diseases with intratympanic drug administrations has increased rapidly in recent years, and this has become a frequently used method, especially for SSNHL. Direct targeting of the affected area without reaching the whole body is the main advantage of the method. In addition, this minimally invasive, easy-to-apply method provides a high drug concentration in the inner ear fluids with no risk of the systemic side effects of the drugs. In recent years, it has been used not only in primary or combined treatment, but also as a recovery treatment for patients who have not benefited from systemic steroid treatment.[6,14] In the current study, 29 patients received primary ITS therapy, and 15 received it as salvage therapy.

Although there are reports in the literature of steroids administered by methods such as needle injection, the myringotomy method (a ventilation tube placed in the eardrum), or by MicroWick (round window microcatheter), the injection technique has been used in most studies.[15,16] In the current study, the steroid was injected with a needle into the middle ear, primarily because the injection method of ITS application has low morbidity.

Methylprednisolone and dexamethasone are the most commonly used molecules in ITS treatment, and each can be administered at different frequencies and amounts.[11,17] In the study by Parnes et al.[7] on animals, it was shown that methylprednisolone concentration was the highest and remained the longest in both the perilymph and endolymph when compared

with dexamethasone and hydrocortisone. They reported that methylprednisolone concentration slowly decreased below the detection level in the perilymph within 24 hours, whereas dexamethasone and hydrocortisone could be detected for only up to 6 hours after middle ear injection.[7,8] This study was conducted on humans in the following years, and similar results were found.[18]

Tarkan et al.[11] and Yang et al.[19] reported that IT methylprednisolone and dexamethasone were not superior to each other, in their study in which they compared the efficacy of dexamethasone and methylprednisolone in patients with SHL.

Berjis et al.[20] evaluated the effectiveness of ITS methylprednisolone and dexamethasone in patients whose hearing loss did not improve with systemic treatment, and reported that hearing was statistically significant in the methylprednisolone group compared to the dexamethasone group ($P < .05$). Based on this information in the literature, we preferred to use the methylprednisolone treatment in our study.

The success rates show significant variability among studies using ITS in the treatment of SSNHL, depending on the type of steroid used, the amount of dose administered, the improvement criteria, the treatment previously received, and the time of starting treatment. Gianoli et al.[21] applied ITS to 23 patients who had not responded to oral steroid treatment, and achieved an average of 15 dB improvement in 10 patients (44%) in the mean pure-tone values. In a study by Guan-Min et al.[9] after 10 days of oral steroid treatment, patients with an improvement of ≤30 dB were considered unsuccessful in terms of this treatment; intratympanic dexamethasone was then applied, and the mean pure-tone improved by 28.39 dB. Herr et al.[22] administered methylprednisolone with a microcatheter to 17 patients who did not benefit from oral steroid treatment, and an average of 24 dB hearing improvement was achieved in 9 patients (53%).

A complete improvement in PTA was determined in 4 patients in the current study, compared to the first control audiograms after intratympanic injection. While no recovery was observed in 10 of 15 patients who underwent recovery treatment, a slight improvement was observed in 2 patients and there was complete recovery in 3 patients.

Recent studies in the literature have reported the initiation of ITS treatment simultaneously with systemic steroid treatment in SSNHL. Toroslu et al.[10] compared patients with SSNHL administered only oral therapy, oral therapy + ITS, oral therapy + hyperbaric oxygen, and only ITS therapy. There was reported to be no statistically significant difference in terms of average hearing gain and recovery status provided by the different treatment methods applied.

In the literature, the studies have compared patients with concomitant ITS therapy plus systemic steroids and standard systemic steroid therapy only, and more successful hearing results have been reported in patients receiving concomitant ITS therapy with systemic steroids.[4,23]

ITS administration has many advantages over systemic steroid treatment. With the application of ITS , a higher perilymphatic concentration is achieved, and the side effects that may occur with the systemic application are avoided.[7] In the current study, similar to the literature, no advantage of either method of steroid application was determined in terms of effectiveness.

In patients who cannot tolerate treatment due to the side effects of systemic steroids, in patients with a high risk of developing systemic complications with steroids, and in patients with poor compliance with multiple drug use, ITS administration is used as primary therapy.

The results of this study demonstrated that in the administration of steroids, the only treatment with proven efficacy in sudden idiopathic hearing loss, there was no superiority in the efficacy of one over the other in terms of the method of administration; It can be suggested that ITS applied alone can be used as a primary treatment in the first application, considering the advantages in terms of avoiding systemic side effects, reducing hospital stay, and ease of administration.

While the small number of patients and the inclusion of patients who did not improve with treatment in both groups were noted as limitations in our study, future studies with larger and more specific patient groups will shed light on the subject. The abundance of variables complicates the creation of standard treatment protocols.

Ethics Committee Approval: Ethical committee aproval was received from the Ethical Board of Ondokuz Mayıs University Faculty of Medicine (2020/433).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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