CLINICAL STUDY

THE SUDDEN SENSORINEURAL HEARING LOSS INCONSISTENT WITH THE DEFINITION CRITERIA

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SUMMARY

Objective: The definition of sudden sensorineural hearing loss (SSHL) is widely used in the literature. However, there are many cases in clinical practice that do not meet this definition. We aimed to analyze these unclassified patients to demonstrate their responses to systemic steroid therapy and their clinical features. We also aimed to compare them with the patients in the literature that are compatible with the definition.

Methods: Thirty five patients with acute onset hearing loss but not meeting SSHL definition criteria in the literature were analyzed. After statistical analysis of audiometric measurements before and after treatment, two groups were recruited. Patients with hearing loss less than 3 frequencies recruited to group 1 and hearing loss at 3 or more consecutive frequencies, but with an average loss of less than 30 dB were included in group 2. Then these two groups were compared.

Results: There were statistically significant differences between the patients at all frequencies before and after treatment (p=0.000, p=0.001, p=0.001, p=0.005, p=0.000, respectively). No statistically significant difference was found between two groups in terms of age, gender, affected side, hipertension, diabetes mellitus, tinnitus, vertigo, hiperlipidemia and recovery rates.

Conclusion: Patients with acute onset hearing loss but did not meet SSHL definition in the literature are common. In our study, we observed that systemic steroid therapy is effective in the treatment of these patients.

Keywords: Sudden sensorineural hearing loss, definition criteria, guideline, systemic steroid therapy

TANI KRİTERİ İLE UYUMSUZ ANİ İŞİTME KAYBI

ÖZET

Amaç: Ani işitme kaybı tanımı literatürde yaygın olarak kullanılmaktadır. Bununla birlikte klinik pratikte bu tanımı karşılamayan birçok hasta mevcuttur. Çalışmamızda bu sınıflandırılmamış hastaların sistemik steroid tedavisine yanıtını ve klinik özelliklerini incelemeyi amaçladık. Ayrıca bu hastaları literatürdeki tanıma uyumlu hastalarla kıyaslamayı hedefledik.

Yöntem: Akut gelişen işitme kaybı olan ancak literatürdeki ani işitme kaybı kriterini karşılamayan 35 hasta incelendi. Tedavi öncesi ve sonrası odyometrik incelemeleri istatistiksel olarak incelendikten sonra iki grup oluşturuldu. Üçten az frekansta işitme kaybı olan hastalar grup bire, ardışık üç veya daha fazla frekansta kaybı olup kayıplarının ortalaması 30 desibelin altında kalanlar grup ikiye dahil edildi.

Bulgular: Tüm hastaların tüm işitme freakanslarında tedavi öncesi ve sonrası arasındaki fark istatistiksel olarak anlamlıydı. (p=0.000, p=0.001, p=0.001, p=0.005, p=0.000, sırayla). İki grup arasında yaş, cinsiyet, etkilenen taraf, hipertansiyon, diyabet, tinnitus, vertigo, hiperlipidemi ve iyileşme oranları arasında istatistiksel olarak anlamlı fark saptanmadı.

Sonuç: Akut gelişen işitme kaybı olan ancak literatürdeki ani işitme kaybı tanımını karşılamayan hastalar yaygındır. Çalışmamızda sistemik steroid tedavisinin bu hastaların tedavisinde etkili olabileceğini gözlemledik.

Anahtar Sözcükler: Ani sensörinöral işitme kaybı, tanı kriteri, guideline, sistemik steroid tedavisi

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INTRODUCTION

The sudden sensorineural hearing loss (SSHL) is an acute and important disorder in ENT practice. The incidence of SSHL is 5 to 27 per 100.000 people in United States, with some estimates ranging as high as 160 per 100.000[1,2,3]. It is well known that more than 90 percent of SSHL is idiopathic. The pathogenesis of SSHL is largely unknown and possible etiologies blamed for SSHL are viral infections, vascular pathologies, inner ear inflammation, autoimmune disease, and central nervous system pathologies[4]. Common causes of non-idiopathic SSHL include vestibular schwannoma (acoustic neuroma),

noise exposure, stroke, malignant diseases and ototoxic agents[5,6].

SSHL definition commonly used in the literature (published criteria for studies) is sensorineural hearing loss of at least 30 dB at three consecutive frequencies within 72 hours[4,7,8,9,10,11]. However, in clinical practice there are many patients who do not meet this definition. We did not find any study investigating this patients so we aimed to analyze these unclassified patients in our research to evaluate their responses to systemic steroid therapy and their clinical features. We also aimed to compare them with the patients compatible with the definition of SSHL in the literature.

MATERIAL and METHODS

Patient Selection and Study Design:

This retrospective study was conducted in our tertiary clinic between January 2015- January 2018. The study was carried out in accordance with international ethical standards of the Helsinki Declaration. The ethical committee of the institution approved the study protocol (Protocol Number: 314, Date: 29.11.2019). Informed consent was obtained from all participants. The patients were hospitalized in our clinic and cases that did not meet the SSHL definition (sensorineural hearing loss of at least 30 dB at three consecutive frequencies within 72 hours) were analyzed. Hearing threshold averages in normal (unaffected) ears was 0-25 dB.

The inclusion criteria were as follows: 1. Medical history of acute sensorineural hearing loss with or without tinnitus that develops over a period of a few hours to three days; 2. Unilateral ear affected; 3. Aged > 18 years; 4. No previous history of hearing loss in either ears; 5. Not having another acute sensorineural hearing loss attack for at least 1 year

Exclusion criteria: 1. Tumors like acoustic neuroma; 2. Retrocochlear pathologies; 3. Previous histories of sudden hearing loss, repetitive fluctuating hearing loss, and/or the possibility of Meniere's disease; 4. Acoustic trauma; 5. Barotrauma; 6. Uncontrolled hypertension or diabetes unsuitable for systemic steroid therapy; 7. Ma¬lignancy; 8. Autoimmune diseases; 9. History of head trauma; 10. Systemic diseases like asthma or chronic obstructive pulmonary disease; 11. Patients with whom we could not start treatment for more than 30 days after the onset of hearing loss; 12. A clinical observation period less than 1 year; 13. Inner ear malformations or hereditary hearing impairments; 14. Patients who meet the definition criteria in the literature.

Audiometric measurements were performed before and after the treatment. We observed that the patients did not meet the definition criteria according to two conditions and then two groups were recruited. Patients with hearing loss less than 3 frequencies recruited to group 1. Patients with hearing loss at 3 or more consecutive frequencies, but with an average loss of less than 30 db (at the affected frequencies) were recruited to group 2.

Evaluation, Treatment and Assessment:

After otoscopic examination; pure tone audiometry (AC 40; Interacoustics, Middelfart, Denmark), standard laboratory tests (e.g. routine blood count, biochemical tests, coagulation panel and viral serology tests) and MR (Gadolinium-Enhanced 3D FLAIR MR images of internal auditory and inner ear) were performed on all patients. Hearing thresholds were measured at 0.5, 1, 2, 4 and 8 kHz frequencies.

Patients were treated with our standard treatment protocol (intravenous methyl prednisolone sodium succinate was administered at 1 mg / kg for 3 days, 40 mg for 3 days, 20 mg for 2 days and 10 mg for 2 days).

For the analysis of hearing improvement, pure tone audiometry was evaluated 1 year after the treatment and the results were classified under three conditions: complete recovery-return to the same hearing level with the other healthy ear; partial recovery-hearing gain of at least 10 dB at one frequency but not return to the same hearing

level as the other ear; no recovery- no hearing gain was observed. Patients were observed for at least 1 year for recurrence.

SPSS 20.0 software was used for statistical analysis. Wilcoxon signed-rank test was used to compare audiometric measurements of the patients before and after the treatment. Pearson chi-square test was employed for comparison of recovery rates and clinical features; T-test was used for mean comparison. $p<0.05$ indicated significant difference.

RESULTS

Between January 2015-January 2018 130 patients admitted to our clinic with sudden onset hearing loss. According to MRI reports, there were 4 patients compatible with acoustic neuroma and 2 patients compatible with meningioma. In the remaining idiopathic patients, 89 patients were consistent with SSHL according to the definition in the literature. The other 35 patients did not meet the SSHL definition and these patients included in our study. Group 1 consists of 16 patients and group 2 consists of 19 patients.

In all 35 patients pre and post treatment bone conduction pure tone averages were (30±17.94) dB-(22.6±15.84) dB for 0.5 kHz; (26.57±17.18) dB-(20.71±15.68) dB for 1 kHz; (27.57±17.88)-(21.86 17.74) dB for 2 kHz; (37.29±21.12)-(33.14±21.88) dB for 4 kHz and (45.71±24.65)-(39.85±23.6) dB for 8 kHz. There were statistically significant differences between the audiometric measurements of the patients at all frequencies before and after the treatment (p=0.000, p=0.001, p=0.001, p=0.005, p=0.000, respectively). Table 1. summarizes the audiometric measurements of the patients before and after the treatment.

Gender distribution of 35 patients were as follows; 25 (71.42%) males and 10 (28.57%) females. The ages of the patients ranged from 22 to 71. The mean age of patients in group 1 was 42.87±15 and in group 2 was 46.10±12.66. There were 10 males and 6 females in group 1; 15 males and 4 females in group 2. In group 1; eight patients were affected in the left ear and eight patients were affected in the right ear. In group 2; ten patients were affected in the left ear and nine patients were affected in the right ear. One patient had hipertension in group 1and two patients had hipertension in group 2. Two patients had DM in group 1 and three patients had in group 2. Tinnitus was observed in 8 patients in both groups. Vertigo was observed in one patient in group 1 and in two patients in group 2. Hyperlipidemia was not observed in any patient. No statistically significant difference was found between the 2 groups in terms of age, gender, affected side, hipertension, diabetes mellitus, tinnitus, vertigo and hiperlipidemia (p=0.44, p=0.45, p=0.87, p= 0.65, p=0.78, p=0.64, p=0.65, respectively)

The treatment of the patients started on the first day of their admission to our clinic. In group one 10 patients were treated within 14 days and 6 patients were treated within 14-30 days; in group two 14 patients were treated within 14 days and 5 patients were treated within 14-30 days. Recovery rate (complete recovery + partial recovery) was 70.83 in group 1 and 81.81 in group 2. There was no statistically significant difference between the groups according to treatment onset (p=0.32). Table 2 shows these results.

In group 1 six patients had complete recovery, five had partial recovery and five had no recovery. In group 2 ten patients had complete recovery, five had partial recovery and four had no recovery. There was no statistically significant difference between the groups in recovery rates (p=0.65). Table 3 shows the hearing recovery rates.

Table 1. Audiometric measurements of patients before and after treatment

	Before (mean, SD and range) (dB)	After (mean, SD and range) (dB)	*P*
0.5 kHz BCT	30±17.94 (0-70)	22.6±15.84 (0-60)	0.000*
1 kHz BCT	26.57±17.18 (10-70)	20.71±15.68 (10-65)	0.001*
2 kHz BCT	27.57±17.88 (10-70)	21.86±17.74 (10-65)	0.001*
4 kHz BCT	37.29±21.12 (10-90)	33.14±21.88 (10-90)	0.005*
8 kHz BCT	45.71±24.65 (15-90)	39.85±23.65 (10-90)	0.000*

* Statistically significant
BCT: Bone conduction threshold

Table 2. Interval between the onset of sudden hearing loss and treatment

	Group 1	Group 2	Recovery rate(%)
Within 14 days	10	14	70.83
Longer than 14 days	6	5	81.81

P value between onset=0.32

Table 3. Hearing recovery rates

	Complete	Partial	No recovery
Group 1	6	5	5
Group 2	10	5	4

P value between group1-group 2=0.65
Total recovery rate (complete+partial) is 74.28%

DISCUSSION

SSHL definition commonly used in literature is sensorineural hearing loss of at least 30 dB at three consecutive frequencies within 72 hours[4,7,8,9,10,11]. However, in clinical practice, many patients who do not meet this definition are frequently encountered. In some patients, hearing loss is less than three frequencies. But in other patients hearing loss is in 3 or more consecutive frequencies, but the average loss is less than 30 db (at the affected frequencies). Although these patients are common in clinical practice, we did not observed a study in the literature investigating these patients. Between January 2015- January 2018 one hundred thirty patients admitted to our clinic with sudden onset hearing loss and 35 of them did not meet the published definition criteria (28.22%). After audiometric measurements, we observed that the patients did not meet the definition according to two conditions. We divided these 35 patients into two groups according to these conditions and analyzed them. No statistically significant difference was found between the 2 groups in terms of age, gender, affected side, hipertension, diabetes mellitus, tinnitus, vertigo and hiperlipidemia (p=0.44, p=0.45, p=0.87, p=0.65, p=0.78, p=0.64, p=0.65, respectively). According to clinical features this two groups seems to represent the same clinical condition.

Treatment options for SSHL are systemic and topical steroids, antiviral agents, hyperbaric oxygen therapy, diuretics, herbal and other

alternative treatments and no treatment (only observation)[9].We treated our patients with our standard treatment protocol for SSHL (intravenous methyl prednisolone sodium succinate was administered at 1 mg / kg for 3 days, 40 mg for 3 days, 20 mg for 2 days and 10 mg for 2 days) because in the literature we can not find a study, guideline or international consensus about this unclassified patients.

Hearing thresholds were measured for 0.5-1-2-4-8000 kHz. There were statistically significant differences between pre and post treatment audiometric measurements at all frequencies (p=0.000, p=0.001, p=0.001, p=0.005, p=0.000, respectively). Hearing recovery at all frequencies are the averages of all 35 patients. Therefore, the average of hearing improvement appears to be below 10 dB. At this point, steroid therapy seems to be effective for these patients. But we do not have a spontaneous recovery group to compare this efficacy. Wider studies with spontaneous healing groups and treatment groups are considered to be necessary to clarify the effects of treatments.

It has been shown that the time of treatment onset may affect the healing process. Chandrasekhar et al recommended initial corticosteroids within 2 weeks of symptom onset in their guideline[9]. Yan Huafeng et al found among the 36 cases with treatment onset less than 14 days, 31 cases had recovery to varying degree, with a recovery rate of 86.1%. Among the 19 cases with treatment onset longer than 14 days, 10 had partial or complete recovery, with a recovery rate of 52.6%. The difference was significant between the groups (p=0.017)12. In our study 10 patients were treated within 14 days and 6 patients were treated within 14-30 days in group 1 and 14 patients were treated within 14 days and 5 patients were treated within 14-30 days in group 2. We can not observe statistically significant difference according to treatment onset. Our small sample size may lead to this outcome, and we believe that the relationship between the onset of treatment and recovery rates should be evaluated in wider or multicentric studies.

Chandrasekhar et al indicated that 32% to 65% of cases of SSHL may have spontaneous recovery[4,13]. A Cochrane review showed 3 studies that met their randomized controlled study standards for steroids versus placebo or no treatment[14]. Two of those studies showed no significant effect between steroids and placebo, but one study showed significant recovery in 61% of patients in the treatment group against 32% in the placebo group[4,15,16]. In our study; in group 1 six patients had complete recovery, five had partial recovery and five had no recovery. In group 2 ten patients had complete recovery, five had partial recovery and four had no recovery. There was no statistically significant difference between the groups in recovery rates (p=0.65). We believe this result also indicates that two group seems to represent the same disease. Our total recovery rate (74.28%) is higher than previous publications. We think that the evaluation methods of the recovery rates may lead to this result. In addition, due to the heterogeneous findings of our groups, we were unable to use a standard assessment method such as Siegel's criteria. We also cannot determine spontaneous recovery rates because we have treated all our patients. We believe that further studies on recovery rates are needed for this unclassified patients.

Marx et al. concluded that systemic steroids are the most widespread primary therapy for SSHL and trans-tympanic steroids used as a salvage therapy is debatable. But several studies showed significant hearing improvements with trans-tympanic steroid salvage therapy[17]. We believe that studies about transtympanic steroid salvage therapy should also conducted for this inconsistent patients.

The main limitation of our study are related to the limited number of enrolled patients. More comprehensive studies are necessery to evaluate

especially the recovery rates and factors affecting them. Another limitation is that we do not have a spontaneous recovery group to compare the treatment efficacy. However, the same limitation applies to many publications in the literature on sudden hearing loss.

CONCLUSION

Patients with acute onset hearing loss but did not meet SSHL definition criteria in the literature are not uncommon. We observed that systemic steroid therapy is effective in the treatment of these patients. We believe that more comprehensive studies are necessary to evaluate the etiology, clinical features and treatment of these patients. We also believe that less stringent criteria should be used for SSHL in the literature, or that these unclassified patients should be considered as another clinical condition. If these patients accepted as a different clinical condition they should be studied separately and specific guidelines should be published for them.

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Compliance with ethical standards

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