



Original Article

Modified Siegel's criteria for sudden sensorineural hearing loss: Reporting recovery outcomes with matched pretreatment hearing grades

Yen-Fu Cheng^{a,b,c,d}, Yuan-Chia Chu^{e,f}, Tzong-Yang Tu^{a,c}, An-Suey Shiao^{a,c}, Shang-Liang Wu^g, Wen-Huei Liao^{a,c,*}

^a Department of Otolaryngology-Head and Neck Surgery, Taipei Veterans General Hospital, Taipei, Taiwan, ROC

^b Department of Medical Research, Taipei Veterans General Hospital, Taipei, Taiwan, ROC

^c Department of Otolaryngology-Head and Neck Surgery, School of Medicine, National Yang-Ming University, Taipei, Taiwan, ROC

^d Department of Speech Language Pathology and Audiology, National Taipei University of Nursing and Health Sciences, Taipei, Taiwan, ROC

^e Information Management Office, Taipei Veterans General Hospital, Taipei, Taiwan, ROC

^f Graduate Institute of Biomedical Electronics & Bioinformatics, National Taiwan University, Taipei, Taiwan, ROC

^g School of Medicine, Griffith University, Gold Coast, Australia

Received January 16, 2018; accepted March 14, 2018

Abstract

Background: Sudden sensorineural hearing loss (SSNHL) is an emergency clinical otology condition defined as hearing loss greater than 30 dB over three consecutive frequencies within 72 h. We aimed to integrate pretreatment hearing grades with reports of treatment recovery outcomes of SSNHL using the modified Siegel's criteria.

Methods: This was a retrospective cohort study comprising 110 patients with SSNHL seen between January 2014 and January 2015. The patients were treated with combined systemic and intra-tympanic steroid therapy. The audiometric results were recorded using the modified Siegel's criteria, including pretreatment hearing grades 1–5 (grade 1: hearing threshold under 25 dB, grade 2: hearing threshold 26–45 dB, grade 3: hearing threshold 46–70 dB, grade 4: hearing threshold 71–90 dB, grade 5: hearing threshold over 90 dB) and hearing recovery outcomes, consisting of complete recovery (CR), partial recovery (PR), slight improvement (SI), no improvement (NI) or non-serviceable ears (NS). Patients were further assessed based on the treatment modality (initial or salvage treatment) and duration of the treatment delay.

Results: Hearing improvements (CR + PR + SI) were seen in 56 patients. Patients with pretreatment hearing grade 3 had the highest improvement rate (88.2% or 30/34). Patients who received the combined steroid therapy as the initial modality had a better overall hearing improvement rate than did the salvage group. Treatment within the first 14 days yielded a better hearing improvement rate than did late treatments of more than 14 days, especially in patients with a pretreatment hearing grade of 5.

Conclusion: Using the modified Siegel's criteria, we report the hearing recovery outcomes with matched pretreatment hearing grades of patients with SSNHL treated with combined intra-tympanic steroid therapy. Our results show the prognostic significance of pretreatment hearing grades in patients with SSNHL.

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Keywords: Hearing recovery outcomes; Pretreatment hearing grades; Siegel's criteria; Sudden sensorineural hearing loss

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

* Corresponding author. Dr. Wen-Huei Liao, Department of Otolaryngology-Head and Neck Surgery, Taipei Veterans General Hospital, 201, Section 2, Shi-Pai Road, Taipei 112, Taiwan, ROC.

E-mail address: whliao@vghtc.gov.tw (W.-H. Liao).

<https://doi.org/10.1016/j.jcma.2018.03.012>

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1. Introduction

Sudden sensorineural hearing loss (SSNHL) is an emergency clinical otology condition that is defined as hearing loss greater than 30 dB over three consecutive frequencies within 72 h, with abnormalities of the cochlea, auditory nerve, or central auditory system.¹ The incidence rate of SSNHL has been reported to be 5–27/100,000 persons per year.^{2–4} The causative etiologies for SSNHL included viruses, microcirculation abnormalities, and autoimmune disorders. However, definitive evidence remains elusive.^{5,6} Currently, steroids are the treatment of choice due to their effects on the inner ear such as immunosuppression and circular enhancement.^{6–8} Combined systemic and intra-tympanic steroid treatment has previously been reported to be beneficial for SSNHL patients, with overall better treatment outcomes.^{9–15} However, due to the heterogeneous pathological nature and spontaneous recovery potential of the disease, few controlled studies exist in the literature. As a result, the treatment strategies of SSNHL remain a controversial issue in clinical practice.

Furthermore, it is difficult to compare treatment results among the published reports due to a lack of a universal system to assess treatment efficacy and outcomes of SSNHL. Hearing recovery is the key indicator for the treatment of SSNHL, and various systems have been used to report the outcomes.^{16–20} Among the reporting systems, Siegel's criteria of hearing improvement is the most commonly used to show final hearing outcomes and absolute hearing gains.¹⁶ However, the four-outcome categorization proposed by Siegel might not be sufficient to correspond to recent advancements in hearing amplification devices.

Therefore, a modification of Siegel's criteria is proposed to assess the treatment outcomes of SSNHL. In the present study, the matched pretreatment hearing grades were integrated into the system to further evaluate the prognostic factors of treatment. In addition, patients with poor hearing outcomes were further classified, as patients with thresholds over 90 dB may receive limited benefit from hearing amplification through a hearing aid. We aimed to standardize the report of treatment recovery outcomes of patients with SSNHL by integrating the pretreatment hearing grades.

2. Methods

2.1. Patients and indications

A total of 110 patients, who were diagnosed with SSNHL and underwent combined systemic and intra-tympanic steroid therapy at a tertiary referral hospital between January 2014 and January 2015, were enrolled in this study. All patients were hospitalized to receive the combined steroid therapy and appropriate follow-up care. Sudden sensorineural hearing loss was defined according to the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) practice guidelines as follows: greater than 30 dB of hearing loss

occurring in at least three contiguous frequencies in less than 72 h without an obvious cause. The patient medical records were retrospectively analyzed.

Combined steroid therapy was given as follows: concurrent intravenous dexamethasone 10 mg/day and intratympanic dexamethasone 5 mg/day for 5 days, which was then tapered off with oral methylprednisolone. Patients who visited the clinic without previous treatments were considered an initial treatment group, while patients who failed previous oral steroid treatments were categorized as a salvage treatment group.

The patient auditory measurements were based on pure tone audiometry (0.25, 0.5, 1, 2, 4, and 8 kHz). The frequency of 3 kHz was measured only if the differences in thresholds at 2 and 4 kHz were 20 dB or more. Pure-tone averages were measured by the mean threshold value at 0.5, 1, 2, and 4 kHz. Audiograms were obtained at the initial visit (pretreatment) and at 1 weeks, 2 weeks, 1 month, 3 months, and 6 months of post-treatment follow-up. The last measured audiometric thresholds at the 6-month follow-up were defined as the final hearing levels. The protocol of this study was reviewed and approved by the Institutional Review Board of the Taipei Veterans General Hospital (IRB: 2017-10-003CC).

The baseline characteristics of the study patients are summarized in Table 1. Among the 110 patients who received treatments for SSNHL, 43 were female (39%), and 67 were male (61%). The average age of affected patients was 48 ± 17 years old. The average pretreatment hearing level of affected patients was 74 ± 27 dB HL, and the average final hearing level of affected patients was 52 ± 29 dB HL.

2.2. Main outcome measurements using the modified Siegel's criteria

Patients were categorized by a proposed grading system modified from Siegel's criteria.¹⁶ Pre-treatment hearing loss was graded from 1 to 5. The hearing recovery outcomes were further classified into 5 groups, including complete recovery (CR), partial recovery (PR), slight improvement (SI), no improvement (NI), and non-serviceable ear (NS) (Table 2).

Table 1
Characteristics of study subjects (n = 110).

Variables	Means \pm SD (range)/n (%)
Age	48 \pm 17 (15–87)
Gender	
Male	67 (61%)
Female	43 (39%)
Pure tone averages (dB HL)	
Pre-treatment hearing level	74 \pm 27 (30–120 dB)
Final hearing level	52 \pm 29 (6–110 dB)
Treatment modality	
Initial	60 (55%)
Salvage	50 (45%)
Treatment delay in days	16 \pm 20 (1–150)

SD = standard deviation.

Table 2
Modified Siegel's criteria for pre-treatment hearing grades and hearing recovery outcomes.

Levels of pre-treatment hearing grades	
Grade 1	Average threshold value ≤ 25 dB HL
Grade 2	Average threshold value 26–45 dB HL
Grade 3	Average threshold value 46–75 dB HL
Grade 4	Average threshold value 76–90 dB HL
Grade 5	Average threshold value > 90 dB HL
Levels of hearing recovery outcomes	
Complete recovery (CR)	Final hearing level ≤ 25 dB
Partial recovery (PR)	More than 15 dB hearing gain and final hearing level 26–45 dB
Slight improvement (SI)	More than 15 dB hearing gain and final hearing level 46–75 dB
No improvement (NI)	Less than 15 dB hearing gain or final hearing level 76–90 dB
Non-serviceable ear (NS)	Final hearing level > 90 dB

2.3. Statistics

Continuous variables are presented as the means and standard deviation, and categorical variables are presented as proportions. A two-sample test of proportion was used to compare hearing improvements between the two treatment modalities (initial vs. salvage group). The two-sample test of proportion was also applied to show the association between treatment delay (within or more than 14 days) and hearing outcomes. The statistical analyses were performed using STATA version 14 (STATA Corp, Inc., College Station, TX). A two-sided p value of < 0.05 was considered significant.

3. Results

3.1. What modified Siegel's criteria indicate: pretreatment hearing grades and post-treatment recovery outcomes

The pretreatment hearing grades and the hearing recovery outcomes are reported in Table 3. The difference in hearing recovery outcomes between the Siegel's and modified Siegel's criteria are shown in Table 4.

Hearing improvements, including patients who achieved complete recovery, partial recovery, or slight improvement (CR + PR + SI), were observed in 56 of 110 patients after treatment. Among these patients, hearing improvement was

seen in 26% of grade 2 patients, 88% of grade 3 patients, 56% of grade 4 patients, and 30% of grade 5 patients.

The results indicated that 54 patients with the final hearing threshold of over 75 dB HL, or less than 15 dB of hearing gain, were originally categorized as the “no improvement” group using Siegel's criteria. In this study, 12 patients with a threshold over 90 dB HL after treatment were assigned as “NS”, as they may not benefit from traditional hearing amplification such as hearing aids and need to consider other methods of amplification such as contralateral routing of sound (CROS) or cochlear implants.

3.2. Applications - hearing outcome predictions using the modified Siegel's criteria

3.2.1. Treatment modality differences in hearing improvements

Hearing outcomes were analyzed according to the patient's treatment modality group (Table 5). Comparisons between two groups showed that patients who received the initial treatment modality had a better outcome than the salvage treatment group (63% vs. 36%, $p = 0.004$).

3.2.2. Treatment delay associations with recovery outcomes based on pretreatment hearing grades

The hearing recovery outcomes related to the initiation of treatment after disease onset are shown in Table 6. Overall, treatment initiated within 14 days of disease onset was shown to be associated with better outcomes than delayed treatment (63% vs. 24%, $p < 0.001$). Further analysis indicated that 11 out of 24 patients who had pretreatment hearing grade 5 and received treatment within 14 days were determined to have hearing improvements. When the combined steroid treatment was delayed beyond 2 weeks of hearing loss onset, none of the grade 5 patients showed any hearing improvements. The results indicated a significant hearing improvement in patients with grade 5 hearing who received treatment within 14 days of disease onset (45% vs. 0%, $p = 0.004$).

4. Discussion

Siegel's criteria of hearing improvement have been widely used to report the amount of absolute hearing gains (i.e., the difference between pretreatment and post-treatment hearing

Table 3
Pre-treatment hearing grades and post-treatment hearing recovery outcomes using the modified Siegel's criteria.

Pre-treatment hearing grade	Post-treatment hearing recovery outcomes					
	Complete recovery	Partial recovery	Slight improvement	No improvement	Non-serviceable ear	Hearing improvement (CR + PR + SI)/subtotal
Grade 2 (26–45 dB)	6	0	0	17	0	6/23 (26%)
Grade 3 (46–75 dB)	10	16	4	4	0	30/34 (88%)
Grade 4 (76–90 dB)	3	1	5	6	1	9/16 (56%)
Grade 5 (> 90 dB)	1	2	8	15	11	11/37 (30%)
Total	20	19	17	42	12	56/110 (51%)

Table 4
Comparison of hearing recovery outcomes between Siegel's (column) and modified Siegel's (row) criteria.

Siegel's criteria	Modified Siegel's hearing recovery outcomes					Total
	Complete recovery	Partial recovery	Slight improvement	No improvement	Non-serviceable ear	
Complete recovery	20	0	0	0	0	20
Partial recovery	0	19	0	0	0	19
Slight improvement	0	0	17	0	0	17
No improvement	0	0	0	42	12	54
Total	20	19	17	42	12	110

Table 5
Comparison of hearing recovery outcomes between two treatment modalities.

	Complete recovery	Partial recovery	Slight improvement	No improvement	No n-serviceable ear	Hearing improvement (CR + PR + SI)/subtotal
Initial treatment						
Grade 2 (26–45 dB)	4	0	0	10	0	4/14 (29%)
Grade 3 (46–75 dB)	9	11	3	1	0	23/24 (96%)
Grade 4 (76–90 dB)	1	1	2	2	0	4/6 (67%)
Grade 5 (>90 dB)	1	2	4	6	3	7/16 (44%)
Total	15	14	9	19	3	38/60 (63%)
Salvage treatment						
Grade 2 (26–45 dB)	2	0	0	7	0	2/9 (22%)
Grade 3 (46–75 dB)	1	5	1	3	0	7/10 (70%)
Grade 4 (76–90 dB)	2	0	3	4	1	5/10 (50%)
Grade 5 (>90 dB)	0	0	4	9	8	4/21 (19%)
Total	5	5	8	23	9	18/50 (36%)

Table 6
Comparison of hearing improvement rates between treatments within and more than 14 days.

	Disease onset		<i>p</i>	No. of patients with hearing improvement
	≤14 days %(n)	>14 days %(n)		
Grade 2 (26–45 dB)	38% (6/16)	0% (0/7)	0.059	6
Grade 3 (46–75 dB)	92% (24/26)	75% (6/8)	0.196	30
Grade 4 (76–90 dB)	70% (7/10)	33% (2/6)	0.149	9
Grade 5 (>90 dB)	45% (11/24)	0% (0/13)	0.004**	11
Total	63% (48/76)	24% (8/34)	<0.001**	56

** indicates $p < 0.01$ by proportional test.

levels) or the absolute threshold of final hearing.¹⁶ Complete recovery (CR) is defined as having a final hearing threshold better than 25 dB HL. Partial recovery (PR) is a final hearing threshold of 26–45 dB HL and more than 15 dB of hearing gain. Slight improvement (SI) is a final hearing threshold poorer than 46 dB HL and less than 15 dB of hearing gain. No improvement (NI) means a final hearing threshold poorer than 76 dB HL or less than 15 dB of hearing gain.¹⁶ Many research groups, including the AAO-HNS and others, have reported the degree of hearing improvement or treatment outcomes of SSNHL in a similar setting. However, there is no universal system for treatment outcome assessments.^{1,17–22}

One of the limitations is that in most reporting systems, a 10 or 15 dB absolute gain after treatment has been addressed or emphasized to be a meaningful improvement, regardless of the initial hearing status. However, “hearing improvement” does not necessarily indicate a “serviceable” ear. For example,

even with an absolute gain of 15 dB, a patient with an over 110 dB pretreatment hearing threshold may still be “non-serviceable” with hearing aids. Recovery to a serviceable hearing level usually indicates that the patient can benefit from hearing amplification such as hearing aids. In our study, 54 of 110 patients were found to have an absolute gain less than 15 dB or a final hearing threshold over 76 dB HL. These hearing levels were originally defined as “no improvement” in Siegel's criteria. By stratifying this group of patients via the proposed modified Siegel's criteria, 12 patients with a final hearing threshold over 90 dB HL were further classified as “non-serviceable ear (NS)”. The remaining 42 patients who stayed in the “no improvement (NI)” group may still benefit from hearing aids, even without a greater than 15 dB hearing gain or with a final hearing threshold between 76 and 90 dB HL. Therefore, to evaluate if an absolute improvement is meaningful, a standardized pretreatment hearing status should be reported or graded to supplement the use of existing assessment systems, which only report the absolute hearing gains and final hearing threshold outcomes.

The other purpose of adding pretreatment hearing status in a commonly used hearing outcome reporting system such as Siegel's is to have a better prognostic prediction. For example, in our study, the best hearing recovery outcomes were from patients with a grade 3 pretreatment hearing, where an 88.2% (30/34) overall improvement rate was observed, while patients with grades 2, 4 and 5 had much lower recovery rates (26.1%, 56.3%, and 29.7%, respectively) (shown in Table 4). Interestingly, the further separation of the “dead ears” with over 90 dB HL pretreatment hearing thresholds into a grade 5 group

improved the prediction of treatment outcomes. Patients with pretreatment hearing grade 5 who received treatment within 14 days of disease onset yielded an overall 45% (11/24) recovery rate, while none were determined to have a meaningful recovery if the treatment was delayed more than 14 days of disease onset (0%, or 0/13). However, this favorable outcome was not significant in patients with grade 4 hearing. As a dismal prognosis is predicted, patients with grade 5 hearing should start treatment early, within 14 days of disease onset, and delays over 14 days should, accordingly, seek a fortified or alternative treatment modality, as minimal recovery can be expected with combined steroid therapy.

A two-sample test of proportions was used to compare hearing outcomes and to verify the prognostic significance of pretreatment hearing grading in patients with SSNHL. This statistical method may fail to evaluate some confounding factors; thus, bias may exist in the results.

In conclusion, we reported the treatment results of combined systemic and intra-tympanic steroid therapy for patients with SSNHL using a modified Siegel's criteria. We found a favorable treatment outcome for patients with a pretreatment hearing grade of 5 who initially started treatment within 14 days. Our study demonstrated that the new hearing criteria not only better anticipate the functional outcomes of hearing treatment but also offer prognostic predictions based on pretreatment hearing grades. Further studies are needed to validate the use of our proposed system for the prediction of hearing recovery outcomes for the treatment modalities.

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