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Is Corticosteroid Treatment Beneficial in Sudden Sensorineural Hearing Loss? A Large Retrospective Study

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Abstract: The main treatment approaches for sudden sensorineural hearing loss (SSNHL) involve oral and intratympanic corticosteroids, but their efficacy remains controversial. The study objective was to evaluate the benefit of oral corticosteroids followed by intratympanic salvage treatment. This was conducted by comparing the hearing results of post-treatment patients arriving early and pretreatment patients arriving late over the same time points after the onset of HL. A cohort of 776 patients with SSNHL was classified into four groups by time from onset of symptoms to the initiation of treatment (weeks). The post-treatment audiometry of those patients presenting during the first and second week post-HL was compared to the pretreatment audiometry of those presenting in weeks three and four. The post-treatment audiometry of week one and pretreatment audiometry of week three was conducted 17.2 ± 4 and 19.4 ± 3 (p = 0.13) days post-HL onset, respectively. The post-treatment audiometry of week two and pretreatment audiometry of week four was conducted on days 24.6 ± 4 and 25.2 ± 3 (p = 0.32). The pure-tune average for week one and three groups was 36.7 ± 28 and 37.5 ± 19 dB (p = 0.55), and for weeks 2 and 4, it was 31.7 ± 22 and 36.6 ± 23 dB (p = 0.1). Similarly, no significant differences in speech recognition threshold and speech discrimination were found. These results question the benefit of corticosteroid treatment for SSNHL and suggest that improvements may be due to the natural healing process.

Keywords: hearing loss; corticosteroids; audiogram; intratympanic injection; speech discrimination

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1. Introduction

Sudden sensory neural hearing loss (SSNHL) refers to sensory neural hearing loss appearing within a period of 72 h and deteriorating by at least 30 dB in audiometry measurements at three consecutive frequencies [1,2]. On average, 5–27 people per 100,000 contract SSNHL annually [3]; the chance of spontaneous recovery (i.e., without treatment) is 32–65% [2,4–6]. The degree of hearing loss, the patient's age, and other symptoms, such as tinnitus and vertigo, have been identified as prognostic factors [2].

Various theories have been proposed to explain this obscure hearing loss, but none have gained enough validity. The inflammatory reaction theory is the most acceptable for several reasons: First, SSNHL has been temporarily associated with upper respiratory illnesses [7,8]; second, antibodies for several viruses have been found in patients with SSNHL [9–11]; third, laboratory tests indicate the presence of a cascade of inflammatory cell death in SSNHL [12]. These findings could explain why corticosteroids, as anti-inflammatory drugs, have been the only ones to remain as a treatment option among others that have been abandoned over the years (vasoactive hemodilution substances, systemic antiviral agents, carbogen, vitamins, etc.) [13]. Steroids are used because of their ability to decrease inflammation and edema; however, their specific mode of action is unclear.

A short course of OCSs (oral corticosteroids) is the common standard treatment for SSNHL. This treatment gained validity in a randomized double-blind placebo control study by Wilson et al. in 1980, in which 61% of patients treated with OCSs experienced a significant improvement in hearing, compared to only 32% of patients in the placebo group [14]. However, this study had several biases, which raised many questions and doubts about its conclusions and implications [15,16].

Compared with courses of treatment for chronic disease, SSNHL via steroids is very brief (only about two weeks). Currently, the prevalence of side effects from short courses of steroid use cannot be estimated due to insufficient clinical data. Compared to long-term use of steroids, short-term use is expected to generate fewer side effects. Still, some are already well known, particularly in patients suffering from hypertension or diabetes [17].

Over the last two decades, intratympanic corticosteroid injection (IT) treatment has become very popular because of its theoretical advantage in providing increased drug concentrations to the target organ and the possible avoidance of systemic adverse effects associated with reduced systemic corticosteroid exposure [18]. Treatment of SSNHL by OCSs is considered viable with a moderate level of evidence by the latest American Academy of Otolaryngology (AAO) guidelines; IT is recommended when patients have still not completely recovered from SSNHL after a period of two to six weeks from symptom onset [12].

It is still unclear whether treatment of SSNHL with steroids is advantageous since the outcomes reported from randomized controlled trials (RCTs) are inconsistent, in part due to the small sample sizes of these studies. Indeed, it is challenging to design an RCT with sufficient statistical power to detect a significant treatment effect due to the relatively low incidence of SSNHL [16,19]. Moreover, in patients with moderate to severe hearing loss, the therapeutic outcomes for IT, OCS, and combined therapy (CB) are comparable [20].

In summary, SSNHL remains a poorly understood medical emergency that lacks a rational treatment approach. Furthermore, none of the RCTs evaluated the recent AAO recommendations, which would mean comparing the initial OCS and salvaging an IT with no treatment or placebo. In a previous study, we identified a correlation between the time from symptom onset to treatment initiation and hearing improvement in SSNHL [21]. We found that after 14 days, there was a significant decline in hearing improvement. However, we noticed that the later the patients arrived, the better their hearing test results were. We assumed the natural healing process could be more important than the corticosteroid treatment. Therefore, the current study aims to assess the benefit of hearing improvement from OCS treatment, followed by IT as a salvage treatment, by comparing the post-treatment hearing results of patients arriving early and the pretreatment hearing results of those presenting late. These hearing tests were conducted at the same time point post-SSNHL. These focused comparisons have not been published yet.

2. Materials and Methods

A retrospective cohort study for the period 2012–2022 was performed on patients at Shaare-Zedek Medical Center's (SZMC) Department of Otolaryngology and Head-Neck Surgery who were diagnosed with SSNHL and hospitalized. The study protocol was approved with a waiver of informed consent by the institutional review board. Part of the data in this article was published in our previous paper [21]. However, we substantially enlarged the cohort in this study, focused on significantly different aspects, and used other analysis methods and comparisons.

The general information collected from the patients included demographics, medical background related to vascular risk factors (diabetes mellitus, hypertension, ischemic heart disease, and smoking), accompanying symptoms (vertigo or tinnitus), and the time from onset of symptoms to treatment initiation. Each patient underwent at least two hearing tests (before and at the completion of the treatment) that measured pure-tone audiometry, speech discrimination (SD), and speech recognition threshold (SRT).

The treatment protocol followed the guidelines of the AAO as long as patients presented no contraindications to OCSs. Patients were treated initially with 30 mg prednisone twice daily for one week; if hearing did not improve sufficiently (if at least 10 dB sensorineural hearing loss remained in at least two frequencies), intratympanic dexamethasone was administered by injection once daily as a salvage treatment for a further week while reducing the OCS dose over five days [12].

The inclusion criterion was presentation of SSNHL; the exclusion criteria were a diagnosis other than SSNHL (acoustic trauma, conductive hearing loss, Meniere's disease, vestibular schwannoma), congenital hearing loss, partial treatment, and failure to follow up.

The final cohort of patients included in the study was classified into four groups by time from onset of symptoms to initiation of treatment: group 1: up to one week from onset of symptoms, group 2: 7–14 days, group 3: 14–21 days, and group 4: 21–28 days.

We compared the audiometry test results at the end of treatment for groups 1 and 2 with those before treatment for groups 3 and 4, respectively. We assumed that the time to the end of treatment for group 1 was equivalent to the time before treatment for group 3, and likewise for groups 2 and 4.

2.1. Audiometry Tests

Certified audiologists performed the audiometry tests at our medical center, in soundproof booths, using a Grason-Stadler (GSI-61/AudioStar Pro) audiometer (Eden Prairie, MN, USA), calibrated annually, with standard audiometric parameters. The following parameters were calculated for the analysis: 1. Pure-tone average (PTA), based on 500, 1000, and 2000 Hz; 2. Speech recognition threshold (SRT)—the minimum hearing level that enables recognition of 50% of spondaic words; 3. Maximum speech discrimination score % (SD), obtained at 35 dB above the SRT, unless the standard level exceeded the user's level of comfort or maximum audiometer output, in which case a lower level was used. A list of 50 monosyllabic words was presented mostly via a live voice; the maximum score was calculated as the proportion of words repeated correctly (as a percentage).

2.2. Data Processing

Treatment effectiveness was determined by calculating the improvement for each individual in PTA, SRT, SD, and specific pure-tone frequencies (500, 1000, 2000, 4000, and 6000 Hz). The amplitude of hearing loss was determined absolutely by considering the affected ear alone, and relatively by comparing the hearing loss of the affected ear with that of the healthy ear (assuming the healthy ear was not damaged):

- Absolute: groups 1 and 2 at the end of treatment. Groups 3 and 4 before treatment.
- Relative: groups 1 and 2: affected ear at the end of treatment (AFFend) minus the healthy ear. Groups 3 and 4: affected ear before treatment (AFFbef) minus the healthy ear.

The equation used for the relative SRT measurements of groups 1 and 2:

$$\text{AFFend SRT} - \text{Healthy SRT} \quad (1)$$

The equation used for the relative SRT measurements of groups 3 and 4:

$$\text{AFFbef SRT} - \text{Healthy SRT} \quad (2)$$

The same equations were used for relative PTA and relative SD.

2.3. Statistical Analysis

The data were collated in Microsoft Excel spreadsheets and analyzed in SPSS version 26 (IBM® SPSS® Statistics, Chicago, IL, USA). We used ANOVA or Kruskal–Wallis tests, as required, to test for differences between groups (classified by time from onset of symptoms to treatment initiation); when between-group differences were statistically significant, we

conducted pairwise comparisons using two-tailed *t*-tests or Mann–Whitney tests, with Bonferroni correction for multiple tests. The statistical comparison between groups 1 and 2 and 3 and 4, respectively, was conducted using a two-tailed *t*-test or Mann–Whitney test, as appropriate. Spearman correlations between the time from onset of symptoms to initiation of treatment and other potential prognostic factors and treatment success were performed. Statistical significance was set at $p \leq 0.05$.

3. Results

A total of 939 patients were admitted to SZMC with a diagnosis of SSNHL during 2012–2022. Of these, 163 were removed from the study cohort by the exclusion criteria, leaving 776 patients for the final study cohort, comprising 386 males and 390 females. Left-ear SSNHL was present in 392 patients, while 384 patients presented with right-ear SSNHL. No significant differences related to demographics, medical background, or accompanying SSNHL symptoms were found among the four groups (Table 1).

Table 1. Demographic information, including age, gender, comorbidities, and associated symptoms, as a function of time from symptom onset. M/F: male/female. DM: diabetes mellitus. HTN: hypertension. IHD: ischemic heart disease. *p*-values obtained from Kruskal–Wallis or ANOVA as appropriate.

Weeks	1	2	3	4	*p*
Number	454	194	70	58	
M/F	240/214	89/105	33/37	24/34	0.58
Age Mean ± SD (years)	49.1 ± 20	51 ± 18	47.5 ± 18	47.1 ± 20	0.5
Smoking %	7	11	8	9	0.23
DM %	13	12	14	14	0.43
HTN %	27	19	24	26	0.74
IHD %	6	6	2	5	0.59
Tinnitus %	70	68	65	70	0.35
Vertigo %	33	29	27	21	0.33

On average, 9.2 ± 8 days elapsed from onset of symptoms to initiation of treatment; 648 (83%) patients presented within the first two weeks (Table 1). Nearly half of the patients (349, 45%) reported no or only mild improvement after one week of oral treatment; they were given intratympanic treatment for another week.

Significant differences were found between groups in all of the tested audiometry parameters (Table 2). As per earlier, hearing loss saw the worse results. The correlations between the number of days from onset of hearing loss to treatment initiation and the first PTA and SRT results were significant, and weakly positive (R = 0.2, $p < 0.001$, and R = 0.17, $p < 0.001$, respectively).

Table 2. Results of first hearing tests for all groups. Mean ± SD. *p*-value: Kruskal–Wallis or ANOVA, as appropriate. SRT: speech recognition threshold, dB: decibels, PTA: pure-tone average, SD: speech discrimination.

Weeks	1	2	3	4	*p*
Number	454	194	70	58	
First test SRT dB	58.5 ± 35	46.9 ± 3	38.6 ± 25	39.6 ± 27	<0.001
First test PTA dB	51.9 ± 29	38.9 ± 25	37.5 ± 19	36.6 ± 23	<0.001
First test SD%	53.6 ± 43	69.5 ± 39	78.3 ± 32	76.2 ± 33	<0.001
Relative first SRT dB affected ear—healthy ear.	42.9 ± 34	30.6 ± 26	24.9 ± 19	20.8 ± 23	<0.001
Relative first PTA dB affected ear—healthy ear.	37.5 ± 28	27.3 ± 22	24.7 ± 24	18.1 ± 29	<0.001
Relative first SD% affected ear—healthy ear.	40.5 ± 13	27.3 ± 33	16.7 ± 38	21.6 ± 31	<0.001

On average, the first hearing tests for groups 1 and 2 were performed 4.5 ± 2 and 12.4 ± 2 days after onset of hearing loss, respectively. At the completion of treatment, the last hearing tests were performed 17.2 ± 4 (group 1) and 24.6 ± 4 (group 2) days after onset of hearing loss. The first hearing tests of groups 3 and 4 were carried out 19.4 ± 3 and 25.2 ± 3 days after onset of hearing loss, respectively (Figure 1). No significant difference was found in the number of days of hearing loss between the first hearing test performed on groups 3 and 4 and the last hearing test performed on groups 1 and 2, respectively (p = 0.32, p = 0.13). Likewise, no significant absolute or relative difference in pure-tone audiometry results was found between the last hearing test of groups 1 and 2 and the first hearing of groups 3 and 4 (Figure 2: group 1 vs. group 3; Figure 3: group 2 vs. group 4), at the frequencies tested although a continuous trend of better results for groups 1 and 2 (4 dB on average) was observed.

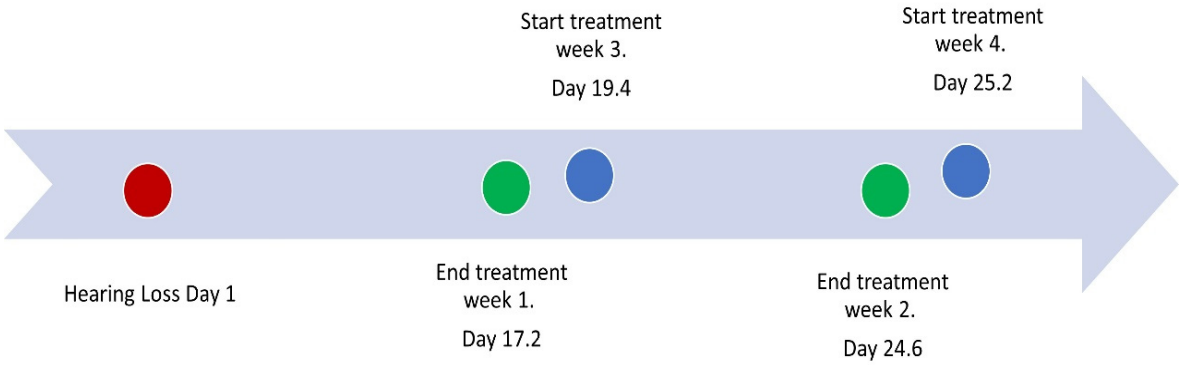

Figure 1. Timeline for the start and end of treatment in days (on average) for all groups regarding hearing loss.

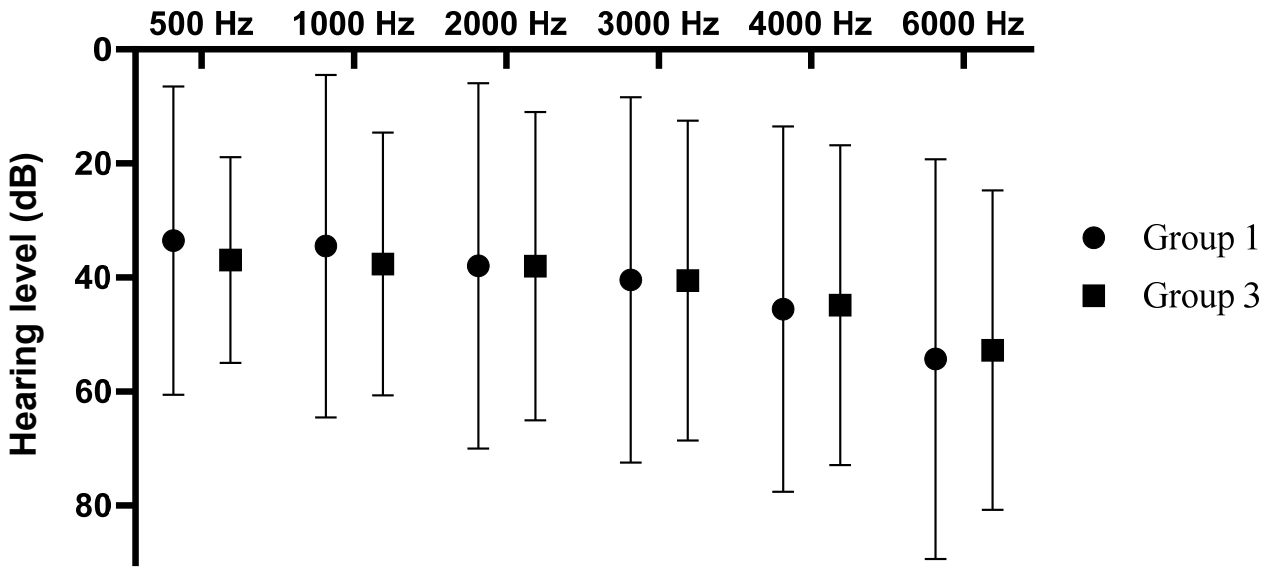

Figure 2. Pure-tone audiometry results from the last hearing tests of group 1 and the first hearing tests of group 3 (same time point from hearing loss). No significant difference was found for any of the frequencies tested. Hz: Hertz. dB: decibels.

No significant differences were found in the absolute or relative audiometry parameters (SRT, PTA, and SD) of groups 1 and 2 at the end of treatment and of groups 3 and 4 before treatment, respectively (Table 3). Furthermore, no significant differences in absolute or relative SRT, PTA, or SD were found at the end of the treatment (Table 4). In other words, all groups demonstrated the same hearing results, on average, regardless of the period that elapsed between symptom onset and initiation of treatment.

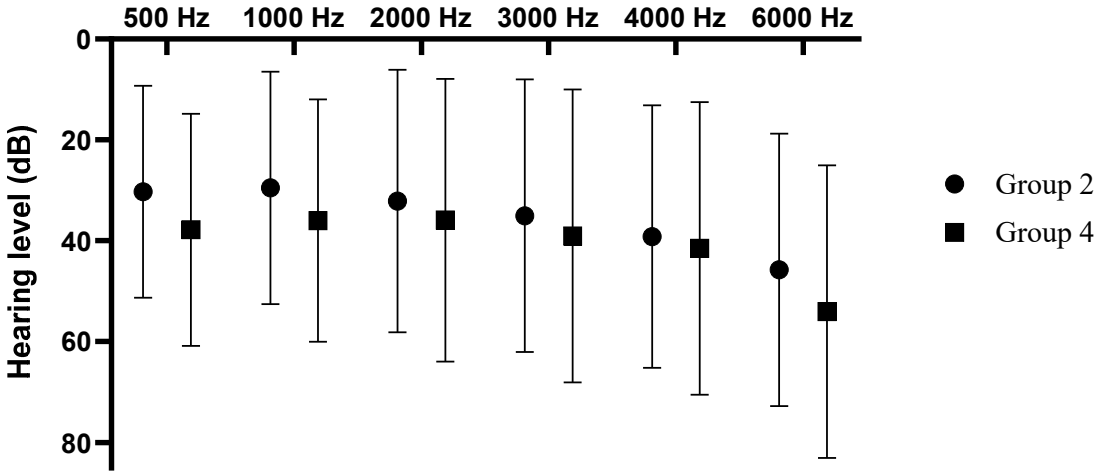

Figure 3. Pure-tone audiometry results from the last hearing tests of group 2 and the first hearing tests of group 4 (same time point from hearing loss). No significant difference was found for any of the frequencies tested. Hz: Hertz. dB: decibels.

Table 3. Comparisons between the last hearing test results of groups 1 and 2 and the first hearing test results of groups 3 and 4, respectively. Mean ± SD. *p*-value: *t*-test or Mann–Whitney, as appropriate. SRT: speech recognition threshold, dB: decibels, PTA: pure-tone average, SD: speech discrimination.

Weeks	1 Post-Treatment	3 Pretreatment	*p*	2 Post-Treatment	4 Pretreatment	*p*
Number	454	70		194	58	
SRT dB	39.7 ± 32	38.6 ± 25	0.95	34.3 ± 26	39.6 ± 27	0.1
PTA dB	36.7 ± 28	37.5 ± 19	0.55	31.7 ± 22	36.6 ± 23	0.1
SD%	73.9 ± 36	78.3 ± 32	0.55	80.9 ± 31	76.2 ± 33	0.12
Relative SRT dB affected ear—healthy ear.	20.1 ± 35	24.9 ± 19	0.22	15.6 ± 29	20.8 ± 23	0.08
Relative PTA dB affected ear—healthy ear.	33.3 ± 28	24.7 ± 24	0.09	29.3 ± 22	18.1 ± 29	0.34
Relative SD% affected ear—healthy ear.	17.4 ± 30	16.7 ± 38	0.91	11.4 ± 33	12.8 ± 35	0.32

Table 4. Last hearing test results for all groups. Mean ± SD. *p*-value: Kruskal–Wallis or ANOVA, as appropriate. SRT: speech recognition threshold, dB: decibels, PTA: pure-tone average, SD: speech discrimination.

Weeks	1	2	3	4	*p*
Number	454	194	70	58	
Last test SRT dB	39.7 ± 32	34.3 ± 26	33.2 ± 25	36.8 ± 29	0.59
Last test PTA dB	36.7 ± 28	31.7 ± 22	32.7 ± 22	34.7 ± 26	0.61
Last test SD%	73.9 ± 36	80.9 ± 31	84.2 ± 27	78.3 ± 35	0.3
Relative last SRT dB affected ear—healthy ear.	20.1 ± 35	15.6 ± 29	19.1 ± 25	16.2 ± 36	0.87
Relative last PTA dB affected ear—healthy ear.	33.3 ± 28	29.3 ± 22	30.5 ± 22	31.7 ± 25	0.97
Relative last SD% affected ear—healthy ear.	17.4 ± 30	11.4 ± 33	10.1 ± 34	12.2 ± 31	0.83

4. Discussion

This study aimed to provide a quantitative assessment of the efficacy of oral corticosteroids (OCSs), followed by intratympanic salvage injection (IT), by comparing the results of treated SSNHL patients to those patients who did not receive treatment during the same time points. The hearing test results of the patients who arrived during the third and fourth weeks following hearing loss (without treatment) were compared to those at

the end of treatment for patients who arrived during the first and second weeks, respectively. No statistically significant differences in pure-tone audiometry, SRT, PTA, or speech discrimination were found between the treated (corticosteroids) and nontreated patients.

This is the first study to examine the AAO Head and Neck Surgery recommendations by administering IT with dexamethasone as a salvage treatment after OCS treatment fails and comparing the results to a group of untreated patients [12,22]. The patients in the treatment groups received 60 mg of prednisone daily for a week. Patients who experienced significant improvement in hearing (baseline or close to baseline) by the end of the week of OCS treatment received another week of reduced OCS treatment. Patients who experienced no or slight improvement were treated with CO_2 laser myringotomy followed by once daily IT with dexamethasone for another week. Audiometry test results at the completion of the treatment (whether they ended with IT or OCS) were compared to the first audiometry test results (before treatment) for patients who arrived during the third and fourth weeks. No significant benefit was found in the treated patients.

With respect to the severity of hearing loss, it appears that patients who commenced treatment at an earlier point in time after onset of symptoms presented with more severe hearing loss, both for SD and SRT, compared to patients who commenced treatment later (Table 2). There are several potential explanations for this phenomenon. Patients with milder hearing loss may feel a less urgent need for treatment because the hearing loss is less noticeable; however, more than 40% of the patients in groups 1 and 2 also presented with mild or moderate hearing loss (as in groups 3 and 4) even though they arrived earlier. However, perhaps this trend simply reflects a natural healing process over time that has no relation to treatment. Patients who arrived after two weeks may have initially suffered from more significant hearing loss that improved over time. Indeed, concerning onset of hearing loss, we observed no difference in audiometry parameters between patients who received treatment and those who did not. Therefore, the improvement in the groups that presented earlier may not be due to the treatment but instead may reflect a natural process of hearing improvement that took place similarly in the group that presented later. However, the late-arriving groups do not have earlier audiograms for comparison; hence, we cannot conclusively say that their thresholds improved over the first weeks. It is possible that they had the same hearing loss as presented, and they had not improved over time.

Comparing the severity of hearing loss and its subsequent improvement among different patients carries significant, intrinsic difficulties. Usually, the patient's hearing threshold prior to the hearing loss event is unknown; thus, it is not possible to determine the severity of the hearing loss and the degree of subsequent improvement. This problem can be overcome using the approach of Cvorovic et al. [23]: in cases of unilateral hearing loss, the audiometry results from the healthy ear are used as a reference for the initial state of the affected ear prior to hearing loss, since we can assume that for most patients hearing was symmetrical before the onset of hearing loss (unless otherwise known). According to this method, we note that hearing loss severity and improvement are presented in relative and absolute terms (comparing the affected ear before and after treatment).

Few randomized control trials (RCTs) have been published that evaluate the efficacy of corticosteroid treatment for SSNHL. All of them included a low number of patients and had inherent biases. Wilson et al. concluded that "steroids have a definite positive effect on recovery" [14]; however, their study included only 67 patients from more than one institution with different therapy protocols. Furthermore, they did not use randomization to determine which patients received the study drug or placebo. In an RCT that included 41 patients in four groups (only 10 were treated with OCS), Cinamon et al. did not find any benefit compared to the placebo group [24]. In an RCT that included 93 SSNHL patients, Nosrati-Zarenoe et al. concluded that prednisolone does not seem to influence the recovery of SSNHL [25].

These three studies were the sole sources of data for the meta-analysis published by Wei et al., based on only 201 patients, which suggested no benefits from OCS treatment [16]. In a previous meta-analysis, Conlin et al. also did not find any benefit from OCS treatment

vs. the placebo [19]. Chaushu et al., in another meta-analysis, observed a 60.28% pooled spontaneous recovery from SSNHL, which was no less than the outcome following treatment recovery [26]. Nevertheless, the clinical practice guidelines of AAO recommend OCSs as the only treatment on offer to patients that has a reasonable therapeutic effect [22].

A meta-analysis by Myrian and Ovesen found no significant difference in recovery from SSNHL following treatment based on OCS or IT alone. Moreover, no significant difference was found between combined treatment (OCS followed by IT) vs. OCS or IT alone [20]. This meta-analysis did not compare the treatments to untreated patients regarding the studies it analyzed.

It is hard to find a similar example in medicine with no valid proof of benefit that is still common practice worldwide.

There are several limitations to this study. First and foremost, this study is retrospective, and as such does not include a control group for comparison. We believe the untreated groups (weeks 3 and 4) can represent the control group in real life. It can be assumed that their late arrival was due to insufficient availability of urgent hearing tests. All the other parameters: demographic, medical background, and associated symptoms, were without difference across all groups (Table 1). Furthermore, since this study's final cohort constitutes a larger study sample than all other studies conducted to date (794), our results carry critical statistical and clinical significance. Another limitation of this study is that it does not stratify the groups according to the severity of hearing loss. We know that the extent of hearing loss may potentially affect recovery. A comparison between the groups with further stratification of hearing loss severity will result in small groups without significance, especially in the late arrival groups (groups 3 and 4), in which most patients presented with milder hearing loss compared to the earlier groups (groups 1 and 2).

This study is also limited by its short-term follow-up since the last audiometry tests were conducted at the end of the treatment. Nevertheless, the aim of this study was to identify the benefits of treatment at this point in time, and no significant differences were observed. Indeed, most improvements in hearing occur in the first few weeks, up to the end of treatment [27], and no significant improvement or deterioration have been found in the long term, whether at the scale of months or years [28,29].

5. Conclusions

We did not find any statistically significant difference between the end-of-treatment hearing threshold for patients arriving early and the pretreatment hearing threshold for patients arriving late (same time point after hearing loss). Moreover, all groups demonstrated the same hearing thresholds at the completion of the treatment. Considering the limitations of this retrospective study, the results substantially question the benefit of corticosteroid treatment for SSNHL and suggest that the improvement may be due to the natural healing process. However, our findings are insufficient to be accepted as a guide to action, and we do not recommend changing the current standard practice until further research is carried out.

Author Contributions: I.C. and R.P. helped design the research, performed the research, assisted in data analysis, and took part in writing the manuscript and the revisions. They are equal contributors. S.E. and O.M. conducted the study and assisted in data analysis. R.S. and J.-Y.S. helped design the research and write the manuscript. C.S. designed the study, analyzed the data, and drafted the paper and the revisions. All authors have read and agreed to the published version of the manuscript.

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