

# Hearing results with combination steroid therapy for sudden sensorineural hearing loss

## *Resultados auditivos con terapia combinada esteroidea para la hipoacusia neurosensorial súbita idiopática*

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### Abstract

**Background:** Sudden Sensorineural Hearing Loss was described by Mc. Cabe in 1979 and, since then, many authors have tried to define, explain and correctly treat this disease. The National Institute on Deafness and Other Communication Disorders defines it as sudden sensorineural hearing loss of at least 30 dB in three contiguous audiometric frequencies in a period of 72 hours. Among the therapeutic strategies, corticosteroids have been shown to have the greatest benefit due to their anti-inflammatory and anti-cellular stress effects. **Objective:** To determine the hearing results with combined steroid therapy in patients with sudden sensorineural hearing loss (SSHL), according to the Siegel recovery criteria scale. **Method:** Study carried out in the otorhinolaryngology and head and neck surgery service of the Centro Médico Naval, Ciudad de México, where 150 patients diagnosed with SSLH and who received combined therapy with intratympanic dexamethasone and systemic prednisone were included. **Results:** Therapeutic effectiveness was demonstrated by correlating therapeutic success in 82% of cases and therapeutic failure in 18% of cases, by correlating it with the Siegel recovery criteria scale. When evaluating the general average of the pure tone average levels at the beginning and 6 weeks after treatment, a statistically significant difference was obtained ( $p = 0.001$ ). The average of the speech audiometry at the beginning and 6 weeks later had a statistically significant difference ( $p = 0.001$ ). **Conclusions:** Initial combined steroid treatment for SSLH has been shown to have beneficial results according to Siegel recovery criteria scale.

**Keywords:** Hearing loss. Sudden. Treatment. Steroid. Results.

### Resumen

**Antecedentes:** La Hipoacusia Neurosensorial Súbita Idiopática fue descrita por Mc. Cabe en 1979 y, desde entonces, muchos autores han tratado de definir, explicar y tratar correctamente esta enfermedad. El Nacional Institute on Deafness and Other Communication Disorders la define como pérdida auditiva neurosensorial brusca de al menos 30 dB en tres frecuencias audiométricas contiguas en un periodo de 72 horas. Entre las estrategias terapéuticas, los corticosteroides han demostrado tener mayor beneficio por sus efectos antiinflamatorios y antiestrés celular. **Objetivo:** Determinar los resultados auditivos con la terapia de esteroides combinados en pacientes con hipoacusia neurosensorial súbita idiopática (HNSI), de acuerdo a la escala de criterios de recuperación de Siegel. **Método:** Estudio realizado en el servicio de otorrinolaringología y cirugía de cabeza y cuello del Centro Médico Naval, en Ciudad de México, en el que se incluyeron 150 pacientes con diagnóstico de HNSI y que recibieron terapia combinada con dexametasona intratimpánica y prednisona sistémica. **Resultados:** Se demostró una efectividad terapéutica al correlacionar el éxito terapéutico en el 82% de los casos y un fracaso terapéutico en el 18% de

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los casos según la escala de criterios de recuperación de Siegel. Al evaluar el promedio general de los niveles de promedio de tonos puros al inicio y 6 semanas posterior al tratamiento se obtuvo una diferencia estadísticamente significativa ( $p = 0.001$ ). El promedio de las logaudiometrías al inicio y 6 semanas posterior al tratamiento tuvo una diferencia estadísticamente significativa ( $p = 0.001$ ). **Conclusiones:** El tratamiento combinado con esteroides de manera inicial para la HNSI ha demostrado tener resultados benéficos de acuerdo con la escala de criterios de recuperación de Siegel.

**Palabras clave:** Hipoacusia. Súbita. Tratamiento. Esteroideo. Resultados.

## Introduction

According to the National Institute on Deafness and Other Communication Disorders<sup>1,2</sup>, sudden idiopathic sensorineural hearing loss (SISNHL) is defined as a sensorineural hearing loss of generally sudden onset, with rapid or abrupt progression of, at least, 30 dB across 3 contiguous audiometric frequencies within a 72-hour period, with no identifiable etiology in most cases.

The approximate incidence of SISNHL is between 5 and 20 cases per 100,000 inhabitants per year and affects individuals of any age, though it is most widely observed in the fifth decade of life. It occurs equally in both sexes, presenting unilaterally in up to 96% of cases and bilaterally in 4% (of these, more than half do not occur simultaneously)<sup>3</sup>.

The etiological factors can be determined in 10% up to 15% of cases; for the remaining sudden hearing losses, the term “idiopathic” is used<sup>4</sup>. There are various theories regarding the mechanisms involved based on case series studies, including cochlear inflammation due to viral infection, bacterial infections, autoimmune diseases, microvascular events, ototoxic substances, neoplasms, and trauma<sup>5</sup>. The viral theory is the most documented, both anatomopathologically in necropsies with findings related to herpes simplex virus type 1 infection and due to the frequent history of upper respiratory tract infections; however, specific serological profiles and a single response to antiviral treatments have not been demonstrated<sup>6</sup>. Another theory is changes the microcirculation of the inner ear, presenting transient ischemia phenomena in the inner ear, with a certain genetic predisposition to thrombosis in patients with cardiovascular risk, particularly those with mitral prolapse or antiphospholipid syndrome, as well as during general anesthesia or an episode of intralabyrinthine hemorrhage, demonstrated by magnetic resonance imaging<sup>7,8</sup>. It often goes unnoticed or presents a delay in diagnosis for being painless, with nonspecific symptoms, and symptoms are often attributed by the patient to everyday causes,

such as respiratory infections, allergies, or cerumen impaction, among others<sup>9</sup>. The diagnosis of sudden hearing loss is suspected in a patient with concordant clinical findings and absence of identifiable causes based on history and normal otolaryngological physical examination; therefore, a detailed clinical and paraclinical assessment should be performed, sometimes requiring imaging or serological studies<sup>10,11</sup>. Audiometry is required for all these patients, as it not only confirms the diagnosis but also establishes the severity, prognosis, and follow-up<sup>12</sup>. The most frequent associated symptoms are aural fullness and tinnitus, in more than 90% of cases; vestibular symptoms have been described in 20% up to 60% of cases, and less frequently otalgia or paresthesias<sup>13</sup>.

Treatment remains controversial due to the lack of solid scientific evidence clearly supporting any of the proposed options, with widely varying doses<sup>14</sup>. Oral corticosteroid administration is recommended for initial management, while intratympanic administration is traditionally reserved as a bailout therapy or in the presence of contraindications to high-dose systemic corticosteroids<sup>15</sup>. The use of intratympanic corticosteroids is based on increasing cochlear blood flow after ischemia induced by injury<sup>16</sup>, stabilizing cellular and lysosomal membranes, inhibiting prostaglandins and proinflammatory cytokines (tumor necrosis factor- $\alpha$ , interleukins 2 and 6, and interferon- $\gamma$ ), inhibiting chemotactic factors and factors that increase capillary permeability, and inhibiting the recruitment of inflammatory cells to the affected regions<sup>17</sup>. The benefit of intratympanic corticosteroids has been observed in patients with moderate-to-severe hearing loss, excluding cases of profound hearing loss<sup>18</sup>. Antiviral therapy has been proposed as a complement to conventional treatment due to the debated role of viral agents in its pathogenesis<sup>19</sup>. The use of hyperbaric oxygen therapy has been debated<sup>20</sup>. The use of oral magnesium and antioxidants (vitamins E and C) has shown some benefit in small studies<sup>21</sup>.

Various scales have been used to assess patient improvement<sup>22</sup>. The most common and recommended

by consensus on the diagnosis and treatment of sudden hearing loss established by the Madrid Society of Otolaryngology in 2010 are the Siegel scale, the Furuhashi scale, and the recovery rate<sup>23</sup>. The Siegel scale is a graded scale proposed in the 1970s to assess the degree of recovery in patients with sudden hearing loss based on two parameters: the number of decibels recovered in the pure tone average (PTA) and the final PTA. It is the strictest scale, making it more difficult to consider a patient successful in therapy<sup>24</sup> (Table 1).

Sudden hearing loss usually has a good prognosis, especially in patients with isolated high or low-frequency loss<sup>25</sup>. Conversely, patients with profound hearing loss across all frequencies have a reserved prognosis<sup>26</sup>. Clinical criteria such as advanced age and the presence of vertigo are notable predictors of poor prognosis<sup>27</sup>.

The present study evaluates the auditory outcomes of combined steroid therapy based on systemic prednisone and intratympanic dexamethasone in patients with SISNHL, according to the Siegel recovery criteria scale.

## Method

We conducted an observational, analytical, retrospective, and cross-sectional study in the otolaryngology and head and neck surgery service of the Naval Medical Center in Mexico City, Mexico. It included a total of 150 patients diagnosed with SISNHL through an audiological profile that included tonal audiometry and speech audiometry, who agreed to be treated with combined therapy of intratympanic dexamethasone (with prior informed consent, as it is an invasive procedure) and systemic prednisone, from January 2009 through November 2021. Patient records that met the inclusion criteria were reviewed: diagnosis of SISNHL confirmed by a complete audiological profile, initial combined treatment with prednisone at a dose of 1 mg/kg per day for 30 days and dexamethasone 8 mg/2 mL (after applying 5 drops of tetracaine, 5 mg/mL, in the external auditory canal of the affected ear and aspirating it after 20 minutes, with the support of a microscope to apply 1 mL of dexamethasone previously loaded in an insulin syringe with a 24-gauge needle in the posteroinferior quadrant for deposition in the tympanic cavity, and after completing the infiltration, the patient's head is turned to the opposite side of the application to maximize exposure of the solution in the middle ear on the round window

**Table 1. Siegel recovery scale criteria**

| Siegel criteria   |                                                |                     |
|-------------------|------------------------------------------------|---------------------|
| Complete recovery | Final PTA $\leq$ 25 dB regardless of dB gained | Therapeutic success |
| Partial recovery  | Improvement $>$ 15 dB and final PTA: 25-45 dB  |                     |
| Slight recovery   | Improvement $>$ 15 dB and final PTA $>$ 45 dB  | Therapeutic failure |
| No recovery       | Improvement $<$ 15 dB or final PTA $>$ 75 dB   |                     |

PTA, pure tone average

membrane for 50 minutes, with a cotton plug placed at the entrance of the external auditory canal, avoiding swallowing, speaking, and performing Valsalva maneuver during the procedure to prevent drug leakage through the Eustachian tube), performed once daily for 5 consecutive days, with clinical follow-up at 6 weeks after treatment by conducting a second follow-up audiological profile. Clinical records of patients with Meniere's disease, trauma, fluctuating hearing loss, radiation-induced hearing loss, noise-induced hearing loss, or any other identifiable cause of sensorineural hearing loss, chronic pre-existing conditions in the affected ear, pregnancy or lactation, or comorbidities that would prevent steroid treatment were excluded. Records of patients who did not complete the steroid therapy regimen or had incomplete information were also excluded.

Initial and collective audiometry was assessed by obtaining the PTA and speech audiometry prior to combined steroid treatment and its controls at 6 weeks after treatment, categorizing the degree of hearing loss and affected frequencies before and after treatment. Variables such as sex, age, laterality of hearing loss, presence of tinnitus, and comorbidities were determined, as well as the association of the therapeutic window by evaluating the days elapsed from the onset of symptoms to the start of combined steroid treatment, and therapeutic success and failure according to the Siegel recovery criteria scale, where success was defined as a PTA  $<$  25 dB or a hearing gain  $>$  15 dB and a PTA 25-45 dB after treatment, while failure was defined as a hearing gain  $>$  15 dB and PTA  $>$  45 dB, or a hearing gain  $<$  15 dB and PTA  $>$  45 dB.

The study was conducted in full compliance with the bioethical principles for clinical research in humans, considering the confidentiality of patient information and the autonomy of participating subjects,

and taking into account the considerations of the Declaration of Helsinki, the Nuremberg Code, and the General Health Law of the United Mexican States. It was authorized by the Local Committee on Bioethics and Research and received permission from the Medical Directorate of the Naval Medical Center for access to documents and information from regulatory authorities.

Audiometric studies and clinical information from the electronic health records of the HIS (Hospital Information System) of target patients with code H912 from the ICD-10, corresponding to the diagnosis of SSNHL, were used. Additionally, a laptop was used to capture the database with the Office software package and perform statistical analysis using Graph Pad Prism 8.

Descriptive statistics were performed to summarize variables, using percentages, means, and ranges. Data distribution was then analyzed. Given the normality of measurements, parametric tests were used. ANOVA was employed to determine whether there was a statistical difference between the different groups, Pearson correlation test was used to correlate numerical variables and determine the existence of a negative or positive relationship between these variables, and paired Student t-test was used to find differences between PTA and speech audiometry figures at baseline and 6 weeks after treatment, with the patient serving as their own control.

## Results

A total of 150 electronic health records of patients diagnosed with idiopathic sudden sensorineural hearing loss (ISSHL) on combined therapy with intratympanic dexamethasone and systemic prednisone from January 2009 through November 2021 at the otolaryngology and head and neck surgery department of the Naval Medical Center were included. Among these, 64 (43%) were women and 86 (57%) were men. The mean age of the patients was  $52.31 \pm 16.23$  years, with a minimum of 19 years and a maximum of 87 years (Fig. 1).

Regarding recorded comorbidities, 39 (26%) patients had 1 disease at the time of their initial assessment, 5 (3.3%) had 2 concurrent diseases, and 2 (1.3%) had 3 concurrent diseases. Among the comorbidities found, 26 (17.3%) patients had a diagnosis of systemic arterial hypertension (which could be related to the vascular etiology of ISSHL), 10 (6.6%) had a diagnosis of type 2 diabetes mellitus, 5 (3.3%) had

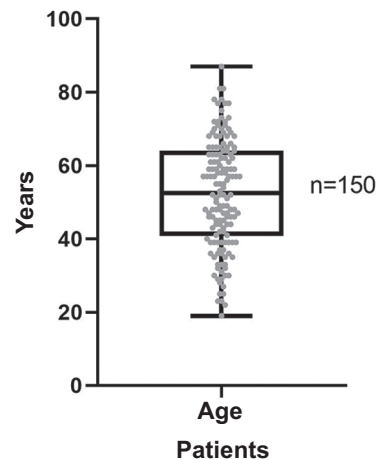


**Figure 1.** Age distribution of patients represented individually in years.

a diagnosis of dyslipidemia, 3 (2%) had a diagnosis of some form of heart disease, 1 (0.6%) had hypothyroidism, 1 (0.6%) had systemic lupus erythematosus, and 1 (0.6%) suffered from chronic kidney disease (Fig. 2).

Regarding the affected ear's laterality, 79 (53%) patients had left ear involvement and 71 (47%) had right ear involvement.

On the presence of tinnitus, 67 (44.6%) reported having tinnitus at the time of their initial assessment, and 83 (55.3%) reported no tinnitus.

In terms of individual dB gain, according to the therapeutic goals of the Siegel recovery criteria scale, 110 (73.3%) patients showed an improvement  $> 15$  dB, and 40 (26.7%) showed an improvement  $< 15$  dB, with a mean dB gain of 20.22 dB and a standard deviation of 7.39 dB, ranging from a minimum of 1 dB to a maximum of 42 dB.

On the mean affected audiometric frequencies before treatment, the greatest involvement was observed in high frequencies in 58 (38.6%) patients, followed by low frequencies in 52 (34.6%) and mid frequencies in 40 (26.6%), with a pattern of decreased damage in each frequency after treatment, resulting in a mean 59 (39.33%) patients with no damage in any frequency.

Initial evaluation of hearing loss degrees according to the World Health Organization showed that 23 (15.3%) patients had mild hearing loss, 100 (66.6%) had moderate hearing loss, 26 (17.3%) had severe hearing loss, and 1 (0.6%) had profound hearing loss.

Regarding the correlation between the therapeutic window and hearing outcomes expressed in PTA, the

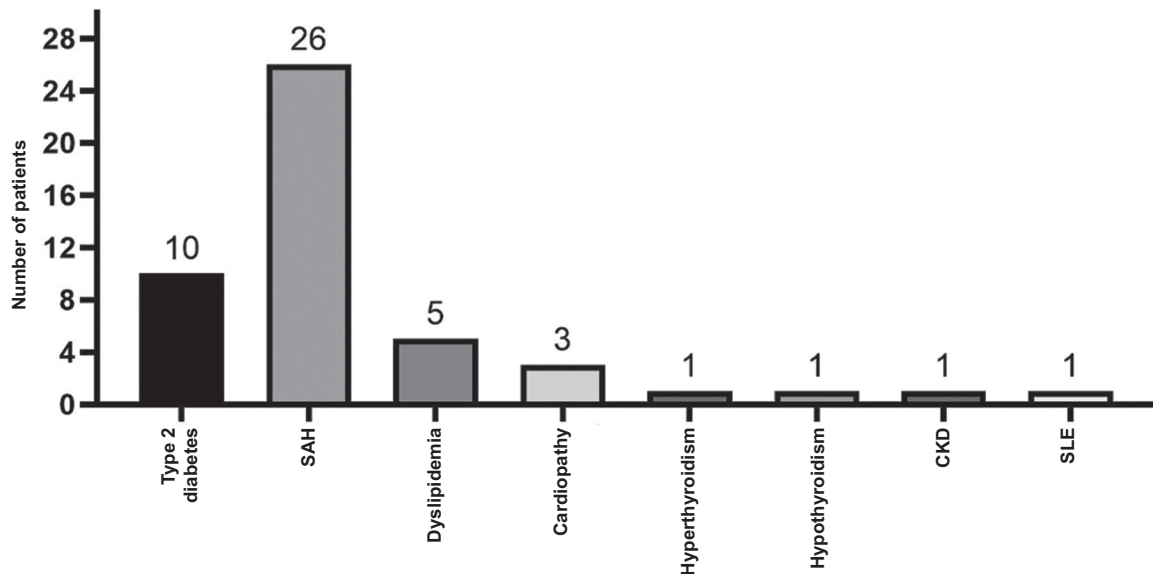


**Figure 2.** Distribution of associated comorbidities. DM2: type 2 diabetes mellitus; CKD: chronic kidney disease; SAH: systemic arterial hypertension; SLE: systemic lupus erythematosus.

population was categorized into 4 groups: > 1 to < 7 days, 75 cases (50%); > 8 to < 14 days, 40 cases (26.6%); > 15 to < 21 days, 26 cases (17.3%); and > 22 to < 28 days, 9 cases (6%). The mean time from symptom onset to diagnosis was 9.36 days, with no statistically significant relationship or relevance found ( $p = 0.2557$ ;  $R = 0.015$ ) (Fig. 3).

Correlation between patient age and hearing outcomes expressed in PTA using Pearson's test revealed no statistically significant relationship or relevance ( $p = 0.779$ ;  $R = 0.02$ ) (Fig. 4).

Regarding the overall PTA average in audiometry before and after treatment, the mean was 57.87 dB with a standard deviation of 14.59 dB before treatment, and after the same test at 6 weeks, the mean was 35.65 dB with a standard deviation of 10.01 dB, showing a statistically significant difference ( $p = 0.001$ ) (Fig. 5).

In terms of the overall results of the logaudiometry before and after treatment, a mean of 42.63 dB with a standard deviation of 19.36 dB was observed before treatment, and after the same test at 6 weeks, a mean of 32.3 dB with a standard deviation of 15.14 was found, representing a statistically significant difference ( $p = 0.001$ ) (Fig. 6).

When evaluating the average degree of auditory recovery according to the Siegel recovery criteria scale, 107 (71%) patients had partial recovery,

16 (11%) had complete recovery, and 27 (18%) had slight recovery.

Regarding therapeutic success versus failure according to the Siegel recovery criteria, success was observed in 123 patients (82%) and failure in 27 (18%).

## Discussion

The main objective of this study was to determine the auditory changes recorded in audiometries of patients diagnosed with ISSHL who underwent combined treatment with intratympanic dexamethasone and systemic prednisone, and to correlate these changes according to the Siegel recovery criteria scale to assess therapeutic success or failure. To this end, a total of 150 electronic health records of patients meeting the selection criteria and their characteristics were analyzed to assess differences between them and the homogeneity of the sample.

The evaluation of the overall PTA average in audiometry before and after treatment showed a mean of 57.87 dB with a standard deviation of 14.59 dB before treatment, and after the same test at 6 weeks, a mean of 35.65 dB with a standard deviation of 10.01 dB, representing a statistically significant difference ( $p = 0.001$ ).

The results obtained suggest therapeutic effectiveness, with therapeutic success in 82% of cases and

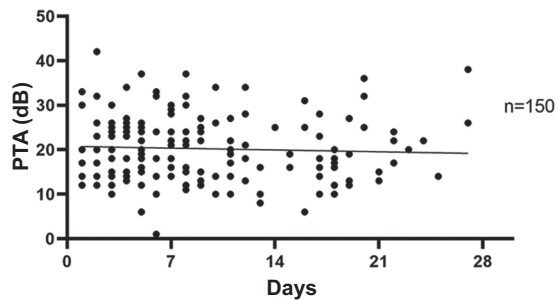


**Figure 3.** Pearson correlation test with linear regression between the therapeutic window and auditory outcomes measured with PTA.

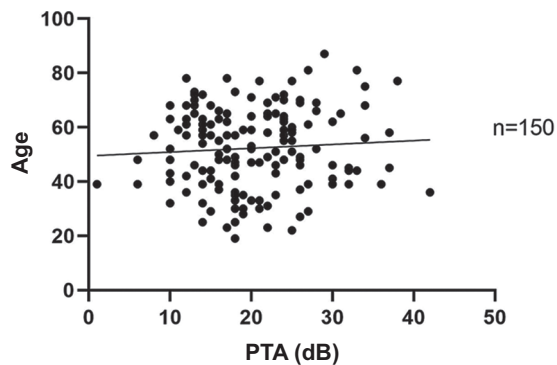


**Figure 4.** Pearson correlation test with linear regression between age and auditory outcomes measured with PTA.

therapeutic failure in 18%, correlating the results with Siegel's criteria.

Given the significant auditory improvement with pharmacological treatment and knowing that some studies demonstrate that the timing of treatment initiation is a crucial prognostic factor, we analyzed the results using Pearson's test to establish a correlation between the therapeutic window and hearing outcomes expressed in PTA, categorizing the population into 4 groups: > 1 to < 7 days, 75 cases (50%); > 8 to < 14 days, 40 cases (26.6%); > 15 to < 21 days, 26 cases (17.3%); and > 22 to < 28 days, 9 cases (6%). The mean time from symptom onset to diagnosis was 9.36 days, with no statistically significant relationship or relevance found ( $p = 0.2557$ ;  $R = 0.015$ ). However, the difference in values between the groups was not large enough to rule out the possibility that the lack of correlation was due to random sampling variability. Similarly, correlating patient age with hearing outcomes expressed in PTA using Pearson's test revealed no statistically significant relationship or relevance ( $p = 0.779$ ;  $R = 0.02$ ). This correlation is important, as numerous studies have

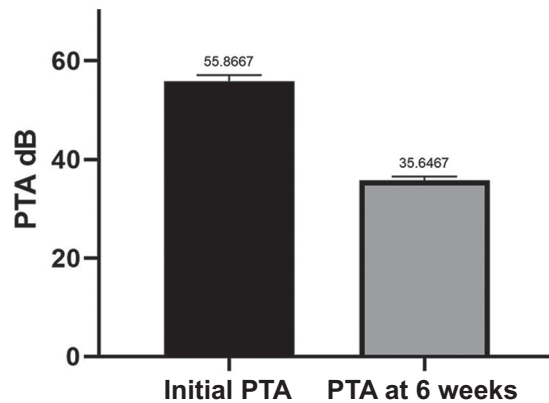


**Figure 5.** Paired Student t-test to determine significant differences in the average PTA before and after treatment.

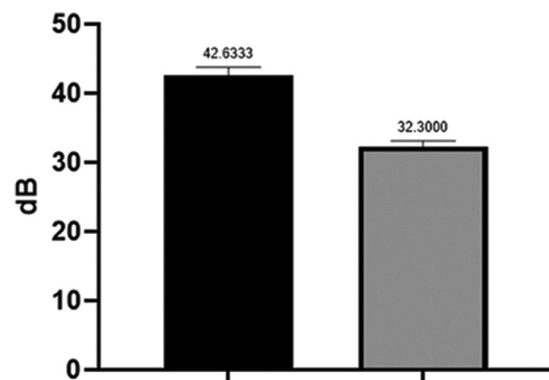


**Figure 6.** Paired Student t-test to determine significant differences in the average logaudiometry before and after treatment.

shown that advanced age can be a negative prognostic factor.

There are many risk factors for ISSHL, including cardiovascular disease, diabetes, hypertension, dyslipidemia, and smoking<sup>28</sup>. Among the 150 patients studied, 39 (26%) had 1 disease at the time of assessment, 5 (3.3%) had 2 concurrent diseases, and 2 (1.3%) had 3 concurrent diseases. Among the comorbidities found, 26 (17.3%) patients had a diagnosis of systemic arterial hypertension (which could be related to the vascular etiology of ISSHL), 10 (6.6%) had a diagnosis of type 2 diabetes mellitus, 5 (3.3%) had a diagnosis of dyslipidemia, 3 (2%) had a diagnosis of some form of heart disease, 1 (0.6%) had hypothyroidism, 1 (0.6%) had systemic lupus erythematosus, and 1 (0.6%) had chronic kidney disease. These risk factors have not shown correlation with the degree of patient recovery in most studies.

## Conclusions

Tonal audiometry is a good indicator of patient progress with ISSHL and has shown evident changes with the administered treatment<sup>29</sup>. The correlation of PTA results and logaudiometry results before and at 6 weeks after treatment demonstrates statistically significant improvement.

Combined steroid treatment initially for ISSHL has shown an 86% success rate at 6 weeks according to the Siegel recovery criteria scale.

The therapeutic window plays an important role in hearing recovery; some studies demonstrate that early treatment influences therapeutic success, but in our study, we did not find a statistically significant correlation, likely due to our sample size<sup>30</sup>.

Patient age appears to be an important factor in recovery after treatment, as numerous studies have demonstrated that advanced age can be a negative prognostic factor, although this effect could not be correlated in our study<sup>31</sup>.

Most cases of sudden sensorineural hearing loss are idiopathic, involving primarily infectious, autoimmune, and vascular processes. Correlating these conditions in our studied population is challenging due to the low percentage of patients with comorbidity, with a predominance of cardiovascular and metabolic origins.

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None declared.

## Conflicts of interest

None declared.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this study.

**Confidentiality of data.** The authors declare that they have followed the protocols of their work center on the publication of patient data.

**Right to privacy and informed consent.** The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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