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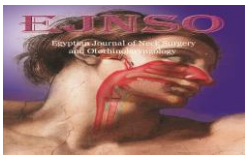

Intratympanic steroid injection versus oral steroid as treatment of post COVID-19 Sudden sensorineural hearing loss (SSNHL)

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Abstract:

Background: At the end of 2019 the world was attacked by coronavirus disease 19 (COVID-19) caused by severe acute respiratory syndrome coronavirus, there is a direct association between COVID-19 and SSNHL. Corticosteroids are widely used as a first-line treatment option for SSNHL. Our objective was to evaluate and compare between the efficacy of both known treatments of SSNHL, which are oral steroid versus intratympanic steroid injection in post COVID 19 hearing loss.

Patients and methods: Twenty patients with confirmed COVID-19 reported SSNHL were included in this study with different degrees of hearing loss ranged from mild to profound hearing loss. Different approach of steroid therapy including intratympanic steroid injection, high dose oral steroid and both systemic steroid with intratympanic injection.

Results: There were no statistically significant differences in the mean of each frequency pre and post treatment audiogram, but there was significant difference in overall change in frequencies which means general improvement. In the other hand there was significant difference between the mean of post treatment low and high frequencies thresholds with more improvement in low than high frequencies. Compering the three groups, there was statistically significant difference in median of all frequencies between the group receiving systemic steroid and the other two groups.

Conclusion: COV-SARS-2 virus infection seems to induce SSNHL, Early treatment for sudden hearing loss induced by COVID-19 with high dose of systemic steroid is the most probable option of treatment, and intratympanic injection can be used as a salvage treatment.

Key words: COVID 19; SSNHL; Steroid therapy; Intratympanic steroid injection.

Introduction

No one was equipped for the pandemic that attacked the world at the end of 2019; since the introduction of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2), which produced coronavirus disease 19 (COVID-19), the world has been combating this pandemic. [1]

What at first appeared to be merely a respiratory infection quickly turned out to be a systemic disease that might be fatal and varied from asymptomatic to that involved both thromboembolic and inflammatory processes, COVID-19 exhausted all the medical resources in persons and in medicine and still annoying all medical centers. [2]

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About one-third of cases of the illness may be asymptomatic, triggering SARS-CoV-2 [3] or promoting the disease's transmission.[4] This novel coronavirus, which was discovered in human airway epithelial cells, is thought to spread via aerosols and direct contact and has incubation duration of 2–7 days that can last up to 14 days.[5]

Cough, sore throat, fever, muscle soreness, headache, diarrhea, and dyspnea are some of the most typical COVID-19 symptoms. Respiratory infection and Pneumonia have been the main causes of COVID-19-related mortality, many sporadic symptoms were identified to be caused by COVID 19 infection, and some of them were neurological, including facial paralysis, anosmia, and sudden sensorineural hearing loss (SSNHL). [6]

SSNHL is described by > 30 dB of hearing loss in three consecutive frequencies on pure tone audiometry (PTA) and is typically followed by vestibular and tinnitus symptoms.[7] SSNHL is described as sudden hearing loss of rapid onset within 72 hours.

The relationship between hearing loss and COVID 19 has been extensively addressed in the literature. Neuritis or Labyrinthitis, which consequences in manifestations like hearing loss, tinnitus, and vertigo, take place owing to upper respiratory tract infection brought on by Coronavirus infection [8], cross-reaction may induce inner ear antigens to be mistaken for a foreign agent and be threatened by the antibodies [9], vasculitis and coagulopathy [10] and finally, proinflammatory cytokines high production that induces hearing loss are thought to be the main mechanisms by which COV-SARS-2 can induce SSNHL. [11]

Narrative reviews on COVID 19 and hearing loss have been published, according to certain authors; **Kilic et al**. investigated the relation between COVID-19 and SSNHL in one of the first published papers, who found one patient with positive PCR of COVID-19 virus out of five individuals diagnosed with sole SSNHL. This study increased otologists' awareness of the vagueness of COVID-19 patients' presentations.[12]

Another systematic review was conducted recently exploring the audio vestibular symptoms in COVID-19 by **Umashankar et al**., they reported that; there is a possible correlation between COVID-19 and SSNHL. The virus can also have an impact on the auditory system by either directly infecting the inner ear or inducing neuritis or labyrinthitis, by establishing an embolus or thrombus that affects the microcirculation in the inner ear, or by impacting the auditory center in the temporal lobe. [8]

Globally, corticosteroids are frequently utilized as the first-line medication for SSNHL. Intravenous, oral, or intratympanic instillations of corticosteroids are all acceptable administration methods. Because of the possible advantages of a high local concentration producing a more desirable profile of side effects contrasted to systemic administration, corticosteroid injected directly into the middle ear cavity has become a more often used technique. [13, 14]

Mohammed et al. reported that intratympanic steroid injection seems to be a protected, relatively efficient, and feasible technique of SSNHL medication throughout COVID-19 pandemic if early utilized. [9]

The study's objective was to validate and compare between the efficacy of both known treatments of SSNHL, which are oral steroid versus intratympanic steroid injection in cases of COVID 19 infection.

Patients and methods:

This a two centres retrospective, observational study conducted at tertiary care referral otolaryngology departments [Assiut university and Assiut Azher university branch] in the period between January 2021 to October 2021 and approved by Research Ethics Committee and Institutional Review Board in Assiut university with IRB local approval number 17300723.

This study was a part of work entitled the prevalence of SSNHL after COVID 19 and the eligible candidates were presented with SSNHL. All patients diagnosed with SSNHL in a period of days to few weeks with COVID-19 participated in this study. The eligible patients were presented with SSNHL which was described as a SNHL of > 30 decibels at three consecutive frequencies at minimum over duration of < 3 days. [7]

All the COVID-19 cases participated in this study were positive reverse transcription polymerase chain reaction (RT-PCR) for SARS-CoV-2 complained of sudden hearing loss were evaluated by both otolaryngologist and audio vestibular medicine specialist.

Patients who met the following criteria were included in the study: recorded instance (positive PCR), recovered (2 negative PCR), experiencing recent sudden SNHL, and managed as home separated.

Initial assessment and evaluation:

- Personal history included age, sex, residency, occupation, special habits.
- Detailed medical history including history of the ear with previous trauma, surgeries, congenital anomalies, chronic inflammation, history of the noise exposure, ototoxic drugs, age associated hearing loss, mumps, thyroid diseases, rubella, meningitis, measles, syphilis, hypertension, kidney diseases and diabetes mellitus.
- History about the COVID-19 infection (duration, course, onset and any complications).
- Any prior audiological testing, all subjects underwent otological evaluations, comprising otoscopic examinations and tuning fork tests.

Audiological Evaluation:

All of the participants were getting a basic audiological evaluation, which included pure tone audiometry and tympanometry. Procedures for safety of the COVID-19 pandemic infection were followed during the pure tone audiometry. Pure tone audiometry results were performed at frequencies 250, 500, 2000, 4000 and 8000 Hz utilizing Interacoustics AC 40 two-channel pure tone audiometer with a locally produced sound-treated booth. Calculations were made to determine the mean hearing threshold at 500Hz, 1000Hz, and 2000Hz.

Hearing loss was deemed to exist when the pure tone mean exceeded 25 db. Tympanometry was carried out with help of the Interacoustics AT 235: 226 HZ single-frequency tympanometry to rule out middle ear pathology.

Treatment and flow up:

Treatment started once the diagnosis was established, all patients underwent either oral corticosteroid, prednisone 1 mg/ kg/day for two weeks with taper the dose over two weeks [15], Intratympanic (IT) steroid (dexamethasone 4mg/ml) injection every three days five cycles using local anesthesia [local lidocaine cream 5% for 30 minutes], under microscopic guide, injected using 25-gauge spinal needle in the posteroinferior quadrant of the tympanic membrane for contraindicated cases or continued intratympanic steroid injection after systemic steroid as

salvage treatment according to general health or duration of hearing loss. [13,15]

The choice of line of treatment was depending on the patients' medical condition, if there was a contraindication for systemic steroid therapy as in cases with hypertension, diabetes mellitus, intratympanic steroid injection was used. Otherwise systemic therapy was the protocol.

Interval audiometric testing after 2 weeks was done to all patients for flow up the results. One month follow up was done but there were no significant changes in the PTA results.

Statistical analysis

The IBM-SPSS/PC/VER 24 was used to evaluate the acquired data once the researcher had verified it and it was coded. Statistically descriptive data Calculations included means, medians, ranges, standard deviations, and percentages. The major variables' normality was examined using the Shapiro-Wilk test.

The post-hoc test was computed utilizing Bonferroni adjustments for continuous variables with more than two categories in order to assess the data's median differences that do not meet a normal distribution.

The data's mean differences that follow a normal distribution and have repeated measures were examined using the two-way ANOVA test (between groups, within groups and overall difference). A p-value of 0.05 or less was regarded as significant.

Results

Twenty patients diagnosed with COVID-19 reported sudden SNHL were involved in this study. The mean age among these patients was 43.15 (± 15.64) years ranging from 25 to 60 and 11 (55 %) were females. Six patients were known to be hypertensive, and five patients had diabetes mellitus. Patients participated in our study were classified into the following: 12 patients were diagnosed with SSNHL after typical COVID-19 infection symptoms, 5 patients were complaining of ageusia and anosmia, and 3 patient diagnosed with COVID-19 by positive PCR test form nasopharyngeal swapes to prove infection complained only from hearing loss (Table 1).

11 (55%) patients had hearing loss in the left ear, 9 (45%) in the right. Among the 20 patients, the mean duration of hearing loss was 27.05 (± 23.997) days ranging from 1 to 90 days after deafness before seeking medical advice. Most of the patients experienced the HL in the first week of infection (8.15 ± 6.32 days) (median 6.5 days) with one patient after one month of infection (Table 2).

Hearing loss' degrees were varied from mild to severe with very wide range of hearing loss degrees with 7 patients reached profound hearing loss. All patients sought medical advice because of tinnitus as all patients complained of it, and 6 patients (30%) complained from vertigo. No other neurological manifestation was detected. All patients had type A tympanogram (Table 2).

Eleven patients had intratympanic steroid injection, six patients had high dose oral steroid and three patients had systemic steroid then intratympanic injection (Table 2).

Effect of treatment among all patients by comparing the mean difference in each frequency pre and post treatment (Table 3 & Fig. 1). Table 4 shows a comparison between the results of efficacy of each type of treatment by comparing the median of follow up audiogram in all patients.

Table 1: Baseline Demographic and Clinical Characteristics of the Study Cohort

Parameter		n = 20
Age in years	• **Mean ± SD**	43.15 ± 15.64
	• **Median (Range)**	41 (25 - 60)
Sex	• **Female**	11 (55%)
	• **Male**	9 (45%)
Risk Factors	• **DM**	5 (25%)
	• **HTN**	6 (30%)
COVID-19 Symptoms	• **Only Symptom**	3 (15%)
	• **Taste and Smell**	5(25%)
	• **Typical COVID-19**	12(60%)

Table 2: Hearing Loss Related Characteristics of the Study Cohort

Parameter		n = 20
Onset of HL Post-COVID	**Mean ± SD.**	8.15 ± 6.32
	Median (Range)	6.5 (3 – 30)
Duration of HL/days	**Mean ± SD**	27.05 ± 23.997
	Median (Range)	27.5 (1 - 90)
Side of HL	**Left**	11 (55%)
	Right	9 (45%)
Severity	**Mild**	2 (10%)
	Moderate	4(20%)
	Moderate-Severe	1 (5%)
	Severe	6 (30%)
	Profound	7 (35%)
Associated Symptoms	**Tinnitus**	20 (100%)
	Vertigo	6 (30%)
Tympanogram	**Type A**	54 (100%)
Other neurological Manifestations	**No**	20 (100%)
Treatment	**ITS**	11 (55%)
	Oral	6 (30%)
	Both	3 (15%)

Table 3: Effect of Treatment on PTA thresholds

Parameter	Pre-treatment	Post-treatment	P-value*
	Audiogram Frequency		
250 Hz	60.25 ± 6.2	56.00 ± 6.6	= 0.101
500 Hz	63.25 ± 6.3	57.75 ± 6.6	**= 0.020**
1000 Hz	66.25 ± 6.8	62.50 ± 7.6	= 0.135
2000 Hz	64.00 ± 7.6	61.75 ± 7.5	= 0.336
4000 Hz	67.90 ± 7.4	67.50 ± 7.6	= 0.817
8000 Hz	69.25 ± 7.5	70.25 ± 8.3	= 0.723
P-value**	= 0.375	**= 0.012**	**= 0.018*****

***Mean differences Within Group Comparison
**Mean differences between Group Comparison
***Two-way Repeated Measure ANOVA was used to compare the mean differences over time

Table 4: Differences in Audiogram Findings according to Type of Treatment

Median (IQR)	ITS (n = 11)	Oral (n = 6)	Both (n = 3)	P-value*
Audiogram Frequency PTA thresholds				
250 Hz	65 (45)	30 (16)	77.5 (41)	**= 0.018**
P-value**	**I vs. II = 0.044**	**II vs. III = 0.043**	I vs. III = 0.947	
500 Hz	65 (58)	22.5 (18)	72.5 (36)	**= 0.038**
P-value**	**I vs. II = 0.039**	**II vs. III = 0.026**	I vs. III = 0.957	
1000 Hz	77.5 (44)	17.5 (8)	82.5 (36)	**= 0.015**
P-value**	**I vs. II = 0.042**	**II vs. III = 0.033**	I vs. III = 0.981	
2000 Hz	82.5 (54)	20 (15)	80 (34)	**= 0.015**
P-value**	**I vs. II = 0.032**	**II vs. III = 0.040**	I vs. III = 0.977	
4000 Hz	85 (41)	25 (21)	80 (46)	**= 0.016**
P-value**	**I vs. II = 0.027**	**II vs. III = 0.048**	I vs. III = 0.957	
8000 Hz	95 (59)	27.5 (18)	92.5 (24)	**= 0.038**
P-value**	**I vs. II = 0.046**	**II vs. III = 0.049**	I vs. III = 0.981	

*Kruskal Wallis test was used to compare the median difference between groups
I: ITS II: oral steroid III: Both ITS and systemic
**Post-hoc test was used for pairwise comparison with Bonferroni correction.

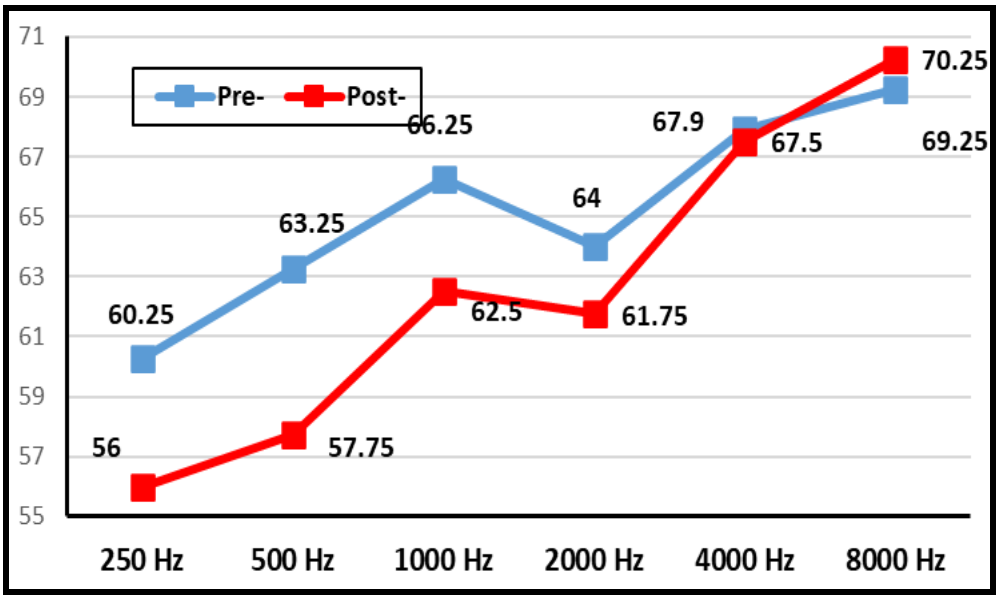

Figure 1: Effect of steroid treatment on pure tone audiometry.

Discussion :

One of the most terrifying experiences for people is SSNHL, which would cause severe bilateral deafness or be a life-threatening condition. A hearing loss of at minimum 30 dB at three different frequencies during a minimum of three days was considered to be SSNHL. [16]

Viral neuritis or cochleitis, which has long been believed to be the most common cause of sudden SNHL, is a well-discussed etiology of SSNHL. One month prior to the commencement of their hearing loss, 28% of patients who present to a doctor with SSNHL report having an upper respiratory infection that is viral in nature. [17] Investigations that show elevated viral titers in these individuals, several pathologies compatible with viral infection, and viral seroconversion studies [18–19] are additional proof of a viral etiology for sudden SNHL.

Mao et al., 2020 was the first to characterize the neurological side effects of COVID-19, noting that 36% of their inpatient cohort experienced neurological symptoms, including CNS symptoms like dizziness, headache, impaired consciousness, stroke, ataxia, and epilepsy, peripheral nervous system manifestations like hyposmia, hypogeusia, neuralgia, and muscular manifestations. COV-SARS-2 virus has been thought to induce sudden SNHL in the last two year and many authors published studies to support this theory. [15]

This retrospective observational preliminary study included twenty patients complained of hearing loss after infection with SARS-COV-2 in the period between January 1sts 2021 and October 31st, 2021. All patients were diagnosed to have infection by CT chest and/or PCR of nasopharyngeal samples. Of the 20 patients, eleven were females (55%).

The mean duration of hearing loss before seeking medical advice was 27.05 ± 23.997 days with four patients came after eight to twelve weeks which affect their prognosis. Five patients had DM, and six patients had hypertension, with no other predisposing factors of hearing loss were found in these patients (noise exposure, ototoxic drugs, head trauma, cardiovascular disease, renal diseases, and thyroid dysfunction).

15% of the patients (three) had only SSNHL as a symptom of COVID-19 infection (diagnosed by PCR test for nasopharyngeal swabs), 25% patients (five) had loss of taste and smell senses, and the rest of patients 60% (twelve) had typical symptoms of COVID-19 infection (muscle pain, sore throat, cough, headache, fever, and dyspnea). Hearing Loss was diagnosed in most of the patients the in the first week of infection (8.15 ± 6.32 days) (median 6.5 days) with only one patient after one month of infection. One month is the known upper limit of viral infection as a suspected cause of SSNHL. [17]

Normal ear examination with normal tympanic membrane found in all patients. In tuning fork test using 512 Hz tuning fork, Patients with left-sided hearing loss exhibited lateralization toward the right side on the Weber test, while those with right-sided hearing loss exhibited lateralization toward the left side. 11 patients had SSNHL in the left ear (55%) and 9 patients in the Right ear (45%). Wide range of hearing loss severity degree found in patients with seven (35%) of them had profound hearing loss. All patients had normal eustachian tube function and normal middle ear (Type A tympanogram).

Persistent tinnitus was the most motivating prevalent symptom to 100% the patients to seek medical advice. Only 6 patients (30%) had vertigo and disequilibrium that improved in a week form the complaint as reported by the

patients. Except for the four patients that complained from anosmia and augsia, no other neurological manifestations detected .

Eleven cases were treated by intratympanic steroid injection because of having a risk factor [diabetes and hypertension] preventing systemic steroids, six cases with systemic steroid and three cases had intratympanic steroid injection after systemic steroid as salvage mediation as they show no improvement.

There were no statistically significant differences in the mean of each frequency pre and post treatment audiogram evaluation in the air conduction thresholds for all patients except at 500 Hz air conduction (P value 0.020), but there was significant difference (P value 0.018) in overall change in frequencies in air conduction which means general improvement in all patients in hearing loss' degree. In contrast, there was significant difference between the mean of post treatment low and high frequencies air conduction (P value 0.012) with more improvement in low than high frequencies.

Comparing the three groups, there was statistically significant difference in median of all frequencies between the groups had systemic steroid and the other two groups. The patients who had systemic steroid had more improvement, reaching to normal hearing, than patients who had intratympanic injection alone or had intratympanic injection after systemic steroid. More improvement was more in the low frequency regions.

Four factors appear to influence the prognosis of post-Covid SSNHL: 1) loss severity, 2) audiogram shape, 3) existence of vertigo, and 4) age. The more severe the loss, the worse the recovery prognosis, and tremendous losses have an especially poor prognosis. Down sloping and flat losses recover more commonly than upsloping and midfrequency losses. Although not all studies agree on this point, the existence of vertigo, especially with a down sloping loss, is a poor prognostic indicator. Speech discrimination impairment has a poor prognosis. Finally, the studies' majority demonstrate that children and adults over the age of 40 have a worse prognosis than others. [3,19]

The majority of recovery takes place within the first two weeks of onset; as a result, the prognosis for recovery decreases as the loss persists. Without any kind of medication, a significant percentage of patients (30% to 65%) recover completely or partially. [20]

Most of the authors were targeted more to announce the presence of a case or multiple cases in his center or to the prevalence and incidence of SSNHL at the era of COVID-19 and wither the number of cases increased or not with little attention to the treatment. [20,21]

Tsuda et al. found no significant differences in post-treatment results between cases treated with either intravenous or intratympanic steroids and recommended intratympanic steroid as an early primary treatment of SSNHL in time of COVID-19 pandemic to avoids complications of systemic steroid. In contrast to their study, our results show more improvement using systemic steroid than intratympanic injection regaining normal hearing in all patients had such treatment. [10]

Lastly, the prognosis of such a disease in most of the patients was bad even with recommended treatment with little or no improvement at all, which may be due to late diagnosis, late treatment, and presence of profound hearing loss at time of diagnosis. [10,22]

Conclusion:

COV-SARS-2 virus infection seems to induce sudden SNHL with a mechanism which is not fully understood, by straight forwardly infecting the inner ear and inducing labyrinthitis/ neuritis, by establishing a thrombus/ embolus in the inner ear and influencing the microcirculation, or by impacting the auditory center in the temporal lobe.

At the end of this study, we recommend systemic steroids in high dose which is most likely potential treatment for COVID-19-induced sudden hearing loss as an initial medication, and intratympanic injection can be used in contraindicated cases or as a salvage treatment for refractory cases.

Limitation of the study:

This study is restricted by its few numbers of patients receiving the steroid therapy as being a retrospective study.\

Abbreviation:

SSNHL: Sudden Sensorineural Hearing loss
PCR: Polymerase Chain Reaction
PTA: Pure Tone Audiometry
ITP: Intratympanic Steroid Perfusion
SARS: Severe Acute Respiratory Syndrome
SPSS: Statistical Package for Social Sciences
CNS: Central Nervous System

Ethical Approval of studies and informed consent:

All patients signed their written informed consent to participate. The study was performed in accordance with the Helsinki Declaration of 1975 and its amendments. This study protocol was approved by the Research Ethics Committee and Institutional Review Board at Faculty of Medicine, Assiut University, Egypt with IRB local approval number 17300723.

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Conflicts of interest: The authors have no conflicts of interest.

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