

A PROSPECTIVE STUDY TO ASSESS THE OTOPROTECTIVE ROLE OF ANTIOXIDANT MULTIVITAMIN SUPPLEMENTATION IN SENSORINEURAL HEARING LOSS.

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ABSTRACT

BACKGROUND

In the general practice of an otolaryngologist, a significant number of patients present with sensorineural hearing loss (SNHL). Vascular compromise and oxidative stress contribute to the development of acquired hearing loss. Our research was formulated to confront the dilemma faced in offering an efficacious therapy to patients with SNHL.

METHODS

This prospective study was attempted to evaluate the therapeutic effect of antioxidant vitamins (A, C, and E) in SNHL in adult patients. Pre-treatment audiogram served as the baseline. PTA was repeated for all frequencies after antioxidant supplementation at the end of 1 year. Hearing gain was determined relative to each patient's baseline PTA values. Treatment success was based on improvement in PTA values.

RESULTS

In our study, there was a marginal improvement in the mean PTA values from baseline to post-antioxidant treatment values. Though there was no significant gain in hearing among our study population, the further hearing deterioration was believed to be arrested or slowed after supplementation with antioxidants.

CONCLUSION

Our study suggests the existence of a salient otoprotective role of oral combination of vitamins A, C and E against SNHL.

Keywords

Hearing impairment; Sensorineural hearing loss; Pure tone audiometry; Vitamins; Antioxidants.

BACKGROUND

Hearing impairment is a highly prevalent sensory deficit.¹ Vitamins/antioxidant have been studied as therapeutic strategies to prevent and/or delay the risks of human diseases as well as hearing loss.² Sensorineural hearing loss (SNHL) is a relatively common complaint in otological and audiological practices.³ Oxidative stress can be a severely damaging condition resulting in an imbalance of antioxidant defences and excessive production of free radicals such as reactive oxygen species like superoxide, hydroxyl, peroxy, alkoxyl, hydroperoxyl, and reactive nitrogen species such as nitric oxide and nitrogen dioxide.⁴ Excessive formation of free radicals may result in mitochondrial injury, glutamate excitotoxicity, and injury caused by ischemia/reperfusion.⁴

Pharmacological interventions using antioxidant drugs restore the balance between antioxidant defence and the formation of free radicals in the cochlea.⁴ The antioxidant properties of vitamins

beta carotene, C and E have been shown to protect from inner ear damage caused by aging, noise exposure, acoustic trauma, aminoglycosides, and cisplatin.⁵

The objective of our study is to find out the efficacy of medical treatment modality using antioxidant multivitamins in SNHL.

METHODOLOGY

OBJECTIVE OF THE STUDY

- To assess the beneficial effect of oral antioxidant multivitamin supplementation in SNHL.

A. DESIGN OF THE STUDY:

Prospective study

Sample size and its calculation:

- Sample size estimation done using OPENEPi software version 2.
- With 95% Confidence level,
- And 80% Power of the study,
- Sample size was estimated and it is 60.

Inclusion criteria:

- Patients with hearing loss presenting to the outpatient department of Otorhinolaryngology at HSK Hospital, Bagalkot willing to take part in the study.
- Bilateral SNHL.
- Patients ≥ 18 years age of both the genders.

Exclusion criteria:

- Patients below the age of 18 years.
- Patients with prior ear surgery.
- Patients with presence of external or middle ear disorders.
- Patients found to have congenital hearing deficit.

Collection of data:

- Data of patients attending outpatient Department of ENT, HSK Hospital, Bagalkot with hearing loss was recorded.
- Hearing impairment was analyzed with the help of Pure Tone Audiometry (PTA) and hearing gain was assessed.

Investigations:

- Otomicroscopy
- Pure Tone Audiometry

B. MATERIALS AND METHODS

This is a prospective study conducted in Department of ENT, HSK Hospital, Bagalkot for a period of 2 years and 4 months from August 2020 to December 2022. This study was carried out in 60 patients suffering from hearing loss after obtaining ethical clearance. Patients of 18 years or above in age were included in our study after receiving their consent.

All patients underwent audiological assessment involving a case history, physical examination, otomicroscopy and baseline audiological evaluation with PTA. PTA was performed for both air conduction and bone conduction for 250 Hz to 8 kHz. All the patients were treated with antioxidant multivitamin supplementation for 1 year. Patients received capsules containing 2.4 mg vitamin A (beta-carotene), 25 mg vitamin C (ascorbic acid) and 8 mg of Vitamin E (tocopherol) once daily from day 1 till the completion of treatment.

PTA was repeated for all frequencies at completion of treatment at the end of 1 year. Pre-treatment audiogram served as the baseline. Hearing gain was determined relative to each patient's baseline PTA values. Treatment success was based on improvement in PTA values.

Thus, treatment outcome in terms of hearing gain was evaluated. Its statistical significance was studied to determine the efficacy of antioxidants in therapy of SNHL.

STATISTICAL ANALYSIS

Data was entered in the Microsoft excel and analysed using SPSS software version 19. Percentages & proportions was used for qualitative data and mean and standard deviation for quantitative data. Appropriate statistical tests were applied. $p < 0.05$ was considered as statistically significant.

RESULTS

A total of 60 patients were included in the study who presented with sensorineural hearing loss at the Department of ENT, HSK Hospital, Bagalkot from August 2020 to December 2022. All these patients met the inclusion and exclusion criteria of our study. Of these, 32 were female and 28 were male (Table 1). The average age of presentation was 55.72 years. All these patients had reported bilateral hearing loss. Most of them had accompanying symptoms of tinnitus (31%) and vertigo (25%).

Table 1: Patient demographics.

Gender(n=60)	Distribution
Female	53.33%
Male	46.67%

We evaluated the degree of hearing loss in terms of the PTA threshold at the start of the study using Amplaaid 311 Type 1 IEC 645 audiometer (Figure 1). Majority of the patients had moderate SNHL (66%), while 19% had mild SNHL, and the remaining had moderately severe SNHL.

Figure 1: Pure tone audiometer.



The PTA threshold shifts were measured after 1 year in all the patients. There was no significant difference in the threshold shift in these individuals. But there was an improvement in the mean PTA values from baseline to post-antioxidant treatment values seen at frequencies 1000Hz, 2000Hz, 4000Hz and 8000Hz. Audiological gain was found to be 7.12 in right ear and 15.37 in left ear after supplementation with antioxidants (Table 2).

Table 2: The mean pure tone audiometry values of both ears of patients before and after vitamin supplementation.

Hearing loss:	Right	Left
Mean Pre treatment PTA value (dB)	63.16	69.65
Mean Post treatment PTA value (dB)	56.04	54.28
Mean hearing gain (dB)	7.12	15.37

The results of our treatment were reported as: complete recovery, where hearing thresholds returned to their normal values; marked recovery, where more than 30 dB recovery in mean hearing level was reported; partial recovery, a recovery of 10–29 dB in mean hearing, and no response (<10 dB in mean hearing level).³ Only patients showing complete recovery were considered as successfully treated in the current study.

The outcome was obtained by assessing the

number of patients who had a complete recovery from SNHL on therapy with antioxidant vitamins in our study group. It was found that none of the patients reached full recovery after administration of antioxidant vitamins. However, we could see a marginal improvement of mean hearing in the study group who received the vitamin therapy; though, this improvement was not significant. Only few patients reported relief in associated symptoms of tinnitus and vertigo.

Many factors can affect the results of treatment. The severity of initial hearing loss can affect the recovery rate, which was also worse in patients who had vertigo and/or tinnitus at the time of loss of hearing as compared to those who did not experience those symptoms; however, the difference was not statistically significant.

All the patients had only received vitamin supplementation as their treatment modality. Among most of the patients, no other etiopathogenesis other than aging could be elucidated. Patients with uncontrolled comorbidities such as diabetes mellitus and other systemic diseases were not present in our study. The fact that heterogeneity among our study was negligible strengthens our results. Although the study population showed better outcome at the end of treatment, only the complete recovery patients were of interest to discuss to have a more robust conclusion.

The aetiology and appropriate cure of SNHL remain unclear. Antioxidants can attenuate the decline of cochlear structure and function.⁶ Vitamins A, C, and E are the major antioxidant vitamins. Each vitamin has a different mechanism of action, e.g. vitamin A can reduce the concentration of singlet oxygen and repair damaged hair cells, vitamin E can reduce peroxy radicals in the cell membrane, and vitamin C can detoxify free radicals in the aqueous phase.³ Hence, these vitamins can improve the outcome of the management of SNHL.

Supplementation with vitamins A, C, and E significantly increased the antioxidant capacity of

inner ear tissues.⁶ This fact was evident through the lack of progression of hearing impairment in the patients after antioxidant therapy in our study. Based on our data, we recommend to provide antioxidant vitamins to patients with SNHL. However, more research is required to collect data about which among the antioxidant vitamins is most effective, as well as its therapeutic dosage and duration.

DISCUSSION

Oxidative stress has been linked to noise- and drug-induced as well as age-related hearing loss.⁶ Deleterious effects of hearing loss in adults also generate morbidity as hearing loss has been linked to poor overall physical functioning and social interaction, as well decreased overall quality of life.⁷ Medical therapies for hearing loss have remained elusive despite the number of persons living with disabling hearing loss worldwide and the multi-dimensional burden of hearing loss.⁷

Several experimental models have proved that the onset and progression of hearing loss are closely linked to the availability of nutrients and their metabolism.⁸ These studies support the potential of nutritional therapy for the protection against hearing loss progression, which is especially relevant to the aging process and related quality of life.⁸

In the study conducted by Shivappa L et al,⁹ the incidence of SNHL was seen at higher frequencies in patients treated with chemoradiotherapy along with Vitamin E found to be 10% as compared to the incidence of 65.38% seen in patients who have not received Vitamin E supplement.

Rebamipide 100 mg + alpha lipoic acid 100 mg + acetylcysteine 100 mg along with combination of cinnarizine 20 mg, and dimenhydrinate 40 mg and steroids was proposed as a clinically relevant approach to treat age-related and other sensorineural hearing loss in the study done by Udagatti et al.¹⁰

Regarding the effect of vitamin E, Furukawa, et al. Kapoor et al. and Burlutsky et al point out that this vitamin benefits individuals with sensorineural hearing loss and also stops their evolution.¹¹

Vitamins C, E, and beta carotene have shown promising otoprotection in animal studies, possibly due to their antioxidant properties.¹² Shargorodsky et al, however, found no association between these vitamins and the overall incidence of hearing loss.¹²

Patients with hearing problems who do not tolerate hearing aids, ear implants may provide improvement in sound quality and clarity; but the cost is a major limitation for widespread use.¹⁰ Antioxidant micronutrients may neutralize free radicals, reduce inflammation, and decrease the effect of glutamate toxicity; thus, it reduces the cochlear damage, inhibits processes or pathways that damage cochlear cells and enhance processes that enhance cochlear cell survival.¹⁰

During the data collection stage of this project, an attempt was made to document associated symptoms, such as tinnitus, or vertigo, so as to study the resolution of these symptoms with therapy. On analysing the patients who received oral antioxidant therapy, it is interesting to note that although PTA improvement was seen, the effect on accompanying symptoms was not statistically significant.

We failed to track dietary intake of antioxidants and is an area of weakness in this study. A study that includes oral intake in diet as well as pharmacological therapy of antioxidants is necessary to be able to effectively assess this mode of treatment.

Medical management of SNHL by oral antioxidant therapy can be a more desirable choice as it is safe and economical without producing any marked side effects. However, further research is needed in this aspect regarding the suitable way to tackle the ever-growing number of patients suffering from SNHL.

CONCLUSION

The study of the effect of vitamins in hearing loss has attracted the attention of numerous researchers.⁸ Vitamins, as micronutrients, have potential beneficial effects in the treatment/prevention of hearing loss due to either their antioxidant properties or their essential role in the proper functioning of the ear.⁸ Through our study, we have taken on the challenge encountered in managing SNHL and proposed the potential beneficial role possessed by these antioxidant vitamins in resolving this predicament.

Abbreviations

SNHL: Sensorineural hearing loss; PTA: Pure Tone Audiometry.

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Author contributions

All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical clearance was obtained from Ethical Review Committee of SNMC-Institutional ethics committee on human subjects research recognized by Medical Council of India and affiliated to RGUHS, Bangalore. Patient privacy was protected. All data obtained in the course of the study were kept confidential and used only for this study.

Consent for publication

All participants consent for publication.

Conflict of interests

The authors declare that they have no conflict of interests.

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