International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

Hearing Loss in Chronic Otitis Media Patients and Covid Vaccination - Is There a Relation?

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Abstract: ***Introduction**: Chronic otitis media (COM) is an inflammatory condition of the middle ear, characterised usually by chronic otorrhea (i.e., lasting > 6-12 weeks) through a perforation in the tympanic membrane. COM most commonly leads to some degree of conductive hearing loss. However, recurrent ear infections result in diffusion and absorption of toxins and macromolecules into the inner ear, and this can lead to sensorineural hearing loss (SNHL). Corona Virus-2019 (nCoV-19) is the cause of the recent "COVID-19" pandemic. The outbreak emanated from Wuhan, China, in December 2019. The aim of this study is to evaluate if there is a positive correlation between the hearing loss in COM patients and Covid Vaccination. **Methods**: This is Cross sectional Observational study which included 200 patients who presented to ENT department: Bharati Hospital Pune, India. A detailed history of COM patients was taken, specifically asking for Covid Vaccination history. A pure tone audiogram of all patients was then obtained. All data was analysed identifying cases with disproportionate conductive, mixed or SNHL to look for statistical correlation between the hearing loss and Covid vaccination. **Results**: Of 78 cases without any H/O COVID-19 vaccination, 35 (44.9%) had conductive, 24 (30.8%) had mixed and 19 (24.4%) had sensorineural hearing loss. Of the total 122 cases with the H/O COVID-19 vaccination, 74 (60.7%) had conductive, 39 (32.0%) had mixed and 9 (7.4%) had sensorineural hearing loss. Of 31 cases who received one dose of COVID-19 vaccination, 19 (61.3%) had conductive, 9 (29.0%) had mixed and 3 (9.7%) had sensorineural hearing loss. Of 91 cases who received two doses dose of COVID-19 vaccination, 55 (60.4%) had conductive, 30 (33.0%) had mixed and 6 (6.6%) had sensorineural hearing loss. **Conclusion**: The conductive hearing loss was more common (60.7%) among the cases with the H/O COVID-19 vaccination as compared to group of cases without H/O COVID-19 vaccination. Significantly higher proportion of cases with the H/O COVID-19 vaccination had lower prevalence of sensorineural hearing loss (7.4%) compared to group of cases without the H/O COVID-19 vaccination. Mixed Hearing loss was somewhat equally observed between both the groups of vaccinated and unvaccinated patients (32.08% vs 30.8%).*

Keywords: Chronic otitis media (COM), Sensorineural hearing loss (SNHL), Covid-19 pandemic, Covid vaccination

1.Introduction

Chronic otitis media (COM) is an inflammatory condition of the middle ear, characterized usually by chronic otorrhea (i.e., lasting > 6-12 weeks) through a perforation in the tympanic membrane. COM most commonly leads to some degree of conductive hearing loss. However, recurrent ear infections result in diffusion and absorption of toxins and macromolecules into the inner ear, and this can lead to sensorineural hearing loss (SNHL). (1)(2)(3)

Sensorineural Hearing Loss (SNHL) is defined as loss of 20 dB or greater in bone conduction values in at least three consecutive frequencies. Some viral infections can cause SNHL that can be congenital or acquired, unilateral or bilateral. COM patients are more vulnerable to entry of viruses into the middle ear cleft through the EAC as well as through the nasopharynx. Viral infections have been proposed as a cause of SNHL through damage of inner ear structures or by precipitating inflammatory responses which then cause this damage. (4) (5) (6) (7) (8) (9)

At this time of the COVID-19 pandemic, thorough research and investigation to find potentially effective vaccines were undertaken. With the advent of Covid vaccination people started getting vaccinated on a mass scale post the first and second waves of the pandemic.

We planned to determine the frequency of different types of hearing loss in chronic otitis media patients and whether the frequency of sensorineural hearing loss has shown an increased incidence in this pandemic era due to mass administration of Covid vaccinations.

Aim

To evaluate the effect of Covid vaccination on the degree and type of hearing loss in chronic otitis media patients.

Objectives

1) To analyze the data collected from pure tone audiograms and identify cases with sensorineural or mixed hearing loss
2) To ascertain if there is any statistical correlation between the hearing loss and Covid vaccination.
3) To establish if the number of doses of Covid Vaccination received, has a bearing on the type and degree of hearing loss.

2.Materials and Methods

This is Cross sectional Observational study which included the patients from September 2020 to September 2022 who presented to ENT department; Bharati Hospital Pune, (BVDUMC).

Study Design: Cross sectional Observational study
Study Area: Patients presented to ENT department; Bharati Hospital Pune.
Study Subjects: The study was conducted on patients of both sex of all age groups presenting to ENT department; Bharati Hospital Pune after taking a written consent that fulfilled the inclusion criteria.
Sample Size: Total sample sizes-200 cases
Sampling Methods: Patients above age of 5 years were selected **PERIOD**: September 2020 to September 2022

Selection of Patients

Inclusion criteria:

1. All patients aged more than 5 yrs with COM coming to ENT OPD BHRC from (SEP 2020-SEP 2022)

Exclusion criteria:

1) History of head trauma or meningitis.
2) H/O previous tympanomastoid surgeries
3) H/O systemic ototoxic drug therapy.
4) No family history of congenital SNHL.
5) Incomplete Clinical records and Missing audiograms
6) COM with any clinical or Radiological Complication

Methodology of Study

A detailed history of the patient will be taken, specifically asking for history of covid vaccination, number of dose(s) of vaccination received, history of any Ototoxic drug intake and duration and type of discharge.

A thorough ENT examination will then be carried out.

The patient diagnosed with COM will be first clinically evaluated with tuning fork tests using 256Hz, 512Hz, 1024 Hz Tuning forks respectively to look for mild decrease in bone conduction. Following this, the patients' respective pure tone audiograms would be retrieved. Pure tone audiometry would be performed in a soundproof booth by a trained and experienced audiologist.
We will compare the bone conduction values of the diseased ear(s) of all COM patients with standard bone conduction values. Any reduction in Bone Conduction below 20dB in any frequency will be considered as a sensorineural deafness.

All data collected from tuning fork tests and pure tone audiograms are analysed identifying cases with disproportionate conductive, mixed or SNHL to look for statistical correlation between Covid Vaccination and the hearing loss.

Data Analysis

Data analysis included following steps.

1. Step I:

All responses were tabulated by the investigator using Microsoft-Excel 2017

Software. Graphical representations were made wherever necessary.

2. Step II:

Data analyzed by using SPSS software version 25.0

Statistical tools were used were proportions & percentages & other appropriate Statistical tests of significance

3.Observations and Results

The present research was conducted with patients with COM who presented to ENT OPD during Covid pandemic era, to evaluate the degree and type of hearing loss in these patients.

This cross-sectional observational study included a total of two hundred cases and satisfying inclusion/exclusion criteria (mean age 38.50 years, min age-7 years, max age-75 years) of both genders, who had chronic otitis media (COM) on presentation. Following section shows the detailed statistical analysis along with interpretation and graphical representation of the statistical results on the available data.

Table 1: Distribution of type of hearing loss according to sex of cases studied

	Type of Hearing Loss								
Sex	**Conductive (n=109)**		**Mixed (n=63)**		**Sensorineural (n=28)**		**Total (n=200)**		**P-value**
	n	%	n	%	n	%	n	%	
Male	51	51.5	33	33.3	15	15.2	99	100.0	0.699^{NS}
Female	58	57.4	30	29.7	13	12.9	101	100.0	
Total	**109**	**54.5**	**63**	**31.5**	**28**	**14.0**	**200**	**100.0**	
P-value by Chi-square test, P-value < 0.05 is considered to be statistically significant. NS – Statistically non-significant.									

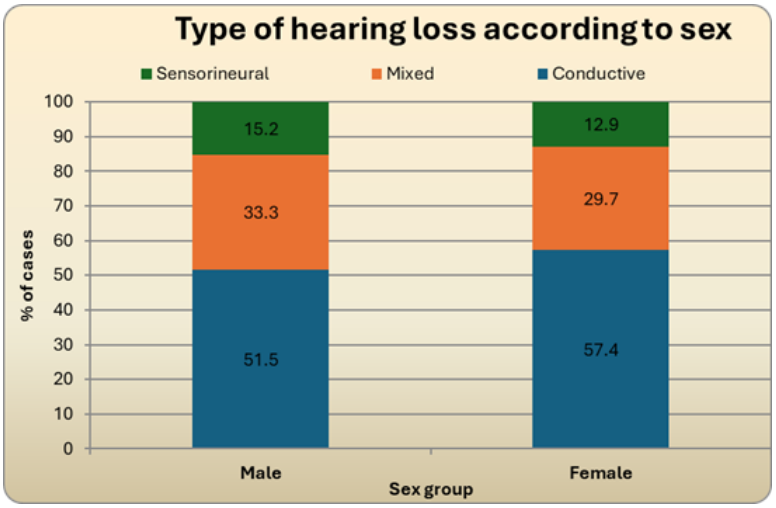

Figure 1

Table 2: Distribution of type of hearing loss according to type of disease among the cases studied.

Type of disease	Tyoe of hearing loss						Total (n=200)		P-value
	Conductive (n=109)		Mixed (n=63)		Sensorineural (n=28)				
	n	%	n	%	n	%	n	%	
Mucosal	76	60.3	37	29.4	13	10.3	126	100.0	0.050*
Squamosal	33	44.6	26	35.1	15	20.3	74	100.0	
Total	**109**	**54.5**	**63**	**31.5**	**28**	**14.0**	**200**	**100.0**	

P-value by Chi-square test, P-value < 0.05 is considered to be statistically significant.
*P-value < 0.05

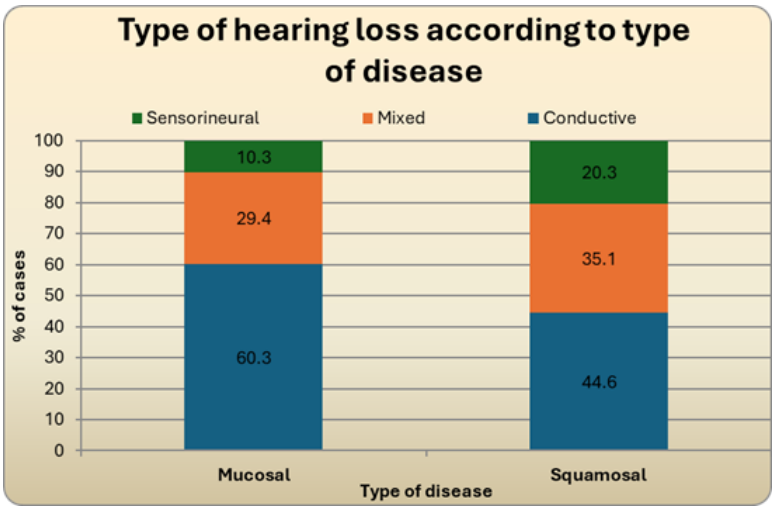

Figure2

Table 3: Distribution of type of hearing loss according to H/O COVID-19 Vaccination among the cases studied.

	Type of hearing loss								
	Conductive (n=109)		Mixed (n=63)		Sensorineural (n=28)		Total (n=200)		P-value
COVID-19 Vaccination	n	%	n	%	n	%	n	%	
No	35	44.9	24	30.8	19	24.4	78	100.0	**0.002**
Yes	74	60.7	39	32.0	9	7.4	122	100.0	
Total	109	54.5	63	31.5	28	14.0	200	100.0	

P-value by Chi-square test, P-value < 0.05 is considered to be statistically significant.
*P-value < 0.01

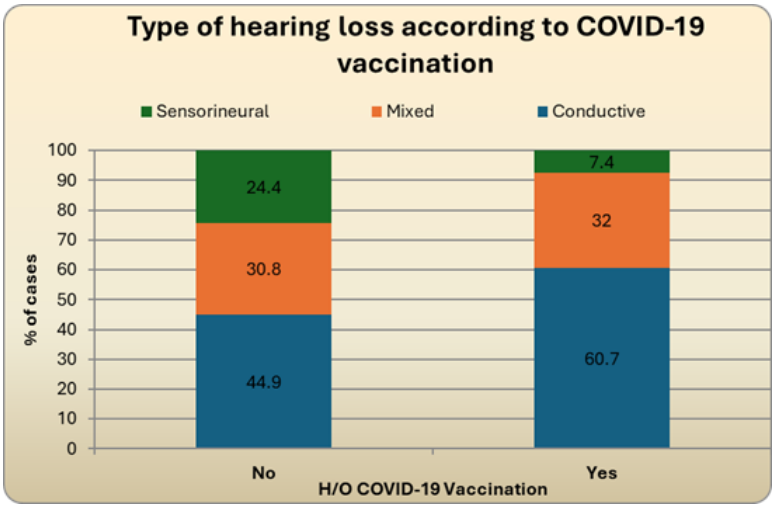

Figure 3

Table 4: Distribution of type of hearing loss according to doses of COVID-19 Vaccination among the cases studied.

	Type of hearing loss								
	Conductive (n=109)		Mixed (n=63)		Sensorineural (n=28)		Total (n=200)		P-value
Doses of COVID-19 Vaccination	n	%	n	%	n	%	n	%	
0	35	44.9	24	30.8	19	24.4	78	100.0	0.015*
1	19	61.3	9	29.0	3	9.7	31	100.0	
2	55	60.4	30	33.0	6	6.6	91	100.0	
Total	**109**	**54.5**	**63**	**31.5**	**28**	**14.0**	**200**	**100.0**	

P-value by Chi-square test, P-value < 0.05 is considered to be statistically significant.
*P-value < 0.05

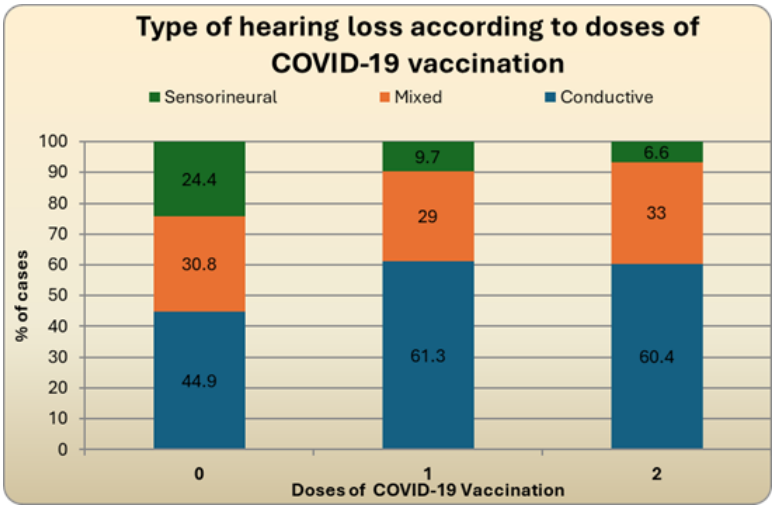

Figure 4

4.Results

1.Distribution of type of hearing loss according to sex (Table1, Figure 1)

Of 99 male cases, 51 (51.5%) had conductive, 33 (33.3%) had mixed and 15 (15.2%) had sensorineural hearing loss.

Of 101 female cases, 58 (57.4%) had conductive, 30 (29.7%) had mixed and 13 (12.9%) had sensorineural hearing loss.

2. Distribution of type of hearing loss according to type of disease (Table 2, Figure 2)

Of 126 cases with mucosal disease, 76 (60.3%) had conductive, 37 (29.4%) had mixed and 13 (10.3%) had sensorineural hearing loss.

Of 74 cases with squamosal disease, 33 (44.6%) had conductive, 26 (35.1%) had mixed and 15 (20.3%) had sensorineural hearing loss.

3.Distribution of type of hearing loss according to H/O COVID-19 vaccination (Table 3, Figure 3)

Of 78 cases without any H/O COVID-19 vaccination, 35 (44.9%) had conductive, 24 (30.8%) had mixed and 19 (24.4%) had sensorineural hearing loss.

Of 122 cases with the H/O COVID-19 vaccination, 74 (60.7%) had conductive, 39 (32.0%) had mixed and 9 (7.4%) had sensorineural hearing loss.

4.Distribution of type of hearing loss according to doses of COVID-19 vaccination (Table 4, Figure 4)

Of 78 cases without any H/O COVID-19 vaccination, 35 (44.9%) had conductive, 24 (30.8%) had mixed and 19 (24.4%) had sensorineural hearing loss.

Of 31 cases who received one dose of COVID-19 vaccination, 19 (61.3%) had conductive, 9 (29.0%) had mixed and 3 (9.7%) had sensorineural hearing loss.

Of 91 cases who received two doses dose of COVID-19 vaccination, 55 (60.4%) had conductive, 30 (33.0%) had mixed and 6 (6.6%) had sensorineural hearing loss.

5.Discussion

Distribution of type of hearing loss according to sex

Distribution of type of hearing loss did not differ significantly between group of males

and group of female cases studied (P-value>0.05). Both gender groups (males and females) had approximately equal distribution of type of hearing loss in the study group **(Table 1, Figure 1)**

Distribution of type of hearing loss according to type of disease

Distribution of type of hearing loss differs significantly between group of cases with mucosal disease and group of cases with squamosal type of disease (P-value<0.05). The Conductive hearing loss was more common among the cases with mucosal disease compared to squamosal disease (60.3% - mucosal vs 44.6% - squamosal); also, significantly higher proportion of cases with squamosal disease had higher prevalence of Sensorineural hearing loss as compared to group of cases with mucosal type of disease (20.3% squamosal vs 10.3% mucosal). The mixed type of hearing loss was approximately equally distributed between both groups (29.4% - mucosal vs 35.1% -squamosal). **(Table 2, Figure 2)**

In another retrospective study by **Amin Amali et al.** (10). 119 post operative patients with unilateral COM were reviewed using records and the bone conduction threshold of the affected ear was compared to the contralateral normal ear. This study showed no correlation of SNHL with the presence of cholesteatoma or ossicular erosion (1). This result is not similar with our present study which shows a higher prevalence of SNHL among patients with squamosal COM.

Distribution of type of hearing loss according to H/O COVID-19 vaccination

In the present study distribution of type of hearing loss differs significantly between group of cases with H/O COVID-19 vaccination and group of cases without the H/O COVID-19 vaccination (P-value<0.05).

The Conductive hearing loss was more common (in higher proportion, 60.7%) among the cases with the H/O COVID-19 vaccination compared to group of cases without H/O COVID-19 vaccination. Significantly higher proportion of cases with the H/O COVID-19 vaccination had lower prevalence of Sensorineural hearing loss (7.4%) compared to group of cases without the H/O COVID-19 vaccination.

The mixed type of hearing loss was approximately equally distributed between cases with the H/O COVID-19 vaccination and group of cases without the H/O COVID-19 vaccination (32.08% vs 30.8%). **(Table 3, Figure 3)**

In a case series compiled by **Junhui Jeong et al,** (11) 03 cases with varying ages from 18-64 years have been reported having developed sudden sensorineural hearing loss (SSNHL) post Covid vaccination. Two of the three cases were males, and one was female. Two out of the three cases developed SSNHL post first dose of vaccination and one of them developed after the second dose of vaccination. Two of the cases had received vaccination from Pfizer-nBiotech and one had received adenoviral vector from Oxford astrazeneca. In all the cases the post vaccination bone conduction threshold value over three frequencies had deteriorated to over 60db (2). The findings of this case series are not similar with the present study where the prevalence of SNHL is found to be higher among the group who were not vaccinated than the group who was vaccinated with Covid 19 vaccination.

Distribution of type of hearing loss according to doses of COVID-19 vaccination

In the present study distribution of type of hearing loss differs significantly between group of cases who received 1 dose or 2 doses of COVID-19 vaccination doses and group of cases without the H/O COVID-19 vaccination (P-value<0.05). **(Table 4, Figure 4)**

The Conductive hearing loss was more common (in higher proportion, 61.3% - one dose and 60.4% - two doses) among the cases with the H/O COVID-19 vaccination (both one dose and two doses) compared to group of cases without H/O COVID-19 vaccination. Significantly higher proportion of cases with the H/O COVID-19 vaccination of one dose or two doses had lower prevalence of Sensorineural hearing loss (9.7% and 6.6% respectively) compared to group of cases without the H/O COVID-19 vaccination. The mixed type of hearing loss was approximately equally distributed between cases with the H/O COVID-19 vaccination of one dose or two doses and group of cases without the H/O COVID-19 vaccination (29.0% - One dose vs 33.0% - Two dose vs 30.8% - No vaccination).

6.Conclusion

In the present study which was conducted to evaluate the hearing loss in Chronic otitis media (COM) patients in this Covid pandemic era, the aim was to assess whether Covid 19 vaccination and the number of doses have any effect on the hearing loss in cases of COM.

- Distribution of type of hearing loss did not differ significantly between groups of male and female cases studied. Both gender groups (males and females) had approximately equal distribution of type of hearing loss in the study group
- The Conductive hearing loss was more common among the cases with mucosal disease compared to squamosal disease. (60.3% - mucosal vs 44.6% - squamosal)
- Inversely significantly higher proportion of cases with squamosal disease, had higher prevalence of sensorineural hearing loss compared to the group of cases with mucosal type of disease (20.3% squamosal vs 10.3% mucosal).
- The mixed type of hearing loss was approximately equally distributed between group of cases with mucosal and group of cases with squamosal type of disease. (29.4% - mucosal vs 35.1% - squamosal).
- The conductive hearing loss was more common (60.7%) among the cases with the H/O COVID-19 vaccination as compared to group of cases without H/OCOVID-19 vaccination.
- Significantly higher proportion of cases with the H/O COVID-19 vaccination had lower prevalence of sensorineural hearing loss (7.4%) compared to group of cases without the H/O COVID-19 vaccination.
- Mixed Hearing loss was somewhat equally observed between both the groups of vaccinated and unvaccinated patients (32.08% vs 30.8%).

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