

Radiotherapy-Associated Sensorineural Hearing Loss in Patients With Head and Neck Malignancies: A Prospective Observational Study

Dr. Harshit Bhutani^{1*}, Dr. Amit Modwal², Dr. Shubhangi Gupta³

Qualification – MBBS

Dept. & Institution – 3rd year PG Resident, Dept. of Otorhinolaryngology, National Institute of Medical Sciences & Research, Rajasthan, Jaipur

Qualification – MBBS, MS ENT

Dept. & Institution - Professor & Head, Dept. of Otorhinolaryngology, Balvir Singh Tomar Institute of Medical Sciences & Research, Science Tech city, Jaipur, Rajasthan

Qualification – MBBS, MS ENT

Dept. & Institution - Assistant Professor, Dept. of Otorhinolaryngology, National Institute of Medical Sciences & Research, Rajasthan, Jaipur

***Corresponding Author**

Dr Harshit Bhutani

Address – NIMS University, NH-11C, Delhi-Jaipur Highway, Chandwaji Jaipur, Rajasthan-302131

E-mail – hbhutani6@gmail.com

ABSTRACT Background

Background: Radiotherapy (RT) is an important treatment modality for head and neck malignancies, but exposure of auditory structures may result in sensorineural hearing loss (SNHL). Early objective assessment is important because hearing deterioration may occur without prominent subjective symptoms. Methods: This prospective observational study included 86 biopsy-confirmed patients aged 35–60 years undergoing RT for head and neck malignancy at the Departments of Otorhinolaryngology and Radiotherapy, National Institute of Medical Sciences and Research, Jaipur. Patients with pre-existing SNHL or hearing loss attributable to other causes were excluded. Audiological assessment was performed before RT and repeated at 1 and 3 months after treatment. Pure-tone average (PTA) was the principal outcome. Repeated measurements were analysed using the Friedman test, followed by Wilcoxon signed-rank pairwise comparisons with Bonferroni correction. Results: The mean age was 49.76 ± 9.47 years and 74 (86.0%) participants were male. Mean baseline PTA was 15.23 ± 6.64 dB in the right ear and 15.64 ± 5.47 dB in the left ear. At 1 month, PTA increased to 67.73 ± 24.30 dB and 68.02 ± 22.76 dB, respectively. At 3 months, values remained elevated at 63.84 ± 29.08 dB and 64.24 ± 26.89 dB. The overall change across time was statistically significant in both ears (Friedman $\chi^2=146.916$, $p<0.001$). Moderate hearing loss was most frequent (30.2%), followed by severe (27.9%) and profound (22.1%); bilateral involvement was recorded in 83 (96.5%) patients. Conclusion: Substantial bilateral deterioration in hearing thresholds was observed following RT in this cohort. Baseline and serial audiological monitoring should be incorporated into the management of patients receiving head and neck RT.

Keywords: Head and neck cancer; radiotherapy; sensorineural hearing loss; pure-tone audiometry; ototoxicity

How to cite this article: Harshit Bhutani^{1*} Dr. Amit Modwal² Dr. Shubhangi Gupta³. Radiotherapy-Associated Sensorineural Hearing Loss in Patients With Head and Neck Malignancies: A Prospective Observational Study. Int J Drug Deliv Technol. 2026;16(82s):1516-1519. DOI: 10.25258/ijddt.16.82s.173.

INTRODUCTION

Head and neck malignancies frequently require radiotherapy, either as a primary treatment or as part of multimodality management. The close anatomical relationship between several head and neck tumour sites and the auditory apparatus means that the cochlea, vestibulocochlear nerve and surrounding microvascular structures may receive clinically relevant radiation exposure. Radiation-related auditory injury is multifactorial and may involve damage to cochlear hair cells, stria vascularis and spiral ganglion cells, together with vascular injury, oxidative stress, inflammation and neural damage. Because the cochlea has limited regenerative capacity, clinically important hearing impairment may persist or progress after treatment.

Published studies have demonstrated considerable variation in the frequency and severity of radiation-associated SNHL. The variability is influenced by tumour site, radiation dose to the cochlea, treatment technique, concurrent chemotherapy, baseline hearing and duration of follow-up. Systematic reviews have

reported that hearing loss may be more evident at high frequencies and that cochlear radiation exposure is an important determinant of risk. These observations support prospective audiological surveillance in patients undergoing head and neck RT.

The present study was undertaken to evaluate changes in hearing following RT in patients with biopsy-confirmed head and neck malignancies. The objectives were to assess post-treatment hearing change, describe the severity and laterality of hearing impairment, and evaluate hearing status at 1 and 3 months following RT.

MATERIALS AND METHODS

Study design and setting

This prospective observational study was conducted over 18 months in the Departments of Otorhinolaryngology and Radiotherapy at National Institute of Medical Sciences and Research Hospital, Jaipur, Rajasthan. The study population comprised patients with head and neck malignancies undergoing RT as part of their treatment. The sample size was 86, selected using purposive sampling.

Participants

Patients of either sex aged 35–60 years with biopsy-proven head and neck malignancy who were planned for RT and provided informed consent were eligible. Patients with proven SNHL before the diagnosis of cancer or SNHL attributable to other causes were excluded.

Audiological assessment

Written informed consent was obtained before enrolment. Demographic characteristics, clinical history, tumour site and treatment information were recorded on a structured proforma. Baseline audiological assessment was performed before initiation of RT and included pure-tone audiometry, speech audiometry and otoacoustic emissions as described in the study protocol. Pure-tone audiometry was subsequently repeated at approximately 1 month and 3 months after RT. PTA was used as the principal quantitative hearing outcome, and hearing loss severity was classified according to the study protocol based on WHO categories.

Statistical analysis

Data were entered and analysed using Microsoft Excel; the thesis also reports analysis using SPSS. Continuous variables were summarized as mean $\pm$ standard deviation (SD), and categorical variables as frequencies and percentages. PTA was assessed separately for the right and left ears at baseline, 1 month and 3 months. As the repeated-measure PTA data were non-normally distributed, differences across the three time points were assessed using the Friedman test. Pairwise comparisons were performed using the Wilcoxon signed-rank test with Bonferroni correction for multiple comparisons. A two-sided p value <0.05 was considered statistically significant.

Ethics

The study received approval from the Institutional Scientific and Ethics Committee of National Institute of

Table 1. Baseline demographic and clinical characteristics

Characteristic	n (%) / Mean $\pm$ SD
Total participants	86
Age, years	49.76 $\pm$ 9.47
Male	74 (86.0%)
Female	12 (14.0%)
Nasal cavity/paranasal sinus	22 (25.6%)
Larynx	19 (22.1%)
Salivary gland	15 (17.4%)

Table 2. Pure-tone average and statistical comparison over follow-up

Time point / comparison	Right ear PTA (dB)	Left ear PTA (dB)	Right p	Left p
Baseline	15.23 $\pm$ 6.64	15.64 $\pm$ 5.47	—	—
1 month	67.73 $\pm$ 24.30	68.02 $\pm$ 22.76	<0.001	<0.001

Medical Sciences and Research, Jaipur. Written informed consent was obtained from all participants.

RESULTS

A total of 86 patients were included and all completed the 3-month follow-up. The mean age was 49.76 $\pm$ 9.47 years. There was a marked male predominance, with 74 (86.0%) males and 12 (14.0%) females. The most frequent tumour site was the oral cavity (22, 25.6%), followed by larynx (19, 22.1%), salivary gland (15, 17.4%) and pharynx (12, 14.0%). All patients had biopsy-confirmed malignancy and received RT.

Baseline PTA was near the normal range, averaging 15.23 $\pm$ 6.64 dB in the right ear and 15.64 $\pm$ 5.47 dB in the left ear. At 1 month after RT, mean PTA increased to 67.73 $\pm$ 24.30 dB in the right ear and 68.02 $\pm$ 22.76 dB in the left ear. At 3 months, mean PTA remained elevated at 63.84 $\pm$ 29.08 dB and 64.24 $\pm$ 26.89 dB, respectively.

The Friedman test demonstrated a statistically significant change across the three assessment points in both the right ear ($\chi^2=146.916$, $p<0.001$) and left ear ($\chi^2=146.916$, $p<0.001$). Pairwise Wilcoxon testing showed significant differences between baseline and 1 month (right $p=2.35e-15$; left $p=2.332e-15$), baseline and 3 months (right $p=1.53e-13$; left $p=1.53e-13$), and 1 and 3 months (right $p=0.003253$; left $p=0.003283$). All comparisons remained significant after Bonferroni correction.

Moderate hearing loss was the most common severity category (26, 30.2%), followed by severe (24, 27.9%), profound (19, 22.1%) and mild loss (15, 17.4%); 2 (2.3%) patients were recorded as having no measurable hearing loss. Bilateral involvement was recorded in 83 (96.5%) patients, while 3 (3.5%) had no bilateral involvement. At the 3-month assessment, 83 (96.5%) patients demonstrated a change in hearing status. No participant reported tinnitus or other ear-related symptoms.

Pharynx	12 (14.0%)
Oral cavity	8 (9.3%)
Thyroid	5 (5.8%)
Buccal mucosa	2 (2.3%)
Parotid gland	2 (2.3%)
Astrocytoma	1 (1.2%)
Biopsy-confirmed malignancy	86 (100%)
Received radiotherapy	86 (100%)

3 months	63.84 $\pm$ 29.08	64.24 $\pm$ 26.89	<0.001	<0.001
Overall Friedman test	$\chi^2=146.916$	$\chi^2=146.916$	$p<0.001$	$p<0.001$
1 vs 3 months (Wilcoxon)	$p=0.0033$	$p=0.0033$	Significant	Significant

PTA values are mean $\pm$ SD. Pairwise *p* values were obtained using Wilcoxon signed-rank testing; Bonferroni-adjusted significance threshold was 0.0167.

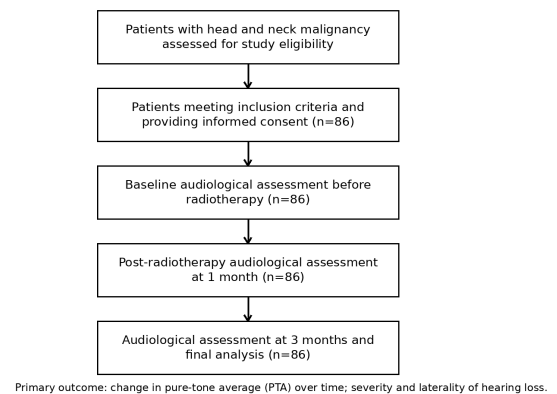
Table 3. Severity, laterality and associated symptoms

Outcome	n (%)
Nil hearing loss	2 (2.3%)
Mild	15 (17.4%)
Moderate	26 (30.2%)
Severe	24 (27.9%)
Profound	19 (22.1%)
Bilateral involvement	83 (96.5%)

Figure 1. STROBE-style participant flow

No bilateral involvement	3 (3.5%)
Change in hearing status at 3 months	83 (96.5%)
No change	3 (3.5%)
Tinnitus	0 (0%)
Other ear symptoms	0 (0%)

STROBE-style participant flow



No number of excluded patients at screening is stated in the source dataset; therefore no exclusion count has been added to the flow diagram.

DISCUSSION

The present prospective study demonstrates a marked deterioration in audiometric thresholds after RT among patients with head and neck malignancies. Baseline PTA values were close to normal, whereas both ears showed a substantial rise in PTA at 1 month that persisted at 3 months. Statistical analysis of the individual patient-level dataset confirmed that the change across time was highly significant in both ears.

The bilateral nature of the findings is notable. In this cohort, 96.5% of patients were recorded as having bilateral involvement. Radiation-related cochlear injury is biologically plausible because the auditory system may be exposed directly or indirectly depending on tumour location and radiation field. Previous literature has emphasized the importance of cochlear dose, treatment technique and follow-up duration in determining the magnitude of hearing loss.

The distribution of severity indicates that the observed deterioration was clinically relevant rather than limited to small threshold shifts. Moderate hearing loss was the most frequent category, while severe and profound loss together represented nearly half of the cohort. At the same time, the absence of tinnitus or other ear symptoms illustrates that subjective symptoms may not reliably identify audiometric deterioration, supporting objective hearing surveillance.

The slight reduction in mean PTA between 1 and 3 months in both ears should not be interpreted as recovery

to baseline. Although some patients may have shown improvement, group-level thresholds remained markedly elevated compared with pre-treatment values. The short follow-up also prevents conclusions regarding permanence, delayed progression or long-term rehabilitation outcomes.

These findings are broadly consistent with previous reports describing radiation-associated SNHL and with systematic reviews showing heterogeneity according to cochlear dose, tumour site, treatment modality and follow-up. Prospective work by Pan et al. emphasized the relationship between inner-ear radiation dose and subsequent hearing loss, while reviews by Mujica-Mota et al. and Theunissen et al. highlighted cochlear exposure and other treatment-related factors as important determinants. Radiation-induced ear toxicity has also been described in the wider literature, reinforcing the need for prevention, monitoring and multidisciplinary management.

From a clinical perspective, baseline audiometry provides an objective reference against which post-treatment changes can be measured. Serial testing can identify deterioration before the patient develops disabling communication difficulty and may facilitate timely counselling and hearing rehabilitation. Where oncologically appropriate, attention to cochlear dose constraints and modern treatment-planning techniques may help reduce unnecessary radiation exposure to auditory structures.

Strengths and Limitations

Strengths include the prospective design, standardized baseline and follow-up audiological assessments, inclusion of biopsy-confirmed malignancies, and separate evaluation of both ears. The patient-level dataset also permitted formal repeated-measures statistical testing rather than relying only on descriptive comparisons.

Limitations include the single-centre design, moderate sample size and absence of a non-radiotherapy control group. Follow-up was limited to 3 months and therefore cannot establish long-term reversibility or progression. Detailed radiation dose distribution, cochlear dose and concurrent chemotherapy were not fully analysed in the source study, limiting dose-response interpretation and the ability to separate radiation effects from other ototoxic exposures. Advanced audiological measures such as otoacoustic emissions were described in the methodology but were not incorporated into the principal outcome analysis.

CONCLUSION

In this prospective cohort of 86 patients with head and neck malignancies, substantial and statistically significant deterioration in PTA occurred following radiotherapy, with predominantly bilateral hearing involvement. Moderate, severe and profound hearing loss accounted for most post-treatment classifications. The findings support routine baseline audiological assessment before radiotherapy and structured follow-up thereafter. Longer-term multicentre studies incorporating cochlear dose, radiotherapy technique, chemotherapy exposure and advanced audiological testing are warranted to define risk more precisely and identify strategies for hearing preservation.

DECLARATIONS

Ethics Approval: The study was conducted after approval from the Institutional Scientific and Ethics Committee of the National Institute of Medical Sciences and Research, Jaipur.

Informed Consent: Written informed consent was obtained from all participants before enrolment in the study.

Funding: No external funding was reported for this study.

Conflict of Interest: The authors declare that they have no conflict of interest.

Data Availability: The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request, subject to institutional and ethical restrictions.

Author Contributions: All authors contributed to the conception and design of the study, data collection and/or analysis, interpretation of results, drafting or critical revision of the manuscript, and approved the final version of the manuscript.

ACKNOWLEDGEMENTS: The authors acknowledge the support and cooperation of the Departments of Otorhinolaryngology and Radiotherapy, National Institute of Medical Sciences and Research, Jaipur.

REFERENCES

1. Theunissen EA, de Bree R, de Jong R, et al. Sensorineural hearing loss in patients with head and neck cancer after chemoradiotherapy and radiotherapy: a systematic review of the literature. *Head Neck*. 2015;37(2):281-292.
2. Mujica-Mota M, Waissbluth S, Daniel SJ. Characteristics of radiation-induced sensorineural hearing loss in patients with head and neck cancer. *Head Neck*. 2013;35(9):1354-1360.
3. Jereczek-Fossa BA, Orecchia R, D'Onofrio A, et al. Radiotherapy-induced ear toxicity. *Radiother Oncol*. 2003;66(3):347-352.
4. Honoré HB, Jensen J, Overgaard J. Sensorineural hearing loss after radiotherapy for head and neck cancer. *Radiother Oncol*. 2002;63(2):145-149.
5. Pan CC, Eisbruch A, Lee JS, et al. Prospective study of inner ear radiation dose and hearing loss in head-and-neck cancer patients. *Int J Radiat Oncol Biol Phys*. 2005;61(5):1393-1402.
6. Low WK, Toh ST, Wee J. Sensorineural hearing loss after radiotherapy and chemoradiotherapy: a single institution experience. *Laryngoscope*. 2006;116(4):619-622.
7. Schultz C, Goffi-Gomez MV, Liberman PH, Pellizzon AC, Carvalho AL. Hearing loss and complaints in patients with head and neck cancer treated with radiotherapy. *Radiother Oncol*. 2010;95(3):345-350.
8. Shi W, Liu Y, Zhang Y, et al. Mechanism and protection of radiotherapy-induced sensorineural hearing loss for head and neck cancer. *Biomed Res Int*. 2021;2021:3548706.
9. Shorter P, McGurk M, McGarry GW. Sensorineural hearing loss after treatment for head and neck cancer. *Am J Otolaryngol*. 2014;35(1):53-58.
10. Schuette A, Lander DP, Kallogjeri D, et al. Predicting hearing loss after radiotherapy and cisplatin chemotherapy in patients with head and neck cancer. *JAMA Otolaryngol Head Neck Surg*. 2020;146(2):106-112.