

To Compare the Severity of Hearing Loss in Two Modalities of Treatment for Head and Neck Cancer Cases

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Abstract

Background: Ototoxicity is the cellular degeneration of cochlear and/or vestibular tissues leading to its functional deterioration, due to the usage of certain therapeutic agents. The present study was undertaken to compare hearing loss in patients receiving radiotherapy alone and concurrent chemoradiation therapy was done. **Materials & Methods:** All patients with head and neck cancers who visited the Department of Otorhinolaryngology and Head and Neck surgery and undergone treatment, after histological confirmation, at the Department of Radiation Oncology at Sardar Patel Medical College, Bikaner, Rajasthan from November 2019 to October 2020 were taken up for the study. 80 patients who fulfilled the inclusion and exclusion criteria and given informed, written consent were divided into 2 groups, A and B of 40 each. Group A were treated with radiotherapy only and group B with concurrent chemoradiotherapy. Data was entered in Microsoft Excel and was subsequently imported to Statistical package for the social sciences (SPSS) free version 21.0 and Epi info version 3.0 for analysis. **Results:** Our study consisted of 80 subjects out of which 52 (65%) were male and 28 (35%) females. The age of the subjects ranged from 30 to 60 years, with highest number of patients belonged to the age group of 51-60 (57.5%) years. In our study, majority of the patients had carcinoma oral cavity (35%) followed by Larynx (28.75%), Hypopharynx (16.25%), Oropharynx (8.75%), Nose & PNS (6.25%), Nasopharynx and Occult primary with secondary neck (each 2.5%). In group A (RT), 50% had conductive hearing loss after completion of treatment which declined to 37.5% after 3 months follow up. Similarly, 45% developed conductive hearing loss after completion of treatment which also declined to 30% after 3 months follow up in group B (RT+CT). Otitis media with effusion and Eustachian tube dysfunction are temporary and reversible side effects of the irradiation of the ear. Conductive hearing loss develops as a reversible side effect of radiation of the ear. The impact of radiation dose on hearing loss was studied and was found that patients with radiation dose less than 60 Gy showed no hearing loss. Dose of the radiation is proportional to development of ototoxicity. Total radiation dose of minimum 60 Gy is required to produce noticeable ototoxic effects. On comparing the hearing loss, after completion of treatment with radiotherapy 30% developed significant hearing loss whereas in RT+CT group 45% had significant hearing loss while after 3 months follow up, 37.5% and 62.5% developed significant hearing loss in RT and RT+CT group respectively. The hearing loss was persistent. Statistical analysis was done, and it was found that there was significant difference in proportions of hearing loss due to RT and RT+CT ($p < 0.05$) after completion of treatment and 3 months follow up. **Conclusion:** Thus, we conclude that patients who received concomitant chemoradiation experienced greater hearing loss as compared with patients treated with radiotherapy alone and hearing loss was predominately of sensorineural type. In our study, cobalt 60 teletherapy was used as a method of radiation administration and radiation induced such ototoxicity can be reduced by newer techniques of radiation administration that can limit the dose of radiation to cochlea and preventing hearing loss.

Keywords: Ototoxicity, radiotherapy, chemoradiation therapy.

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Introduction

The annual incidence of head and neck cancers worldwide is more than 550,000 cases with around 300,000 deaths each year.

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Male to female ratio ranges from 2:1 to 4:1. About 90% of all head and neck cancers are squamous cell carcinomas (HNSCC)[1]. HNSCC include malignant tumours that arise in lip, oral cavity, nasal cavity, paranasal sinuses, pharynx and larynx. Before 20th century, chemotherapy and radiation were seldom used in treatment of upper aero digestive tract cancers but recently the trend is towards organ preservation technique so the therapy is used extensively in conjugation with surgical techniques. The head and neck region embodies complex anatomical structures which are essential for vital

functions such as breathing, chewing, swallowing of food and speech, hence the treatment for tumour area is focussed on minimizing mutilation and preserving function. These multiple functions involved warrant a multidisciplinary approach by a treatment team including head and neck surgeons, medical oncologists, radiation oncologists, as well as dentists, dieticians, speech and swallow therapists, specialized nurses, and physical therapists. The main stays of treatment are surgery, concurrent chemoradiation and radiotherapy. The treatment modality used depends on tumour site, stage, radiological and histological characteristics and comorbidities of the patient. Patients with stage I or II HNSCC are treated with surgery or radiotherapy alone. A combination of chemotherapy and radiation therapy is used in patients with inoperable or unresectable cancers [stage III and IV]. Cisplatin is the most commonly used drug for HNSCC given as concomitant therapy along with radiation, either as primary treatment or as adjuvant treatment following surgery. Studies have shown the benefit of adding cisplatin to radiotherapy. Pignon et al. 2 suggested that cisplatin has a synergistic effect on radiotherapy. They reported an absolute survival benefit of 6.5% and an improved locoregional control by addition of concomitant chemotherapy to radiotherapy[2]. Addition of a high dose, single agent cisplatin to conventional fractionated radiotherapy significantly improves the survival but also increases the toxicity[3]. Ototoxicity is the cellular degeneration of cochlear and/or vestibular tissues leading to its functional deterioration, due to the usage of certain therapeutic agents[4]. Damage to the auditory system due to drugs can present in various ways: tinnitus, hearing loss, hyperacusis, aural fullness, dizziness and vertigo[5]. The present study was undertaken to compare hearing loss

in patients receiving radiotherapy alone and concurrent chemoradiation therapy was done.

Materials & methods

All patients with head and neck cancers who visited the Department of Otorhinolaryngology and Head and Neck surgery and undergone treatment, after histological confirmation, at the Department of Radiation Oncology at Sardar Patel Medical College, Bikaner, Rajasthan from November 2019 to October 2020 were taken up for the study. 80 patients who fulfilled the inclusion and exclusion criteria and given informed, written consent were divided into 2 groups, A and B of 40 each. Group A were treated with radiotherapy only and group B with concurrent chemoradiotherapy. All newly biopsy proven cases of head and neck cancer, the patients with age group between 30-60 years included in the study. Patients with pre-existing ear diseases such as otitis media with effusion, tympanic membrane perforation, otosclerosis with conductive hearing loss or who have undergone ear surgeries, Patients who previously being treated by chemoradiotherapy or ototoxic drug, Patients with diseases such as diabetes, renal failure, Patients not having ear in the field of radiation, Patients with type of tympanogram other than type A curve were excluded from the study. 80 patients of either sex with newly diagnosed, histologically proven HNSCC were included in the study. Patient details such as demographic information, site of cancer and biopsy report were recorded. Routine investigations such as complete blood picture, renal function tests, liver function tests, blood sugar and viral markers were done and recorded. The dose of radiotherapy and chemotherapy (cisplatin and 5-fluorouracil) regimen used in group A and group B were as follows:

Table 1: Regimen used in group A and group B

GROUP A

Treatment modality	Dose & regimen	Route	Days
Radiotherapy	2 Gy/d, 5 fractions/week (30-35 fractions)		Over 6-7 weeks

GROUP B

Treatment modality	Dose & regimen	Route	Days
Concurrent chemoradiotherapy			
Cisplatin	80-100 mg/m ² /cycle (3 cycles)	Intravenous over 6-8 hours	0,3,6 weeks
	Alternatively, 40 mg/m ² /cycle (7 cycles)	Intravenous over 6-8 hours	0,1,2,3,4,5,6 weeks
5-fluorouracil	500-1000 mg/m ² weekly	Intravenous over 6-8 hours	0,4,7 weeks
Radiotherapy	2 Gy/d, 5 fractions/week (30-35 fractions)		

Mode of radiation therapy - Cobalt 60 teletherapy

It is generally understood that 5-fluorouracil is not ototoxic. Therefore, in this study we only observed the relation between administration of cisplatin and development of hearing loss. A complete ENT examination was done: Otoscopic examination using Welch allyn Oscope was performed and tympanic membrane status was seen. Any active discharging ear, tympanic membrane perforations or healed perforations were excluded from the study. Tuning fork test was done using 256, 512 and 1024 Hz Tuning forks. In Nose examination anterior rhinoscopy was done. Oral cavity was examined, and neck examination was done to look for any enlarged lymph nodes and secondaries. Indirect Laryngoscopy was performed using a 90° endoscope. Audiological evaluation was done using LABAT AUDIOLAB audiometer calibrated to ANSI S3. 6-1996,1969 and impedance audiometry was done using OSCILLA TSM400 tympanometer by a single audiologist. Baseline pure tone audiometry both for air conduction and bone conduction was performed at 250, 500, 1000, 2000, 4000 and 8000 Hz along with Impedance audiometry before the commencement of treatment. These tests were repeated: after completion of treatment and 3 months post completion of treatment. Decrease of 20 dB in an isolated frequency or of 10 dB in two or more successive frequencies was taken as criteria for reduction in auditory acuity (ASHA criteria). Descriptive

statistics was performed by calculating mean and standard deviation for the continuous variables. The statistical tests used were: Chi-square test was used to investigate whether distributions of categorical variables differ from one another. The p-value was taken significant when less than 0.05 and a confidence interval of 95% was taken. Fisher Exact Probability Test was performed using the Freeman-Halton extension of the Fisher exact probability test for a two-rows by three-columns contingency table. Data was entered in Microsoft Excel and was subsequently imported to Statistical package for the social sciences (SPSS) free version 21.0 and Epi info version 3.0 for analysis.

Results

Our study consisted of two groups; group A were subjected to radiotherapy while group B undergone concurrent chemoradiation. In this study age of the subjects ranged from 31-60 years. The mean age of the study group was 55.5 years. The commonest age group was from 51-60 years of age with 46 (57.5%) patients. There was male predominance in overall study. Out of 80 subjects, 65% were male and 35% were female. Male to female ratio was 1.85. Most of the subjects were farmers by occupation. The distribution of subjects according to their occupation was 57.5% were farmers, 30% were labourers, 2.5% were shopkeepers, 1.25% were carpenters and 8.75%

others. Table 2 shows that majority of the subject i.e., 28 subjects (35%) had carcinoma Oral cavity, 23 subjects (28.75%) had carcinoma Larynx, 13 subjects (16.25%) had carcinoma Hypopharynx, 7 subjects (8.75%) had carcinoma Oropharynx, 5 subjects (6.25%) had carcinoma Nose & PNS, 2 subjects (2.5%) had carcinoma Nasopharynx and 2 subjects (2.5%) had Occult primary with secondary neck.

Table 3 shows that 62.5% subjects had moderately differentiated SCC, 12.5% had Well differentiated SCC and 25% had Poorly differentiated SCC. Table 4 shows that after completion of radiotherapy, 20% (n = 8) & 30% (n = 12) had OME and ET dysfunction (Type B/Type C tympanogram) respectively. After 3 months follow up, 25% (n=10) had ET dysfunction and 12.5 % (n=5) had OME.

Table 5 shows that after completion of Chemoradiotherapy, 20 % (n = 8) & 25 % (n = 10) had OME and ET dysfunction (Type B/Type C tympanogram) respectively. After 3 months follow up, 20% (n=8) had ET dysfunction and 10 % (n=4) had OME.

Table 6 shows that in group A, 10% (n=4) and 30% (n=12) patients had SNHL at speech and high frequency respectively after completion of treatment. After 3 months follow up, 15% (n=6) and 37.5% (n=15) patients had SNHL involving speech and high frequencies respectively.

Table 7 shows that in group B, 15% (n=6) and 45% (n=18) patients had SNHL at speech and high frequency respectively after completion of treatment. After 3 months follow up, 27.5% (n=11) and 62.5% (n=25) patients had SNHL involving speech and high frequencies respectively.

Table 8 shows that in radiotherapy induced hearing loss in group A, 62.50% subjects had no hearing loss and 33.70% subjects had hearing loss, among which 30% subjects had mild hearing loss whereas 7.5% subjects had moderate grade hearing loss after 3 months follow up.

Table 9 shows that in chemoradiotherapy induced hearing loss in group B, 37.5% subjects had no hearing loss and 62.5% subjects had hearing loss, among which 37.50% subjects had moderate, 17.5%

subjects had mild grade hearing loss and 7.5% had moderately severe hearing loss.

Table 10 shows that in group A, 32 patients who received radiation dose between 60-70 Gy, 15 patients (46.8%) had SNHL after 3 months post radiotherapy while 8 patients receiving palliative radiotherapy with radiation dose less than 60 Gy showed no hearing loss.

Table 11 shows that in group A, patients developed around 2.5 dB average hearing loss immediately post radiotherapy and 7.11 dB average hearing loss after 3 months post radiotherapy. Here average hearing threshold is average of hearing threshold at 500, 1000 and 2000 Hz frequencies.

Table 12 shows that in group A, patients developed around 9.63 dB average hearing loss immediately post radiotherapy and 14.25 dB average hearing loss after 3 months post radiotherapy. Here average hearing threshold is average of hearing threshold at 8000 Hz frequency.

Table 13 shows that in group B, patients developed around 8.13 dB average hearing loss immediately post chemoradiotherapy and 16.47 dB average hearing loss after 3 months post chemoradiotherapy. Here average hearing threshold is average of hearing threshold at 500, 1000 and 2000 Hz frequencies.

Table 14 shows that in group B, patients developed around 18.96 dB average hearing loss immediately post chemoradiotherapy and 22.97 dB average hearing loss after 3 months post chemoradiotherapy. Here average hearing threshold is average of hearing threshold at 8000 Hz frequency.

There was statistically significant difference between the results of two groups (p value < 0.0001), with hearing loss more in Group B (RT+CT) compared to Group A (RT) involving speech frequency after completion of treatment and 3 months follow up respectively. Similarly, results were also statistically significant (p value <0.0001) between the two groups involving high frequency, with hearing loss more in Group B (RT+CT) as compared to Group A (RT) after the completion of treatment and 3 months follow up respectively.

Table 2: Site of Cancer

Site of cancer	No. of subjects (group A)	No. of subjects (group B)	Total
Oral cavity	15	13	28
Larynx	11	12	23
Hypopharynx	7	6	13
Oropharynx	4	3	7
Nasopharynx	-	2	2
Nose and PNS	3	2	5
Occult primary with Secondary neck	-	2	2
Total	40	40	80

Table 3: Histopathological Differentiation Of SCC

Histopathology	No. of subjects	Percentage
Well differentiated SCC	10	12.5%
Moderately differentiated SCC	50	62.5%
Poorly differentiated SCC	20	25%
Total	80	100%

Table 4: Types Of Tympanogram Observed In Patients At Different Follow Up Periods In Group A Radiotherapy

Type of tympanogram	Completion of treatment		3 months follow up	
	n	%	n	%
Type A	20	50%	25	62.5%
Type B	08	20%	05	12.5%
Type C	12	30%	10	25%
Total	40	100%	40	100%

Table 5: Type Of Tympanogram Observed In Patients At Different Follow Up Periods In Group B

Type of tympanogram	Completion of treatment		3 Months follow up	
	n	%	n	%
Type A	22	55%	28	70%
Type B	08	20%	04	10%
Type C	10	25%	08	20%
Total	40	100%	40	100%

Table 6: Sensorineural Hearing Loss In Group A

	After completion of treatment		3 months follow up	
	Speech frequency	High frequency	Speech frequency	High frequency
No of cases/% of cases with SNHL (out of 40)	4/10%	12/30%	6/15%	15/37.5%

Table 7: Sensorineural Hearing Loss In Group B

	After completion of treatment		3 months follow up	
	Speech frequency	High frequency	Speech frequency	High frequency
No of cases/% of cases with SNHL (out of 40)	6/15%	18/45%	11/27.5%	25/62.5%

Table 8: Severity Of Sensorineural Hearing Loss In Group A

Hearing loss	No. of subjects	Percentage
No hearing loss	25	62.50%
Mild	12	30%
Moderate	3	7.5%
Moderately severe	-	-
Severe	-	-
Total	40	100%

Table 9: Severity Of Sensorineural Hearing Loss In Group B

Hearing loss	No. of subjects	Percentage
No hearing loss	15	37.5%
Mild	7	17.5%
Moderate	15	37.50%
Moderately severe	3	7.5%
Severe	-	-
Total	40	100%

Table 10: Dose Of RT Versus Impact On Hearing In Group A

No. of patients	Total dose of RT received (Gy)	SNHL at 3 months post RT
32	60-70	15/32 (46.8%)
8	Less than 60	0/8 (0%)

Table 11. Mean Bone Conduction Thresholds At Different Frequencies In Hearing Loss Patients In Group A

	Speech Frequency		
	Baseline	Completion of treatment	Follow up 3 months
reshold (dB)	23.88 (dB)	26.38 (dB)	30.99 (dB)

Table 12. Mean Bone Conduction Thresholds At High Frequency In Hearing Loss Patients In Group A

	High Frequency		
	Baseline	Completion of treatment	Follow up 3 months
Mean threshold (dB)	24.26 (dB)	33.89 (dB)	38.51 (dB)

Table 13. Mean Bone Conduction Thresholds At Different Frequencies In Hearing Loss Patients In Group B

	Speech Frequency		
	Baseline	Completion of treatment	Follow up 3 months
Mean threshold (dB)	22.42 (dB)	30.55 (dB)	38.89 (dB)

Table 14. Mean Bone Conduction Thresholds At High Frequency In Hearing Loss Patients In Group A

	High Frequency		
	Baseline	Completion of treatment	Follow up 3 months
Mean threshold (dB)	22.32 (dB)	41.28 (dB)	45.29 (dB)

Discussion

Our Study consisted of 80 subjects with carcinoma Head and Neck region which were treated by radiotherapy alone or radiotherapy and cisplatin chemotherapy who visited to Department of Otorhinolaryngology and Department of Radiation Oncology PBM Hospital, Bikaner, Rajasthan.

The age of the patients in this study ranged from 30-60 years among which majority of patients were in 51-60 years (46 patients, 57.5%) followed by 41-50 years (20 patients, 25%) and 31-40 years (14 patients, 17.5%). The mean age of the study group was 55.5 years, similar was observed by Upadhyay et al.[6], where maximum number of patients suffering from head and neck carcinoma were in the age group of 51–70 years. In a study by Abhineet Jain et al[7], mean age

of 60.2 years was reported.

There was male predominance in overall study. Out of 80 subjects, 65% were male and 35% were female. Male to female ratio was 1.85 which was again consistent with study done by Monika PPS⁸, where male to female of 2:1 in RT group and 1.8:1 in RT+CT group was observed. Among the 80 cases of Head and Neck malignancies, oral cavity lesions contributed the largest group (28 patients, 35%) followed by Laryngeal (23 patients, 28.75%) and Hypopharyngeal cancers (13 patients, 16.25%). Next in order were Oropharyngeal, Nasopharyngeal, Nose and PNS tumours. Smallest group was of occult primary with secondaries in neck with 2.5% (2 patients) of cases.

All the selected patients had histopathological proved carcinoma of

head and neck region, among which 62.5% had moderately differentiated SCC, followed by poorly differentiated (25%) and well differentiated (12.5%) SCC.

Common complaints experienced by the patients after irradiation was ear heaviness, earache, decreased hearing, tinnitus and dizziness. All these were acute and transient complaints which may start as early as immediately after the radiotherapy, may appear later or might last till 6 months. Bohne et al.[9] in their study have mentioned slight pain or discomfort in the ear as well as tinnitus as symptoms of serous otitis media resulting due to ionizing radiation of the ear.

Coplan J et al[10]. in their study of hearing loss after radiotherapy revealed thickening of the tympanic membrane while Bhandare et al[11]. found erythema (congestion) or opacification of the tympanic membrane as one of the signs of middle ear inflammation resulting from radiation induced middle ear damage.

Patients in group A receiving radiotherapy alone, on completion of treatment type B tympanogram was observed in 20% which decreased to 12.5% on 3 months follow up while type C tympanogram was observed in 30% which declined to 25% after 3 months follow up.

Above data shows that following radiotherapy serous otitis media and Eustachian tube dysfunction can occur as temporary and reversible side effects. These can occur as early as immediately following radiotherapy to up to 3 months following radiotherapy. At 3 months post radiotherapy number of patients with serous otitis media and Eustachian tube dysfunction decreased significantly as compared to immediate post- radiotherapy. However longer study period is needed to prove such findings as shown by Upadhyaya et al[6]. in which 25.71% had type B tympanogram immediately after RT which decreased to 5.71% after 6 months post RT while 42.85% had type C tympanogram immediate post RT which declined to 31.42% after 6 months post RT.

Among these 40 cases, 50% cases developed conductive deafness immediately post-radiotherapy which decreased to 37.5% after 3 months follow up showing that conductive deafness resulting from effects of radiotherapy is reversible in nature. Similar results were found by Upadhyaya et al[6]. where 28.57% cases regained normal hearing within 6 months of radiotherapy i.e., conductive deafness resulting from effects of radiotherapy was reversible in 28.57% of cases within 6 months following radiotherapy.

Similarly, in group B receiving concurrent chemoradiation, on completion of treatment type B tympanogram was observed in 20% which decreased to 10% on 3 months follow up while type C tympanogram was observed in 25% which declined to 20% after 3 months follow up. Among these 40 cases, 45% cases developed conductive deafness immediately post- chemoradiotherapy which decreased to 30% after 3 months followup.

In our study, in group A patients out of 40 patients who were subjected to RT, incidence of SNHL was seen in 10% involving speech frequency after completion of treatment which rose to 15% after 3 months follow up while incidence of SNHL involving higher frequency (8000 Hz) was seen in 30% after completion of treatment which increased to 37.5% at 3 months follow up.

The observation that higher frequency hearing was generally more affected than lower frequency hearing is consistent with findings from other studies[12,13]. The significant variation in SNHL after RT in different studies may be attributed to factors including the study design, patient selection, total dose, fraction, size, length of follow up and variation in evaluation and interpretation[11].

L F Wang et al[14]. in their study concluded that hearing deterioration may begin as early as 3 months after completion of radiotherapy and the effect of radiation on hearing tended to be chronic and progressive while the early changes may be transient.

In the present study we observed that hearing loss can be noticed by 1 month following treatment which is similar from study by Monika PPS[8], who reported incidence of post RT sensorineural hearing loss in 45.45% at 1 months and increased to 51.51% after 6 and 12 months. In the group B where patients were treated with concurrent chemoradiation the incidence of significant SNHL in speech frequency was 15% which rose to 27.5% after completion of

treatment and follow up after 3 months respectively while at higher frequency (8000 Hz) incidence of SNHL was 45% which rose to 62.5% after completion of treatment and 3 months follow up respectively. Similarly, in a study by Abhineet Jain et al[7].

SNHL at higher frequency was 42.5% at the completion of treatment showed linear increase to 67.5 and 82.5% at 8 and 16 weeks follow up period respectively whereas at low frequency SNHL was reported in 15% at the completion of treatment and 32.5% after 8 weeks follow up period. Monika PPS[65] also in her study found that incidence of significant hearing loss was 67.64% after 1 month and increased to 70.58% after 6 months in patients who received concurrent chemoradiation.

In group A, who were subjected to RT, 46.8% cases who developed ototoxic effects after irradiation had received curative RT i.e., total 60-70 Gys, cases who received palliative RT i.e., less than 50 Gys, did not showed any ototoxic effect indicating that minimum 50–60-Gys total radiation dose is required to produce noticeable ototoxic effects.

Evans et al[15]. also did not find any statistically significant hearing loss in his study of 18 patients with total 55–60 Gy radiation dosage in daily fraction of 2–2.2 Gy. He concluded that hearing loss is unlikely if daily fraction is less than 2 Gy and total dose is less than 60 Gy.

In the present study it was found that patients in the chemoradiotherapy group experienced greater sensorineural hearing damage than patients in the radiotherapy group and the results were statistically significant(p<0.05). Similar results were reported by Bhandare et al[11].

Conclusion

Thus, we conclude that patients who received concomitant chemoradiation experienced greater hearing loss as compared with patients treated with radiotherapy alone and hearing loss was predominately of sensorineural type. In our study, cobalt 60 teletherapy was used as a method of radiation administration and radiation induced such ototoxicity can be reduced by newer techniques of radiation administration that can limit the dose of radiation to cochlea and preventing hearing loss.

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