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Oral and otolaryngological complications of radiotherapy for head and neck cancers among patients attending Ocean Road Cancer Institute, Tanzania

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Abstract

Background
The prevalence of head and neck cancers is on the increase worldwide. Treatment modalities include surgery, radiotherapy and chemotherapy. The aim of this study was to determine the proportion of acute oral and otolaryngological complications of radiotherapy with or without chemotherapy for head and neck cancers.

Methods
A retrospective cross-sectional, hospital based study was done to 80 patients with head and neck cancers who have just completed radiotherapy with or without chemotherapy at Ocean Road Cancer Institute (ORCI). Data was collected using a structured questionnaire within one week after completion of radiotherapy. Patients who reported hearing loss underwent otoscopy and audio-logical assessment including tympanometry and pure tone audiometry. Data was analyzed using SPSS program.

Results
The proportion of males was higher than that of females in the ratio of 2:1 and majority of the patients involved were in the 6^{th} decade of life, (27.5%). Out of the 80 study participants, 80% were found to have oropharyngeal mucositis, 90% were found to have xerostomia and 50% were found to have dysphagia. In addition, 76.2% of patients reported to have developed taste disorders after radiotherapy and 43.1% reported to have developed voice disorders. The proportion of hearing loss following radiotherapy was 21.9% though this should be taken with caution since there was no before and after intervention taken. Patients with sinonasal cancers had the least proportion of oral and oropharyngeal mucositis (50%), xerostomia (64.3%) and voice disorders (14.3%). Most of patients who developed hearing loss had nasopharyngeal cancer (85.6%) and salivary gland cancer (66.7%) while patients with oropharyngeal cancer, hypopharyngeal cancer and laryngeal cancer did not develop hearing loss at all.

Conclusion
Oral and otolaryngological complications of radiotherapy with or without chemotherapy for head and neck cancers at ORCI are quite prevalent. Prevention of complications should be highly regarded especially by using shield protectors on uninvolved areas and advanced radiotherapy machines should be considered to minimize such complications.

Key words: Oral, otolaryngological, head, neck, cancers, Tanzania.

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Background

Head and neck cancers refers to a heterogeneous group of primary cancers involving the upper aerodigestive tract. The aetiology of head and neck cancers like most cancers is not clear, however there are several risk factors being associated with them (1,2).
Head and neck cancers are primarily treated by three main modalities: surgery, radiotherapy and chemotherapy administered alone or in combination. Radiotherapy alone is the most common modality of treatment for certain types of head and neck cancers such as nasopharyngeal carcinoma (1). For locoregional advanced cancers concurrent chemoradiotherapy is mainly used (1,2).

Regardless of the clinical intent, radiotherapy produces tissue changes that may profoundly affect patients' quality of life later (1,3,5,6). Toxicities from radiation therapy (RT) for head and neck cancers are classified as early (acute) or late (delayed) effects based on the time course of their development relative to the radiotherapy (3).
Early complications develop during the course of RT or shortly after completing RT (about 2-3 weeks) and usually subside thereafter (4,5,6). They include oral and oropharyngeal mucositis, xerostomia, taste dysfunction, dysphonia and laryngeal oedema and otological complications such as middle ear effusion and ototoxicity (4,5,6).
Oral and oropharyngeal mucositis is a common acute complication of radiotherapy for head and neck malignancies (7). Nearly all patients with head and neck cancers who receive radiotherapy develops notable mucosal toxicities but once radiotherapy is combined with chemotherapy there is a significant increase in incidence, severity and duration of oropharyngeal mucositis (1). Radiation induced xerostomia, (dry mouth) is a frequent complication of radiotherapy for head and neck cancers. Head and neck radiotherapy commonly damages the salivary glands, decreasing salivary flow rate and changing salivary composition, as a result a sensation of oral dryness (xerostomia) occurs early during the irradiation treatment (7). Taste dysfunction, dysphonia, middle

ear effusion and ototoxicity are also common acute complications of radiotherapy with or without chemotherapy to head and neck cancers (8,9,10). However, the use of cisplatin based chemotherapeutic agents have shown to increase ototoxicity as compared to radiotherapy alone (11).

The site of the head and neck cancer to be irradiated has been associated with specific oral or otolaryngological complication. Dysphonia and laryngeal oedema has shown to be more common in irradiation of laryngeal and hypopharyngeal tumors while otological complications more common in nasopharyngeal carcinoma (5,12).

Despite the existing evidence of RT complications in patients with head and neck cancers, data from Southern and Eastern Africa remains scarce. There are very few reports on the complications of RT in patients with head and neck cancers. The objective of this study was to determine the prevalence and pattern of acute oral and otolaryngological complications of radiotherapy with or without concurrent chemotherapy for head and neck cancers among patients attending Ocean Road Cancer Institute in Dar es Salaam, Tanzania of which it will lay a basis for the limited data in Sub-Saharan Africa.

Methods

Study design and participants

This was a hospital based descriptive retrospective cross-sectional study and it was carried out between June and December 2015 and included patients with head and neck cancers who have just completed Radiotherapy with or without chemotherapy at Ocean Road Cancer Institute in Dar es Salaam, Tanzania.

Study population

The study included patients with head and neck cancers who have just completed radiotherapy with or without chemotherapy.

Sampling method

Convenience sampling technique was used in which selection based on most available sample. Patient who met the inclusion criteria were chosen provided they were available during data collection and they were added up till the desired sample size was achieved.

Inclusion and exclusion criteria

Patients with head and neck cancers who have just completed radiotherapy with or without chemotherapy and guardians of under 18 children who agreed to participate in the study and sign a consent form. Patients who were not able to communicate well even by writing hence express their symptoms.

Sample Size Calculation

The sample size, n was calculated from the following formula;

$$n = \frac{z^2 p (1-p)}{E^2}$$

z = 95% confidence interval, which is 1.96

E=Margin of error (taken to be 5% in this study)

p = Prevalence of one of the complications of radiotherapy for head and neck cancers. In this case, prevalence of oropharyngeal mucositis, (88.5%) which was reported by M Solomon in Kenya was used (18).

Therefore, from the above formula the adjusted sample size used was 168 patients after considering non response rate of 10%.

Treatment protocols at Ocean Road Cancer Institute

ORCI provides External Beam Radiotherapy by a machine that uses Cobalt-60 to emit gamma rays to all patients with head and neck malignancies requiring radiotherapy.

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Treatment protocol for curative radiotherapy is 1.8 to 2 Gy per fraction for about 20 to 25 fractions i.e. conventional fractionation and for palliative radiotherapy is 3 Gy per fraction for about 10 fractions. In both cases one fraction dose is given per day in week days and radiotherapy free weekends. ORCI provides radiotherapy in concurrent with chemotherapy for over 70% of patients with head and neck cancers. Various chemotherapeutic agents are given in combination depending on the histological type of head and neck cancer.

Data collection methods

Data collection was done by the principal investigator and trained Medical Doctors working at ORCI using structured head and neck radiotherapy questionnaire, (Swahili version). The questionnaire assessed socio-demographic characteristics, site and treatment modality of the head and neck cancers. It also assessed oral and otolaryngological complications of radiotherapy for patients with head and neck cancers. Here the questionnaire assessed changes in the oral and throat condition, swallowing, taste, voice and changes in hearing. Patients with history of voice changes and hearing loss prior to radiotherapy were not assessed for those complications after radiotherapy. Patients who were found to have complications were counseled accordingly and referred for appropriate management.

Patients who reported hearing loss which has occurred during or just after completion of radiotherapy with or without chemotherapy underwent otoscopic examination first and then referred to Muhimbili National Hospital (MNH) audiology unit for audio-logical assessment including tympanometry and pure tone audiometry. Audio-logical assessment provided details of the type of hearing loss whether conductive, sensorineural or mixed hearing loss following radiotherapy with or without chemotherapy.

Information on radiotherapy dosage fractionation, chemotherapy used if any and the type of head and neck cancer was obtained from patients' record files at ORCI

Data analysis

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Data analysis was done using the Statistical Package for Social Sciences (SPSS) version 21. Statistical association between age, sex, site of head and or neck cancer, treatment modality and complications of radiotherapy was done using cross tabulations and Chi-square test was used to compare proportions. P value of <0.05 was considered statistically significant.

Ethical considerations

Patients were provided with an informed consent and then asked to provide written consent to participate in the study. For patients younger than 18 years, informed consent was obtained from their parents or guardians. Ethical approval was provided by Senate Research and Publications Committee of the Muhimbili University of Health and Allied Sciences (MUHAS).

Results

Demographic characteristics of the study population

Between June and December 2015, a total of 80 patients with head and neck cancers were recruited at ORCI. Out of 80 patients who were involved in the study, the proportion of males (66.2%) was higher than that of females (33.8%) in the ratio of 2:1. However this difference was not statistically significant with the p value of 0.349. Majority of the patients who were involved in the study were in their 6th decade of life, (27.5%) and this was also not statistically significant compared to other involved age groups. (**Table 1**)

Table 1: Distribution of patients with head and neck cancers who developed oral and laryngological complications by age and sex

Age (yrs.)	Sex	Total

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	Male N (%)	Female N (%)	N (%)
11 - 20	3 (75)	1 (25)	4 (5)
21 - 30	2 (66.7)	1 (33.3)	3 (3.8)
31 - 40	10 (62.5)	6 (37.5)	16 (20)
41 - 50	9 (50)	9 (50)	18 (22.5)
51 - 60	16 (72.7)	6 (27.3)	**22 (27.5)**
61 - 70	10 (90.6)	1 (9.1)	11 (13.7)
71 - 80	3 (60)	2 (40)	5 (6.2)
81 - 90	0 (0)	1 (100)	1 (1.3)
Total	**53 (66.2)**	**27 (33.8)**	**80 (100)**

Treatment given to head and neck cancer patients and the type of cancer

Patients who received radiotherapy alone, (48.8%) were almost the same as those who received chemoradiotherapy (51.2%). Most of the patients involved had oral cancer (32.5%) followed by sinonasal cancer (17.5%) and laryngeal cancer (15%). However, these findings were statistically insignificant with p value of 0.493. (**Table 2**)

Table 2: Distribution of the study population according treatment given and type of cancer

Type of cancer	Radiotherapy alone N (%)	Chemoradiotherapy N (%)	Total N (%)
Oral	14 (35.9)	12 (29.3)	26 (32.5)
Hypopharyngeal	2 (5.1)	5 (12.2)	7 (8.8)
Nasopharyngeal	5 (12.8)	5 (12.2)	10 (12.5)

Salivary gland	5 (12.8)	1 (2.4)	6 (7.5)
Oropharyngeal	2 (5.1)	3 (7.3)	5 (6.2)
Laryngeal	6 (15.4)	6 (14.6)	12 (15)
Sinonasal	5 (12.8)	9 (22)	14 (17.5)
Total	39 (48.8)	41 (51.2)	80 (100)

Oral and laryngeal complications by site of Cancer

Xerostomia was a complication with the highest proportion of 90%, followed by oral and oropharyngeal mucositis, 80% whereas hearing loss had the least proportion of 21.9% (**see table 3 below**)

The proportion of oropharyngeal mucositis was higher in patients with oropharyngeal cancer (100%), hypopharyngeal cancer (100%) and oral cancer (96.2) while it was lower in patients with sinonasal cancer (50%) and the difference was statistically significant. P value = 0.02 (**see table 3 below**)

Sinonasal cancers had the least proportion of developing xerostomia (64.3%) as compared to other type of cancers such as salivary gland cancers (100%) and the difference is statistically significant with p value of 0.02 (**see table 3 below**)

All patients with oropharyngeal cancer developed taste disorders while those with sinonasal cancer rarely developed taste disorders (42.9%) and these differences were statistically significant with p value of 0.017 (**see table 3 below**)

Most of the patients with hypopharyngeal cancer developed voice change (85.7%) and patients with sinonasal cancer were the least to develop voice change (14.3%) with these differences being statistically significant. P value = 0.011 (**see table 3 below**)

Most of the patients who developed hearing loss had nasopharyngeal cancer (85.6%) and salivary gland cancer (66.7%) while patients with oropharyngeal cancer, hypopharyngeal cancer and laryngeal cancer did not develop hearing loss at all. The differences in hearing loss among these patients was statistically significant with p value of 0.000 (**see table 3 below**)

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Table 3: Oral and laryngeal complications among patients with head and neck cancers by site of cancer (n=80)

Oral and Laryngological complications	Site of cancer						
	Oral (%)	Hypopharyngeal (%)	Nasopharyngeal (%)	Salivary gland (%)	Oropharyngeal (%)	Laryngeal (%)	Sinonasal (%)
Mucositis							
Present	25 (96.2)	7 (100)	9 (90)	3 (50)	5 (100)	8 (66.7)	7 (50)
Absent	1 (3.8)	0 (0)	1 (10	3 (50)	0 (0)	4 (33.3)	7 (50)
Xerostomia							
Present	23 (88.5)	7 (100)	10 (100)	6 (100)	5 (100)	12 (100)	9 (64.3)
Absent	3 (11.5)	0(0)	0 (0)	0 (0)	0 (0)	0 (0)	5 (35.7)
Taste							
Normal	3 (11.5)	3 (42.9)	1 (10)	2 (33.3)	0 (0)	2 (16.7)	8 (57.1)
Abnormal	23 (88.5)	4 (57.1)	9 (90)	4 (66.7)	5 (100)	4 (83.3)	6 (42.9)
Voice							
Normal	9 (42.9)	1 (14.3)	6 (87.5)	4 (66.7)	1 (33.3)	NA	12(85.7)
Abnormal	12 (57.1)	6 (85.7)	1 (14.3)	2 (33.3)	2 (66.7)	NA	2 (14.3)
Hearing							
Normal	20 (83.3)	7 (100)	1 (14.3)	2 (33.3)	5 (100)	11 (0)	11(84.6)
Lt HL	1 (4.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (15.4)
Rt HL	2 (8.3)	0 (0)	3 (42.9)	2 (33.3)	0 (0)	0 (0)	0 (0)
Bilateral HL	1 (4.2)	0 (0)	3 (42.9)	2 (33.3)	0 (0)	0 (0)	0 (0)

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Types of hearing loss developed by the patients

Of the ears that developed hearing loss, most (86.4%) had conductive hearing loss with the right ear (59%) being more affected than the left ear. (**See table 4 below**)

	CHL N (%)	**SNHL N (%)**	**Mixed HL N (%)**	**Total N (%)**
Right Ear	11 (50)	2 (9.1)	0 (0)	13 (59)
Left Ear	8 (36.4)	1 (4.5)	0 (0)	9 (41)
Total	19 (86.4)	3 (13.6)	0 (0)	22 (100)

Discussion

The aim of the study was to determine the proportion and pattern of acute oral and otolaryngological complications of radiotherapy with or without chemotherapy for head and neck cancers. Of all the study participants, 80% were found to have oropharyngeal mucositis, 90% had xerostomia and 50% had dysphagia. Moreover, 76.2% developed taste disorders and 43.1% had voice disorders after radiotherapy. The proportion of hearing loss following radiotherapy was 21.9% though this should be taken with caution since there was no before and after intervention taken. Most of the patients who developed hearing loss had nasopharyngeal cancer (85.6%) and salivary gland cancers (66.7%) while patients with oropharyngeal cancer, hypopharyngeal cancer and laryngeal cancer did not develop hearing loss at all. Patients with sinonasal cancers had the least proportion of oral and oropharyngeal mucositis (50%), xerostomia (64.3%) and voice disorders (14.3%).

Head and neck cancers are reported to be more common in men than women (14). In this study, the proportion of males (66.2%) involved in the study was higher than that of females (33.8%) in the ratio of 2:1. C Mwansasu et al (15) on his study on pattern of head and neck cancers among patients attending Muhimbili National Hospital and J.F Onyango et al in Kenya (16) had the same male to female ratio.

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Normally head and neck cancers are more common in advanced ages especially in the 5th and 6th decade of life. In this study the majority of patients (27.5%) involved were in the 6th decade of life, followed by the 5th decade (22.4%). This observation is similar to a study by C. Mwansasu et al who found that the mean age at diagnosis of head and neck cancers is 51±18 years and J.F Onyango et al (16) from Kenya who found a wide range of age distribution with peak age of 50 – 60 years

Majority of the patients with head and neck cancers involved in this study had oral cancer (32.5%) followed by sinonasal cancers (17.5%) and laryngeal cancer (15%). These results are the same as those obtained by C. Mwansasu et al (15) who found sinonasal cancers are the most common followed by laryngeal cancer though he did not include oral cancers. However, these results seem to differ slightly differ from those obtained in Kenya by J.F Onyango et al (16) who found laryngeal cancer to be the most common head and neck cancer, 15% followed by oral cancers,13.5% and nasopharyngeal cancers, 12.5%. Again, a study which was conducted in USA by W.J Goodwin et al (17) laryngeal cancers were the most common followed by oral cancers. The differences could be explained by the fact that the study in Kenya and USA did not include lip cancers in oral cancers

The proportion of oral and oropharyngeal mucositis following radiotherapy for head and neck cancers in this study was 80%. This is almost the same proportion as the one which was obtained by M Solomon in Kenya where the proportion of mucositis was 79.4% (18). The proportion of mucositis from the above two studies is low compared to a study by Zhang XX et al in China who found that patients involved in the study developed oral mucositis (24). However, the high proportion in this study could be explained by the fact that all involved patients received also chemotherapy which have the tendency of increasing mucosal toxicity. Depending on the site of cancer, the proportion of oropharyngeal mucositis in this study was higher in patients with oropharyngeal cancer (100%) hypopharyngeal cancer (100%) and oral cancer (96.2) while it was lower in patients with sinonasal cancer (50%). This is due to the fact that

radiations cause direct effect in the oral cavity, oropharynx and hypopharynx causing mucositis as compared to patients with sinonasal cancer.

This study found that the proportion of radiation induced xerostomia, (dry mouth) was 90%. This proportion is slightly lower compared to the one obtained by M Solomon in Kenya who found 96.8% developed xerostomia (18). The small difference could be explained by the fact that patients with sinonasal cancer who develop less xerostomia following radiotherapy were many in this study, 17.5% compared to M Solomon's study, less than 12.5%. In a study done in Belgium by P Dirix et al (20) it was found that majority of patients (93%) suffer from dry mouth. This was nearly the same prevalence as one obtained in this study.

The site of the head and neck cancer to be irradiated has been associated with proportion of xerostomia. In this study, sinonasal cancers had the least proportion of xerostomia (64.3%) as compared to other type of cancers such as salivary gland cancers (100%). Koukourakis M et al (25) in Greece showed that radiation induced xerostomia is a frequent consequence of radiotherapy for head and neck cancer patients whose parotid glands are included in the radiation field. On the other hand, Dirix P et al (13) in Belgium showed that salivary gland sparing radiation technique have shown to decrease the incidence of xerostomia. This involves parotid gland shielding or use of modern radiation techniques such as IMRT (intensity modulated radiation therapy) which are not available at ORCI.

This study has shown that about 50% of patients with head and neck cancers develop difficult in swallowing following radiotherapy. Different studies elsewhere have shown different proportion of dysphagia. In Kenya, M Solomon (18) found that 71.1% develop difficult in swallowing following radiotherapy, while A. Rose-ped et al (1) in US found that 88% of participants develop difficult in swallowing. Szczesniak, M et al in Sydney found that 59% of patients report impaired swallowing following head and neck radiotherapy. The low proportion of dysphagia in this study compared to other studies

could be explained by the fact that majority of the hypopharyngeal and oropharyngeal cancers were not assessed for the complication due to previous dysphagia prior to radiotherapy.

One of the early complications of radiation therapy is taste disorder. Several studies have been done elsewhere to determine the proportion of individuals who develop taste disorders following radiation therapy. The proportion found in our study is low (76.2%) compared to what has been reported by Rose-ped et al (1) where nearly all patients, 90% reported changes in taste sensation which included complete loss of taste (54%), distorted taste (33%) and reduced taste (13%). The differences in results could be due to interval of the study following radiotherapy whereby Rose-ped et al studied more than 5 years after radiotherapy where complications are more marked. Similarly, the proportion of taste loss as it has been shown by P Dirix et al (13) was 63% which is also lower compared to what was found from our study.

Radiotherapy effects on voice have been identified in terms of patients rated performance of function. (9) In this study the proportion of voice disorders after radiotherapy was 43.1%. This proportion is high compared to a study by A. Hamdan et al (8) in Lebanon who found 15% of patients report their voice as being poor and almost 85% reported their voice as being fair. On the other hand, a study done by J.M Vaimshtein et al (22) on patient-reported voice and speech outcomes after whole-neck intensity modulated radiation therapy and chemotherapy for oropharyngeal cancer, voice quality of patients decreases maximally at 1 month, with about 68% of patients reporting worse scores compared with before treatment. These differences in proportions could be explained by different scoring methods as well as patient rating performance of function.

Dysphonia and laryngeal oedema is less common for radiotherapy to non-laryngeal and non hypopharyngeal tumors. In this study majority of patients with hypopharyngeal cancer developed voice disorders (85.7%) and patients with sinonasal cancer were the least to develop voice disorders (14.3%). A study by Van der Molen L et al (12) showed

that 70% of patients judged their voice as 'not as it used to be' and out of those, the larynx-hypopharynx tumor group was more strained, whereas non-larynx tumor voices were judged less strained. Another study by Nguyen N et al (5) showed that only 1 patient out of 44 patients reported a change in voice quality following radiotherapy. However, these patients were treated with IMRT which reduces much of radiotherapy side effects.

Post- radiotherapy to the head and neck, otitis media with effusion is considered to be due to Eustachian tube dysfunction, and plays the major part in hearing loss after radiotherapy. In this study the proportion of hearing loss was 21.9% and majority of patients, (86.4%) had conductive hearing loss. M Saluja et al (23) in their study on radiotherapy induced hearing loss in 25 patients with head and neck cancers in Denmark reported that 9 (36%) patients complained of subjective hearing loss. The differences in proportion of hearing loss could be explained by the duration of study after finishing radiotherapy whereby M Saluja et al tested for hearing loss 20 weeks post radiotherapy while this study tested within a week after completing radiotherapy. On the other hand, this study depended on subjective patient report of hearing loss following radiotherapy as compared to M Saluja et al who did PTA before and after treatment.

Majority of patients who developed hearing loss had nasopharyngeal cancer (85.6%) and salivary gland cancer (66.7%) while patients with oropharyngeal cancer, hypopharyngeal cancer and laryngeal cancer did not develop hearing loss at all. This could be explained by the fact that irradiation to nasopharynx or salivary glands (parotid) could result into blockage and hence eustachian tube dysfunction and hence hearing loss. However, patients with nasopharyngeal cancer may have conductive hearing loss prior to radiotherapy due to blockage of the eustachian tube by the tumor itself.

Study Limitations

This study had several limitations. Before and after radiotherapy interventions were not taken so as to establish whether the reported hearing loss was purely the side effect of

radiotherapy with and without chemotherapy or not. The study involved one center, the results are not necessarily generalizable. Patients' records had limited socio-demographic data and also the targeted sample size could not be met because of the limited duration for the study. Our study however is to the best of our knowledge the first in Tanzania to describe the pattern of complications following RT in patients with head and neck cancers.

Conclusion

Oral and otolaryngological complications are quite common among patients with head and neck cancers receiving radiotherapy with or without chemotherapy at ORCI in Tanzania and this calls upon the introduction of advanced techniques of delivering radiotherapy to patients such as use of intensity modulated radiotherapy which minimizes effects of radiation to sites that are not targeted for irradiation.

List of Abbreviations

CHL, Conductive hearing loss
Lt, Left
NA, Not applicable
ORCI, Ocean Road Cancer Institute
Rt, Right
SNHL, Sensorineural hearing loss
IMRT, Intensity modulated radiotherapy

Declarations

Ethics approval and consent to participate

The approval to conduct the study was granted by Ethics and Research Committee for Muhimbili University of Health and Allied Sciences

Availability of data and material

The detailed reported information can be obtained from the corresponding authors when needed and from archives of the department of otorhinolaryngology-MUHAS

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

ZAS participated in preparation of the manuscript. BN participated in study design, data collection and analysis. EN: Participated in design of the study and data analysis. DN participated in design of the study. BM participated in preparation of the manuscript.

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