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A PROSPECTIVE ANALYSIS ASSESSING ORAL MUCOSITIS IN PATIENTS OF HEAD AND NECK CANCER TREATED WITH CONFORMAL CHEMO-RADIATION.

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Abstract

Background: Objectives: Head and neck cancers are the sixth most common malignancy worldwide, accounting for approximately 3.3% of all cancers, with a higher burden in Asia, particularly India. In view of the rising incidence in our region, this study aimed to analyze the incidence and grading of oral mucositis in patients with head and neck cancers undergoing chemoradiotherapy, and to evaluate its association with total radiation dose, fraction size, duration of treatment, and sequencing of chemotherapy and radiotherapy. ***Materials and Methods:*** This prospective observational study was conducted over a period of 18 months after obtaining approval from the institutional ethics committee. A total of 127 patients with head and neck cancer receiving chemoradiotherapy were enrolled. Clinical assessment of oral mucositis was carried out using Radiation Therapy Oncology Group (RTOG) grading criteria. Patient demographics, smoking status, oral hygiene, histopathological type, and treatment-related variables were recorded and analyzed. ***Results:*** The mean age of patients was 57.11 ± 14.36 years, with a male predominance (69.3%). Among the participants, 55.1% were smokers and 44.9% were nonsmokers. Most patients had moderate oral hygiene (74.8%), followed by poor (22%) and good oral hygiene (3.2%). Squamous cell carcinoma was the most common histological type (n=113). Regarding mucositis grading, the majority of patients had RTOG grade 2 mucositis (46.5%), followed by grade 1 (23.6%) and grade 3 (22%). Among patients receiving 70 Gy in 35 fractions, grade 2 mucositis was most common, followed by grades 1, 3, and 4. In those receiving 66 Gy in 33 fractions, grade 2 mucositis predominated, with occurrences of grades 3 and 1. Similarly, among patients treated with 60 Gy in 30 fractions, grade 2 mucositis was most frequent, followed by grades 3, 1, and 4. ***Conclusion:*** The study demonstrates that nearly all patients undergoing chemoradiotherapy for head and neck cancers develop some degree of oral mucositis, irrespective of radiation dose or treatment sequence. These findings emphasize the need for effective preventive and management strategies to minimize treatment-related morbidity and improve patient quality of life.

Keywords: Chemo radiation, Head and neck cancer, Oral mucositis, Radiation toxicity, Squamous cell carcinoma.

INTRODUCTION

Head and neck cancers (HNCs) are the sixth most common malignancy worldwide, accounting for approximately 3.3% of all cancers, with nearly 500,000 new cases diagnosed annually1. A substantial proportion of these cases occur in Asia, particularly in India, where HNCs constitute nearly 30% of all cancers2,3. A study from our region in 2016 reported that the incidence of Head and neck cancers is approximately 7.9% and is the 3rd most common cancer after GI and lung cancers4. Regional studies have also reported an increasing incidence, highlighting the growing burden of this disease and the importance of evaluating treatment-related complications.

Head and neck cancers (HNCs) represent a heterogeneous group of malignancies, of which squamous cell carcinoma (SCC) is the most common, arising from the epithelial lining of the oral cavity, oropharynx, hypopharynx, and larynx. Tobacco and alcohol consumption are major etiological factors5,6. Radiotherapy plays a central role in the management of HNCs and is used in nearly 75% of patients, either alone or in combination with chemotherapy. Modern techniques such as three-dimensional conformal radiotherapy (3DCRT) and intensity-modulated radiotherapy (IMRT) have improved tumor targeting while minimizing damage to surrounding normal tissues7,8.

Despite these advancements, treatment-related toxicities remain significant. Among them, oral mucositis is one of the most common and debilitating complications. It is characterized by erythema, edema, and ulcerations of the oral mucosa9. Its pathogenesis involves a complex sequence of inflammatory and cellular events, often described in a five-phase model as suggested by Sonis10. The incidence and severity of oral mucositis depend on multiple factors, including radiation dose, fractionation, chemotherapy regimen, nutritional status, and oral hygiene. Radiation-induced oral mucositis (RIOM) occurs in 100% of altered fractionation radiotherapy head and neck cancer patients11. It typically develops during the early phases of treatment and can become severe in 65–70% of patients receiving concurrent chemo-radiotherapy12. Severe mucositis adversely affects quality of life, leading to pain, reduced oral intake, increased risk of infections, and treatment interruptions. Given the lack of region-specific data, this study aims to evaluate the incidence and severity of oral mucositis in patients with head and neck cancers undergoing chemo-radiotherapy and its association with treatment-related factors.

MATERIALS AND METHODS

The study was carried out in the Departments of Radiation Oncology and ENT at Government Medical College (GMC), Srinagar, after obtaining approval from the Institutional Ethics Committee. This prospective observational study was conducted over a period of 18 months. Patients having Age ≥18 years, Karnofsky Performance Status >70, Histopathologically confirmed head and neck cancer, local or locally advanced disease planned for chemo-radiotherapy with Normal oral mucosa at baseline (Grade 0 mucositis) were included.

Patients with Metastatic disease at presentation, Prior radiotherapy to the head and neck region, Synchronous malignancies, Chronic or immunocompromised conditions precluding chemo-radiotherapy, Connective tissue disorders or Pregnancy and lactation were excluded All patients underwent detailed baseline evaluation including Comprehensive history and clinical examination, Direct or indirect laryngoscopy, Detailed oral cavity examination, Histopathological confirmation via biopsy, Contrast-enhanced computed tomography (CECT) of the neck, chest, abdomen, and pelvis to assess disease extent and exclude metastasis, Baseline laboratory investigations (complete blood count, renal and liver function tests, serum electrolytes) and Two-dimensional echocardiography. All relevant data were recorded using a predefined proforma.

Assessment of Oral Mucositis

Oral mucositis was assessed during treatment using standardized grading systems:

RTOG Criteria: Grades 0–IV based on clinical severity ranging from no change to ulceration, hemorrhage, or necrosis **(13)**.

Grade	Description
0 (none)	No change over baseline
I (mild)	Irritation, may experience slight pain, not requiring analgesics
II (moderate)	Patchy mucositis that may produce inflammatory serosanguinous discharge, or moderate pain requiring analgesics
III (severe)	Confluent, fibrinous mucositis, may include severe pain requiring narcotics
IV (life threatening)	Ulceration, hemorrhage, or necrosis

Common Terminology Criteria for Adverse Events (CTCAE): Graded 1–5 based on clinical findings and functional impairment.
This scale is divided into two parts: a clinical exam and a functional/symptoms-based exam.

Functional/Symptoms-Based Exam

Grade 1 = Asymptomatic or mild symptoms, and intervention is not indicated as well as the patient maintains a normal diet.
Grade 2 = Moderate pain or ulcer that does not interfere with oral intake, and the patient requires a modified diet.
Grade 3 = Severe pain which interferes with oral intake
Grade 4 = Life-Threatening consequences that require urgent intervention
Grade 5 = Death

Clinical Exam

Grade 1 = mucosal erythema
Grade 2 = patchy ulceration or pseudomembranes
Grade 3 = Minor trauma resulting in bleeding, confluent ulcers, or pseudomembranes. Grade 4 = Tissue necrosis, spontaneous bleeding, life-threatening events.
Grade 5 = Death.

World Health Organization (WHO) Scale: Grades 0–4 combining objective findings and patient symptoms, including dietary limitations.
Grade 0 = No oral mucositis
Grade 1 = Erythema and soreness
Grade 2 = Ulcers, able to eat solids
Grade 3 = Ulcers, requires a liquid diet (due to mucositis)
Grade 4 = Ulcers, alimentation not possible (due to mucositis)

The World Health Organization Oral Mucositis Scale and The National Institute of Health Common Terminology Criteria for Adverse Events[14]:

Grade		Description
A	0 (None)	None
	I (Mild)	Oral soreness, Erythema
	II (Moderate)	Oral Erythema, Ulcers, solid diet is tolerated
	III (Severe)	Oral Ulcers, only liquid diet is possible
	IV (Life threatening)	Oral alimentation is impossible
B	0	None
	1	Asymptomatic or mild symptoms, intervention not indicated
	2	Moderate pain, not interfering with oral intake, modified diet indicated.
	3	Severe pain, interfering with oral intake
	4	Life threatening consequences, urgent intervention indicated
	5	Death

Statistical Analysis
Data were entered into Microsoft Excel and analyzed accordingly. Continuous variables were expressed as mean ± standard deviation, while categorical variables were summarized as percentages

RESULTS
A total of 127 patients were included, comprising 88 males (69.3%) and 39 females (30.7%), with a mean age of 57.11 ± 14.36 years. The majority (53.4%) were between 51–70 years. Most patients were from rural areas (72.4%), and 55.1% were smokers. ECOG performance status was predominantly 0 (33.1%) and 2 (31.5%). Hypertension was the most common comorbidity (33.9%), followed by diabetes (15.7%). Oral hygiene status was moderate in 74.8% of patients, poor in 22%, and good in only 3.2% [Table 1].

Table 1: Demographic profile

Parameter	Category	Frequency	Percent
Age (years)	18-30	6	4.7
	31-50	34	26.8
	51-70	68	53.4
	>70	19	14.9
Gender	Male	88	69.3
	Female	39	30.7
Ethnicity	Rural	92	72.4
	Urban	35	27.6
Smoker	Yes	70	55.1
	No	57	44.9
ECOG	0	42	33.1
	1	37	29.1
	2	40	31.5
	3	8	6.3
	4	0	0
Oral hygiene	Poor	28	22
	Moderate	95	74.8
	Good	4	3.2
Comorbidity	Hypertension	43	33.9
	Diabetes	20	15.7
	Hypothyroidism	13	10.2

Among 127 patients most of them were home makers and farmers, each accounted for similar distribution of 21.3% (n = 27) each.

Table 2: Occupation distribution

Occupation	Frequency (n)	Percent (%)
Homemaker	27	21.3
Farmer	27	21.3
Govt. employee	19	14.9
Labourer	18	14.2
Businessman	13	10.2
Shopkeeper	11	8.7
Driver	5	3.9
Tailor	2	1.6
Student	2	1.6
Teacher	2	1.6
Total	127	100

The most commonly affected site was tongue (22.3%), followed by the pharynx (18.1%) and larynx (17.3%), while tonsils, mandible, and hypopharynx were least involved [Table 3].

Table 3: Site involved

Site	Frequency	Percent
Tongue	29	22.3
Pharynx	23	18.1
Larynx	22	17.3
Vocal cord	14	11
Glottis	10	7.9
Parotid	9	7.1
Pyriform sinus	6	4.7
Supraglottis	3	2.4
Maxilla	3	2.4
Buccal mucosa	3	2.4
Oral cavity	2	1.6
Tonsils	1	0.8
Mandible	1	0.8
Hypopharynx	1	0.8

Histologically, squamous cell carcinoma predominated (n=113), with 45 well-differentiated, 58 moderately differentiated, and 10 poorly differentiated cases. All nasopharyngeal carcinomas were undifferentiated, and all mucoepidermoid carcinomas were high-grade [Table 4].

Table 4: Type of malignancy

Histological type	Differentiation	Frequency	Percentage
Squamous cell carcinoma (n=113)	Well	45	35.4
	Moderate	58	45.7
	Poor	10	7.9
Nasopharyngeal (n=8)	Undifferentiated	8	6.3
Mucoepidermoid	Low	0	0
	Intermediate	0	0
	High	5	3.9
Adenoid cystic (n=1)	N/A	1	0.8
Total		127	100

Most tumors were AJCC stage III (64.6%), followed by stage II (29.9%), with only one stage IV case. The majority of patients (86.6%) received concurrent chemoradiotherapy (CCRT), while 13.4% received radiotherapy alone. IMRT was the most commonly used modality (54.3%), followed by VMAT (40.2%) and IGRT (5.5%). A radiation dose of 70 Gy was administered to 48% of patients, followed by 66 Gy in 38.6%. Treatment duration was most commonly 6–7 weeks [Table 5].

Table 5: AJCC cancer staging

		Frequency	Percent
AJCC Staging	I	6	4.7
	II	38	29.9
	III	82	64.6
	IV	1	0.8
Chemo-Radiotherapy	CCRT	110	86.6
	RT only	17	13.4
Technique of RT	IMRT	69	54.3
	VMAT	51	40.2
	IGRT	7	5.5
Radiation Dose	70Gy/35#	61	48
	66Gy/33#	49	38.6
	60Gy/30#	12	9.4
	63Gy/28#	2	1.6
	65.25Gy/29#	1	0.8
	68Gy/34#	1	0.8
	54Gy/30#	1	0.8
Duration of Therapy	5 weeks	15	11.8
	6 weeks	48	37.8
	7 weeks	42	33.7
	8 weeks	20	15.7
	9 weeks	2	1.6

Majority of patients had an RTOG score of 2 (46.5%), followed by scores of 1 (23.6%) and 3 (22%) [Table 6].

Table 6: Radiation therapy oncology group(RTOG) toxicity scoring of head & neck cancer.

RTOG Score	Frequency	Percent
0	0	0
1	30	23.6
2	59	46.5
3	28	22
4	10	7.9

Mucositis severity varied with radiation dose and treatment duration. Among patients receiving 70 Gy, most developed grade 1–2 mucositis, with fewer cases of grade 3–4. Similar trends were observed for 66 Gy and 60 Gy groups. Mucositis was more frequent in patients with treatment durations of 6–7 weeks. Severe mucositis (grade 4) was predominantly observed in patients receiving concurrent chemoradiotherapy. In this group, grade 2 and grade 1 mucositis were also common. Among patients receiving radiotherapy alone, grade 2 mucositis was most frequent, with fewer cases of higher grades. [Table 7].

Table 7: Mucositis grade with respect to dose, duration and sequence of treatment

		Mucositis Grade				
		0 (n=0)	**1 (n=30)**	**2 (n=59)**	**3 (n=28)**	**4 (n=10)**
Mucositis grade with respect to Dose/Fraction	70Gy/35# (n=61)	0	17	28	14	2
	66Gy/33# (n=49)	0	11	19	12	7
	60Gy/30# (n=12)	0	2	6	3	1
	63Gy/28# (n=2)	0	0	2	0	0
	65.25Gy/29# (n=1)	0	0	1	0	0
	68Gy/34# (n=1)	0	0	1	0	0
	54Gy/30# (n=1)	0	0	1	0	0
Mucositis grade with respect to treatment duration	5 weeks (n=15)	0	3	6	4	2
	6 weeks (n=48)	0	13	22	9	3
	7 weeks (n=42)	0	11	20	9	2
	8 weeks (n=20)	0	3	9	5	3
	9 weeks (n=2)	0	0	1	1	0
Mucositis grade with respect to Treatment Modality	CCRT (n=110)	0	28	48	24	10
	RT alone (n=17)	0	2	11	4	0
	Only chemotherapy (n=0)	0	0	0	0	0

DISCUSSION

Mucositis is a significant clinical challenge and causes a major burden for head and neck cancer patients and their caregivers; its impact on the cost of care may be substantial. Accurate characterization of the significance of these burdens is complicated by underreporting of mucositis, inconsistent measurement of severity, retrospective assessments of risk and severity, and failure to examine outcomes from the patient's perspective.

In the present study, the mean age of patients was 57.11±14.36 years (Table I). The most common affected age-group was 51-70 years, accounted for 53.4% (n=68), followed by 26.8% (n=34) in 31-50 years. 14.9% (n=19) patients were seen having age of more than 70 years, while 4.7% (n=6) of patients were seen in the age between 18-30 years. Similar findings were reported by the study from Mourad M et al(15) from US, where it was found that patients with head and neck cancer (HNC) are nearly 60% already over 60 years old. Another study from Germany also stated that, approximately 70% of patients with head and neck cancer are over 65 years old16.

Moreover, in our study, 88 (69.3%) were males and 39 (30.7%) were females (Table I). Similar pattern was reported by Park JO et al.17 in which it was found that male patients are more prone for head and neck cancers due to increased tobacco use and smoking. Dong M et al.18 also found that male gender is more affected by head and neck cancers than female. Hoang T et al.19 in their study on head and neck cancer of 1108 patients, also found that 713 (73.9%) were men.

It was also found in our study that 55.1% (n=70) were smokers. Also, 72.4% (n=92) patients belonged to rural areas and 27.6% (n=35) belonged to urban areas. The underlying co-morbidities in our study population was hypertension in 33.9% (n=20), diabetes in 15.7% (n=20) and hypothyroidism in 10.2% (n=13). The high incidence of hypertension and hypothyroidism in our study subjects is because of high prevalence of hypertension21 (35% to 57%) in rural Kashmiri population and prevalence of hypothyroidism22 is 11.6% to 18.4% (Table I).

Most of the patients in our study were homemakers and farmers, each showed equal distribution of 21.3% (n=27) (Table 2). Awan KH et al.20 in their analysis found that occupational or environmental toxins have a potential role in carcinogenesis that are specific to head and neck, however, previous epidemiological studieshad small sample size to study the association of occupations by HNC subsites and inadequate adjustment for the potential confounding by tobacco smoking, alcohol drinking, race, study, geographical region, education, and sex.

The most common organ involved in head and neck cancer was tongue and pharynx, accounted for 22.3% (n=29) and 18.1% (n=23) (Table 3). Larynx was involved in 17.3%, vocal cord in 11.0%, glottis in 7.9%, parotid in 7.1%, pyriform sinus in 4.7%. supraglottic, maxilla and buccal mucosa showed equal distribution of 2.4% each. Other sites include; tonsils (n=1) mandible and hypopharynx. Pampori et al.45 in a study on head at neck cancers in Kashmir valley, laryx was the most common cancer among head and neck cancer. Qurieshi MA et al.23 in an epidemiological cancer study in Kashmir has observed that laryx was the most common site involved among head as neck cancers. Similarly another study from our region by Rasool et al.24 also found thyroid cancer as most common head and neck cancer. However, when we compare

with Coelho K et al.25 in rest of India oral cancer ranks among the top three of all cancers owing to the habit of chewing tobacco.

Head and neck cancers comprise heterogenous group of malignancies, predominantly squamous cell carcinoma (WHO classification26, NCI27). Our study also had predominated squamous cell carcinoma (n=113), with 45 well-differentiated, 58 moderately differentiated, and 10 poorly differentiated cases. [Table 4]

In the present study mainly four types of radiation modulaties were given to patients including IMRT in 54.3% (n=69), VMAT in 40.2% (n=51) and IGRT in 5.5% (n=7) (Table 5). The most common radiation dosage given was 70 GY/35# and 66 GY/33#, accounted for 48% (n=61) and 38.6% (n=49) respectively. 60 GY/30# was used for 9.4% (n=12), 63GY/28# in 1.6% (n=2), 65.25 GY/29#, 68 GY/34# and 54 GY/30# in 0.8% (n=1) each. Intensity-modulated radiotherapy (IMRT) is an advanced approach to three-dimensional (3D) treatment planning and conformal therapy. It optimises the delivery of irradiation to irregularly shaped volumes and has the ability to produce concavities in radiation treatment volumes. For head and neck cancer, the clinical target volume 1 (CTV1), which includes the primary tumour and the involved nodes, typically receives a higher radiation dose than CTV2. The different doses to CTV1 and 2 can be delivered simultaneously, while sparing the parotid salivary glands and the spinal cord. In the head and neck region, IMRT has a number of potential advantages: (i) it allows for greater sparing of normal structures such as salivary glands, oesophagus, optic nerves, brain stem and spinal cord28,29 (ii) it allows treatment to be delivered in a single treatment phase without the requirement for matching additional fields to provide tumour boosts, and eliminates the need for electron fields to the posterior (levels II and V) neck nodes; and (iii) it offers the possibility of simultaneously delivering higher radiation doses to regions of gross disease and lower doses to areas of microscopic disease—the so-called simultaneous integrated boost (SIB) IMRT30. Mucositis may be evaluated using mucositis scales such as the World Health Organization (WHO) mucositis scale, the National Cancer Institute (NCI) scale for oral mucositis and the Common Terminology Criteria for Adverse Events (CTCAE). The WHO mucositis scale is the most commonly used scale in clinical and research settings. In patients receiving a typical 6–7 week course of RT, Oral mucositis present as erythema of the oral mucosa in the first 2–3 weeks of RT and progresses to ulceration and pseudomembranes as the dose of radiation increases. Most of the treatment longed for 6 weeks and 7 weeks accounted for 37.8% (n=48) and 33.7% (n=42) respectively. 15.7% (n=20) had upto 8 weeks, 11.8% (n=15) upto 5 weeks and 1.6% (n=2) had upto 2 weeks.

It was also found in our study that most of the patients had oral mucositis of RTOG grade 2 46.5% (n=59), 23.6% (n=30) had grade 1, 22% (n=28) had grade 3 and 7.9% (n=10) had grade 4 (Table 6). Oral mucositis is nearly a universal toxicity with grade 2 mucositis being most common observed severity level as reported by Trotti et al., JCO2, in a systematic review.

In our study, patients who received a radiotherapy dosage of 70 grays in 35 fraction showed the higher incidence of oral mucositis, of which 28 had grade 2 mucositis followed by grade 1 in 17 patients and grade 3 in 14 (Table 7). Similarly patients who received 66 Grays in 33 fractions also developed mostly grade 2 mucositis (n=19) followed by grade 1 (n=11) and grade 3 (n=12). The highest grade of mucositis in our study was grade 4, in which 7 patients had received 66 Grays in 33 fractions followed by 2 patients who received 70 Grays in 35 fractions and 1 patient received 60 Grays in 30 fractions respectively. Similar findings were reported by Sonis Stephen T(10) which established that mucositis severity is dose dependent typically appearing at 20-30 Gy and becoming clinically significant (Grade ≥2) around 30-40Gy. Most of the patients who developed mucositis had therapy duration of 6 to 7 weeks. Patients who had 6 months duration for therapy, 22 developed grade 2 mucositis, 13 developed grade 1, 9 developed grade 3 and 3 developed grade 4 mucositis. Our results are in consistent with Trotti Andy et al, JCO 20032 which demonstrates that longer treatment duration and cumulative dose increases both incidence and severity.

Most (n=10) of the patients who developed grade 4 mucositis received concurrent chemoradiotherapy and in same group, 48 patients developed grade 2 and 28 developed grade 1 mucositis. While as in patients who received radiotherapy alone, 11 patients developed grade 2 mucositis, 4 patients developed grade 3 and 2 patients developed grade 1 mucositis. Pignon Jean-Pierre et al.31 meta-analysis of chemotherapy in head and neck cancers(MACH-NC) shows that concurrent chemoradiotherapy significantly increases acute toxicities including mucositis compared to RT alone. Also Bourhis Jean et al.32 in a meta-analysis resulted that altered fractionation (Hyperfractionation, Accelerated RT) increased mucositis due to reduced mucosal recovery time.)

Our study had a certain limitations that included limited duration of inclusion period and small sample size. Treatment and follow-up considering the management for oral mucositis was not part of the study. A large study group is recommended to overcome the limitation and validate our findings.

CONCLUSION

Oral mucositis remains a difficult complication in patients undergoing chemoradiotherapy for head and neck cancers, as it increases the morbidity and affects the treatment regimen of the patient. From the present study we concluded that, almost all patients develop some grade of oral mucositis, irrespective of dose and sequence undergoing chemoradiotherapy for head and neck malignancies.

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