ORIGINAL ARTICLE

Weekly Assessment of Acute Oral Mucositis on Concurrent Chemo Radiotherapy in Oral Cavity Cancers

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ABSTRACT

Objective: This study aimed to assess the weekly progression of acute oral mucositis in patients with oral cavity cancer undergoing concurrent chemoradiotherapy.
Methodology: A descriptive study was conducted at the Department of Oncology, Dr Ziauddin University Hospital from September 2020 to December 2021. Patients with SCC of oral cavity with ages between 18 and 70 years, planned for radiation therapy as adjuvant (after surgery) with chemotherapy were recruited. The severity of mucositis was evaluated weekly during the treatment according to RTOG/EORTC criteria of adverse events. The severity of mucositis was compared between patients aged below and above 45 years and between genders.
Results: Total 126 patients were included in the study. At Week 07, Grade 3 radiation induced oral mucositis constituted the highest proportion in patients aged <45 years, i.e. 74.4%, followed by Grade 4 (23.3%), and Grade 2 (2.3%) oral mucositis, which seemed similar to the oral mucositis grades in patients who are >45 years of age. The p-value (0.783) indicated that the observed differences in grade distribution between the age groups were not statistically significant. At Week 07, the percentage of Grade 3 XRT induced oral mucositis was higher than Grade 4 and Grade 2 oral mucositis in both female and male patients. The p-value (0.979) indicated that the observed differences in grade distribution between genders were not statistically significant.
Conclusion: Acute oral mucositis is a common and severe toxicity in oral cavity cancer patients undergoing concurrent chemoradiotherapy, typically peaking at Grade 3 by Week 7, with no significant differences observed across age or gender, highlighting the need for uniform supportive care strategies.

Keywords: Oral cavity Squamous cell carcinoma (OCSCC), Chemo radiation CCRT, Oral mucositis (OM)

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INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer worldwide, and its incidence is projected to increase 30% by 2030, reaching approximately 1.08 million new cases annually, according to GLOBOCAN[1-3]. The elevated incidence of HNSCC in regions like Southeast Asia is linked to the habitual use of products that contain particular carcinogenic substances. Oral mucositis (OM) is a frequent and debilitating complication experienced by patients with HNSCC receiving radiation therapy (RT), whether administered independently or alongside chemotherapy. It is marked by severe inflammation and ulceration of the mucosa of the mouth and throat. It includes intense inflammation and ulceration of the oral and pharyngeal mucosa, leading to significant pain and discomfort. These symptoms often impair essential functions such as speaking, swallowing, and eating, thereby greatly affecting the patient's over all quality of life[4].

OM is associated with higher rate of opioid use, weight loss, feeding tube placement, and hospitalization among patients with HNSCC. These symptoms put patients at risk for treatment delays that can compromise patient outcome[5]. Currently, there is no universally accepted method for assessing the severity of OM. Various

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clinical and research-based scoring systems have been developed and reported in the literature, each differing in their criteria, sensitivity, and clinical applicability[6].

Earlier research employed assessment tools to explore the relationship between the severity of OM and patient-reported quality of life (QOL). With advancements in modern radiotherapy (RT) planning for head and neck cancers (HNC), normal tissue can now be preserved better. Prior to and during the treatment, all patients must receive education as per institutional management[7]. According to Western Literature, 80-83% of patients receiving radiotherapy to head and neck region, develop OM, out of whom 19% develop mild, 35% moderate, and 28% of patients develop severe mucositis[8]. The objective of this study is to determine the frequency and graded severity of acute oral mucositis developing during treatment in patients with head and neck cancers undergoing concurrent chemoradiotherapy. This evaluation aims to better understand the clinical burden of mucosal toxicity and its potential impact on treatment tolerance and over all patient well-being.

METHODOLOGY

ERC/IRB Approval: A descriptive study was conducted at the Department of Oncology, Dr Ziauddin University Hospital from September 2020 to December 2021 with ERC Reference Code 0050217FARONCO and CRC Reference Code: 0030116RDTH

Patients with SCC of oral cavity of ages between 18 and 70 years, planned for radiation therapy as adjuvant (after surgery) with chemotherapy, were recruited to assess the incidence and severity of acute oral mucositis (occurring during treatment). This condition, characterized by inflammation of the oral mucosa due to radiotherapy, commonly presents with symptoms such as swelling, redness (erythema), ulceration, and bleeding.

In this study, only those patients were included who were treated with 3-Dimensional Radiotherapy techniques (conventional form of radiotherapy). Approximately one-third of the study patients received concurrent chemotherapy consisting of weekly cisplatin at a dose of 40 mg/m², administered alongside radiation therapy. Pertinent clinical pathologic data were collected from the medical records and stored in a secure Research Electronic Data Capture (REDCap) database[9].

Currently, multiple grading systems exist for evaluating oral mucositis (OM), each with distinct assessment criteria. The World Health Organization (WHO) scale considers both objective indicators such as the presence of erythema and ulceration and functional aspects related to the patient's ability to eat and sustain oral intake. Likewise, the National Cancer Institute (NCI) introduced the Common Terminology Criteria for Adverse Events (CTCAE), which grades the severity of mucositis based on its anatomical site and the type of treatment responsible, including chemotherapy, radiotherapy, or combined modalities[10].

Oral mucositis is a prevalent and potentially severe adverse effect observed in head and neck cancer (HNC) patients undergoing radiotherapy, with incidence ranging from 85% to 100%. Considering a frequency of 85%, a 95% confidence level, and a 7% (0.07) margin of error, the calculated sample size was determined to be 100.

Sample size calculated for the estimated frequency of oral mucositis was larger than the one for severity of oral mucositis. Non probability purposive sampling was done. Therefore, a total of 126 head and neck cancer patients who had developed oral mucositis during the course of radiotherapy were recruited to be comprehensively evaluated, fulfilling the study's objectives.

Existing literature reported the frequency of OM in patients receiving radiotherapy for HNC as 80%[11]. This assumption gives the maximum sample size; therefore, to estimate the frequency, with 95% confidence level and with 7% (0.07) bound on error of estimation, a sample of 126 patients was calculated and recruitment was done.

All patients with HNC referred to us for radiotherapy, were enrolled in this study on meeting the inclusion and exclusion criteria and after giving written informed consent. Assessments of patients for the severity of oral mucositis were done before starting radiotherapy, then on a weekly basis, and on the day of completion of radiation according to the toxicity pro forma based on RTOG criteria, displayed at the end. Each patient was examined and findings were collected for the severity of OM. Data form of each patient was filled every week according to the study protocol. Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 19. A descriptive analysis was carried out and results were presented as mean ± standard deviation for variables like age, gender, receiving concurrent chemoradiotherapy. For stratification of outcome, variables like age, gender receiving concurrent chemotherapy are presented in the form of cross tabulation.

The association of frequency and severity of oral mucositis to variables of treatment were done using cox-regression. A p-value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

In this study of 126 patients, week 1 results showed that among patients younger than 45 years, 58.1% had Grade 0 and 41.9% had Grade 1 CCRT-induced oral mucositis. Among patients older than 45 years, a higher proportion had Grade 0 (61.3%) compared to Grade 1 (38.8%), indicating a slight skew toward milder presentation in the older age group. The p-value of 0.737 indicated that the difference between Grade 0 and Grade 1 CCRT induced oral mucositis is not statistically significant in week 1. However, at the end of week 1, Grade 0 CCRT induced oral mucositis was observed in 46.4% and Grade 01 in 53.6% of the female patients who underwent CCRT, as compared to the male patients who showed a notable decrease in the proportion of Grade 1 oral mucositis (35.8%). The p-value of 0.091 indicated a moderate level of significance, suggesting difference in proportions between Grade 0 and Grade 1 for males and females. The results of week 2 suggested Grade 0 (51.2%) and Grade 1 (48.8%) CCRT induced oral mucositis among patients younger than 45 years. However, the patients above 45 years of age showed an equal proportion in Grade 0 and Grade 1 CCRT induced oral mucositis (50%).

The high p-value (0.902) suggested that the variation among different age groups is statistically insignificant. At the end of week 2, an increase in proportion of Grade 01 oral mucositis was observed in female patients (60.7%), in comparison to the male (46.3%) patients. The p-value (0.181) at the end of week 2 suggested that the observed differences in gender distribution were not statistically significant.

At week 3, in patients of both age groups, Grade 01 oral mucositis (67.4% in less than 45 years and 80% in more than 45 years) showed the dominating pattern as compared to the Grade 02 oral mucositis.

The p-value (0.122) suggested that the observed differences in age distribution between <45 and >45 groups were not statistically significant.

However, a higher number of patients with Grade 01 CCRT induced OM were observed in both females (67.9%) and males (77.9%), in comparison to Grade 02 OM.

The p-value (0.277) at the end of week 3 also suggested that the observed differences in gender distribution were not statistically significant.

At week 4 of radiotherapy, a higher proportion of patients in both age groups exhibited Grade 1 OM compared to Grade 2, with (67.4%) in patients younger than 45 years and (90%) in those older than 45 years. Therefore, the low p-value (0.047) suggests that the observed differences in age distribution between <45 and >45 year groups are statistically significant. In contrast, at the end of Week 4, the p-value (0.247) suggested that the observed differences in gender distribution are not statistically significant. At week 5, in <45 years group, Grade 3 OM (53.50%) slightly exceeded Grade 2 OM (46.50%). While in >45 years group, Grade 2 (53.80%) slightly exceeded Grade 3 (46.30%).

The p-value (0.444) suggests that the observed differences in grade distribution between <45 and >45 groups are not statistically significant.

At week 5, the Grade 3 OM (60.70%) exceeded Grade 2 OM (39.30%) in female patients. However, Grade 2 OM (54.70%) exceeded Grade 3 (45.30%) in male patients.

The p-value (0.151) at week 5 also suggested that the observed differences in grade distribution between females and males were not statistically significant. By week 6, Grade 3 radiotherapy-induced OM had the highest proportion (70.0%) in patients older than 45 years, followed by Grade 2 (18.8%) and Grade 4 (11.3%). A similar distribution of OM grades was observed in patients younger than 45 years. A p-value of 0.187 indicated that there was no statistically significant difference in the distribution of Grades 2, 3, and 4 OM between <45 and >45 age groups. On the contrary, at week 6, the data indicated that within the female patients, Grade 3 OM had the highest proportion (64.30%), followed by Grade 2 and Grade 4, both at 17.90%, fairly comparable to OM in male patients. A p-value of 0.595 indicated no statistically significant difference in the distribution of Grades 2, 3, and 4 OM between females and males in this study.

At week 7, the patients aged <45 years showed Grade 3 CCRT induced OM in the highest proportion, i.e. 74.4%, followed by Grade 4 (23.3%) and Grade 2 (2.3%), which seemed similar to the OM grades in patients who are >45 years of age. The p-value (0.783) indicated that the observed differences in grade distribution between the age groups were not statistically significant. At week 7, the percentage of Grade 3 CCRT induced OM was higher than Grade 4 and Grade 2 OM in both female and male patients.

The p-value (0.979) suggested that the observed differences in grade distribution between genders were not statistically significant.

DISCUSSION

Radiation therapy serves as a cornerstone in the treatment of oral cavity cancers, utilized in both definitive and adjuvant settings to maximize local disease control, especially when administered alongside

Table 1: Stratification of Weekly (Week 1 and 2) assessment of oral mucositis according to according to age group to age and gender

	Age Group	Grade 0	Grade 1	p-Value	Gender	Grade 0	Grade 1	p-Value
Week 1	<45	25 (58.1%)	18 (41.9%)	0.737	Female	13 (46.4%)	15 (53.6%)	0.091
	>45	49 (61.3%)	31 (38.8%)		Male	61 (64.2%)	34 (35.8%)	
Week 2	<45	22 (51.2%)	21 (48.8%)	0.902	Female	11 (39.3%)	17 (60.7%)	0.181
	>45	40 (50%)	40 (50%)		Male	51 (7.5%)	44 (46.3%)	

Table 2: Stratification of Weekly (Week 3 and 4) assessment of oral mucositis according to according to age group to age and gender

	Age Group	Grade 1	Grade 2	p-Value	Gender	Grade 1	Grade 2	p-Value
Week 3	<45	29 (67.4%)	14 (32.6%)	0.122	Female	19 (67.9%)	9 (32.1%)	0.277
	>45	64 (80%)	16 (20%)		Male	74 (77.9%)	21 (22.1%)	
Week 4	<45	33 (76.7%)	10 (23.3%)	0.047	Female	22 (78.6%)	6 (21.4%)	0.247
	>45	72 (90%)	8 (10%)		Male	83 (87.4%)	12 (12.6%)	

Table 3: Stratification of Weekly (Week 5) assessment of oral mucositis according to according to age group to age and gender

	Age Group	Grade 2	Grade 3	p-Value	Gender	Grade 2	Grade 3	p-Value
Week 5	<45	20 (46.5%)	23 (53.5%)	0.444	Female	11 (39.3%)	17 (60.7%)	0.151
	>45	43 (53.8%)	37 (46.3%)		Male	52 (54.7%)	43 (45.3%)	

Table 4: Stratification of Weekly (Week 6 and 7) assessment of oral mucositis according to according to age group to age and gender

	Age Group	Grade 2	Grade 3	Grade 4	p-Value	Gender	Grade 2	Grade 3	Grade 4	p-Value
Week 6	<45	13 (30.2%)	23 (53.5%)	7 (16.3%)	0.187	Female	5 (17.9%)	18 (64.3%)	5 (17.9%)	0.595
	>45	15 (18.8%)	56 (70%)	9 (11.3%)		Male	23 (24.2%)	61 (64.2%)	11 (11.6%)	
Week 7	<45	1 (2.3%)	32 (74.4%)	10 (23.3%)	0.783	Female	1 (3.6%)	21 (75%)	6 (21.4%)	0.979
	>45	3 (3.8%)	62 (77.5%)	15 (18.8%)		Male	3 (3.2%)	73 (76.8%)	19 (20%)	

concurrent chemotherapy[12]. Precise prediction of toxicity severity is crucial for guiding effective management strategies and enhancing over all patient outcomes[13]. According to Globocan 2012 cancer fact sheet regarding Pakistan, the lip and oral cancer was the most common head and neck cancer in males and the second most common in females.

In our study, 76% of participants were male and 24% were female, yielding a male-to-female ratio of 3:1. Over all, men are two to four times more likely to develop head and neck squamous cell carcinoma (HNSCC) than women[14]. The median age at diagnosis for non–virus-associated HNSCC is approximately 66 years, while cancers related to HPV and Epstein-Barr virus (EBV) tend to occur at relatively younger ages[15]. The installation of mucositis in our study resulted in a few of the patients experiencing Grade II OM at the end of the first week of treatment whereas, it was observed two weeks after the start of radiotherapy in literature[16].

Patients 45 years of age and above were more vulnerable to mucositis in our study. Similar results were found in another study suggesting acute toxicity in older patients with more severe OM (Grades III and IV) than in their younger counterparts, suggesting a decrease in both tolerance and immunity. This was consistent with other studies with similar findings in about 50% patients having experienced Grade II or Grade III oral mucositis[17]. A Brazilian study found that oral mucositis most commonly occurred during the third and the sixth weeks of treatment, predominantly as Grade 1 and Grade 2 reactions[18].

Typically, acute OM begins to manifest within 5 to 14 days of the initiation of conventional fractionated radiotherapy. However, in this study, the dose delivered per fraction appeared to have played a key role in the earlier onset and higher frequency of Grade I OM. Notably, all patients developed OM during the course of radiation therapy, with the majority exhibiting Grade II and Grade III severity levels[19]. In our group, 20%

developed Grade IV OM towards the completion of treatment and at three months follow up. A recently published Indian study reported treatment gaps in up to 39% patients due to extreme grades of OM[20]. In the current study, the absence of treatment interruptions among patients was primarily attributed to the proactive insertion of feeding tubes prior to the initiation of radiotherapy, which effectively minimized nutritional deficiencies. It was also observed that Grade I and II OM occurred more frequently during the early phase of treatment (weeks 1-4), whereas the incidence of Grade III OM became more prominent in the later phase (weeks 5-7).

In another study done in M. D. Anderson Cancer Centre, the results were suggestive of the higher incidence of OM mainly between the third and the seventh week with high percentages of Grade III OM[21-22]. After 1-2 weeks of radiotherapy treatment (i.e. after receiving 20Gy dose), edema was observed. After the completion of three weeks treatment and receiving about 30 Gy radiotherapy dose, mainly vascular permeability was increased leading to a rise in edema formation[23].

Keeping the results of studies mentioned above and comparing them with our study, the conclusion is that the signs of OM become more visible from the third week onwards. A wide spectrum of predictive factors has been identified for the severity of OM and dysphagia, highlighting their multifactorial and complex pathophysiology. Among these, genetic predisposition plays a significant role, as genome-wide association studies (GWAS) have revealed specific genetic variants that are correlated with an increased susceptibility to developing acute OM[23,24].

We hope that these findings would provoke an understanding of the incidence and toxicity of this debilitating effect of head and neck radiation therapy in our patient population. This will enable our treating oncologists to render more attention towards prescription, planning, and verification of radiotherapy treatment, especially for the group of patients who have undergone surgery and are planned to have chemotherapy along with radiation, thus minimizing acute toxicity. Furthermore, our findings would provide baseline statistics for comparison with late toxicities for the presence of any relation.

Modern radiotherapy machines equipped with advanced techniques such as IMRT and VMAT have significantly reduced the incidence of OM. Therefore, we recommend the use of these technologies, where available, to minimize its occurrence[25].

As a tertiary care hospital with radiotherapy facilities, we receive most patients as referrals from hospitals outside Karachi. Consequently, post-treatment follow-up for up to 90 days is typically conducted at their local centers for toxicity evaluation. Therefore, our study was limited to outcomes assessed up to the final day of treatment.

This study was a single-center investigation conducted in a tertiary care setting; therefore, the findings may not be generalizable to the broader population. The onset of severe OM was closely associated with the need for feeding tube placement, increased hospitalization rates, opiate dependence for pain control, and significant weight loss. These complications not only exacerbate the clinical burden but also lead to a marked decline in patients' quality of life (QOL) and impose substantial financial strain. Therefore, continued advancements in the prevention, early detection, and management of OM are essential to mitigate these detrimental outcomes and enhance overall patient well-being[26].

CONCLUSION

Acute oral mucositis remains highly prevalent in patients with oral cavity cancer undergoing concurrent chemoradiotherapy, with the majority developing Grade 3 OM by Week 7 of treatment. The severity and progression of OM did not differ significantly across age groups or gender, suggesting a broadly uniform risk profile among patients. These findings highlight the need for proactive, standardized OM prevention and management strategies to mitigate treatment-related morbidity and improve patient tolerance to therapy.

Future studies should focus on larger, diverse populations with external validation and standardized definitions for predictors and outcomes to strengthen evidence on OM in head and neck squamous cell carcinoma.

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Authors' Contribution: FA developed the concept of the research under the guidance of **JAM. AHO** conducted literature search and drafted the manuscript. **AH, SJ, AS, and HS** contributed to data collection. **QB** carried out data analysis and assisted in manuscript writing. **AHK** contributed to data analysis, literature search, and manuscript writing. **SH** also contributed to manuscript drafting. **JAM** provided over all supervision and final approval of the manuscript.

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