Original Article

Acute Toxicity Pattern In 3D-CRT Versus IMRT For Locally Advanced Oral Cavity Cancer

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Abstract

Objective: Locally advanced oral cavity cancers (OCC) present substantial treatment challenges and require radiotherapy as a primary intervention. Although intensity-modulated radiation therapy (IMRT) provides better dose precision than 3D conformal radiation therapy (3D-CRT), their acute toxicity differences, notably mucositis, dysphagia, and dermatitis, are crucial for optimising patient outcomes, particularly in regions where advanced-stage disease is prevalent and resources are limited.

Methods: This prospective comparative study enrolled 110 postoperative patients with OCC (55 per arm) receiving adjuvant IMRT or 3D-CRT (66–70 Gy). Patients were assessed weekly during radiation therapy until completion and at the 2nd, 4th, and 6th weeks post-treatment using the NCI-CTCAE v4.03 criteria to evaluate radiation-induced mucositis, dysphagia, and dermatitis. Exclusion criteria were concurrent chemotherapy or prior radiotherapy. Statistical analysis employed the chi-square test (SPSS v20; significance: $p < 0.05$).

Results: During the treatment phase, the incidence of mucositis, dysphagia, and radiodermatitis was comparable between the 3D-CRT and IMRT arms. In the post-treatment period, however, the IMRT arm demonstrated a more rapid resolution of acute toxicities. At 4 weeks post-RT, the proportion of patients with grade 3 mucositis was significantly lower with IMRT than with 3D-CRT (4.1% vs. 48.8%; p = 0.0001). Dysphagia severity was greater in the 3D-CRT arm, with grade 3 dysphagia observed in 62.5% versus 28.6% of patients at week 7 (p = 0.003). Although radiodermatitis grades were similar post-treatment, recovery was faster in the IMRT group, with grade 1 radiodermatitis at 6 weeks post-RT in 75% versus 24.4% of patients in the 3D-CRT arm (p = 0.0001).

Conclusions: IMRT significantly reduces the post-treatment toxicity burden, with a higher resolution rate for mucositis, dysphagia, and dermatitis compared to 3D-CRT. These findings underscore the clinical advantage of IMRT in improving patient recovery and quality of life and advocate for its prioritised use in locally advanced OCC.

Keywords: Oral cavity cancers, Radiotherapy, Conformal, Dysphagia, Radiodermatitis.

Introduction

The head and neck cancers ranked as the seventh most common cancer worldwide in 2018, and precisely squamous cell carcinomas of the head and neck were the ninth most frequent neoplasms globally.[1] Within this, oral cavity cancers (OCC) established a significant proportion, with an estimated 377,713 new cases globally in 2020. Yet, Southeast Asia has the highest occurrence of head and neck cancers in the world.[2] Radiation therapy plays an essential part in the treatment of advanced oral cavity cancers.[3] Three-dimensional conformal radiation therapy (3D-CRT) is a technique of radiation therapy that uses recent innovations in imaging and treatment planning systems to adjust the shape of individual radiation beams without beam intensity modification. In contrast, intense modulated radiation therapy (IMRT) is a subtle technique for maximum localised dose delivery through beam intensity modification. Nevertheless, despite the high efficacy of localised radiotherapy in the treatment of OCC, both techniques can cause significant damage to normal adjacent tissues and structures, resulting in severe, debilitating, and potentially treatment-limiting effects.[4] IMRT, known for its advanced technology, delivers precise tumoricidal doses and reduced doses to surrounding tissues more efficiently than 3D-CRT.[3] However, in our region, where advanced-stage tumours are prevalent, large treatment volumes may lead to comparable adverse effects between IMRT and 3D-CRT, suggesting no significant difference in outcomes.

The authors' opinion there is currently a lack of published data from Pakistan, despite the high incidence of OCC in the region. This study seeks to assess and compare the acute treatment-related toxicities of 3D-CRT and IMRT in patients with OCC. This study aims to fill this gap by assessing acute radiation-induced toxicities in the Pakistani population and providing much-needed local evidence. The objective is to determine whether IMRT offers significant clinical benefits in terms of toxicity reduction compared to 3D-CRT in real-world settings. If toxicity profiles are found to be comparable, 3D-CRT may be considered a clinically acceptable and cost-effective alternative in resource-constrained environments.

Materials And Methods

This was a single-institution, prospective study that was initiated following approval by the Ethical Review Committee (reference number: 3380221HSRAD). This study used a quasi-experimental design to compare radiation-induced side effects between 3D-CRT and IMRT, including post-operative patients aged > 18 years,

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AHL JM - Conception, Design
HS QUAB FA AK - Acquisition, Analysis, Interpretation
HS AK - Drafting
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performance status of ECOG 0-2, diagnosed with locally advanced squamous cell carcinoma of the oral cavity, and recommended for adjuvant radiation therapy using either technique. Patients who underwent concurrent chemotherapy were excluded to ensure that the analysis focused exclusively on radiation-induced toxicities. In addition, patients who had previously received radiation treatment for the same site were excluded. A sample size of 110 patients (55 in each arm) was calculated using a 95% confidence interval and a power of the study 80%, via Open Epi, Version 3.01.[5] Data were collected using a modified NCI-CTCAE v4.03-based questionnaire between April 2021 and December 2022 at the Radiation Oncology Department of Dr. Ziauddin Hospital after taking written consent. Patients included in this study received adjuvant radiotherapy at doses of either 70 Gy in 35 fractions over 7 weeks (five fractions per week) or 66 Gy in 33 fractions over 7 weeks, as determined by the treating physician's discretion. Patients were assessed weekly during treatment to evaluate acute side effects, specifically mucositis, dysphagia, and dermatitis, after obtaining their written informed consent. Follow-up continued until the end of radiation therapy, up to the 7th week of radiation, and extended to the post-completion 2nd, 4th, and 6th weeks to assess the resolution and recovery of side effects.

Statistical analyses were performed using the IBM SPSS software (Statistical Package for Social Sciences), version 20.0. For categorical variables, frequencies and percentages were calculated, and for numerical variables, the mean and standard deviation were calculated. The Chi-Square test was applied to find an association of toxicities. Statistical significance was attributed to p-values less than 0.05.

Results

The mean age of patients in 3D-CRT was 44.5 ± 15.7 years, and in IMRT was 38.88 ± 13 years. The predominant gender among patients in both groups was male, 85.4% in the 3D CRT group and 81% in the IMRT group. In both arms, the most prevalent diagnosis was cheek carcinoma, followed by tongue carcinoma. In 3D-CRT, stage III cancer was diagnosed in 52.7% of patients, and in IMRT, 49% patients were diagnosed with stage III carcinoma. Conversely, 47.2% of cases were diagnosed as stage IV-A disease in 3D-CRT, and 51% were identified as stage IV-A disease in IMRT. Most patients received 66 Gy in 33 fractions in 3D-CRT, while in IMRT, the majority of patients received 70 Gy in 35 fractions (Table 1). Ten patients voluntarily withdrew their participation from the study in the 3D-CRT and eight patients from the IMRT arm. (Figure 1). Data were calculated for patients who had completed their radiation treatment as well as planned follow-ups.

Table 1: Baseline characteristics of patients.

Baseline Characteristics		Mode of XRT	
		3D-CRT n (%)	IMRT n (%)
Age	18-30	10 (18)	19 (34.5)
	31-50	26 (47)	25 (45.4)
	51-70	15 (27.2)	11 (20)
	71-90	4 (7.2)	0
Gender	Female	8 (14.5)	10 (18.1)
	Male	47 (85.4)	45 (81.8)
Diagnosis	CA Cheek	38 (69)	32 (58)
	CA Tongue	8 (14.5)	11 (20)
	CA Retromolar trigone	5 (9)	7 (12.7)
	CA Hard Palate	4 (7.2)	5 (9)
Stage	Stage III	29 (52.7)	27 (49)
	Stage IV A	26 (47.2)	28 (50.9)
Dose	66 Gy	30 (54.5)	20 (36.3)
	70 Gy	25 (45.4)	35 (63.6)

Initially, during the first week of treatment, the patients in the 3D-CRT arm exhibited a slightly higher grade of mucositis than those in the IMRT arm. During the second week of treatment, 90% of patients in the 3D-CRT arm experienced grade 1 mucositis, while 68% of patients in IMRT had a similar experience of mucositis (p-value 0.003).

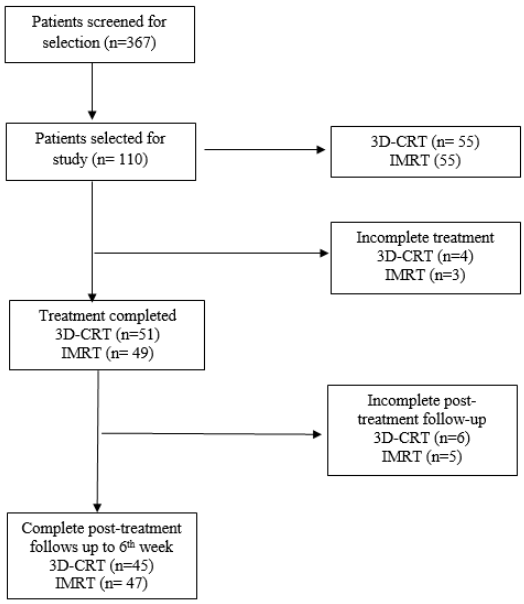

Figure 1: CONSORT Flow diagram

By the 3rd, 4th, 5th, and 6th week of treatment, the outcomes between the two groups did not yield statistically significant differences. At the end of treatment, the prevalence of grade 3 mucositis in both arms was observed (91.6% in the 3D-CRT arm and 93.8 in the IMRT), with an insignificant p-value. Following the completion of treatment, in the second week of the post-treatment period, it was observed that patients in IMRT experienced a significant reduction in grade 3 mucositis (56.2%) since treatment completion. In contrast, patients in the 3D-CRT arm did not exhibit a similar reduction, with grade 3 mucositis (88.8%) persisting (p=0.0001). By the fourth week of the post-treatment period, grade 2 mucositis was more prevalent in IMRT (89.5%) than in the 3D-CRT arm (48.8%). In comparison, grade 3 mucositis continued to be significantly prevalent in the 3D-CRT group (48.8%) as compared to IMRT (4.1%) (p= 0.0001). In the last follow-up of the study in the sixth week of the post-treatment period, a notable number of patients in the IMRT group transitioned to grade 1 mucositis (43.7%) compared to those in the 3D-CRT group with grade 1 mucositis (6.66%) (p=0.0001). In contrast, 15.55% of patients in the 3D-CRT group retained grade 3 mucositis, while there were no cases of grade 3 mucositis in IMRT (Figure 2). Notably, none of the patients in either group reported complete resolution of mucositis until the post-treatment 6th week follow-up.

Regarding dysphagia, in the 1st week of treatment, approximately 16% of patients in the 3D-CRT arm developed grade 1 dysphagia, in contrast with only 2% in the IMRT group, and this difference was statistically significant p = 0.01). No significant differences were observed between the two groups throughout the 2nd, 3rd, 4th, and 6th weeks of treatment. However, in the 5th week, a notable distinction emerged p = 0.02), revealing a higher prevalence of grade 2 dysphagia in the 3D-CRT arm (76%) compared to the IMRT group (70%). Remarkably, at the end of the treatment in the 7th week, 62.5% of patients in the 3D-CRT arm developed grade 3 dysphagia, necessitating tube feeding.

In contrast, the rate of total parenteral nutrition (TPN) was lower in the IMRT arm, standing at 28.6%, and this disparity was statistically significant p = 0.003). Two weeks after completing radiation treatment, a considerable proportion of patients in the 3D-CRT arm (62.2%) continued to experience difficulty swallowing and relied on tube feeding. In contrast, in the IMRT arm, 33.3% exhibited grade 3 dysphagia (p=0.05). By the fourth week post-treatment, 57.8% of patients had grade 2 dysphagia in the 3D-CRT arm, while 53.2% in the IMRT arm. Notably, grade 3 dysphagia remained more prevalent in the 3D-CRT arm at 35.6%, compared to 17% of patients in the IMRT arm, and this difference was statistically significant p = 0.009). In the sixth week of follow-up, a noteworthy resolution of dysphagia was observed in the IMRT arm, where approximately 68.3% of patients demonstrated improvement and transitioned to grade 1. In contrast, in 3D-CRT, 62.2% of patients still presented with grade 2 dysphagia (p=0.0001) (Figure 3).

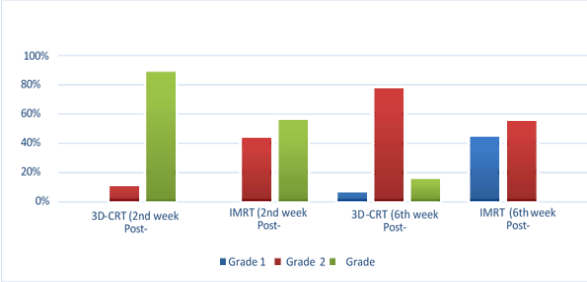

Figure 2: Mucositis in post-treatment 2nd and 6th week

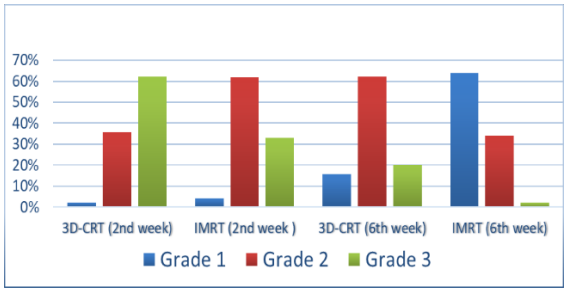

Figure 3: Dysphagia in Post-treatment 2nd and 6th week

Concerning skin toxicity, in the first week of treatment, 100% of patients in both groups showed no skin reactions. By the second week, 70% of 3D-CRT patients had no skin reactions, compared to 100% in the IMRT group, with 30% of 3D-CRT patients developing grade 1 reactions (p = 0.0001).

By the 4th week, 2% of 3D-CRT and 4% of IMRT patients had no reactions, with 84% and 86% developing grade 1 reactions, respectively, and 14% of 3D-CRT and 10% of IMRT patients developing grade 2 reactions (p = 0.42).

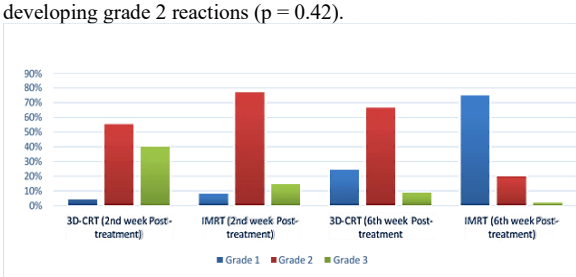

Figure 4: Radiodermatitis in post-treatment 2nd and 6th week

In the 5th week, grade 2 reactions were seen in 50% of 3D-CRT and 28% of IMRT patients (p = 0.025). By the 6th week, grade 3 reactions were observed in 10% of 3D-CRT and 4% of IMRT patients (p = 0.032). In the 7th week, grade 2 reactions occurred in 66.6% of 3D-CRT and 71.4% of IMRT patients, and grade 3 reactions in 29.2% of 3D-CRT and 28.6% of IMRT patients (p = 1.000). Post-treatment, in the 2nd week, grade 2 reactions in 55.5% of 3D-CRT and 77.1% of IMRT patients, and grade 3 reactions in 40% of 3D-CRT and 14.6% of IMRT patients (p = 0.006). By the 4th week post-treatment, grade 1 reactions were seen in 13.3% of 3D-CRT and 41.7% of IMRT patients, grade 2 reactions in 77.8% of 3D-CRT and 52.1% of IMRT patients, and grade 3 reactions in 8.9% of 3D-CRT and 4.2% of IMRT patients (p = 0.013). Finally, in the 6th-week post-treatment, grade 1 reactions were present in 24.4% of 3D-CRT and 75% of IMRT patients, grade 2 reactions in 66.7% of 3D-CRT and 20.1% of IMRT patients, and grade 3 reactions in 8.9% of 3D-CRT and 2.1% of IMRT patients (p = 0.0001) (Figure 4).

Discussion

In our study, we observed no significant differences in acute toxicities between IMRT and 3D-CRT during radiation therapy. These findings align with an Indian randomised controlled trial by Gupta et al., which reported no statistically significant differences in acute toxicities (mucositis, dermatitis, and dysphagia) between the two techniques in patients with head and neck cancer.[6] However, our study noted a higher prevalence of grade 3 mucositis in the IMRT arm throughout the treatment period, although this difference was not statistically significant. This observation is consistent with the findings of Rocha et al., who demonstrated that IMRT delivered significantly higher doses to mucosal structures (e.g., labial mucosa, buccal mucosa, and soft palate) compared to 3D-CRT ($p < 0.05$).[7] Conversely, Ghosh et al. reported no significant differences in mucositis and skin toxicity between the two techniques, although grade 3 mucositis was more frequent in the 3D-CRT arm.[8]

Dysphagia was more pronounced in the 3D-CRT arm, with a statistically significant p-value of 0.01. By the 7th week of treatment, 62.5% of patients in the 3D-CRT arm developed grade 3 dysphagia, necessitating tube feeding, compared with only 28.6% in the IMRT arm (p = 0.003). These findings are supported by a prospective analysis by Kucha et al., who reported higher rates of grade 3 mucositis and dysphagia in the 3D-CRT arm compared with IMRT, particularly in the 7th week of radiation.[9] The likely threshold dose associated with dysphagia was identified as approximately 63 Gy for the superior pharyngeal constrictor muscle, 56 Gy for the inferior constrictor muscle, and 50 Gy for the oesophagus.[10] However, a key limitation of our study is the absence of a detailed dosimetric evaluation, which could have provided a more comprehensive understanding of the relationship between the dose distribution and observed toxicities. Another study, Yadav et al. also aligned with our study, which reported 40.7 % grade 3 dysphagia in the 3D-CRT group and only 7.4 % in the IMRT arm at the treatment completion, supporting our findings.[11]

Regarding skin toxicity, our study demonstrated significantly higher rates of dermatitis in the 3D-CRT arm than in the IMRT arm during the treatment course. However, by the final week of treatment, skin toxicity levels became comparable between the two groups, with an insignificant p-value. This is consistent with the findings of Gupta et al. and Ghosh et al., who reported no significant differences in acute dermatitis between IMRT and 3D-CRT (6,8).

We systematically evaluated patients at 2, 4, and 6 weeks post-radiation to assess the resolution of treatment-related acute side effects. Our results indicated that IMRT facilitated a quicker and more effective resolution of mucositis, dysphagia, and skin reactions, with statistically significant p-values for all variables. For instance, Vergeer et al. reported dysphagia rates of 31.6% and 28.7% in the 3D-CRT and IMRT arms, respectively, at 6 weeks post-treatment.[12] By the 6-month follow-up, dysphagia rates were 26.9% in the 3D-CRT arm and 24.7% in the IMRT arm, suggesting a gradual convergence in outcomes over time. Similarly, grade 3 mucositis was higher in the 3D-CRT arm in the first week post-treatment, but no grade 3 mucositis was observed in the IMRT arm by the fifth week. Skin toxicity also showed notable differences, with 86% of IMRT patients and 74% of 3D-CRT patients experiencing grade 2 or higher dermatitis at week 7, although this discrepancy resolved by week 8.

In this study, radiation was delivered using an image guidance technique for both arms. In one study, image-guided IMRT and IMRT without imaging guidance showed different results at the 6-month follow-up.[13] The Oral mucositis was reported in 8% of patients treated with IMRT, and 13% of those treated with IMRT without image guidance. The reduction in high-dose radiation to pharyngeal muscles with IMRT and the optimisation of dose distribution likely contributed to these improved outcomes.[14] Our study revealed a significant decline in grade 3 mucositis in the IMRT group, from 28.6% during the 7th week of treatment to 14.6% by the 2nd week post-treatment. However, at 6 weeks post-treatment, the incidence of grade 3 dysphagia persisted in approximately 9% of patients in the 3D-CRT group, compared with only 1% in the IMRT group, indicating a significantly higher likelihood of feeding tube dependence in patients treated with 3D-CRT. This finding is consistent with the study by Lohia S et al., who reported superior outcomes of IMRT in reducing PEG tube dependence when compared with 3D-CRT for oropharyngeal cancers.[15]

With respect to radiodermatitis, the incidence of grade 3 reactions in the 3D-CRT group increased from 29.2% during the 7th week of treatment to 40% by the 2nd week post-treatment, as compared to the IMRT group. This may be attributed to the higher proportion of patients in the 3D-CRT arm presenting with dermal tumour involvement, as the skin dose distribution varies significantly between techniques. In such cases, radiation oncologists often prioritise delivering higher skin doses to ensure adequate tumour coverage.[16] Although our study did not quantify the extent of dermal tumour involvement, it is plausible that the administration of intentionally higher skin doses in such cases contributed to the observed increase in skin toxicity. Our findings are consistent with a study by Lohia S et al., reporting acute grade 3 skin toxicities in 23% of the 3D-CRT group and 7% of the IMRT group, though long-term follow-up data on skin toxicity were not reported.[15]

This study is limited by its short follow-up duration, lack of long-term toxicity assessment, and absence of detailed dosimetric correlation with clinical outcomes and morbidity. Future studies should incorporate prospective designs with longer follow-up periods, comprehensive dosimetric analyses of each organ at risk (OAR), and patient-reported outcome measures to better assess the long-term toxicity burden and its impact on quality of life. Such data will further support the development of personalised and resource-appropriate radiotherapy strategies for managing oral cavity cancers.

Conclusions

We observed no significant differences in the acute toxicity profiles between IMRT and 3D-CRT during the radiation treatment of patients with locally advanced OCC. However, the faster resolution of mucositis, dysphagia, and radiodermatitis in the IMRT arm underscores its potential to mitigate treatment-related adverse effects and improve patient outcomes. These findings highlight the importance of advanced radiation techniques, such as IMRT, in optimising therapeutic efficacy while minimising morbidity. Future studies with long-term follow-up and larger cohorts are needed to further validate these results and explore the broader implications for patient care and quality of life.

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