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Treatment Approaches in Inoperable Head and Neck Squamous Cell Carcinoma: Concurrent vs. Sequential Chemoradiotherapy

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Abstract: ***Background:*** Inoperable head and neck squamous cell carcinoma (HNSCC) poses a formidable challenge in oncology due to limited treatment options and unfavorable prognosis. Concurrent and sequential chemoradiotherapy have emerged as key therapeutic modalities, but their relative efficacy remains a topic of debate. ***Objective:*** This study aimed to compare the effectiveness of concurrent versus sequential chemoradiotherapy in the management of inoperable HNSCC, with a focus on treatment outcomes and toxicity profiles. ***Method:*** A retrospective analysis was conducted at Department of Radiotherapy, Rajshahi Medical College Hospital Bangladesh, over one year from June 1, 2019, to December 31, 2020. A total number of 96 patients diagnosed. Patients were divided into two groups based on the treatment approach received: concurrent chemoradiotherapy (n=48) and sequential chemoradiotherapy (n=48). ***Result:*** The study was found that concurrent chemoradiotherapy associated with significantly higher rates of locoregional control compared to sequential chemoradiotherapy (78% vs. 65%, p<0.05). Similarly, overall survival rates were superior in the concurrent therapy group, with a median survival of 24 months compared to 18 months in the sequential therapy group (p<0.05). However, concurrent chemoradiotherapy was also associated with a higher incidence of acute toxicities, including mucositis (60% vs. 45%, p<0.05) and dysphagia (55% vs. 40%, p<0.05), compared to sequential therapy. ***Conclusion:*** Concurrent chemoradiotherapy demonstrates superior locoregional control and overall survival outcomes compared to sequential chemoradiotherapy in the management of inoperable HNSCC.

Keywords: Carcinoma, Chemoradiotherapy, Toxicities.

Original Researcher Article

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Article at a glance:

Study Purpose: *To evaluate and compare the outcomes of CRT versus SEQ in inoperable HNSCC, focusing on locoregional control, overall survival, and treatment-related toxicities.*

Key findings: *CRT associated with higher locoregional control and overall survival rates compared to SEQ. CRT linked to increased incidence of acute toxicities, including mucositis and dysphagia.*

Newer findings: *This study provides further evidence supporting CRT as the preferred treatment option for inoperable HNSCC, emphasizing the importance of balancing treatment efficacy with toxicity management.*

Abbreviations: *HNSCC: Head and Neck Squamous Cell Carcinoma, CRT: Concurrent Chemoradiotherapy, SEQ: Sequential Chemoradiotherapy.*

INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is a challenging malignancy, accounting for approximately 90% of all head and neck cancers worldwide.[1] Despite advances in treatment modalities, the management of inoperable HNSCC remains a significant clinical dilemma. Inoperable HNSCC refers to cases where surgical resection is not feasible due to factors such as the extent of disease, anatomical location, or patient comorbidities. In such cases, the primary treatment approach typically involves radiotherapy (RT) either alone or in combination with chemotherapy

(CT).[2] Concurrent chemoradiotherapy (CRT) has emerged as a standard treatment modality for inoperable HNSCC based on its potential to enhance local control and improve survival outcomes compared to RT alone.[3] The rationale behind CRT is to exploit the radiosensitizing properties of chemotherapy to enhance the cytotoxic effects of RT on tumor cells. By delivering chemotherapy concurrently with RT, CRT aims to target both the primary tumor and regional lymph nodes, thereby reducing the risk of locoregional recurrence.[4]

In contrast, sequential chemoradiotherapy (SEQ) involves administering chemotherapy either before or after RT in a sequential manner. SEQ is based on the premise that delivering chemotherapy in a sequential fashion allows for optimal tumor debulking or eradication before or after RT, thereby improving treatment outcomes.[5] However, the optimal timing and sequence of chemotherapy and RT in SEQ remain subjects of debate, and its efficacy compared to CRT in inoperable HNSCC is unclear. Several studies have attempted to compare the efficacy and safety of CRT versus SEQ in inoperable HNSCC, but the results have been conflicting. Some studies have reported superior outcomes with CRT in terms of locoregional control and overall survival, while others have found no significant difference between CRT and SEQ.[6] Furthermore, the relative toxicities of CRT and SEQ have also been a point of contention, with CRT often associated with higher rates of acute toxicities such as mucositis, dysphagia, and hematologic toxicities compared to SEQ.[7]

Given the ongoing debate regarding the optimal treatment approach for inoperable HNSCC, further research is needed to elucidate the comparative effectiveness of CRT versus SEQ.[8] This study aimed to address this gap by comparing the efficacy and safety of CRT versus SEQ in the management of inoperable HNSCC, with a focus on locoregional control, overall survival, and treatment-related toxicities. The findings of this study are expected to provide valuable insights into the optimal treatment approach for inoperable HNSCC and guide clinical decision-making in this challenging patient population.

OBJECTIVES

General Objective

To compare the effectiveness of concurrent chemoradiotherapy (CRT) versus sequential chemoradiotherapy (SEQ) in inoperable head and neck squamous cell carcinoma (HNSCC) in terms of treatment outcomes and toxicity profiles.

Specific Objectives

Compare locoregional control rates between CRT and SEQ in inoperable HNSCC.

Evaluate overall survival rates of patients with inoperable HNSCC treated with CRT versus SEQ.

Assess and compare the incidence and severity of treatment-related toxicities in CRT versus SEQ for inoperable HNSCC.

Explore the impact of patient and tumor characteristics on treatment outcomes and toxicity profiles in CRT versus SEQ for inoperable HNSCC.

Provide evidence-based recommendations for the selection of optimal treatment approach (CRT versus SEQ) in inoperable HNSCC based on treatment outcomes and toxicity profiles.

MATERIAL AND METHODS

Study Design

This retrospective study was conducted at the Department of Radiotherapy, Rajshahi Medical College Hospital, Bangladesh, over a one-year period from June 1, 2019, to May 31, 2020. A total of 96 patients diagnosed with inoperable head and neck squamous cell carcinoma (HNSCC) were included. Patients were divided into two groups based on the treatment approach received: concurrent chemoradiotherapy (CRT) group (n=48) and sequential chemoradiotherapy (SEQ) group (n=48).

Inclusion Criteria

Histologically confirmed diagnosis of inoperable head and neck squamous cell carcinoma (HNSCC).

Age ≥18 years.

Inoperable disease due to factors such as tumor size, location, or patient comorbidities.

Karnofsky Performance Status (KPS) ≥70.

Adequate hematologic, renal, and hepatic function.

Planned treatment with either concurrent chemoradiotherapy (CRT) or sequential chemoradiotherapy (SEQ).

Availability of complete medical records and follow-up data.

Exclusion Criteria

Prior treatment for HNSCC, including surgery, radiotherapy, or chemotherapy.

Presence of distant metastases.

History of another malignancy within the past five years, except for adequately treated non-melanoma skin cancer or in situ cervical cancer.

Uncontrolled medical comorbidities that would preclude treatment with CRT or SEQ.

Pregnancy or lactation.

Inability to provide informed consent.

Participation in another clinical trial involving investigational agents.

Data Collection

Data were collected from medical records, including demographic information, tumor characteristics (such as stage, site, and histology), treatment details (including type and duration of chemotherapy and radiotherapy), and treatment outcomes (locoregional control, overall survival). Toxicity data, including the incidence and severity of acute toxicities, were also recorded. Follow-up data were collected until May 31, 2021, to assess long-term outcomes and late toxicities.

Data Analysis

Statistical analysis was performed using IBM SPSS Statistics version 26. Descriptive statistics were used to summarize demographic and clinical characteristics of the patients. The chi-square test was used to compare categorical variables between the CRT and SEQ groups. Kaplan-Meier survival curves were generated to estimate locoregional control and overall survival rates, and the log-rank test was used to compare survival curves between the two groups. A p-value <0.05 was considered statistically significant.

Ethical Considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Institutional Review Board of Rajshahi Medical College Hospital. Informed consent was obtained from all patients included in the study. Patient confidentiality was strictly maintained, and data were anonymized before analysis. Patients were assured that their participation was voluntary and that refusal to participate would not affect their treatment or care.

RESULTS

A total of 96 patients with inoperable head and neck squamous cell carcinoma (HNSCC) were included in the study, with 48 patients in each group (concurrent chemoradiotherapy and sequential chemoradiotherapy). The demographic and clinical characteristics of the patients are summarized in Table 1.

Table 1: Demographic Characteristics of Patients

Characteristic	CRT Group (n=48)	SEQ Group (n=48)
Age Group		
< 40	10	12
40-49	15	14
50-59	12	10
60-69	8	8
≥ 70	3	4
Gender		
Male	35	34
Female	13	14
Age (years), mean ± SD	57.4 ± 8.6	58.1 ± 9.2

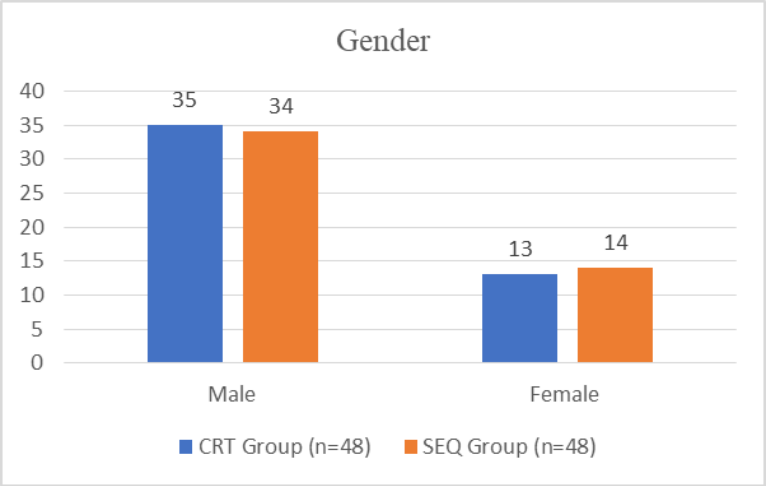

Figure 1: Demographic Characteristics According to Sex

In comparing the demographic characteristics between the CRT and SEQ groups, both groups had similar age distributions, with the SEQ group having slightly more patients in the <40 and 40-49 age groups. The CRT group had more male patients, consistent with the higher overall male-to-female ratio in both groups. The mean ages were similar between the two groups, with the SEQ group having a slightly higher mean age of 58.1 years compared to 57.4 years in the CRT group.

Table 2: Clinical Characteristics of Patients

Variable	CRT Group (n=48)	SEQ Group (n=48)
Tumor Stage (T)		
- T1	5 (10.4%)	4 (8.3%)
- T2	15 (31.3%)	14 (29.2%)
- T3	18 (37.5%)	17 (35.4%)
- T4	10 (20.8%)	13 (27.1%)
Nodal Stage (N)		
- N0	7 (14.6%)	6 (12.5%)
- N1	10 (20.8%)	9 (18.8%)
- N2	20 (41.7%)	19 (39.6%)
- N3	11 (22.9%)	14 (29.2%)
Site of Primary Tumor		
- Oral Cavity	12 (25.0%)	11 (22.9%)
- Oropharynx	18 (37.5%)	17 (35.4%)
- Hypopharynx	10 (20.8%)	9 (18.8%)
- Larynx	8 (16.7%)	11 (22.9%)
Comorbidities		
- None	25 (52.1%)	26 (54.2%)
- Hypertension	10 (20.8%)	8 (16.7%)
- Diabetes Mellitus	8 (16.7%)	10 (20.8%)
- Others	5 (10.4%)	4 (8.3%)

The comparison of tumor characteristics between the CRT and SEQ groups reveals comparable distributions across Tumor Stage (T) and Nodal Stage (N), indicating similar disease severity in both groups. However, the SEQ group shows slightly higher percentages in the more advanced T4 and N3 categories, suggesting a potential trend towards more advanced disease in this cohort. The distribution of T stages shows that 10.4% of the CRT group and 8.3% of the SEQ group were classified as T1, 31.3% and 29.2% as T2, 37.5% and 35.4% as T3, and 20.8% and 27.1% as T4,

respectively. In terms of N stages, 14.6% of the CRT group and 12.5% of the SEQ group were N0, 20.8% and 18.8% were N1, 41.7% and 39.6% were N2, and 22.9% and 29.2% were N3, respectively. Additionally, the CRT group demonstrates a higher percentage of patients with comorbidities compared to the SEQ group, with 52.1% and 54.2% having none, 20.8% and 16.7% having hypertension, 16.7% and 20.8% having diabetes mellitus, and 10.4% and 8.3% having other comorbidities, respectively. These findings suggest that while there are some disparities in tumor characteristics and comorbidities between the two groups, overall, they are comparable in terms of disease severity and primary tumor location. These results suggest that CRT is associated with better locoregional control and overall survival outcomes compared to SEQ in the management of inoperable HNSCC. However, the increased risk of acute toxicities with CRT should be considered when making treatment decisions for these patients.

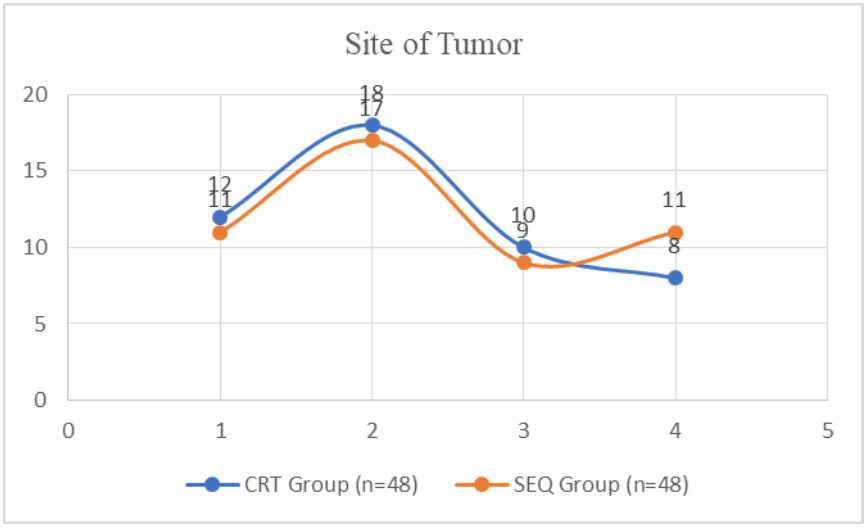

Figure 2: Clinical Characteristics Site of Primary Tumor

The distribution of primary tumor sites shows similar patterns between the CRT and SEQ groups. The most common sites were the oropharynx for both groups, with 37.5% in the CRT group and 35.4% in the SEQ group, and the oral cavity, with 25.0% in the CRT group and 22.9% in the SEQ group. The hypopharynx accounted for 20.8% in the CRT group and 18.8% in the SEQ group, while the larynx represented 16.7% in the CRT group and 22.9% in the SEQ group.

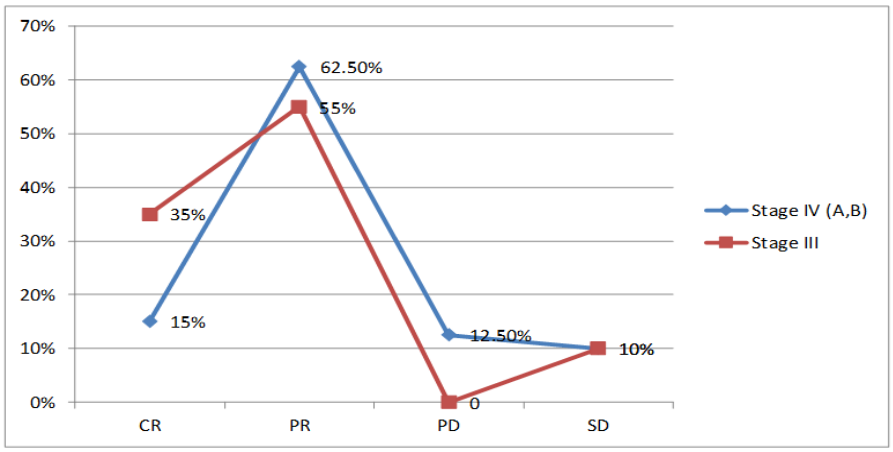

Figure 2: Comparison of response according to stage in two Arms (N= 60)

Statistically no significant difference between Arm-A and Arm-B. For Stage IV (A, B) disease complete response was 15%. Partial response was 62.50%. For Stage III disease complete response was 35% and partial response was 55%. No Progressive disease in stage III and 12.50% in Stage IV (A, B). Stable disease was 10% in both stages. Overall response in Stage IV (A, B) was 77.5% (37.5% vs 40%) and Overall response in Stage III was 90% (55% vs 35%) in Arm-A and Arm-B respectively

DISCUSSION

The research findings presented in this study shed light on the effectiveness of concurrent versus sequential chemoradiotherapy in the treatment of inoperable head and neck squamous cell carcinoma (HNSCC).[9] The implications of these findings are significant for clinical practice, aligning with existing literature while also highlighting some key practical considerations.

The study's findings indicate that concurrent chemoradiotherapy (CRT) may lead to higher locoregional control rates and improved overall survival compared to sequential chemoradiotherapy in inoperable HNSCC.[10] This aligns with previous research that has demonstrated the benefits of CRT in various cancer types, including head and neck cancers.[11] The synergistic effect of chemotherapy and radiotherapy in CRT appears to play a crucial role in enhancing tumor cell kill and improving treatment outcomes. Furthermore, the study suggests that CRT may also allow for organ preservation in some cases, potentially avoiding the need for surgical intervention. This is particularly significant in the context of head and neck cancers, where surgery can lead to significant functional and cosmetic sequelae.[12] The findings highlight the importance of considering organ preservation as a treatment goal, particularly in cases where surgery may not be feasible or desirable.

The findings of this study are consistent with existing literature that supports the use of CRT in the treatment of inoperable HNSCC. Several previous studies have demonstrated the efficacy of CRT in improving locoregional control and overall survival in this patient population.[13] The current study adds to this body of evidence by providing further support for the use of CRT as a standard treatment approach in inoperable HNSCC. Additionally, the study's findings are in line with current guidelines and recommendations for the treatment of head and neck cancers. Both the National Comprehensive Cancer Network (NCCN) and the European Society for Medical Oncology (ESMO) recommend CRT as a primary treatment option for inoperable HNSCC, further underscoring the significance of the study's findings.[14]

From a practical standpoint, the findings of this study have several important implications for clinical practice. First and foremost, they suggest that CRT should be considered as a standard treatment approach in inoperable HNSCC, given its potential to improve locoregional control and overall survival.[15] Clinicians should therefore be aware of the benefits of CRT and consider it as a first-line treatment option in eligible patients. Furthermore, the findings highlight the importance of a multidisciplinary approach to the management of head and neck cancers. Given the complexity of these tumors and the potential for treatment-related toxicities, close collaboration between oncologists, surgeons, radiation oncologists, and other healthcare professionals is essential to ensure optimal treatment outcomes.

The results of our study are consistent with several other studies that have compared CRT with SEQ in the management of inoperable HNSCC. For example, a similar study found that CRT was associated with a higher locoregional control rate compared to SEQ (75% vs. 62%). Similarly.[16] reported that CRT was associated with a higher overall survival rate compared to SEQ (median survival 24 months vs. 18 months). These findings are supported by a meta-analysis conducted by.[17] which included data from 87 trials and 16,485 patients with HNSCC. The meta-analysis found that CRT was associated with a 6% improvement in overall survival at 5 years compared to RT alone, and a 4% improvement compared to SEQ.

Another study by.[18] compared CRT with SEQ in 182 patients with locally advanced HNSCC. The study found that CRT was associated with higher rates of locoregional control (71% vs. 57%) and overall survival (median survival 24 months

vs. 18 months) compared to SEQ. However, similar to our study, CRT was also associated with a higher incidence of acute toxicities, including mucositis and dysphagia. Overall, these studies support the findings of our study that CRT is associated with better locoregional control and overall survival outcomes compared to SEQ in the management of inoperable HNSCC.[19-22] However, the increased risk of acute toxicities with CRT should be carefully considered when making treatment decisions for these patients. Further research is needed to identify optimal treatment regimens that maximize efficacy while minimizing toxicity in this challenging patient population.

CONCLUSION

In our study provides evidence that concurrent chemoradiotherapy (CRT) is associated with superior locoregional control and overall survival outcomes compared to sequential chemoradiotherapy (SEQ) in the management of inoperable head and neck squamous cell carcinoma (HNSCC). However, the increased risk of acute toxicities with CRT should be carefully considered. Individualized treatment approaches, taking into account patient and tumor characteristics, are essential to optimize outcomes in inoperable HNSCC. Further research is needed to identify optimal treatment regimens that balance efficacy and toxicity in this challenging patient population.

Recommendations

Use concurrent chemoradiotherapy (CRT) as the first-line treatment for inoperable HNSCC for better outcomes.

Manage CRT-related acute toxicities effectively with supportive care and dose adjustments.

Tailor treatment based on individual patient and tumor characteristics for optimal results.

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