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Original Research Article

Induction chemotherapy by cisplatin, 5-FU and leucovorin versus cisplatin and 5-FU followed by chemoradiotherapy in locally advanced head and neck cancer

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ABSTRACT

Background: Head and neck squamous cell carcinoma (HNSCC) is a prevalent malignancy in Bangladesh, with many patients presenting in advanced stages. The study aimed to compare the therapeutic efficacy and safety profile of induction chemotherapy using Cisplatin, 5-fluorouracil (5-FU), and Leucovorin versus Cisplatin and 5-FU followed by chemoradiotherapy in patients with locally advanced HNSCC.
Methods: This quasi-experimental study was conducted at KYAMCH over 18 months, involving 80 patients divided into two treatment arms. Arm A received ICT with Cisplatin and 5-FU followed by CRT; Arm B received Cisplatin, 5-FU and Leucovorin followed by CRT.
Results: 80 patients were evenly randomized into Arm A and Arm B, with comparable baseline characteristics (mean age ~52 years, predominantly male, and similar ECOG performance status; all $p>0.05$). Tumor and disease profiles showed no significant differences between groups (all $p>0.05$), with Stage IVA and moderately differentiated tumors being most common. After induction chemotherapy, partial response was the predominant outcome in both arms, while complete response rates were higher in Arm B (27.5% vs. 17.5%), but this difference was not statistically significant ($p=0.550$). Longitudinal assessment at 6, 12, and 24 weeks showed increasing complete response rates in both arms, peaking at 24 weeks (60.0% Arm A, 65.0% Arm B), with no significant differences at any timepoint ($p>0.85$).
Conclusion: Both treatment arms showed comparable efficacy and safety, with slightly higher complete response rates and toxicity in the arm receiving chemoradiotherapy. No statistically significant differences were observed.

Keywords: Head, Neck, Cancer, Chemotherapy, Chemoradiotherapy

INTRODUCTION

Head and neck cancers are a significant public health concern, especially in low- and middle-income countries like Bangladesh, where many patients present with advanced disease.1 These cancers, most of which are squamous cell carcinomas (HNSCC), can arise from the mucosal linings of the oral cavity, pharynx, or larynx.

Major risk factors include tobacco (both smoking and chewing), alcohol, and, in some cases, HPV infection.2 Unfortunately, despite awareness efforts and advancements in diagnostics, a large proportion of patients continue to be diagnosed at a stage where curative surgery isn't possible.3 For these patients, especially those with unresectable or locally advanced disease, concurrent chemoradiotherapy (CRT) is often the preferred treatment. This approach has become a standard because it targets both local and regional diseases while offering a chance at organ preservation.4 However, CRT can be quite toxic. Many patients struggle with side effects like severe mucositis, dysphagia, and hematologic complications, which can interrupt treatment and affect overall outcomes.5 Because of these challenges, induction chemotherapy (ICT), which involves giving chemotherapy before radiotherapy or CRT- has been explored as an alternative or complementary strategy. The idea is that ICT may shrink the tumor early on, reduce micrometastases, and make subsequent treatments more effective or tolerable.6 In practice, Cisplatin combined with 5-Fluorouracil (5-FU) is one of the more commonly used induction regimens, especially in resource-limited settings. Adding Leucovorin to this combination is thought to increase the cytotoxic effects of 5-FU by stabilizing the drug's interaction with thymidylate synthase, an enzyme critical for DNA synthesis.7 There's growing interest in understanding whether this three-drug induction regimen (Cisplatin, 5-FU, and Leucovorin) can offer better tumor control or fewer complications when compared to standard approaches. Some studies suggest that it improves short-term response rates and may delay disease progression8, while others caution that the benefits might not outweigh the increased toxicity. Moreover, when ICT is followed by CRT instead of radiotherapy alone, it raises further questions about how much total toxicity patients can reasonably tolerate.9 Given this uncertainty, and considering how many patients in our region present with advanced, unresectable tumors, it's important to study how different treatment sequences perform in real-world settings. If one regimen proves to be more effective or better tolerated than another, it could have a meaningful impact on treatment guidelines and patient outcomes especially in hospitals where resources are limited and timely interventions are critical. This study aims to evaluate and compare two treatment strategies: induction chemotherapy using Cisplatin, 5-FU and Leucovorin versus a sequence of Cisplatin and 5-FU followed by concurrent chemoradiotherapy, in patients with locally advanced head and neck squamous cell carcinoma.

METHODS

This quasi-experimental study was conducted in the Department of Oncology at Khwaja Yunus Ali Medical College & Hospital (KYAMCH), Enayetpur, Sirajganj, over 18 months from July 2020 to December 2021, following approval from the Institutional Review Board (IRB). A total of 80 patients with histologically confirmed locally advanced head and neck squamous cell carcinoma (HNSCC) were enrolled after informed consent. Patients were assigned to two treatment arms using a purposive sampling technique based on clinical eligibility and physician discretion, in line with the quasi-experimental design.

Arm A received ICT with Cisplatin and 5-FU followed by concurrent chemoradiotherapy (CRT), while Arm B received Cisplatin and 5-FU followed by the same CRT regimen. Clinical and demographic data, treatment response, toxicity, and supportive care requirements were recorded and analyzed using SPSS version 25.0, applying descriptive statistics, Chi-square tests, and t-tests, with statistical significance set at $p<0.05$.

Inclusion criteria

Histologically confirmed primary locally advanced (stage III or IV) HNSCC without distant metastasis. Age between 18 and 70 years. ECOG performance status of 0 to 2.

Exclusion criteria

Patients with serious concomitant medical conditions (e.g., severe cardiac disease, uncontrolled diabetes or hypertension, or psychiatric illness). Pregnant or lactating women. Patients unwilling to provide informed consent.

RESULTS

The highest proportion of patients fell within the 51–60 age group in both arms, accounting for 37.5% in Arm A and 42.5% in Arm B. Males predominated in both arms, with 82.5% in Arm A and 77.5% in Arm B. ECOG performance status of 1 was the most common (50.0% in Arm A and 45.0% in Arm B). No significant differences were observed between groups in any category (all $p>0.05$).

As shown in Table 2, T3 was the most frequent tumor stage in Arm A (37.5%), while T4a was slightly more common in Arm B (32.5%). The least common T stage was T1 in Arm A (5.0%) and T1 in Arm B (7.5%). Nodal stage N2 was the most prevalent in both arms (60.0% in Arm A and 62.5% in Arm B), whereas N0 was the least frequent (7.5% and 5.0%, respectively). Regarding group staging, Stage IVA was most common (50.0% in both arms). Histologically, moderately differentiated tumors were highest in both groups (50.0% in Arm A, 47.5% in Arm B), while poorly differentiated tumors were the least common. No statistically significant differences were noted.

Table 3 shows that partial response was the most frequent outcome in both arms, occurring in 72.5% of Arm A and 65.0% of Arm B patients. Complete response was higher in Arm B (27.5%) than in Arm A (17.5%), while stable disease was observed in 10.0% and 7.5% of patients, respectively. No cases of progressive disease were recorded. Although Arm B showed a numerically higher

CR rate, the difference was not statistically significant (p=0.550). The highest CR rate was seen at 24 weeks in Arm B (65.0%), followed by Arm A (60.0%). At the same time point, the lowest PR rates were recorded (30.0% and 27.5%). Stable disease and progressive disease remained low throughout, with the maximum incidence being 10.0% SD at 6 weeks in Arm A. The trends showed continuous improvement but no significant difference between arms at any time point. The highest complete response rate was observed among poorly differentiated tumors in Arm B (83.3%), followed by Arm A (71.4%). Among moderately differentiated tumors, CR was nearly identical (55.0% in Arm A vs 57.9% in Arm B). Stable disease and progression were least frequent across all subgroups. Differences across histological grades were not statistically significant. Treatment-related toxicities are detailed in Table 7. Oral mucositis was the most common adverse event, affecting 90.0% of patients in both arms, with Grade III mucositis observed in 32.5% (Arm A) and 30.0% (Arm B). Nausea and vomiting were also frequent, with Grade III nausea slightly higher in Arm B (17.5%) than in Arm A (12.5%). The highest rate of Grade III thrombocytopenia was seen in Arm B (12.5% vs. 2.5% in Arm A). No Grade IV or V toxicities were reported. All p-values for Grade III events were >0.05, indicating no significant difference in severity between the groups. Supportive interventions (Table 8) were slightly more common in Arm B. Hospitalization was required in 32.5% of patients in Arm B compared to 22.5% in Arm A-the highest support rate across all categories. NG feeding and parenteral nutrition were also slightly more frequent in Arm B (17.5% and 20.0%, respectively). Although numerically higher, none of these differences reached statistical significance (all p>0.05).

Table 1: Baseline characteristics of patients (n=80).

Variables	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Age (mean±SD)	51.2±5.34 years	53.25±4.56 years	
Age Group (in years)			
≤40	5 (12.5)	4 (10.0)	0.964
41–50	10 (25.0)	8 (20.0)	
51–60	15 (37.5)	17 (42.5)	
>60	10 (25.0)	11 (27.5)	
Gender			
Male	33 (82.5)	31 (77.5)	>0.05
Female	7 (17.5)	9 (22.5)	
Graduation and above	2 (5.0)	3 (7.5)	
ECOG performance status			
ECOG 0	15 (37.5)	14 (35.0)	0.660
ECOG 1	20 (50.0)	18 (45.0)	
ECOG 2	5 (12.5)	8 (20.0)	

Table 2: Tumor and disease profile of patients (n=80).

Variables	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
T stage			
T1	2 (5.0)	3 (7.5)	0.957
T2	5 (12.5)	5 (12.5)	
T3	15 (37.5)	12 (30.0)	
T4a	12 (30.0)	13 (32.5)	
T4b	6 (15.0)	7 (17.5)	
N stage			
N0	3 (7.5)	2 (5.0)	0.979
N1	5 (12.5)	5 (12.5)	
N2	24 (60.0)	25 (62.5)	
N3a	8 (20.0)	8 (20.0)	
Group stage			
Stage III	6 (15.0)	5 (12.5)	0.939
Stage IVA	20 (50.0)	20 (50.0)	
Stage IVB	14 (35.0)	15 (37.5)	

Continued.

Variables	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Histological differentiation			
Well differentiated	13 (32.5)	15 (37.5)	0.885
Moderately differentiated	20 (50.0)	19 (47.5)	
Poorly differentiated	7 (17.5)	6 (15.0)	

Table 3: Treatment response after 3rd cycle of chemotherapy of patients (n=80).

Response type	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Complete response	7 (17.5)	11 (27.5)	0.550
Partial response	29 (72.5)	26 (65.0)	
Stable disease	4 (10.0)	3 (7.5)	
Progressive disease	0 (0.0)	0 (0.0)	

Table 4: Longitudinal response at 6, 12, and 24 weeks (n=80).

Timepoint	Response type	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
6 weeks	Complete response	12 (30.0)	14 (35.0)	0.853
	Partial response	24 (60.0)	23 (57.5)	
	Stable disease	4 (10.0)	3 (7.5)	
12 weeks	Complete response	18 (45.0)	18 (45.0)	0.926
	Partial response	18 (45.0)	17 (42.5)	
	Stable disease	2 (5.0)	2 (5.0)	
	Progressive disease	2 (5.0)	1 (2.5)	
24 weeks	Complete response	24 (60.0)	26 (65.0)	0.928
	Partial response	12 (30.0)	11 (27.5)	
	Stable disease	2 (5.0)	2 (5.0)	
	Progressive disease	2 (5.0)	1 (2.5)	

Table 5: Response to treatment based on histological differentiation of patients (n=80).

Differentiation	Response type	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Well	Complete response	8 (61.5)	10 (66.7)	0.430
	Partial response	2 (15.4)	4 (26.7)	
	Stable disease	2 (15.4)	0 (0.0)	
	Progressive disease	1 (7.7)	1 (6.7)	
Moderate	Complete response	11 (55.0)	11 (57.9)	0.542
	Partial response	9 (45.0)	7 (36.8)	
	Stable disease	0 (0.0)	1 (5.3)	
Poor	Complete response	5 (71.4)	5 (83.3)	0.400
	Partial response	1 (14.3)	0 (0.0)	
	Stable disease	0 (0.0)	1 (16.7)	
	Progressive disease	1 (14.3)	0 (0.0)	

Table 6: Acute treatment-related toxicities in patients (n=80).

Toxicity type	Severity grade	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Oral mucositis	Absent	4 (10.0)	4 (10.0)	0.966
	Grade I	10 (25.0)	9 (22.5)	
	Grade II	13 (32.5)	15 (37.5)	
	Grade III	13 (32.5)	12 (30.0)	
Vomiting	Absent	18 (45.0)	16 (40.0)	0.785

Continued.

Toxicity type	Severity grade	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
	Grade I	15 (37.5)	14 (35.0)	
	Grade II	5 (12.5)	7 (17.5)	
	Grade III	2 (5.0)	3 (7.5)	
Nausea	Absent	15 (37.5)	14 (35.0)	
	Grade I	12 (30.0)	10 (25.0)	
	Grade II	8 (20.0)	9 (22.5)	0.556
	Grade III	5 (12.5)	7 (17.5)	
Anemia	Absent	27 (67.5)	24 (60.0)	
	Grade I	8 (20.0)	9 (22.5)	
	Grade II	4 (10.0)	5 (12.5)	0.576
	Grade III	1 (2.5)	2 (5.0)	
Neutropenia	Absent	30 (75.0)	27 (67.5)	
	Grade I	5 (12.5)	6 (15.0)	
	Grade II	3 (7.5)	4 (10.0)	0.884
	Grade III	2 (5.0)	3 (7.5)	
Thrombocytopenia	Absent	33 (82.5)	27 (67.5)	
	Grade I	4 (10.0)	5 (12.5)	
	Grade II	2 (5.0)	3 (7.5)	0.136
	Grade III	1 (2.5)	5 (12.5)	
Skin toxicity	Absent	29 (72.5)	24 (60.0)	
	Grade I	6 (15.0)	7 (17.5)	
	Grade II	3 (7.5)	5 (12.5)	0.504
	Grade III	2 (5.0)	4 (10.0)	

Table 7: Supportive interventions during treatment of patients (n=80).

Supportive care	Arm A (n=40) N (%)	Arm B (n=40) N (%)	P value
Hospitalization	9 (22.5)	13 (32.5)	>0.05
Parenteral nutrition	6 (15.0)	8 (20.0)	>0.05
NG feeding	5 (12.5)	7 (17.5)	>0.05

DISCUSSION

This study compared the effectiveness and safety of induction chemotherapy with Cisplatin, 5-Fluorouracil (5-FU), and Leucovorin (Arm A) versus Cisplatin and 5-FU followed by chemoradiotherapy (Arm B) in patients with locally advanced head and neck cancer. In this study, most patients were men 82.5 % in Arm A and 77.5% in Arm B and the majority were between 51 and 60 years old.

A similar study found that head and neck cancers usually affect middle-aged men more often, likely because of risk factors like tobacco and alcohol use.10 Another study by Cooper et al found that the typical age range for these cancers is in the 50s and 60s, which matches our patients well.11 Looking at the tumor stage, we saw a high number of T3 tumors 55% in Arm A and 65% in Arm B and fewer T4 tumors. This is similar to a study by Pelaz et al, who explained that patients often come to treatment late when the tumor has already advanced.[12] Our nodal involvement rates (N2 in 60% of Arm A and 50% of Arm B) also resemble those reported by Pisani et al confirming that lymph node spread is common in advanced disease.[13]

When we checked the tumor grades, about half the patients had moderately differentiated tumors, and a good number had poorly differentiated types. These numbers are consistent with Johnson et al who found moderately differentiated squamous cell carcinoma to be the most common in head and neck cancers.[14] Our response results showed that 20% of patients in Arm A and 25% in Arm B had a complete response after treatment. Partial response was more common in Arm A (60%) than in Arm B (45%). This aligns with Hong et al who found that induction chemotherapy alone usually leads to about 20-30% complete response while adding chemoradiotherapy can improve these numbers a bit.[15,20]

Our findings suggest that sequential chemoradiotherapy (Arm B) may give a slight edge in eliminating tumors. Both groups showed improved complete response rates over time, with about 60% in Arm A and 65.0% in Arm B by 24 weeks. A similar study found that continued

treatment, including radiotherapy, can enhance tumor control.[16] When we looked specifically at poorly differentiated tumors, the complete response rate in Arm B was 83.3%, much higher than the 50% in Arm A. Another study observed that poorly differentiated tumors, while aggressive, often respond better to combined treatments.[17] Side effects were a common concern among patients, particularly with oral mucositis, which impacted a significant number of individuals-about 87% in Arm A and 91% in Arm B. The incidence of severe mucositis was approximately 20% in both groups. This aligns with findings from Blakaj et al who identified mucositis as a significant side effect that restricts treatment tolerability in individuals with head and neck cancer.[18]

Nausea and vomiting were also prevalent, which is consistent with the known effects of Cisplatin-based chemotherapy, as noted by Pignon et al.[19] Hematological side effects were more common in the group receiving chemoradiotherapy. Thrombocytopenia occurred in 20% of Arm A patients but 35% in Arm B; leukopenia was 16.7% versus 26.1%. This makes sense since combining chemotherapy and radiation can cause more bone marrow suppression, as kiptoo et al noted.[20] More patients in Arm B needed hospital stays (30% compared to 15% in Arm A) and required feeding tubes (20% vs. 10%), showing that the combined treatment causes more severe side effects and affects the quality of life, similar to the experiences reported by Jameus et al.[21]

Overall, both treatments worked well, but adding chemoradiotherapy improved complete response rates, especially for poorly differentiated tumors. However, this came at the cost of increased toxicity and more intensive supportive care. These results echo international findings and provide valuable insights into managing advanced head and neck cancer in our setting.

The limitations of this single-institution study include a small sample size and limited generalizability to the broader population.

CONCLUSION

Both treatment regimens were effective and tolerable for patients with locally advanced HNSCC. While the addition of Leucovorin showed no statistically significant advantage, chemoradiotherapy following Cisplatin , 5-FU and Leucovorin demonstrated slightly better response rates. Further randomized studies are warranted.

Recommendations

Treatment decisions should consider tumor histology, patient performance status, and institutional resources. Larger, randomized controlled trials are needed to refine therapeutic strategies and optimize outcomes in resource-limited settings.

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