Original Article

A Comparative Study of Effectiveness of Induction Chemotherapy between Two Regimens in Locally Advanced Head and Neck Cancer d

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ABSTRACT

Introduction: Locally advanced head and neck cancer occurs when the tumor has grown beyond its point of origin but hasn't spread to other parts of the body. This cancer usually impacts the oral cavity, throat, larynx, and other structures in the head and neck area. Treating and predicting outcomes for locally advanced head and neck cancer can be quite challenging. **Objective:** The objective of this study is to evaluate the efficacy of the Leucovorin, 5-FU, Cisplatin (LFP) regimen in comparison to the Docetaxel, Cisplatin, 5-FU (DCF) regimen followed by external beam radiotherapy for managing advanced head and neck cancer and achieving locoregional control. Methods and Materials: The study was conducted in the Department of Oncology at Khwaja Yunus Ali Medical College and Hospital in Enayetpur, Sirajgonj. The study took place from October 2017 to March 2019. Patients who met the study's criteria and visited the KYAMCH Oncology OPD from October 2017 to March 2019 received induction chemotherapy using the LFP and DCF

regimen, followed by EBRT. Results: More men responded to treatment,

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especially with complete response (64.5%). Older patients (50-59) had higher complete response rates than younger (60-69). Moderate differentiation had the highest complete response rate (25%) compared to well and poorly-differentiated hospitalizations for toxicity management. Overall, most were mild (Grade 2). Neutropenia was most common (26.7% Grade 2, 13.3% Grade 3). Arm A had more radiotherapy-related toxicity than Arm B. **Conclusion:** Managing locally advanced head and neck cancer requires a comprehensive and team-based approach. Significant progress has been made in treatment options and supportive care, leading to better outcomes. However, getting the best results still depends on detecting issues early. Regular screening and awareness of risk factors are essential for early intervention and effective risk management.

Keywords: Neutropenia, Thrombocytopenia, Differentiation, Mucositis, Alopecia, Chemotherapy.

INTRODUCTION

Head and neck cancer ranks as the seventh most prevalent form of cancer globally, encompassing a wide range of tumors that impact the upper aerodigestive tract ^[1]. Head and neck cancers constitute approximately 10% of all cancers ^[2] they are named according to their location and subside in the head or neck. Worldwide, head and neck cancer accounts for more than 650,000 cases and 330,000 deaths annually ^[3].

In the United States, head and neck cancer accounts for 3 percent of malignancies, with approximately 53,000 Americans developing head and neck cancer annually and 10,800 dying from the disease ^[4].

In Europe, there were approximately 250,000 cases (an estimated 4% of the cancer incidence) and 63,500 deaths in 2012 ^[5]. Approximately 27% of these patients are women. Worldwide. approximately 600,000 patients are affected. Nearly 60% of this population presents with locally advanced but no metastatic disease. The usual time of diagnosis is after the age of 40, except for salivary gland and nasopharyngeal cancer (NPCs), which may occur in the younger age group ^[6]. There is no comprehensive statistics of HNC in our country like the developed countries. Still, according to some institution based study done in 1990 3399 new among cancer patients. attending the Department of Radiotherapy, Dhaka Medical College Hospital, revealed head and neck cancer is out of all malignancies about 33.15% in male. 20.78% in female and 28.68% in both sexes. The vast majority of head and neck cancer arises from surface epithelium and are therefore, squamous cell carcinoma (about 90%) or one of its many variants includes lymphoepithelioma, spindle cell verrucous carcinoma carcinoma. and undifferentiated carcinoma^[7].

Most head and neck malignant neoplasms arise from the surface epithelium and are SCC or one of its variants, including lymphoepithelioma, spindle cell carcinoma, verrucous carcinoma, and undifferentiated carcinoma. Lymphomas and a wide variety of other malignant and benign neoplasms make up the remaining cases ^[8]. Unfortunately, in our country, most of the patients with head and neck cancers attend the radiation oncology department in advanced stages, may be due to ignorance, poverty, lack of proper

referral system, illiteracy and some traditional belief. Head and neck region is the sole location of several functions, so called special senses (vision, hearing, balance, taste, speech and smell). Loss of function either by disease or by the treatment produces significant morbidity. Pronounced functional deficit and deformity associated with the disease heighten their relative importance.

Advanced head and neck cancer excision causes substantial morbidity despite better results. Chemotherapy and non-operative radiation improve. Patients with limited functional and structural damage get radiation. T1 and T2 primary lesions with negative cervical nodes: single-modality treatment. Minor nodal neck disease is treated surgically and radiologically. Surgery and treatment are needed for many T3 and T4 primary lesions with cervical node extension. Radiotherapy and chemotherapy are used when anatomy and medical conditions impede surgery. Modern radiation provides advantages over surgery, including avoiding serious surgery complications. Patients consider 1-2% surgical mortality high compared to radiation therapy mortality, which does not remove tissue. Even modest lesion removal can cause cosmetic and functional concerns, but prophylactic lymph node irradiation is safer than elective neck dissection.

Since radiation therapy or concurrent chemo radiotherapy has the advantage of preserving anatomical integrity, the sequential chemotherapy followed by radiotherapy, which has been studied for several decades, remains quite popular in many regions. Induction chemotherapy was developed clinically on the basis of following rationale ^[9] (a) The initial use of systemically active drug (Cisplatin and 5-FU) may reduce loco regional tumors burden and thus facilitate the ultimate complete irradiation of the tumors by radiotherapy, (b) microscopic systemic cannot be treated disease that by radiotherapy alone might be successfully treated with addition of chemotherapy to the treatment modality, (c) Patients who achieve a good partial or complete response to induction chemotherapy might help to avoid surgery and thus radiotherapy can cure the patient with good cosmoses and organ preservation.

the absence of Even in survival improvement, there seemed to be а correlation response between to chemotherapy and subsequent response to RT, which provided a basis for subsequent organ preservation initiatives ^[10]. Finally, patterns of failure were affected with less distant metastases in certain studies when induction chemotherapy was incorporated. As local-regional control improves, the clinically apparent rate of distant metastases is increasing ^[11] and induction chemotherapy is, on average, better tolerated than maintenance therapy as a way to give additional systemic therapy. Although induction chemotherapy before RT alone has not improved survival, investigations have speculated that, addition of induction chemotherapy to RT may decrease distant metastases and have an impact on survival. Several phase-II trials have reported good result with this approach ^[12].

Accurate tumor identification and multiple daily irradiation fractions for a given duration are required for treatment planning. The biological effect of radiation depends on energy absorption per tissue mass. Fractionation divides the dose into several fractions, usually given daily, usually five days a week. The fractionation concept follows radiobiology's four R's. These include sublethal damage repair, cell cycle rearrangement/reassortment, repopulation, reoxygenation, and radiosensitivity.

OBJECTIVE

General Objective:

To compare the effectiveness of treatment by LFP regimen (Leucovorin, 5-FU, Cisplatin) with DCF regimen (Docetaxel, Cisplatin, 5-FU) followed by external beam radiotherapy in locoregional control of advanced head and neck cancer management.

Specific Objective:

To assess the response of tumor after induction chemotherapy of two regimens and to assess the toxicities of the two regimens.

MATERIALS & METHODS

Study Design: Quasi-experimental study.

Place of Study: This study was conducted in the Department of Oncology, Khwaja Yunus Ali Medical College and Hospital, Enayetpur, Sirajgonj.

Duration of Study: October 2017 to March 2019.

Study population: Patients who attended the KYAMCH Oncology OPD during the period (From October 2017 to March 2019) and who meet the inclusion criteria of the study were enrolled in the study and treated with induction chemotherapy with LFP and DCF regimen followed by EBRT. **Sample Size: 60**

Sampling Technique: Convenient and purposive sampling.

Data collection Period: October 2017 to September 2018.

Selection of Patients:

A. Inclusion Criteria:

- Clinically diagnosed and histopathologically proved locally advanced head and neck carcinoma.
- 2. Stage III or IVA, B disease without distant metastasis.
- 3. Age: 18 to 70 years.
- 4. Patients are willing to be included in this study.
- 5. The patient must give informed written consent.

B. Exclusion criteria:

- 1. Patients with distant metastasis.
- 2. Initial surgery (excluding diagnostic biopsy) of the primary site.
- 3. Pregnant or lactating woman and uncontrolled infection.
- 4. Those who are not willing to be included in the study.

Study Method: Two groups of patient were studied – Every alternately

- Arm A: Thirty patients were enrolled in this arm and treated with induction chemotherapy by LFP regimen followed by radiotherapy.
- Arm B: Thirty patients were enrolled in this arm and treated with induction chemotherapy by DCF regimen followed by radiotherapy.

RESULTS

In arms A and B, 60 advanced head and neck cancer patients got chemotherapy. Arm A included 30 patients who received LFP induction chemotherapy and EBRT. An extra 30 patients got DCF induction

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chemotherapy for locally advanced Head and Neck Cancer in Arm B. Both arms had induction chemotherapy patients. 60 patients were enrolled and examined during and after induction chemotherapy, with 3 weekly or 21-day regimens for 3 cycles. Patients were examined during and after therapy per the follow-up schedule.

Figure-1 showing majority of the study subjects were from 50-59 years age group (Arm A 36.7%, Arm B 36.7%). Mean age of patients in Arm A was 52.97 ± 9.07 years and in Arm B was 50.80 ± 9.96 years. Only 10.0 % and 20 % patients were in 30-39 age group for the Arm A and B respectively.

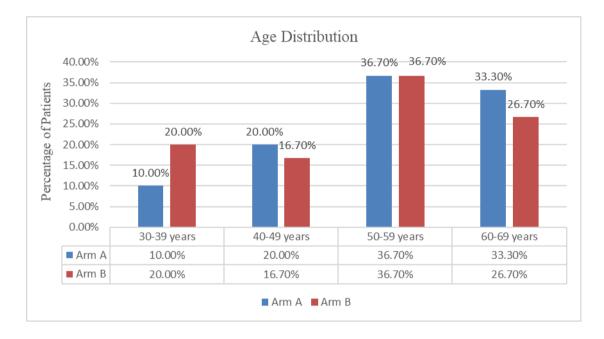


Figure-1: Bar diagram showing age distribution of the study subjects in both the arms.

Table I shows gender distribution in both arms. In both arms, male were more prevalent than female. In arm A, male were 24 (80.0%) and in arm B male were 17 (56.7%). In arm A, arm B, females were 06 (20.0%) and 13 (43.3%) and Male to Female ratio was 4:1 and 1.3:1 in Arm A and B respectively.

Table I: Distribution of patientsaccording to the gender.

Gender	Arm A	Arm B	Total	
	n(%)	n(%)	(N= 60)	
Male	24	17	41	
	(80.0%)	(56.7%)	(68.3%)	
Female	06	13	19	

(20.0%) (43.3%) (31.7%)

Table II Tobacco smoking was the dominant prevailing risk factor which was 35 (58.3%) of patients were smoker, 50 (83.3%) of patients were betel-nut user and 19 (31.7%) of patients had habit of tobacco-chewing in both arms.

Table II: Shows distribution of patients
according to risk factors in both arms.

Risk	Arm A	Arm B	<i>P</i> -	
Factor	(N %)	(N %)	Value	
Smoking	20	15	1.714	

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Habits	(66.7%)	(50.0%)	
Betel-Nut	24	26	0.480
user	(80.0%)	(86.7%)	
Tobacco-	10	9	0.077
chewing	(33.3%)	(30.0%)	

The *Table III* shows that the patients presented with common various clinical features. In Arm A 50% patients were presented with oral ulcerative lesion and difficulty in taking food, 43.3 % with neck

nodes, 33.3 % with difficulty in deglutition and 20.0% had pain in throat or pain in oral cavity and 3.3% were presented with weight loss. In Arm B 33.3 % patients presented with oral ulcerative lesion and difficulty in taking food, 26.7 % presented with neck nodes, 53.3 % with difficulty in deglutition, 26.7 % with pain in throat or pain in oral cavity and 6.7 % had weight loss.

Table III: Distribution of patients according to common various clinical features in both
arms

Presenting complaints	Arm A N (%)	Arm B N (%)	Total (N = 60)
Oral Ulcerative Lesion	15 (50.0%)	10 (33.3%)	24 (41.7%)
Difficulty in Deglutition	10 (33.3%)	16 (53.3%)	26 (43.3%)
Neck Nodes	13 (43.3%)	08 (26.7%)	21 (35.0%)
Pain in throat and or oral cavity	06 (20.0%)	08 (26.7%)	14 (23.3%)
Difficulty in taking food	15 (50.0%)	10 (33.3%)	25 (41.7%)
Hoarseness of Voice	0 (0.0%)	03 (10.0%)	03 (5.0%)
Weight Loss	01 (3.3%)	03 (10.0%)	4 (6.7%)
Neck Swelling	0 (0.0%)	02 (6.7%)	02 (3.3%)
Salivation and or Bleeding	01 (3.3%)	0 (0.0%)	01 (1.7%)

Table IV showing response after completion of 3^{rd} cycle of induction chemotherapy and it was seen that

response were more prevailed among male. Complete response was 20 (64.5 %), partial response 19 (73.1 %) respectively.

Table IV: Treatment response after 3rd Cycle chemotherapy in relation to gender for
both the arms.

Gender Distribution	Complete Response	Partial Response	Stable Disease	Progressive Disease	Total (N = 60)
Male	20 (64.5%)	19 (73.1%)	02 (66.7%)	0 (0.0%)	41 (68.3%)
Female	11 (35.5%)	07 (26.9%)	01 (33.3%)	0 (0.0%)	19 (31.7%)

Table V showing age group 50-59, complete response rate was 15 (68.2%)

and in age group 60-69 years, complete response was 7 (38.9%).

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Table V: Table: Treatment response after completion of 3^{rd} cycle of induction chemotherapy in relation to Age Group of Patients for both the arms (N = 60)

Treatment	Age	Age	Age	Age	Total
Response	Group	Group	Group	Group	P-Value
	30-39	40-49	50-59	60-69	$(\mathbf{N}=60)$
	years	years	years	years	
Complete	04	05	15 (68.2%)	07 (38.9%)	31 (51.7%)
Response	(44.4%)	(45.5%)	07 (31.8%)	09 (50.0%)	0.821
Partial Response	04	06	00 (0.0%)	02 (11.1%)	26 (43.3%)
Stable Disease	(44.4%)	(54.5%)	0 (0.0%)		0.673
Progressive	01	00 (0.0%)			03 (50.0%)
Disease	(11.1%)	0 (0.0%)			0.301

Overall Complete Response of Well, Moderate and Poorly differentiated carcinoma was 25.0%, 15.6% and 20.0%. Complete Response was more in moderately differentiated carcinoma.

Table VI: Response of treatment after completion of 3rd cycle of induction chemotherapy according to the histological grading for both the arms

Histological	Arm A	Arm B	Total	Р-
Differentiation	(N %)	(N %)	(N = 60)	Value
Well	CR: 03 (50.0%)	CR: 02 (22.2%)	CR: 05 (25.0%)	0.517
differentiated	PR: 06 (54.4%)	PR: 07 (77.8%)	PR: 13 (65.0%)	
	SD: 02 (18.2%)	SD: 0 (0.0%)	SD: 02 (10.0%)	
Moderately	CR: 02 (13.3%)	CR: 03 (17.6%)	CR: 05 (15.6%)	0.930
Differentiated	PR: 11 (73.3%)	PR: 08 (47.1%)	PR: 19 (59.4%)	
	SD: 02 (13.3%)	SD: 06 (35.3%)	SD: 08 (25.0%)	
Poorly	CR: 01 (33.3%)	CR: 0 (0.0%)	CR: 01 (20.0%)	0.104
Differentiated	PR: 02 (66.7%)	PR: 02 (100.0%)	PR: 04 (80.0%)	
Undifferentiated	PR: 01 (100%)	CR: 01 (50.0%)	PR: 02 (66.7%)	
	SD: 00 00.0%)	PR: 01 (50.0%)	SD: 01 (33.3%)	

Table VII shows none of the patients needed hospitalization for toxicity management. Dose of 5-FU was reduced to 50% in one patient in arm A and one patient in arm B. Different kinds of toxicities presented in patients of both arm during the course of treatment. The most common toxicity was Grade 2, 3

neutropenia (26.7% and 13.3% respectively). Toxicities included Grade 2, 3 mucositis (26.7%, 6.7%), Grade 2 thrombocytopenia (6.7%), Grade 2 diarrhea (20.0%), Grade 2 nausea (33.3%) and Grade 2 vomiting (16.7%). However, there was no treatment related death. P-value pulled form chi-square test.

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Variables of	Arm A	Arm B	Total	P-Value
Toxicity	N (%)	N (%)	(N = 60)	
Mucositis				
Grade 1	10 (33.3%)	14 (46.7%)	24 (40.0%)	
Grade 2	8 (26.7%)	05 (16.7%)	13 (21.7%)	0.619
Grade 3	2 (6.7%)	03 (10.0%)	05 (8.3%)	
Nausea				
Grade 1	20 (66.7%)	20 (66.7%)	40 (66.7%)	0.608
Grade 2	10 (33.3%)	10 (33.3%)	20 (33.3%)	
Vomiting				
Grade 1	12 (40.0%)	10 (33.3%)	22 (36.7%)	0.773
Grade 2	05 (16.7%)	07 (23.3%)	12 (20.0%)	
Anaemia				
Grade 1	10 (33.3%)	13 (43.3%)	23 (38.3%)	0.696
Grade 2	05 (16.7%)	05 (16.7%)	10 (16.7%)	
Neutropenia				
Grade 1	18 (60.0%)	18 (60.0%)	36 (60.0%)	
Grade 2	08 (26.7%)	06 (20.0%)	14 (23.3%)	0.710
Grade 3	04 (13.3%)	06 (20.0%)	10 (16.7%)	
Thrombocytopenia				
Grade 1	09 (30.0%)	08 (26.7%)	17 (28.3%)	0.686
Grade 2	02 (6.7%)	04 (13.3%)	06 (10.0%)	

Table VII : Toxicities Grading (Mucositis, Nausea, Vomiting, Anaemia, Neutropeniaand Thrombocytopenia) after completion of 3rd cycle of induction chemotherapy for
both the arms

Table VIII shows the toxicities of grading(Diarrhoea, Alopecia, Weight Loss, SkinToxicity and Renal impairment) after

completion of 3rd cycles of Induction Chemotherapy for both the Arms. The pvalue was not statistically significant.

Table VIII: Toxicities Grading

Variables of Toxicity	Arm A N (%)	Arm B N (%)	Total (N= 60)	P-Value
Diarrhoea	Ν (70)	1 (70)	(11-00)	
	00(2000)		16 (06 70())	
Grade 1	09 (30.0%)	07 (23.3%)	16 (26.7%)	
Grade 2	06 (20.0%)	04 (13.3%)	10 (16.7%)	0.298
Grade 3	0.0 (0.0%)	03 (10.0%)	03 (5.0%)	
Alopecia				
Grade 1	17 (56.7%)	15 (50.0%)	32 (53.3%)	

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Grade 2	04 (13.3%)	05 (16.7%)	09 (15.0%)	0.866
Weight Loss				
Grade 1	08 (26.7%)	07 (25.0%)	15 (25.0%)	
Grade 2	08 (26.7%)	07 (25.0%)	15 (25.0%)	0.946
Grade 3	02 (6.7%)	03 (8.3%)	05 (8.3%)	
Skin toxicity				
Grade 1	07 (23.3%)	08 (26.7%)	15 (25.0%)	
Grade 2	06 (20.7%)	06 (20.0%)	12 (20.0%)	0.938
Grade 3	02 (6.7%)	03 (10.0%)	05 (8.3%)	
Renal impairment				
Grade 1	07 (23.3%)	08 (26.7%)	15 (25.0%)	
Grade 2	01 (3.3%)	02 (6.7%)	03 (5.0%)	0.781

Tables IX shows that overall radiotherapyrelated toxicities were more in arm A than those of arm B. Grade 2, 3 oral mucositis were found almost similar in both arms. Other toxicities such as nausea, anemia were almost similar in quantity in both arms.

Variables of	Arm A	Arm B	Total	P-Value
Toxicity	N (%)	N (%)	(N = 60)	
Mucositis				
Grade 1	06 (20.0%)	08 (26.7%)	14 (23.3%)	
Grade 2	11 (36.7%)	11 (36.7%)	22 (36.7%)	0.926
Grade 3	12 (40.0%)	10 (33.3%)	22 (36.7%)	
Grade 4	01 (3.3%)	01 (3.3%)	02 (3.3%)	
Nausea				
Grade 1	11 (36.7%)	11 (36.7%)	22 (36.7%)	0.930
Grade 2	04 (13.3%)	05 (16.7%)	09 (15.0%)	
Anaemia				
Grade 1	06 (20.0%)	06 (20.0%)	12 (20.0%)	
Grade 2	07 (23.3%)	04 (13.3%)	11 (18.3%)	0.783
Grade 3	01 (3.3%)	01(3.3%)	02 (3.3%)	

Table IX: Toxicities (Mucositis, Nausea and Anaemia) in both arms during and after
radiotherapy.

Table X shows the Toxicities (WeightLoss, Skin Toxicity, Xerostomia and Lossof taste sensation) in both arms during and

after radiotherapy. The association between different grade was not significant.

Table X: Toxicities in both arms during and after radiotherapy.

Variables of Toxicity	Arm A	Arm B	Total	P-Value
	N (%)	N (%)	(N = 60)	
Weight Loss				
Grade 1	05 (16.7%)	04 (13.3%)	09 (15.0%)	
Grade 2	01 (3.3%)	02 (6.7 %%)	03 (5.0%)	0.801
Skin toxicity				
Grade 1	14 (46.7%)	16 (53.3 %)	30 (50.0%)	
Grade 2	12 (40.0%)	11 (36.7%)	23 (38.3%)	0.825
Grade 3	04 (13.3%)	03 (10.0%)	07 (11.7%)	
Xerostomia				
Grade 1	9 (30.0%)	11 (36.7%)	20 (33.3%)	
	02 (6.7%)	02 (6.7%)	04 (6.7%)	0.856
Grade 2				
Loss of taste Sensation	16 (53.3%)	18 (60.0%)	34 (56.7%)	

Table XIshows the final result of thisstudy at 3^{rd} follow-up (at week 30). In armAcomplete response was 80% andprogressive disease was seen in 10% of

enrolled patients. In arm B those were 83.3% and 16.7% respectively. Treatment response was not significant (P-value 0.50).

 Table XI: Distribution of patients according to response pattern at 3rd (final) follow-up after completion of treatment.

Treatment Group	Complete Response	Progressive Disease	X ² Value	P-Value
Arm A	24 (80.0%)	06 (20.0%)	0.111	0.50
Arm B	25 (83.3%)	05 (16.7%)		

DISCUSSION

In this study 60 patients who were enrolled, were histologically or cytologically proven to have locally advanced (Stage III or Stage IVA, B) Head-Neck Cancer. The tumor was at inoperable state and had not received any definitive oncologic treatment. The patients were studied randomly in two different arms, Arm A and Arm B. Arm A was given treatment with chemotherapy with LFP (Leucovorin, 5-FU, Cisplatin) regimen and DCF (Docetaxel, Cisplatin, 5-FU) regimen in arm B followed by EBRT in locally advanced Head-Neck cancer. Most of the patients in this study were male and male to female ratio is 4:1 in arm A and 1.3:1 in arm B. In arm A, male 24 (80.0%), in arm B 17 (56.7%). In arm A, female 06 (20.0%), in arm B, female was 13 (43.3%). The usual time of diagnosis is after the age of 40, except for salivary gland and nasopharyngeal cancer (NPCs), which may occur in the younger age group ^[6] this age group and gender percentage were correlates with another study ^[6]. There are 22 (36.7%) patients of age group 50-59 and 18 (30.0%) patients of age

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group 60-69 was affected by malignancy. Mean age of patients was for Arm A 52.97± 9.07 years and for Arm B 50.80±9.96 years. The youngest patient was 32 years old and eldest was 67 years. The Meta-Analysis of Chemotherapy in Head and Neck Cancer (MACH-NC) included 63 randomized trials published from 1965 to 1993, all of which were compared with local-regional treatment with or without chemotherapy, here survival benefit diminished with patient age and, on subset analysis, was not significant in patients over 70 years of age. Head and Neck cancers are very rare below 18 years of age, so 18 to 70 years age group was considered in this study.

In this study shows 35 (58.3%) of patients were smoker, 50 (83.3%) of patients were betel-nut with caustic lime user and 19 (31.7%) of patients were tobacco-chewing in both arms.

In two separate studies ^[7] and describe tobacco use as a greatest risk for head and neck cancer in Indian sub-continent ^[13]. Different kinds of acute toxicities were observed in the patients of both arms course during the of induction chemotherapy. All toxicities among two arms showed no statistical significant differences. Alopecia grade 2 in Arm A was 04 (13.3%) and in arm B was 05 (16.7%). In Arm A and B grade 2 anemia occurred in 05 (16.7%), grade 3 neutropenia in arm A 04 (13.3%) and 06 (20.0%) in this study but neutropenia was grade 3 or 4 in 41% and 18% of patients, respectively ^[14]. Thrombocytopenia grade 2 was 02 (6.7%) in arm A and 04 (13.3%) in arm B. Mucositis grade 3 in arm A, 2 (6.7%) and 03 (10.0%) in arm B but Grade 3 or 4 mucositis was noted in 7% and 3% of Patients, respectively [14], grade 2

nausea in both arms was 10 (33.3%), grade 2 vomiting 05 (16.7%) in arm A, 07 (23.3%) in arm B. In arm A, grade 3 diarrhea was 0.0 (0.0%) and 03 (10.0%) in arm B. Weight loss grade 3 was 02 (6.7%) in arm A and 03 (8.3%) in arm B. Grade 2 renal impairment was 01 (3.3%) in arm A and 02 (6.7%) in arm B. Chemotherapy induced skin toxicity grade 3 was 02 (6.7%) in arm A, 03 (10.0%) in arm B.

After completion of EBRT, radiation induce Grade 3 mucositis was 12 (40.0%) and Grade 4 was 01 (3.3%) for arm A and Grade 3 mucositis for arm B was 10 (33.3%) and Grade 4 was 01 (3.3%). Radiation induced Grade 2 dermatitis for arm A was 06 (20.7%), Grade 3 was 02 (6.7%) and for arm B, Grade 2 was 06 (20.0%),Grade was 03 (10.0%). Xerostomia for arm A was 11 (36.7%) and for arm B was 12 (40.0%). Loss of taste sensation for arm A was 16 (53.3%) and for arm B was 18 (60.0%). Grade 2 weight loss for arm A was 02 (6.7%) and for arm B was 02 (6.7 %). Grade 2 anemia was 07 (23.3%) for arm A and for arm B was 04 (13.3%), for arm A was Grade 3 anemia for arm A and B was 01 (3.3%).

At 1^{st} follow-up after completion of treatment CR was 66.7%, PR was 26.7% and PD was 6.7%. At 2nd follow-up after completion of treatment CR was 78.3%, PR was 11.7% and PD was 10.0% and after completion of 3rd cycles induction chemotherapy, complete response was 06 (20%), partial response 20 (66.7%) and stable disease was 04 (13.3%) in arm A. In arm B, Complete response was 05 (16.7%), partial response 18 (60.0%) and stable disease was 07 (23.3 %). Chi-Square Value (X^2) 1.014 and P-value 0.602. At 3rd follow-up (at weeks 30), in arm at 3rd follow-up (at weeks 30) in arm A complete response was 24 (80%) and progressive disease was seen in 06 (10%) of enrolled patients and in arm B those were 25 (83.3%) and 05 (16.7%) respectively.

In current study, after completion of 3rd cycle induction chemotherapy, complete response was observed in 06 (20%) patients. Partial response was seen in 20 (66.7%) and stable disease was 04(13.3%)in subjects with LFP regimen. In those patients receiving DCF regimen, complete response was revealed in 05 (16.7%) subjects, partial response in 18 (60.0%) and stable disease was 11 (23.3 %) although statistically overall treatment responses were not significant in two group. In a comparable study by a separate study¹⁴, it was seen that complete response was observed in 10 (24%) patients, partial response was seen in 22 (52%) and stable disease was 05 (12%) in subjects with LFP receiving. In almost similar study by a separate study ^[15], complete response was observed in 23 (66 %) patients, partial response was seen in 05 (14 %) subjects with LFP receiving.

In this study, induction chemotherapy with LFP regimen showed similar tumour control with acceptable toxicities in comparison to DCF regimen. But the LFP regimen is low priced as well as cost effective than that of DCF regimen.

CONCLUSION

The purpose of this study was to assess the effectiveness of induction chemotherapy using the LFP and DCF regimen, followed by EBRT, in patients with locally advanced Head and Neck Cancer. The complete response rate, local tumor control, and acute toxicities were similar

between LFP induction chemotherapy and the DCF regimen. Additional research is required to validate the effectiveness of LFP and assess its potential influence on local tumor control, disease-free survival, and overall survival.

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