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Demographic Characteristics of Locally Advanced Laryngeal Cancer with Concurrent Chemo Radiotherapy along with Weekly Paclitaxel versus Weekly Cisplatin in Rajshahi Medical College

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Abstract

Modern multi-modality approaches using definitive concurrent chemoradiation has shown promising results in the treatment of locally advanced laryngeal cancer with intact cartilage and functional larynx. The aim of this study to estimate demographic Characteristics of Locally Advanced Laryngeal Cancer with Concurrent Chemo Radiotherapy along with Weekly Paclitaxel versus Weekly Cisplatin. This quasi-experimental study was conducted at the Department of Radiotherapy, Rajshahi Medical College Hospital, from January 2021 – June 2022 following ethical approval. Total 60 patients with locally advanced squamous cell carcinoma of larynx were included and divided into Arm-A (n=30) and Arm-B (n=30). After taking informed written consent, patients were given injection paclitaxel 30mg/m2 (Arm-A) or injection cisplatin 40mg/m2 (Arm-B) along with radiotherapy 66Gy in 33 fractions over 6.5 weeks. In this study, mean age of all study patients was 56.03±8.88 (SD) years with male predominance (88.3%). Demographic characteristics were similar across the two arms regarding age, gender, and tobacco history (p>0.05). Treatment response was evaluated at 6, 12 and 24 weeks after the completion of treatment. In Arm- A 80.00% showed complete response whereas in Arm- B showed 70.00%. Partial response was 20.00% and 30.00% in Arm-A and Arm-B respectively. Both Arm-A and Arm-B had similar rate of treatment response at each follow up (p>0.05).

Keywords: Concurrent, Chemotherapy, Laryngeal Carcinoma, Toxicities

Introduction

Head and neck cancer is imposing a great threat to mankind worldwide. It is the sixth most common malignancy globally among adults (GLOBOCAN 2020). Overall 57.5% of global head and neck cancer occur in Asia, especially in India [1]. Laryngeal cancer is the most common head and neck malignancy of upper aero digestive tract [2]. The current incidence, prevalence and mortality of laryngeal cancer in world are estimated at 2.76 cases/year per 100,000 inhabitants, 14.33 cases/year per 100,000 inhabitants and 1.66 deaths/year per 100,000 inhabitants [3]. It is one of the seventh leading cancers in Indian sub-continent. In Bangladesh, laryngeal cancer is ranked as 9th common cancer with 3.4% new cases per year and 3% deaths per year (GLOBOCAN 2020). Squamous cell carcinoma (SCC) is the most common type of laryngeal cancer, accounting for approximately 95 % of all cases of laryngeal carcinoma. In Bangladesh, laryngeal cancer is ranked as 9th common cancer with 3.4% new cases per year and 3% deaths per year (GLOBOCAN 2020). Squamous cell carcinoma (SCC) is the most common type of laryngeal cancer, accounting for approximately 95 % of all cases of laryngeal carcinoma [4].

Laryngeal cancer accounts for 4% of cancers in the United States and 5% in South Asia. According to the National Cancer Institute's SEER (Surveillance, Epidemiology and End Results Program) Cancer Statistics Review, an estimated 12,370 men and women in the United States will have been diagnosed with laryngeal squamous cell carcinoma by 2020 [3]. Cigarette smoking and alcohol abuse contribute for about 90% of overall worldwide mortality for laryngeal cancer. According to a recent WHO study, there are 49000 oral cancer cases, 71000 pharynx and laryngeal cancer cases in Bangladesh among those aged ≥30 years. According to the same study, cancers of the oral cavity, larynx, and lungs account for 3.6% of admissions in medical college hospitals for the same age group [5]. Approximately 29% of all laryngeal cancer cases presented as locally advanced at the time of diagnosis. TNM staging classifies locally advanced laryngeal cancer as stages III-IVB [6]. Radiotherapy and concurrent chemotherapy have become the mainstay of treatment for locally advanced laryngeal cancer due to the difficult surgical approach and devastating functional morbidity associated with surgery [7].

These gains in local control and survival, however were achieved at the price of significant functional morbidity from total laryngectomy, the sequelae of which include loss of natural voice, permanent tracheostomy and alteration in swallowing function that often result in social stigmatization and psychological disturbances [8]. Concurrent chemoradiotherapy refers to a treatment technique for malignant diseases where chemotherapy is given simultaneously during the period of application of radiotherapy. Concurrent chemoradiation (CCRT) has shown promising results in treatment of stage III and IV laryngeal cancer with intact cartilage and functional larynx. Chemotherapy agents administered in the induction or concurrent setting comprise of taxanes (docetaxel, paclitaxel), platinum compounds (cisplatin, carboplatin) and fluorouracil (TPF) and many more (National Comprehensive Cancer Network 2018). However, the optimal timing, dosing, and selection of systemic agents are debatable. Despite the fact that cisplatin is still the most widely accepted standard chemotherapy for radiation sensitization, the toxicities are significant. Because of its ability to repair sub-lethal damage, bind thiols and induce chromosomal aberrations, carboplatin has radiation sensitizing properties. It is less nephrotoxic, neurotoxic, and ototoxic than cisplatin. Paclitaxel is a newer active single agent in head and neck cancer. Paclitaxel is also a potent radiosensitizer, as evidenced in pre-clinical and clinical trials, due to its ability to induce cell cycle arrest in the G2/M phase. Observation suggests that paclitaxel induces microtubule stabilization, and a cell cycle blockade at the G2 phase to mitosis (G2/M) transition, 3the most radio-sensitive portion of the cell cycle [9]. An additional mechanism seems to involve enhanced tissue oxygenation. Recently it was shown that paclitaxel activates c-Jun-terminal-kinase (JNK) or protein-kinase A (PKA), leading to the phosphorylation of the antiapoptotic Bcl-2 protein. Phosphorylation of Bcl-2 decreases its binding to the proapoptotic Bax protein and an increase in the free Bax level promotes apoptosis. This apoptotic effect of paclitaxel is independent of the p53 pathway [10, 11]. In a single small phase III trial, a weekly paclitaxel concurrent regimen appeared equivalent to a weekly cisplatin concurrent schedule. However the data must be considered limited. The aim of this study to estimate demographic Characteristics of Locally Advanced Laryngeal Cancer with Concurrent Chemo Radiotherapy along with Weekly Paclitaxel versus Weekly Cisplatin.

Methods

This quasi-experimental study was conducted in Department of Radiotherapy, Rajshahi Medical College Hospital, Rajshahi. The duration of the study period was one year and six months **(**from January 2021 to June 2022). Purposive sampling technique was applied for this study. Patients were selected from Department of Radiotherapy, Rajshahi Medical college Hospital. Total 60 patients were taken as sample. After selecting patients, a written informed consent was taken from each patient before his/her participation in the study. Necessary clinical examination and investigations were done and documented in semi-structured data collection sheet.

In arm- A Before chemotherapy administration, BSA was determined by using Mosteller formula and dose of drug was calculated. Average BSA was 1.4 m2 and average dose of paclitaxel was 42 mg. Usual premedication was given mixed with 500 ml normal saline over 1 hour prior to paclitaxel infusion. Injection paclitaxel 30 mg/m2 mixed with 500 ml normal saline administered and started very slowly at 5-10 drop/min for first 10- 15 minutes then increased gradually and completed over 1 hour was given on day 1, weekly schedule. During the first ten minutes of infusion Pulse and BP were monitored. For paclitaxel, patients were receive oral dexamethasone 12 mg, antihistamine (pheniramine 75 mg) and proton pump inhibitor (omeprazole 20 mg), beginning 1 day before drug administration to reduce the incidence and severity of fluid retention and hypersensitivity reactions, radiotherapy was delivered within 1.5 hours after chemotherapy.

In arm-B, Before chemotherapy administration, BSA was determined by using Mosteller formula and dose of drug was calculated. Average BSA was 1.4 m2 and average dose of cisplatin was 56 mg. Total 2 liter fluid was administered. Usual premedication mixed with 500 ml normal saline administered over 1 hour prior to cisplatin infusion. Then injection cisplatin 40 mg/m2 mixed with 500 ml normal saline and administered over 1 hour. 1000 ml normal saline given as postmedication hydration over 2 hours. followed by injection Lasix 1 ampoule intravenous administration. Radiotherapy was delivered within 1.5 hours after chemotherapy.

Inclusion criteria

- Patients with histopathologically confirmed locally advanced squamous cell laryngeal cancer (stage III to IVB).

Exclusion criteria

- Age below 18 years and above 75 years.
- Patients Eastern Co-operative Oncology Group (ECOG) performance status score >2.
- Initial surgery (excluding diagnostic biopsy) of the primary site.
- Patients with history of prior chemotherapy or radiotherapy to the head and neck region.
- Patients with double primaries.
- Pregnant or lactating woman.
- Serious concomitant medical illness.

Data processing and analysis

The data was tabulated in separate tables for both Arm-A and Arm-B. It was checked, edited, coded manually and entered into computer. Data analysis was done according to the objectives of the study by using the SPSS (Statistical Package for Social Science) software program for windows, version 25.0 available in the institute. The results were presented in tables, figures, diagrams. All reported p values were two sided and $p < 0.05$ was considered statistically significant.

Table 1: Age distribution of patients in two arms (N= 60)

Age group (in years)	Arm A (n=30)		Arm B (n=30)		Total (N=60)		P-value*
	n	%	n	%	n	%	
31-40 8.3	2	6.7	3	10	5		0.751
41-50 10	3	10	3	10	6		
51-60 50	17	56.7	13	43.3	30		
61-75 31.5	8	26.6	11	36.7	19		
Mean±SD	55.83 ± 8.84		56.23±9.06		56.03 ± 8.88		

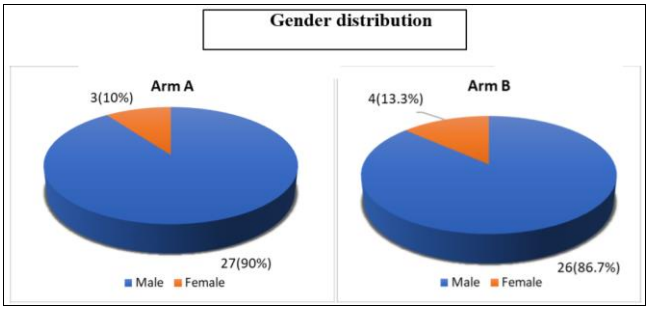


Fig 1: Distribution of patients according to gender(N=60)

Result

Socio-demographic characteristics of the respondents (N=60)

The above Table 1 shows that mean age of all patients was 56.03±8.88 years (range: 32-70). Majority of the patients were more than 50 years of age (81.7%) in both arms. There wasn't any significant difference in terms of age distribution between two groups when compared as the p-value was >0.05.

The above Fig 1 shows majority of the patients were male from both arms, 27 (90.0% of Arm-A) and 26 (86.7% of Arm-B), ratio was 7.3**:**1. But there wasn't any significant difference regarding gender distribution between two arms as the p-value was >0.05.

The below Fig 2 shows majority of the patients from both arms completed their primary education, 10 (33.3%) of Arm A and 8 (26.7%) of Arm B. There wasn't any significant difference regarding educational status between two arms when compared as the p-value was >0.05.

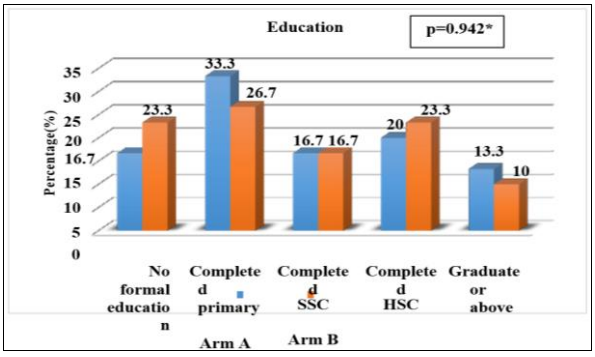


Fig 2: Distribution of patients according to educational status (N=60)

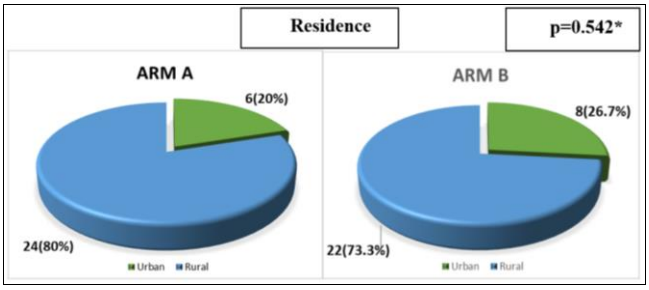


Fig 3: Distribution of patients according to residence between arms (N=60)

Fig 3 shows majority of the patients from both arms were from rural area, 24 (80.0%) of Arm A and 22 (73.3%) of Arm B. But there wasn't any significant difference regarding the residence between two arms (p>0.05).

The Table 2 illustrates distribution of patients according to risk factors. Among all the patients of both arms, 75.0% had positive history of smoking, 8.3% had positive alcohol consumption history, 26.7% had betel nut chewing history and 15.0% had positive tobacco leaf/jarda history. The majority of the patients from both arms had history of smoking, 23 (76.7%) of Arm A and 22 (73.3%) of Arm B.

Table 2: Risk factors of patients in two arms (N = 60)

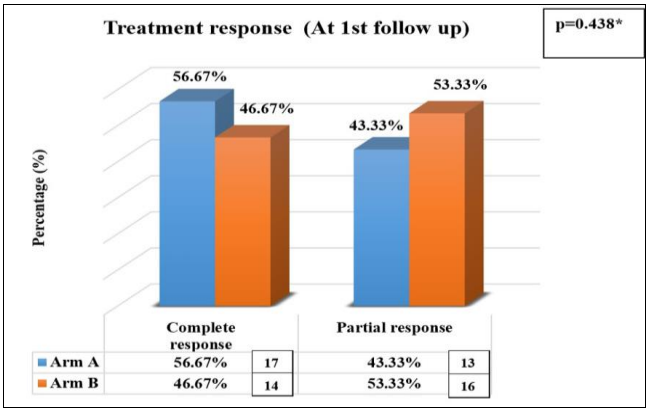
Risk factors	Arm-A		Arm-B		Total		P-value
	n=30	(%)	n=30	(%)	n=60	%	
Smoking	23	(76.7%)	22	(73.3%)	45	(75.0%)	0.881
Alcohol consumption	2	(6.7%)	3	(10.0%)	5	(8.3%)	0.640
Betel nut chewing	9	(30.0%)	7	(23.3%)	16	(26.7%)	0.559
Tobacco leaf/jarda	5	(16.7%)	4	(13.3%)	9	(15.0%)	0.718

Clinical Manifestations of the respondents (N=60)

Table 3: Distribution of patients according to clinical presentations (N=60)

Clinical presentation	Arm A (n=30)		Arm B (n=30)		Total (N=60)		P-value*
	n	%	n	%	N	%	
Hoarseness of voice	21	70	25	83.3	46	76.7	0.222
Dysphagia	14	46.7	12	40	26	43.3	0.694
Neck Node	24	80	22	73.3	46	76.7	0.768
Dyspnoea and stridor	8	26.7	7	23.3	15	25	0.796

The above table shows majority of the patients had hoarseness of voice, 46 (76.7%) and neck node involvement 46 (76.7%) followed by dysphagia 26 (43.3%), dyspnoea and stridor 15 (25.0%). But, there wasn't any significant differnce regarding clinical symptoms between arms when compared as the p-value was >0.05.



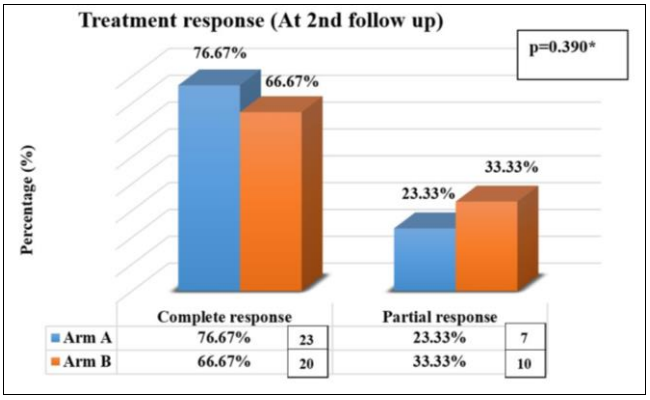


Fig 3: Distribution of patients according to treatment response at 6th weeks to 12th weeks after treatment (N=60)

The below figure shows most of the patients from both arms, 13 (43.3%) of Arm A and 12 (40.0%) of Arm B presented with moderately differentiated SCC. There had no significant difference regarding histopathological differentiation between two arms as p value >0.05.

The another below figure shows distribution of patients according to their treatment response at 12 weeks after treatment. At the 2nd follow-up 12 weeks after treatment of patients,23 patients (76.67%) of Arm A and 20 patients (66.67%) of Arm B had complete response. No significant difference was seen between two arms (p>0.05).

The Table 4 reveals majority of the patients from both arms were in stage III, 18 (60.0%) of Arm A and 16 (53.3%) of Arm B. There wasn't any significant difference between two arms in terms of TNM staging when compared (p>0.05).

Table 4: Distribution of patients by the TNM staging (N=60)

TNM staging	Arm A (n=30)		Arm B (n=30)		Total (N=60)		P-value*
	n	%	n	%	N	%	
III	18	60	16	53.3	34	56.7	0.833
IVA	10	33.3	11	36.7	21	35	
IVB	2	6.7	3	10	5	8.3	

The below Table 5 shows majority of the patients in stage III experienced complete response, 16 (88.9%) of Arm A and 13 (81.2%) of Arm B.

Table 5: Response of primary tumour according to TNM stage (N=60)

Group	TNM Staging	Complete Response n(%)	Partial Response n(%)	P-value*
Arm A (n=18)	III	16 (88.9)	2 (11.1)	0.530
Arm B(n=16) Arm A (n=10)	IVA	13 (81.2) 7 (70)	3 (18.8) 3 (30)	0.757
Arm B (n=11) Arm A (n=2)	IVB	7 (63.3) 1 (50)	4 (36.7) 1(50)	0.709
Arm B (n=3)		1 (33.3)	2 (66.7)	

* p value was determined by Chi-square test

Discussion

Head-Neck cancer is a major worldwide health problem. Regarding the distribution of head and neck cancer, the main bulk of the cancer was formed by the larynx. Radiation has been the standard treatment for locally advanced, unresectable head neck carcinoma. Even the most effective radiotherapy regimens result in local control rates not exceeding 50-70% and disease-free survival rate not more than 30-40%. This circumstance has stimulated the investigation of treatments combining radiotherapy and chemotherapy, the most promising approach being the administration of chemotherapy concurrent with radiation [12]. Cisplatin is one of the most extensively used agents effective in the management of squamous cell carcinoma of head-neck which can be used either as a single agent or can be used as a combination with other drugs, on the other hand, paclitaxel is a newer active single- agent used in head-neck cancer treatment [13].

This current study found that the mean age of all the studied patients was 56.03±8.88 years. And the majority of the patients were more than 50 years of age (81.7%). There wasn't any significant difference in terms of age distribution between the two arms when compared as the p-value was >0.05. Similar age distribution was found in several studies. A study was done in Bangladesh to see the clinicopathology of laryngeal carcinoma and they showed that the 90% of the studied patients were within41-80 years of age where 60% were with 41-60 years of age and 30% were with 61-80 years of age [14]. Another study in India on an epidemiological review on laryngeal cancer showed that more than 50% of the patients both male and female were older than 60 years. The maximum number of cases were reported in the age group of 60-69 years amounting to 31.93% of all larynx carcinoma in males and 27.29% in females. In my study the majority of the patients were male (88.3%) with a male-female ratio of 7.3:1 with no significant difference between arms as the p-value was >0.05, when compared which was consistent with [15].

Among all the patients in this current study, 75.0 % had a positive history of smoking, 8.3% had a positive alcohol consumption history, 26.7% had a betel nut chewing history

and 15% had positive tobacco leaf/jarda history which was correlates with some other studies conducted in Bangladesh. A study in Bangladesh showed that 93.75% of the patients were male and the rest 6.25% were female, they also found that 62.50% of studied patients were smokers, 2.50% had alcohol consumption history, 30% had a history of betel nut chewing and tobacco leaf or jarda taking history [16].

In terms of tumor size and nodal involvement, no significant difference was seen between two arms when compared as the p-value was >0.05. Regarding symptoms of carcinoma of larynx, majority of the patients 76.7% had hoarseness of voice, 76.7% had neck node, 43.3% had dysphagia, 25.0% patients complained dyspnoea and stridor. Almost similar presentations were shown in other studies [17].

In this study, the majority of the studied patients were from rural area (80%) in Arm A, (76.3%) were Arm B. Rural populations had a greater chance of developing larynx cancer than the urban people when compared [18]. Educational and occupational status undoudtedly play a vital role in developing larynx cancer [19]. In this study majority were completed their primary education (Arm A 33.3% and Arm B 26.7%). These findings were almost exactly same as previously conducted studies [18]. This may be due to the fact that these patients have got poor knowledge on risk factors and development of laryngeal cancer and also this group with low level of education does not have a tendency to seek for right medical treatment when they start to experience early symptoms of disease.

A study of weekly paclitaxel versus weekly cisplatin with concomitant chemoradiation in locally advanced head and neck cancer was done in India and they found that, at the 6th week follow up after the completion of the treatment, 69.2% patients of Arm-A achieved complete response and 57.7% of Arm-B achieved complete response. Partial response was achieved in 11.5% versus 15.4% in Arm-A and Arm-B respectively but there wasn't any statistically significant difference regarding response between two arms (p>0.05) [20].

Regarding toxicities, local toxicity such as grade 2 and grade 3 mucositis, skin reaction, dysphagia, xerostomia higher among the Arm-A patients than Arm-B, p value was not significance between two arms (p>0.05). Nausea, vomiting and renal and hematological toxicities (anemia, leucopenia and thrombocytopenia) were more among Arm-B patients than the Arm-A patients but there wasn't any significant difference between two arms when compared as the p-value was >0.05. Several studies which was found relevant with this study. Das *et al*. 2019, also showed that nausea and vomiting was higher among the cisplatin group than the paclitaxel group when compared p value was significant but regarding other toxicities there was not any significant difference between two arms (p>0.05) [21].

Conclusion

Concurrent chemoradiation with weekly paclitaxel has equal treatment response as weekly cisplatin with acceptable toxicities in treatment of locally advanced laryngeal cancer. Concurrent chemoradiotherapy with weekly paclitaxel can be used as an alternative systemic therapy in treatment of locally advanced laryngeal cancer who are not candidates for cisplatin.

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