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Original Research Article **Radiotherapy**

Treatment of Laryngeal Cancer by Sequential Chemo-Radiotherapy and Radiotherapy Alone - A Comparative Study

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Abstract

This cross-sectional comparative study was done at radiotherapy department of Rajshahi Medical College Hospital, Rajshahi from July, 2009-June, 2010. A total number of 60 diagnosed cases of carcinoma larynx (Histologically squamous cell carcinoma) were enlisted and were divided into study group e.g. Chemo-Radiotherapy group (Group A) consisting 30 patients were treated by sequential chemo-radiotherapy with two cycles of cisplatin (20mg/m^2) & 5-FU (500mg) per day for 4 days 3 weeks apart followed by radiotherapy after 1½ weeks at 60-66 Gray in 30-33 fractions in 6-6½ weeks and control group e.g. radiotherapy group (Group B) consisting 30 patients were treated with conventional radiotherapy of 60-66 Gray in 30-33 fractions in 6-6½ weeks. The objective of the study was to observe and compare the results of treatment & side effects of treatment on both arms during & after treatment. In chemo-radiotherapy group (Group-A) complete response (CR) was found in 20 cases (66.67%) and partial response (PR) was found in 10 cases (33.33%). In radiotherapy group (Group-B) complete response (CR) was found in 12 cases (40%) and partial response was found in 18 cases (60%). It was found that complete & partial response was 100%. There was no death or no major complications throughout the study period. Calculated χ^2 value was 4.28 was greater than the table value χ^2 i.e. 3.84. It corresponds to probability of 0.05 in χ^2 table ($P < 0.05$). Hence treatment of laryngeal cancer with sequential chemo-radiotherapy was statistically significant.

Keywords: Laryngeal cancer, Chemoradiotherapy, Radiotherapy, Cisplatin, Treatment response, Squamous cell carcinoma.

INTRODUCTION

Globally, cancer is a growing problem. From 2000-2025 a significant rise in the number of cases is anticipated worldwide. At present, from a world population of 6 billion about 10 million cases are diagnosed annually, with 6 million deaths. However, 50% will occur in developing countries, which have 5% of the resources to treat it. This figure will rise to 20 million by 2020 from a world population of 12 billion, with 12 million deaths. Of these 20 million cases, 70% will occur in developing countries. Cancer is a major cause of death in industrialized societies where life expectancy encompasses the maximum incidence of cancer in middle and old age.[1]

Cancer is one of the major causes of morbidity and mortality among the non-communicable diseases in Bangladesh. Cancer is the sixth leading cause of mortality in Bangladesh and more than half of the cancer patients die within five years of diagnosis. The number of people developing cancer is expected to increase in huge number mainly because of ageing population and lifestyle factors. Cancer load is more than 1,200,000 in Bangladesh. International Agency for Research on Cancer (IARC) has been estimated death from cancer in

Bangladesh is 7.5% in 2005 and projected that it would be increased up to 13% in 2030. A recent WHO study has been estimated that there are 49,000 oral cancer, 71,000 pharynx & laryngeal cancer and 196,000 lung cancer cases in Bangladesh among those aged 30 years or above. The same study observed that 3.6% of the admissions in medical college hospitals for the same age group are due to cancers of oral cavity, larynx and lungs.[2]

About 150,000 cancer patients out of the present 1 million die annually owing to limited treatment facilities in public hospitals and high expenses in private clinics in Bangladesh. About 200,000 cancer patients are added to this overwhelming size every year. According to the 2005 draft annual report of the National Institute of Cancer Research and Hospital the top five cancers in males are lung (24.7 percent), unknown primary site (8.1 percent), larynx (7.3 percent), lymphatic and lymph node (7.3 percent) and esophagus (5.1percent). The leading five cancers in females are cervical (24.6 percent), breast (24.3 percent), lung (5.5 percent), oral cavity (4.1 percent), and ovarian (3.8 percent).[3]

Cancer of Larynx is called Laryngeal cancer. Laryngeal cancer accounts for 0.9% of all cancers and 0.6% cancer deaths. The yearly incidence is about 4 per 100,000 in the UK. In Northern Europe it constitutes 20% of tumours of the head and neck. The highest incidence is reported in Brazil and India. Most of these tumours occur in the fifth to seventh decades. The male: female ratio is 5:1.[1]

The incidence of laryngeal cancer in India is 8.5 per 100,000 in the males and accounts for 7.4% all cancers in them.[4]

Because of the prominent role the larynx plays in speech communication, swallowing, respiration and protection of the lower airway, the treatment of cancer of larynx presents formidable functional consequences in addition to the intrinsic threat to life posed by these cancers.[5]

60–70% of laryngeal tumours arise from the vocal cords, 30% from the supraglottic region and less than 5% from the subglottic area. 95% of laryngeal tumours are invasive squamous carcinomas, usually well differentiated. Verrucous carcinoma is an uncommon variant of squamous carcinoma. Another variant is spindle cell carcinoma. Other verities of tumour are all rare. Smoking is an importation aetiological factor. The mortality from laryngeal cancer in smokers is five times that of non-smokers. Some tumours may be related to human papilloma virus infection.[1]

Cancer at the larynx is generally diagnosed at an earlier stage at development than other head & neck sites primarily due to early manifestation of symptoms. As a result, cure rates are generally higher than for other sites.[5]

OBJECTIVES

General Objectives:

The study was carried out with a view to observe and compare the results of treatment of laryngeal cancer by sequential chemo-radiotherapy and radiotherapy alone.

Specific Objectives:

1. To assess the response and clinical outcome of chemo-radiotherapy.
2. To assess adverse effects and complications of chemo-radiotherapy.
3. To observe the response and clinical outcome of radiotherapy alone.
4. To compare of outcome and complications between chemo-radiotherapy & radiotherapy alone.

METHODOLOGY

Type of study: This study was a cross-sectional type of comparative study.

Period of study: This study was carried out from July, 2009 to June, 2010.

Place of study: This study was carried out in the department of Radiotherapy, Rajshahi medical College Hospital, Rajshahi.

Study of population: Laryngeal cancer patients attending the radiotherapy department of Rajshahi Medical College Hospital for treatment constituted the study population.

Inclusion criteria:

1 Patients of laryngeal carcinoma, histologically diagnosed as squamous cell carcinoma.
2 Patients without distant metastasis.
3 Patients having performance status up to grade-2, international union against cancer (UICC).

Exclusion criteria:

1 Patients with other than squamous cell carcinoma.
2 Previously treated patients.
3 Patients with distant metastasis.
4 Pregnant women.
5 Patients with renal failure.

Sample size: 60 (Chemo-radiotherapy group-30, Radiotherapy group-30)

Selection of Chemo-radiotherapy group (Group A) and Radiotherapy group (Group B) were done by randomization method. A total number of 60 patients were included in this study and were divided into two groups:

i) Chemo-radiotherapy group (Group A): 30 patients, taken into this group were treated by sequential chemotherapy with two cycles of Cisplatin (20mg/m^2) & 5-fluorouracial (500mg) per day for 4 days, 3 weeks apart followed by radiotherapy after $1^1/_2$ weeks at 60-66 Gray in 30-33 fractions in 6-6`5 weeks by cobalt^{60} teletherapy.

ii) Radiotherapy group (Group B): 30 patients, taken into this group were treated with conventional radiotherapy of 60-66 Gray in 30-33 fractions in 6-6`5 weeks by cobalt^{60} teletherapy.

Methods of Sample Size Estimation: The required sample size for the study has been calculated by using the following statistical formula

$$n_0 = \frac{Z^2 pq}{d^2} = \frac{1.96^2 x 0.073 x 0.927}{0.05^2} = 104$$

$$n_c = \frac{n_0}{1+\frac{n_0}{N}} = \frac{104}{1+\frac{104}{108}} = \frac{104}{1+0.96} = 53.08$$

Z=	1.96 at 95% confidence level
p=	Prevalence of Laryngeal cancer in Bangladesh 7.3%=0.073
q=	1-p=1-0.073=0.927
d=	Error limit=5%=0.05

Sampling technique:

- Purposive.
- All the patients with laryngeal cancer (fulfilling the inclusion criteria) attending the Radiotherapy department of Rajshahi Medical College Hospital were brought under study until the total number of samples in each group achieved.

Data collection:

A. Data collection instrument- Data collection sheet & questionnaire.

B. Procedure – After proper counseling about the study, procedure of treatment, expenditure, side effects of chemotherapy & radiotherapy and expected result of treatment 60 patients (fulfilling the inclusion criteria) were assigned into two treatment groups-

i. Group A- Chemo-radiotherapy group.
ii. Group B- Radiotherapy group.

Patients of both groups were interviewed by pre-tested closed ended questionnaire. I took particulars of the patient, chief complaints with duration, history of present illness, past illness, family & drug history. I also examined the patient properly both general & local. Patients' conditions were assessed as followed-

(I) Tumour-

- Clinical examination
- Indirect laryngoscope
- X-ray neck both view

(II) Patient-

a. Symptoms
Neck swelling,
Hoarseness of voice, Dysphagia,
Dyspnoea,
Pain in the throat,
Referred otalgia

b. Sign: -
Lymph node: Size, Tenderness, Fixity
Other general examination

Data analysis:

At first SPSS- 16 version software was installed in computer. Then all data collected by me from the patients were entered into computer. Data were checked for validity and consistency. Then data were analyzed by-

- Frequency table
- Cross tabulation
- Correlation estimation was done to compare the progress at the two treatment strategies.

RESULTS

Table I - Distribution of the patients by socio-demographic characteristics

	Group A		Group B	
	Number	**%**	**Number**	**%**
Number of Patients	30	100	30	100
Age grouping in years				
21 – 30	00	00	00	00
31 – 40	04	13.33	03	10.00
41 – 50	11	36.67	07	23.33
51 – 60	08	26.67	09	30.00

61 – 70	07	23.33	11	36.67
Mean age	51 ± 9.87 years		54.33 ± 9.97 years	
Sex				
Male	28	93.33	28	93.33
Female	02	6.67	02	6.67
Occupation				
Farmer	18	60.00	19	63.34
Labour	06	20.00	07	23.33
Official	01	3.33	01	3.33
Businessmen	03	10.00	01	3.33
House wife	02	6.67	02	6.67

It was found that, in case of group A patients Mean age was 51± 9.87 years and in group B patients Mean age was 54.33 ± 9.97 years. In age group of 31-40 years, 13.33% patients belongs to group A & 10% patients belongs to group B; In age group of 41-50 years, 36.67% patients belongs to group A & 23.33% patients belongs to group B; in years of 51-60, 26.67% patients in group A & 30.00% patients in group B; In age group of 61-70 years, 23.33% patients in group A & 36.67% patients in group B; no patients found in age group of 21-30 years in both groups.

According to sex 93.33% patients were male in both groups & 6.67% patients were female in both groups.

No significant difference was seen in case of occupation. Farmer in group A 60% patients & in group B 63.34% patients, labour in group A 20% patients & in group B 23.33% patients, official in group A 3.33% patients & in group B 3.33% patients, businessmen in group A 10% patients & in group B 3.33% patients, house wife in group A 6.67% patients & in groupB 6.67% patients (Table I).

Table II - Distributions of patients according to site of laryngeal cancer

	Group A		**Group B**	
Site of Tumor	**Number**	**%**	**Number**	**%**
Supra- glottic	13	43.33	11	36.67
Glottic	17	56.67	19	63.33
Sub- glottic	00	00.00	00	00.00

Table II showed that, most of the patients (56.67% in group A & 63.33% in group B) presented with glottic tumours, 43.33% patients in group A & 36.67% patients in group B presented with supraglottic tumours, and no patients were found in both groups with sub-glottic tumours.

Table III - Distribution of patients according to stage of laryngeal cancer

	Group A		**Group B**	
	Number	**%**	**Number**	**%**
Tumor category				
T1	06	20.00	06	20.00
T2	18	60.00	15	50.00
T3	06	20.00	08	26.67
T4	00	00.00	01	03.33
Nodal category				
N0	17	56.67	14	46.67
N1	10	33.33	12	40.00
N2	02	06.67	03	10.00
N3	01	03.33	01	03.33
Stage				
I	05	16.67	04	13.33
II	12	40.00	10	33.33
III	10	33.33	11	36.67
IV	03	10.00	05	16.67

Regarding distribution of patients according to stage of laryngeal cancer, 16.67% patients constituted in group A & 13.33% patients constituted in group B presented with stage I laryngeal cancer, 40.00% patients in group A & 33.33% patients in group B presented with stage II laryngeal cancer, 33.33% patients constituted in group A & 36.67% patients constituted in group B presented with stage III laryngeal cancer, 10% patients in group A & 16.67% patients in group B presented with stage IV laryngeal cancer (Table III).

Table IV A – Relationship between group A & group B patients according to major complications during treatment

	Group A		Group B	
	Number	**%**	**Number**	**%**
Xerostomia	22	73.33	18	60.00
Nausea				
Grade 0	02	06.67	07	23.33
Grade 1	18	60.00	18	60.00
Grade 2	10	33.33	05	16.67
Grade 3	00	00.00	00	00.00
Grade 4	00	00.00	00	00.00
$\chi^2 = 4.43$, df = 2, P > 0.05.				
Vomiting				
Grade 0	02	06.67	12	40.00
Grade 1	14	46.67	11	36.67
Grade 2	12	40.00	07	23.33
Grade 3	02	06.66	00	00.00
Grade 4	00	00.00	00	00.00
$\chi^2 = 12.54$, df = 3, P < 0.05				

In that study 73.33% patients in group A & 60% patients in group B Complain xerostomia. In Group A 6.67% patients complain grade 0, 60% patients complain grade 1, 33.33% patients complain grade 2 nausea. On the other hand, in Group B 23.33% patients complain grade 0, 60% patients complain grade 1, 16.67% patients complain grade 2 nausea. The difference of development of nausea between patients of group A and group B was not statistically significant. (P>0.05).

Furthermore, In Group A 6.67% patients complain grade 0, 46.67% patients complain grade 1, 40% patients complain grade 2 & 6.66% patients complain grade 3 vomiting. On the other hand, in Group B 40% patients complain grade 0, 36.67% patients complain grade 1, 23.33% patients complain grade 2 vomiting. The development of vomiting in group A patients than that of group B was statistically significant (P<0.05) (table IV A)

Table IV B - Distributions of patients according to major complications during treatment

	Group A		Group B	
	Number	**%**	**Number**	**%**
Skin reaction				
Grade 0	16	53.33	22	73.34
Grade 1	11	36.67	07	23.33
Grade 2	03	10.00	01	03.33
Grade 3	00	00.00	00	00.00
Grade 4	00	00.00	00	00.00
$\chi^2 = 2.82$, df = 2, P > 0.05.				
Mucositis				
Grade 0	07	23.33	12	40.00
Grade 1	11	36.67	14	46.67
Grade 2	10	33.33	04	13.33
Grade 3	02	06.67	00	00.00
Grade 4	00	00.00	00	00.00
$\chi^2 = 5.23$, df = 3, P > 0.05				

In that study it was found that in Group A 53.33% patients complain grade 0, 36.67% patients complain grade 1, 10% patients complain grade 2 skin reaction. On the other hand, in Group B 73.34% patients complain grade 0, 23.33% patients complain grade 1, 3.33% patients complain grade 2 23.33% skin reaction. The difference of development of skin reaction between patients of group A and group B was not statistically significant. (P>0.05)

Furthermore, In Group A 23.33% patients complain grade 0, 36.67% patients complain grade 1, 33.33% patients complain grade 2 & 6.67% patients complain grade 3 mucositis. On the other hand, in Group B 40% patients complain grade 0, 46.67% patients complain grade 1, 13.33% patients complain grade 2 mucositis. The difference of development of mucositis

between patients of group A and group B was not statistically significant (P>0.05) (table IV B).

Table V - Distribution of patients according to response pattern in Group-A & Group-B

Treatment group	Complete response	Partial response	Stable disease	Progressive disease
Group – A	20(66.67%)	10(33.33%)	00(00.00%)	00(00.00%)
Group – B	12(40.00%)	18(60.00%)	00(00.00%)	00(00.00%)

In this study I found complete response in 66.67% patients in group A & 40.00% patients in group B. On the other hand, partial response found in10.00% patients in group A and 18.00% patients in group B (table V).

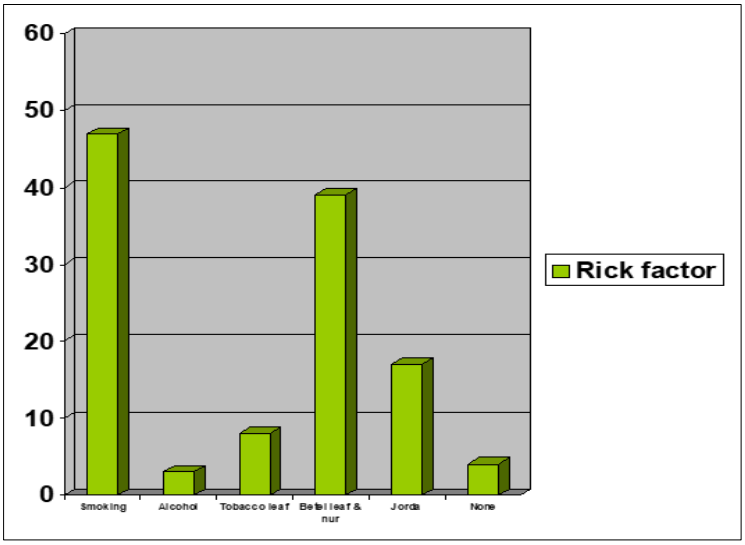

Fig. I: Distribution of patients according to risk factor

From this study it was found that, as risk factor habit of smoking was found in 78.33% patients, alcohol in 5.00% patients, tobacco leaf in 13.33% patients, betel leaf & nut in 65.00% patients and jorda in 28.33% patients. 6.66% patients were found with no risk factor (Fig: VI).

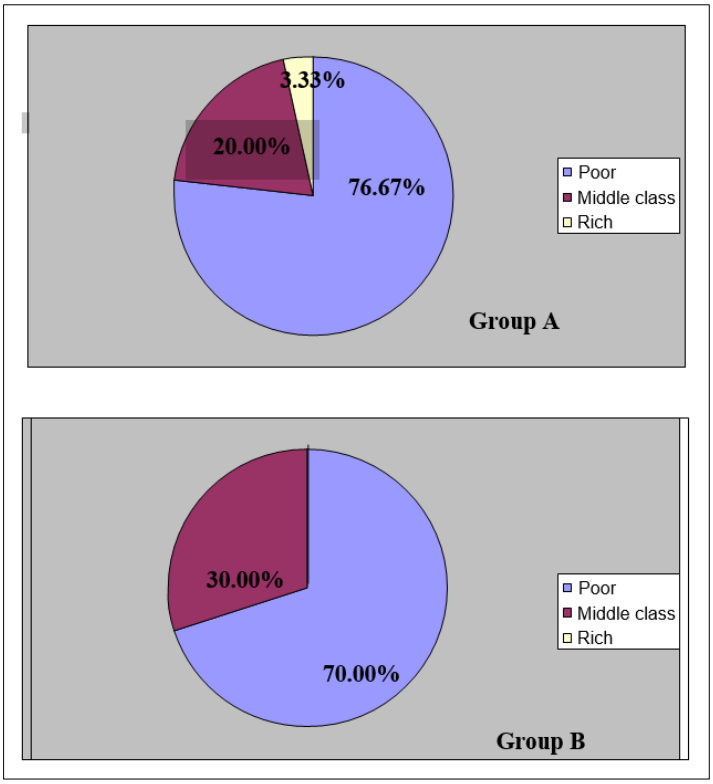

Fig. II: Distribution of patients according to socio- economic condition

It was found that, 76.67% patients were poor (Monthly Income <5,000 Taka.) in group A & 70.00% patients in group B. Secondly 20.00% patients belong to middle Class (Monthly Income 5,000-10,000 Taka.) in group A & 30.00% patients belong to group B. In case of rich (Monthly Income >10,000 Taka.) 3.33% patients were in group A & 0% in group B(Fig: II).

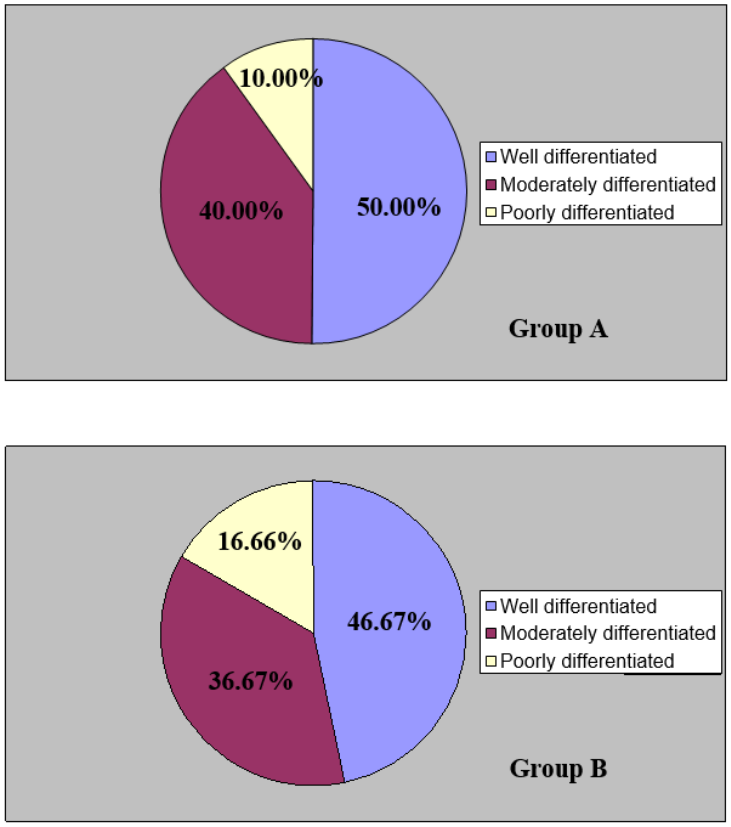

Fig. III: Distribution of patients according to histological grading of squamous cell carcinoma

In this study in group A patients 50.00% well differentiated, 40.00% moderately differentiated, 10.00% poorly differentiated squamous cell carcinoma were found in case of histological grading. On the other hand, in group B patients 46.67% well differentiated, 36.67% moderately differentiated, 16.66% poorly differentiated squamous cell carcinoma were found in case of histological grading (Fig: III).

DISCUSSION

Patients in both groups were above 30 years of age. In case of group A Mean age = 51± 9.87 and in group B Mean age = 54.33 ± 9.97. Another researcher reported that this disease most commonly affects middle aged or older men who have smoked and have consumed excessive alcohol.[6] In my study in both groups more than 88% patients above 40 years of age. 78% patients had long history of smoking & 65% patients had bad habit of betel leaf & nut & 28.33% of them had bad habit of Jorda & betel leaf & nut. Consumption of alcohol only in 5% patients due to rate of alcohol consumption in Bangladesh is lower than western countries.

Kunkler, IH *et. al.,* 2003 stated that in case of laryngeal cancer male: female ratio is 5:1. In my study most of the patients of both groups came from lower socioeconomic condition.[1] Only 4 patients were female and rests were male. Male: Female ratio is 15:1 in our country smoking habit is less in female and habit of ignorance of disease is high. So, very few poor female patients came to hospital for treatment.

According to Burri, RJ *et. al.,* 2009 the TAX 323 trial randomized 358 patients with unresectable stage III and IV head and neck cancer to either docetaxel, cisplatin and fluorouracil (TPF) or cisplatin and fluorouracil (PF) every 3 weeks for four cycles, followed by radiotherapy without concurrent chemotherapy if there was no evidence of disease progression.[7] Most patients were treated with standard fractionated radiotherapy. With a median follow-up of 32.5 months, the median progression-free survival was significantly improved with the addition of docetaxel. Most of the patients in my study came from low socio-economic condition. Cisplatin & 5FU are reasonably cheap than

docetaxel, paclitaxel & carboplatin. But response rate was good & satisfactory.

A phase II study by Shirinian MH et al. (1994) evaluated 64 patients with advanced but resectable head and neck cancer requiring total laryngectomy. Patients received one of two cisplatin-based induction regimens: PBF in 31 cases and PF in 33 cases. Both regimens showed comparable overall complete plus partial response rates.[8] The combined PF and PBF overall response rate for laryngeal cancer was 75%. Complete response after radiotherapy was reported in 88% of cases. Neutropenia was the most frequent hematologic toxicity, occurring in 44% of PF patients and 16% of PBF patients. Grade ≥3 mucositis occurred in 50% of PF patients and 4% of PBF patients. In my study, all patients were reviewed weekly during radiotherapy and every three weeks during chemotherapy. No major complications or severe toxicities were observed. Only grade 2 toxicities such as nausea, vomiting, skin reactions, and mucositis occurred in a few patients and were managed conservatively.

One hundred patients were randomized to receive either radiation therapy alone (Arm A) (at a dose of between 66–72 grays [Gy] at 1.8–2 Gy per day) and the identical radiation therapy with concurrent chemotherapy (Arm B) (5-fluorouracil, 1000 mg/m^2/day, and cisplatin, 20 mg/m^2/day, both given as continuous intravenous infusions over 4 days beginning on Days 1 and 22 of the radiation therapy). Primary site resection was planned for patients with residual or recurrent local disease. Kaplan–Meier projections for the recurrence free interval were 51% versus 62% ($P = 0.04$), projections for a distant metastasis free interval were 75% versus 84% ($P = 0.09$), projections for overall survival with primary site preservation were 34% versus 42% ($P = 0.004$), and projections for local control without surgical resection were 45% versus 77% ($P < 0.001$). Salvage surgery proved to be successful in 63% and 73%, respectively, of the Arm A and Arm B patients with primary site failure. Unrelated death while free of disease occurred in 22% and 32%, respectively, of Arm A and Arm B patients ($P = 0.26$). They proved that the addition of concurrent chemotherapy to definitive radiation in patients with resectable Stage III and IV squamous cell carcinoma of the head and neck improves the likelihood of disease clearance, a recurrence free interval, and primary site preservation. However, overall survival does not appear to be improved, reflecting both effective surgical salvage after local recurrence and competing causes of death. Cancer 2000; 88:876–83. © 2000 American Cancer Society. In my study I could not observe overall survival but complete response was 66.66% in chemoradiotherapy group and only 40% in radiotherapy alone group.

Radiotherapy is a standard treatment for advanced head and neck cancer, but outcomes remain poor due to high locoregional recurrence. David et al. (1998) evaluated whether adding concurrent chemotherapy to hyperfractionated radiotherapy would improve results.[9] Patients receiving radiotherapy alone were treated with 125 cGy twice daily to a total of 7500 cGy. The combined-therapy group received the same fractionation but a total of 7000 cGy plus cisplatin and 5-fluorouracil during weeks 1 and 6. Most patients also received two additional cycles of chemotherapy after radiotherapy. Of 122 randomized patients, 116 were evaluable, and most had unresectable disease. The median follow-up period was 41 months. At three years, overall survival was higher in the combined-therapy group (55%) than in the radiotherapy-alone group (34%). Relapse-free survival was also better with combined treatment (61% vs. 41%). Locoregional control was significantly improved with chemoradiotherapy (70% vs. 44%). They concluded that combined treatment is more effective without causing significantly greater toxicity, and similarly, in my study no severe complications occurred in either group.

David, J *et al.*, (2000) reported mature results from a Phase III randomized trial comparing radiotherapy alone and concurrent chemoradiotherapy in resectable Stage III and IV head and neck cancer.[10] One hundred patients were randomized to either radiation alone or the same radiation with concurrent 5-fluorouracil and cisplatin. Primary site resection was planned for persistent or recurrent local disease. Cervical lymph node dissection was performed for persistent nodal disease or initial N2–3 presentation. After completing all therapy, 82% of Arm A patients and 98% of Arm B patients were disease free (P = 0.02). At a median follow-up of 5 years, overall survival was 48% in Arm A versus 50% in Arm B (P = 0.55). Recurrence-free interval favored Arm B at 62% compared to 51% in Arm A (P = 0.04). Primary site preservation was significantly higher in Arm B (42%) than in Arm A (34%) (P = 0.004). Local control without surgery was also superior in Arm B (77% vs. 45%, P < 0.001). In my study, although overall survival could not be assessed, complete response was 66.66% in the chemoradiotherapy group and 40% in the radiotherapy-alone group.

CONCLUSION

This cross-sectional comparative study conducted at Rajshahi Medical College Hospital from July 2009 to June 2010 evaluated treatment outcomes and early toxicities of sequential chemoradiotherapy versus radiotherapy alone in laryngeal cancer. Group A showed complete response rates of 100% in stage I, 91.66% in stage II, 40% in stage III, and 0% in stage IV, while Group B showed 100%, 80%, 0%, and 0% respectively. Histological grading and tumor-site–based responses were also better in Group A than in Group B. The overall response rate was 100%, and the calculated χ^2 value of 4.28 exceeded the table value of 3.84, indicating statistical significance at P<0.05. Patients receiving sequential chemoradiotherapy demonstrated

better treatment outcomes than those treated with radiotherapy alone. Therefore, sequential chemotherapy with cisplatin and 5-FU followed by radiotherapy may be beneficial for patients with stage II–IV or locally advanced laryngeal cancer.

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