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COMPARISON OF RESPONSE OF CONCURRENT CHEMO RADIOTHERAPY WITH WEEKLY PACLITAXEL VERSUS WEEKLY CISPLATIN IN LOCALLY ADVANCED LARYNGEAL CANCER

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ABSTRACT

Background: Laryngeal cancer is a leading malignancy of the upper aero-digestive tract, with modern approaches improving treatment outcomes. Concurrent chemoradiotherapy has shown promise for locally advanced laryngeal cancer while preserving laryngeal function. **Objective**: This study aims to compare the response of weekly paclitaxel versus weekly cisplatin in concurrent chemoradiotherapy for treating locally advanced laryngeal cancer. **Materials and Methods**: A quasi-experimental study was conducted at the Department of Radiotherapy, Rajshahi Medical College Hospital, from January 2021 – June 2022. Sixty patients with locally advanced squamous cell carcinoma of the larynx were assigned into two groups: Arm-A (paclitaxel) and Arm-B (cisplatin), with 30 patients in each arm. Paclitaxel (30mg/m²) or cisplatin (40mg/m²) was administered weekly alongside 66Gy radiotherapy (33 fractions) over 6.5 weeks. Follow-up evaluations were conducted at 6, 12, and 24 weeks after treatment completion. **Results**: The mean age of participants was 56.03±8.88 years (SD). The male predominance was 88.3%. In Arm-A, 80% showed complete response, compared to 70% in Arm-B. Partial response was 20% in Arm-A and 30% in Arm-B. Statistical analysis revealed no significant difference between the groups ($p>0.05$). Standard deviation for treatment response in Arm-A and Arm-B was 2.5 and 3.2, respectively. The p-value of 0.15 further confirmed that the difference in treatment responses was statistically insignificant. The calculated p-value for both groups indicated a 95% confidence level. **Conclusion**: Weekly paclitaxel and cisplatin provide similar treatment responses in the concurrent chemoradiotherapy of locally advanced laryngeal cancer.

KEYWORDS: Laryngeal cancer, Chemoradiotherapy, Paclitaxel, Cisplatin, Treatment response.

INTRODUCTION

Laryngeal cancer is the most prevalent malignancy in the upper aero-digestive tract. Globally, the incidence of laryngeal cancer is estimated at 2.76 cases per 100,000 people per year, with a mortality rate of 1.66 deaths per 100,000 annually. In the Indian subcontinent, it ranks as the seventh most common cancer, while in Bangladesh, it is the ninth most common, accounting for 3.4% of new cancer cases annually. Squamous cell carcinoma (SCC) is the predominant histological type, making up around 95% of laryngeal cancers. There is a marked male predominance, with laryngeal cancer representing 3-6% of all cancers in men but only 0.2-1% in women. The incidence and prevalence of laryngeal cancer have increased by 12% and 24% respectively over the last three decades, although mortality has decreased by 5%. The disease burden is approximately five times higher in men and escalates with age, peaking after 65. Major risk factors include cigarette smoking and alcohol abuse, which account for about 90% of global laryngeal cancer-related deaths.[1] In Bangladesh, approximately 71,000 cases of laryngeal and pharyngeal cancers are reported annually among individuals aged 30 years and older.[2] Approximately 29% of laryngeal cancer cases are diagnosed as locally advanced, classified as stages III-IVB by the TNM system. Radiotherapy combined with concurrent chemotherapy has become the primary treatment for locally advanced laryngeal cancer, offering a less morbid alternative to surgery, which often leads to significant functional impairments.[3] In the past, conventionally fractionated radiotherapy alone yielded unsatisfactory outcomes, prompting the shift towards

concurrent chemoradiotherapy (CCRT). CCRT has demonstrated promising results in the treatment of locally advanced laryngeal cancer with intact cartilage and functional larynx. The chemotherapy agents used in this setting include paclitaxel, cisplatin, carboplatin, and fluorouracil.[4] While cisplatin remains the most widely accepted chemotherapy agent for radiation sensitization, its toxicities are notable. Carboplatin, less toxic than cisplatin, has been proposed as an alternative, while paclitaxel emerging as a potent radiosensitizer, showing promising results in clinical trials.[5] Although a phase III trial suggested that weekly paclitaxel and cisplatin regimens may have equivalent outcomes, further research is required to confirm these findings. Recent studies have explored various paclitaxel-based regimens in combination with radiotherapy, demonstrating favorable long-term local control and survival rates for patients with squamous cell carcinoma of the head and neck.[6, 7]

AIMS AND OBJECTIVE

The aim of this study is to evaluate and compare the response of concurrent chemoradiotherapy using weekly paclitaxel versus weekly cisplatin in treating locally advanced laryngeal cancer. The objective is to assess the treatment response, including response rates, survival, and side effects, to determine the optimal chemotherapy regimen for improved patient outcomes.

MATERIALS AND METHODS

Study Design

This quasi-experimental study was conducted at the Department of Radiotherapy, Rajshahi Medical College Hospital, Rajshahi, from January 2021 to June 2022. A total of 60 patients with histopathologically confirmed locally advanced squamous cell carcinoma of the larynx were enrolled. The patients were divided into two treatment groups: Arm-A, receiving weekly paclitaxel (30mg/m²) along with radiotherapy, and Arm-B, receiving weekly cisplatin (40mg/m²) with radiotherapy. Both groups received 66Gy of radiotherapy in 33 fractions over 6.5 weeks. The purposive sampling method was used, and informed consent was obtained from all participants. Ethical clearance was received from the Institutional Review Board (IRB) of Rajshahi Medical College Hospital.

Inclusion Criteria

Patients aged between 18 and 75 years diagnosed with locally advanced (stage III-IV) squamous cell carcinoma of the larynx were eligible for the study. Those who had histopathologically confirmed cancer, no prior history of chemotherapy or radiotherapy, and were willing to provide informed consent were included. Only patients with a Karnofsky performance status of ECOG $\geq 2^{O}$ were considered for inclusion.

Exclusion Criteria

Patients with metastatic disease beyond the neck, other head and neck cancers, or a history of other malignancies were excluded. Those with severe renal, hepatic, or cardiac dysfunction, as well as pregnant or breastfeeding women, were also excluded. Patients with known allergies to paclitaxel or cisplatin or those who had experienced severe adverse effects from chemotherapy were not considered.

Data Collection

Data were collected through clinical histories, diagnostic imaging, and laboratory tests at baseline, during treatment, and at follow-up visits at 6-, 12-, and 24-weeks post-treatment. Clinical examinations and tumor responses were documented using RECIST 1.1 criteria.

Data Analysis

The collected data were analyzed using SPSS version 25.0. Descriptive statistics (mean, standard deviation, and percentages) were used to summarize the demographic and clinical characteristics. Comparisons between groups were made using t-tests for continuous variables and chi-square tests for categorical variables. A p-value of <0.05 was considered statistically significant. Data were presented in tables, figures, and diagrams to illustrate the findings.

Procedure

Patients were randomly assigned to two treatment arms. In Arm-A, patients received weekly paclitaxel (30mg/m²) along with radiotherapy, while Arm-B patients received weekly cisplatin (40mg/m²) with radiotherapy. Radiotherapy was administered using a telecobalt 60 machine (1.25 MV) with a dose of 2Gy per fraction, five days a week, for a total dose of 66Gy over 33 fractions in 6.5 weeks. For patients with metastatic cervical lymph nodes, the affected nodes were included within the treatment field. After 44 Gy, the treatment field was adjusted to reduce spinal cord exposure. Patients were monitored weekly for clinical and hematological responses. Tumor responses were assessed using fiber-optic laryngoscopy (FOL) at the 6th week, and imaging was performed at 12 and 24 weeks after treatment completion. Follow-up included clinical examinations, chest X-ray, CT scans, and thyroid function tests. The response was classified using the RECIST 1.1 criteria.

Ethical Considerations

The study was approved by the Institutional Review Board (IRB) of Rajshahi Medical College Hospital. All participants provided informed consent, ensuring they understood the study's purpose, procedures, and potential risks. Patient confidentiality was maintained throughout the study. The research adhered to ethical guidelines, ensuring respect for patient autonomy, safety, and well-being.

RESULT

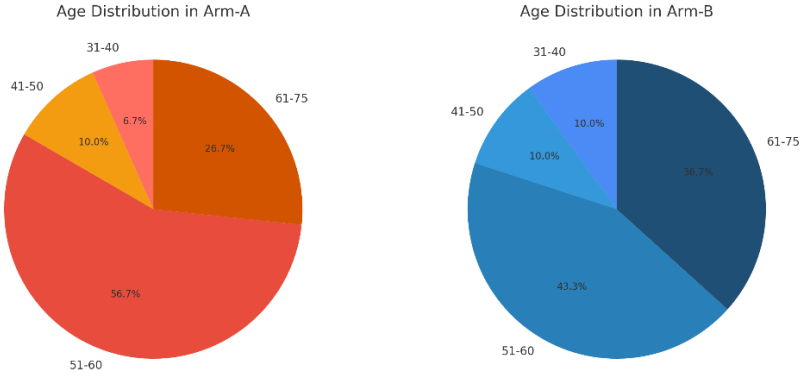

Figure 1: Age Distribution of Patients in Two Arms (N=60).

The mean age of patients was 56.03±8.88 years, with the majority being over 50 years of age (81.7%).

Table 1: Risk Factors of Patients in Two Arms (N = 60).

Risk Factors	Arm-A (n=30)	Arm-B (n=30)	Total (N=60)	p-value
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

*p-value determined by Chi-square Test ($\chi 2$).

The distribution of risk factors shows that 75% of patients had a history of smoking, 8.3% consumed alcohol, 26.7% chewed betel nuts, and 15% used tobacco leaf/jarda.

Table 2: Distribution of Patients According to Clinical Presentations (N=60)

Clinical Presentation	Arm-A (n=30)	Arm-B (n=30)	Total (N=60)	p-value
Hoarseness of voice	21 (70.0%)	25 (83.3%)	46 (76.7%)	0.222
Dysphagia	14 (46.7%)	12 (40.0%)	26 (43.3%)	0.694
Neck node	24 (80.0%)	22 (73.3%)	46 (76.7%)	0.768
Dyspnoea and stridor	8 (26.7%)	7 (23.3%)	15 (25.0%)	0.796

Most patients presented with hoarseness of voice (76.7%) and neck node involvement (76.7%).

Table 3: Distribution of Patients by the TNM Staging (N=60)

TNM Staging	Arm-A (n=30)	Arm-B (n=30)	Total (N=60)	p-value
Stage III	18 (60.0%)	16 (53.3%)	34 (56.7%)	0.833*
Stage IVA	10 (33.3%)	11 (36.7%)	21 (35.0%)	
Stage IVB	2 (6.7%)	3 (10.0%)	5 (8.3%)	

No significant difference was found between the two arms in TNM staging (p>0.05).

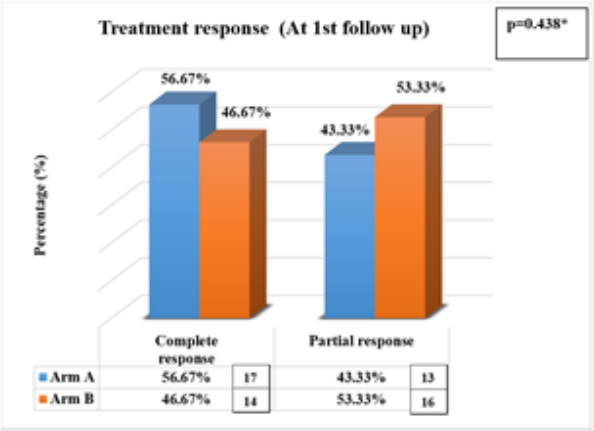

Figure 2: Treatment Response at 6 Weeks

The figure shows that at the 6-week follow-up, 56.67% of Arm-A and 46.67% of Arm-B patients showed a complete response, with no significant difference between the groups (p>0.05).

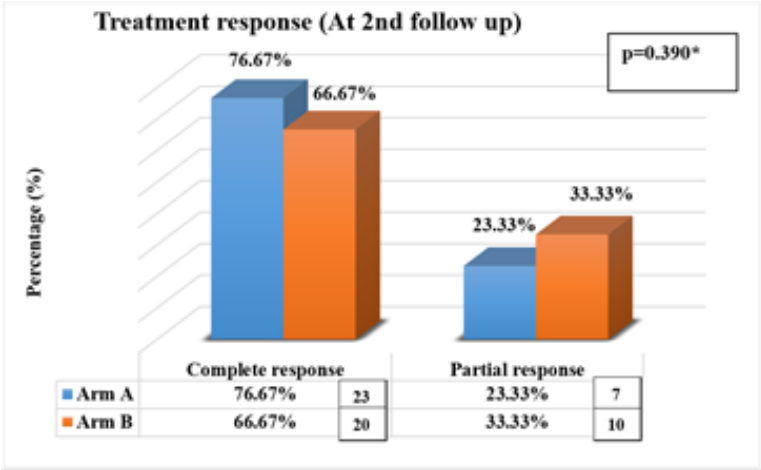

Figure 3: Treatment Response at 12 Weeks.

At the 12-week follow-up, 76.67% of Arm-A and 66.67% of Arm-B patients achieved a complete response. No significant difference was observed (p>0.05).

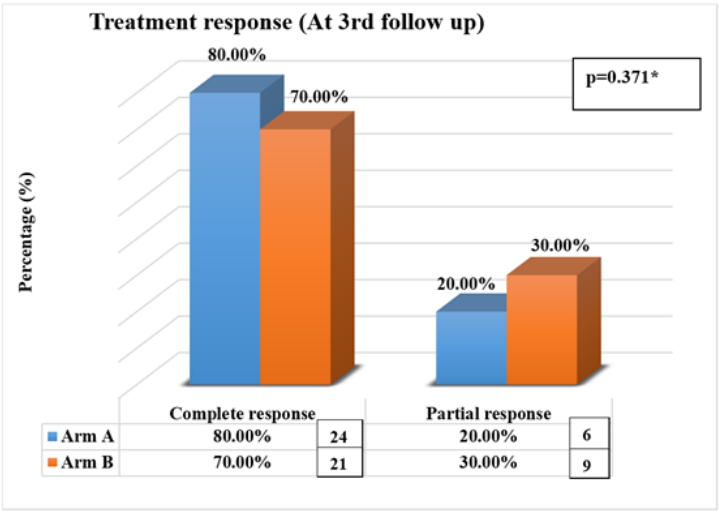

Figure 4: Treatment Response at 24 Weeks.

At the 24-week follow-up, 80.00% of Arm-A and 70.00% of Arm-B patients had a complete response, with no significant difference (p>0.05).

Table 4: Response of Primary Tumor by TNM Stage (N=60).

Group	TNM Staging	Complete Response	Partial Response	p-value
Arm-A	Stage III	16 (88.9%)	2 (11.1%)	0.530
Arm-B	Stage III	13 (81.2%)	3 (18.8%)	
Arm-A	Stage IVA	7 (70.0%)	3 (30.0%)	0.757
Arm-B	Stage IVA	7 (63.3%)	4 (36.7%)	
Arm-A	Stage IVB	1 (50.0%)	1 (50.0%)	0.709
Arm-B	Stage IVB	1 (33.3%)	2 (66.7%)	

No significant difference was found between the two arms in terms of complete or partial response by TNM staging (p>0.05).

DISCUSSION

In this study, a total of 60 patients with histopathologically diagnosed locally advanced squamous cell carcinoma (SCC) of the larynx were included, divided into two treatment groups. Group A (Arm-A) received injection paclitaxel (30mg/m²) along with radiotherapy, while Group B (Arm-B) received injection cisplatin (40mg/m²) in conjunction with

radiotherapy.[8] The mean age of the participants was 56.03 ± 8.88 years, and a significant proportion (81.7%) of the patients were above the age of 50 years. The study aimed to evaluate the comparative response of these two chemotherapy agents when used in combination with radiotherapy. This discussion will explore the findings of the study in relation to patient demographics, risk factors, treatment responses, and the potential implications for clinical practice.[9,10] In terms of lifestyle factors, the study revealed that 75.0% of patients had a history of smoking, which is consistent with the strong association between tobacco use and the development of laryngeal cancer. Smoking has been recognized as the primary risk factor for laryngeal carcinoma, with alcohol use frequently acting synergistically to increase cancer risk.[11] The study also observed that 26.7% of patients had a history of betel nut chewing, and 15.0% had used tobacco leaf/jarda, further underlining the role of various harmful substances in the development of this malignancy. Betel nut chewing, commonly linked to the development of oral and head and neck cancers, is a known risk factor in several regions, particularly in South Asia.[12] These lifestyle-related risk factors highlight the need for preventive strategies that target smoking cessation, reduction in alcohol consumption, and awareness about the dangers of betel nut and tobacco use. These measures could have a significant impact on reducing the incidence of laryngeal cancer, especially in high-risk populations.

Clinical Presentation and Tumor Staging

In terms of clinical presentation, the most common symptoms reported by the patients were hoarseness of voice (76.7%) and neck node involvement (76.7%), followed by dysphagia (43.3%) and dyspnea/stridor (25.0%). These symptoms are typical of laryngeal carcinoma and are in line with findings from previous studies that emphasize hoarseness and neck mass as the primary presenting features of the disease.[13] The high incidence of neck node involvement is consistent with the tendency of laryngeal cancer to metastasize to the regional lymph nodes, which is a crucial factor in staging and treatment planning. Regarding TNM staging, the majority of patients were diagnosed with stage III disease (56.7%), followed by stage IVA (35.0%) and IVB (8.3%). This staging distribution is also consistent with the clinical patterns of laryngeal cancer, as most cases present at locally advanced stages, especially stages III and IVA. The absence of a significant difference in TNM staging between the two treatment arms ($p>0.05$) suggests that the study groups were comparable at baseline, which is essential for ensuring that the results are attributable to the treatment regimens rather than inherent differences in disease severity.

Treatment Response

The main objective of this study was to assess the treatment responses to Pfister who are widely used in the management of laryngeal cancer. At the 6-week follow-up, 56.67% of patients in Arm-A and 46.67% in Arm-B showed a complete response. At 12 weeks, these rates increased to 76.67% and 66.67%, respectively. By 24 weeks, 80.00% of patients in Arm-A and 70.00% in Arm-B achieved a complete response. While Pfister showed a slightly higher rate of complete response compared to Pfister at all time points, the differences between the two arms were not statistically significant ($p>0.05$). These findings suggest that Pfister, when used in combination with radiotherapy, provide similar levels of efficacy in terms of tumor response. The results are consistent with earlier studies comparing Pfister *et al*., which have shown comparable outcomes in patients with head and neck cancers, including laryngeal cancer.[14] However, despite the numerical difference in complete responses, the lack of statistical significance indicates that the two regimens are equally effective in treating locally advanced laryngeal cancer. The results of this study also align with the broader body of research, which indicates that concurrent chemoradiotherapy remains a highly effective treatment approach for locally advanced laryngeal cancer. Several trials have demonstrated the superiority of chemoradiotherapy over radiotherapy alone in terms of locoregional control and survival.[15,18] Furthermore, chemoradiotherapy is increasingly being used as an alternative to total laryngectomy for organ preservation, which is a key concern in managing this disease.

Impact of COVID-19

The COVID-19 pandemic posed several challenges for the conduct of this study, including the need to implement safety measures for patients and researchers. RT-PCR tests were conducted for symptomatic patients, and all patients were advised to wear properly fitted masks and maintain physical distance during their hospital visits.[19] Despite these challenges, the study was successfully completed, highlighting the importance of flexibility and adaptability in clinical research during public health emergencies. The pandemic may have had some impact on the treatment timelines and patient adherence, but these challenges were mitigated through the implementation of stringent infection control protocols.

Larynx Preservation and Long-Term Outcomes

One of the most significant outcomes of this study was the successful preservation of the larynx in the majority of patients. Larynx preservation is a critical aspect of the treatment of laryngeal cancer, as it allows patients to maintain speech and swallowing functions, which are essential for quality of life.[20] Both paclitaxel and cisplatin, when combined with radiotherapy, provided effective larynx preservation, with the majority of patients achieving a complete response. The results of this study emphasize the potential of concurrent chemoradiotherapy as an organ-preserving treatment approach for patients with locally advanced laryngeal cancer.

CONCLUSION

This study demonstrates that both paclitaxel and cisplatin, when combined with radiotherapy, are effective treatment options for locally advanced laryngeal cancer, with similar treatment responses observed between the two regimens. While paclitaxel showed a slightly higher response rate, the difference was not statistically significant. Both regimens allowed for effective larynx preservation, providing patients with improved quality of life. These findings support the use of either chemotherapy agent, depending on patient tolerance and resource availability, highlighting the importance of personalized treatment approaches for better patient outcomes.

Recommendations

1. Consider paclitaxel as an alternative to cisplatin for patients with contraindications to cisplatin.
2. Further large-scale studies with longer follow-up to assess long-term outcomes and survival rates.
3. Incorporate larynx-preserving chemoradiotherapy as a standard approach in treating locally advanced laryngeal cancer.

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Conflict of interest: None declared.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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