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Comparing the Effectiveness and Safety Profiles of Accelerated Fractionation Radiotherapy with Concomitant Boost and Conventional Fractionation Radiotherapy for the Treatment of Inoperable Locally Advanced Non-Small Cell Lung Cancer

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ABSTRACT

Background and aim: Non-small cell lung cancer (NSCLC) has aggressive tumor growth and requires high radiation doses for effective tumor control. The purpose of this study was to compare the therapeutic efficacy and toxicity profiles of accelerated fractionation radiotherapy with a concurrent boost to standard radiotherapy protocols in patients with inoperable locally advanced non-small cell lung cancer (LA-NSCLC).

Material and methods: This randomized controlled trial was conducted in the Radiation Oncology Department, RIMS, among 118 patients of LA-NSCLC distributed in two study arms during the period November 2020 to October 2022. In Arms A (n=59), patients received conventional radiotherapy consisting of 60 Gy delivered in 30 fractions over six weeks. This regimen comprised 25 initial fractions of 2 Gy each, followed by a 5-fraction boost. Arm B (n=59) employed an accelerated fractionation schedule. Patients initially received 19 fractions of 2 Gy each. Subsequently, they underwent twice-daily irradiation: 2 Gy to the primary target volume in the morning, followed by a 1.5 Gy boost to a reduced field in the evening, with a minimum 6-hour interval resulting in a total dose of 59 Gy over 25 fractions in five weeks.

Results: Patient demographics were well-matched. The response rate for Arm-A was 54.2%, and in Arm-B, it was 72.9% (P=0.035). Arm-B demonstrated a longer median progression-free survival of 11 months compared to Arm-A's 9 months. The cumulative radiation-induced toxicities between the two groups did not show any statistically significant differences.

Conclusions: Accelerated fractionated radiotherapy has significant potential as a treatment option for patients with inoperable NSCLC.

1. Introduction

Lung cancer stands as the prevailing malignancy globally and continues to be the primary contributor to cancer-related fatalities worldwide. In histopathological terms, lung cancer can be divided into two main subtypes: non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Of these, NSCLC accounts for about 80–85% of all cases of lung cancer. The primary frontline therapeutic strategy for individuals diagnosed with unresectable locally advanced NSCLC and exhibiting a favorable performance status is concurrent chemoradiation.[1-2] Despite diligent endeavors, radiotherapy, whether administered as a monotherapy or in conjunction with chemotherapy, has regrettably failed to yield substantial enhancements in the 5-year survival rates, which have stagnated within the range of 5-10% for individuals grappling with locally advanced NSCLC. This stagnation in survival outcomes primarily stems from the persistent challenge of inadequate local disease control, resulting in a pronounced detriment to overall survival.[3] Hence, enhancing loco-regional control remains a pivotal factor in extending patient survival. Its rapid tumor proliferation characterizes NSCLC, necessitating the application of notably high radiation doses to achieve tumor sterilization. Emerging evidence supports the notion that a condensed irradiation regimen while maintaining high dosage levels, can exert a more potent influence on tumor cell eradication by limiting the window of opportunity for unchecked tumor cell proliferation.[4]

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Accelerated fractionation R.T. with a concomitant boost represents a hybrid adaptation within the spectrum of accelerated fractionation protocols, characterized by modified radiotherapy scheduling that moderately shortens the treatment duration while maintaining the total radiation dosage within a range akin to conventional regimens. This approach strategically concentrates the highest radiation dosage over a concise treatment period on known tumor areas, effectively countering accelerated tumor repopulation post-initiation of radiation therapy, thereby enhancing local tumor control. The present investigation assessed treatment response and adverse effects, drawing a comparative analysis between Accelerated Fractionation R.T. with Concomitant Boost and conventional R.T. in the context of unresectable LA-NSCLC.

2. Material and methods

Patients

A prospective randomized controlled trial was conducted in collaboration between the Department of Radiation Oncology and the Department of Respiratory Medicine at our institute, spanning a 2-year duration from November 2020 to October 2022. Ethical approval was granted by the Research Ethics Board of our institution to conduct this study (Ref.No.A/206/REB-Comm(SP)/RIMS/2015/745/87/2020). The study cohort comprised patients histopathologically confirmed with unresectable LA-NSCLC who presented at the Department of Radiation Oncology and the Department of Respiratory Medicine and exhibited a Karnofsky Performance Status Score (KPS) of $\geqslant$ 60%, without any concurrent medical or surgical comorbidities or pregnancy/lactation. Each patient underwent a minimum six-month follow-up period.

Study design and treatments

All eligible patients were subjected to randomization, dividing them into two treatment arms. In Arm-A, patients received a cumulative dose of 6000 cGy delivered in 30 fractions over a 6-week period, with treatment sessions occurring five times a week. For the initial 25 fractions, a broad field with a 2 cm margin was exposed to 200 cGy per fraction per day. Subsequently, a boost was administered to the loco-regional area, employing a reduced field with a 1 cm margin for an additional five fractions, maintaining the same daily dosage. Spinal cord-sparing measures were implemented after delivering 4400 cGy in 22 fractions in this arm. In Arm-B, patients were prescribed a total dose of 5900 cGy, distributed across 25 fractions over a 5-week period, with treatments administered five times weekly. During the initial 19 fractions, the large field with a 2 cm margin received a daily radiation dose of 200 cGy per fraction. During the last six treatment days, an accelerated regimen was adopted, with 200 cGy per fraction delivered to the same large field in the morning and 150 cGy per fraction to the loco-regional area in the evening, utilizing a reduced field with a 1 cm margin. A minimum 6-hour gap was maintained between these two fractions of the day. Spinal cord-sparing measures were introduced after reaching a cumulative dose of 4150 cGy in 20 fractions in this arm. R.T. was delivered utilizing the Theratron 780C, a Cobalt-60 teletherapy machine, maintaining a source-to-skin distance (SSD) of 80 cm, and the dosage was prescribed at the mid-plane. Patients were treated supine with two parallel opposed beams with an anterior-posterior (A.P.) to posterior-anterior (P.A.) portal setup. We meticulously calculated the Biological Effective Dose (BED) for both treatment approaches, enabling an accurate comparison of the biological effectiveness between accelerated fractionated R.T. and conventional fractionation.

Follow-up and statistical analysis

The early treatment response was evaluated one month following the completion of radiation therapy, employing the World Health Organization (WHO) Response Criteria. Early toxicities were systematically evaluated weekly throughout the course of radiation treatment and were subjected to grading per the RTOG acute radiation toxicity grading criteria. Late toxicities were systematically assessed at the three-month post-treatment mark and subsequently at three-month intervals up to one year, with evaluations conducted in alignment with the RTOG late radiation morbidity grading system. Data analysis was conducted using IBM SPSS Statistics 26 for Windows (IBM Corp, Armonk, N.Y., USA). Percentages were employed for data summarization. Treatment response and toxicity profiles across the groups were scrutinized using the chi-square test. Survival analysis was executed via Kaplan-Meier survival curves. Statistical significance was defined as a p-value less than 0.05.

3. Results

A total of 118 cases diagnosed with NSCLC were enrolled in the study, conducted at the Department of Radiation Oncology, RIMS, Imphal, spanning from November 2020 to August 2022. The cohort was divided evenly, with 59 patients randomly allocated to Arm-A and Arm-B. Following treatment, these patients were closely observed for at least six months. Notably, no treatment delays or patient dropouts were observed throughout the study. Regular assessments of hematological parameters, lung, and esophageal toxicity were performed on a weekly basis, with prompt interventions, including blood transfusions and Growth Colony-stimulating Factor (GCSF) support, along with other supportive measures, implemented to mitigate treatment disruptions. Table 1 illustrates the characteristics of patients and tumors. The patient population was predominantly male, with a median age of 59 years in Arm-A and 58 years in Arm-B. Most patients exhibited a Karnofsky Performance Status (KPS) score of 80%. Cough was the prevailing clinical presentation in both Arm-A (61%) and Arm-B (67.7%), followed by chest pain, shortness of breath, and hemoptysis, respectively. Of the patients, 59.3% had been diagnosed with squamous cell carcinoma; 46.6% and 53.4% of the cohort had cases of stage IIIA and IIIB disease, respectively.

Table 1. Characteristics of patients and tumors (n=118).

Characteristics	Arm-A (n=59)	Arm-B (n=59)	p-value
Median Age in Years	59	58	0.526
	Sex		
Male	39	42	0.426
Female	20	17	
	KPS		
60%	4	3	
70%	19	22	
80%	24	22	0.93
90%	12	12	
	Clinical presentation		
Cough	36	40	
Chest pain	20	24	
SOB	22	20	0.78
Haemoptysis	10	8	
	Stage		
IIIA	29	26	
IIIB	30	33	0.76
	Histopathology		
Squamous cell carcinoma	36	34	0.7
Adenocarcinoma	23	17	

Following the completion of treatment, a comprehensive evaluation was conducted on the cohort of 118 patients who underwent the prescribed regimens. Fig. 1. represents the response rate in patients according to the WHO response criteria after six weeks of completing treatment. In Arm-A, two patients achieved complete responses, while thirty patients exhibited partial responses. Additionally, twenty-three patients maintained stable disease status, and four patients experienced disease progression. In contrast, Arm-B demonstrated more robust outcomes, with four patients (6.8%) achieving complete responses and thirty-nine (66.1%) demonstrating partial responses. Thirteen patients in Arm-B exhibited stable disease, and three patients faced disease progression. Notably, the overall response rate was 54.2% in Arm A and 72.9% in Arm B. The disparity in response rates between these two arms was statistically significant (P = 0.035).

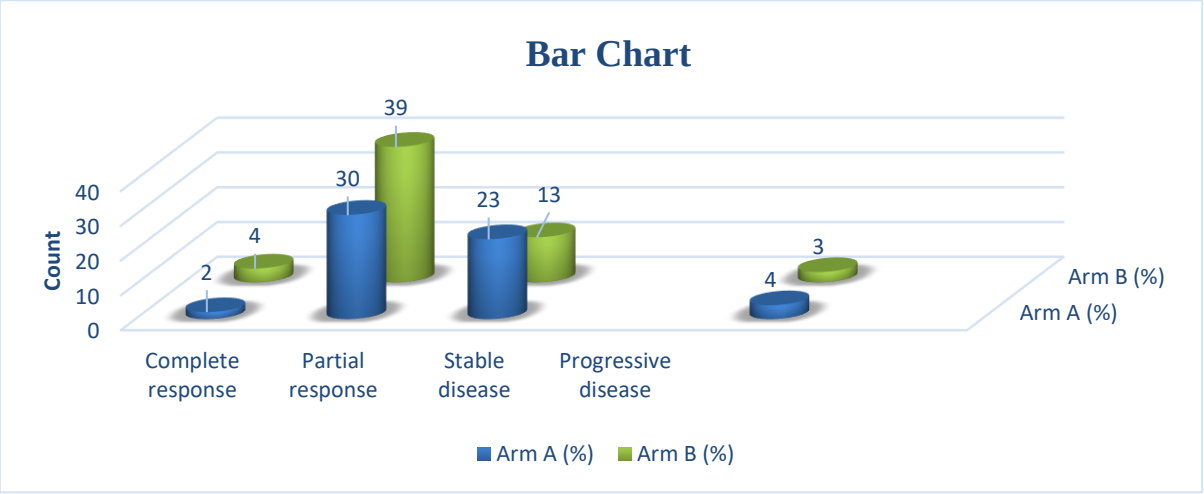

Fig. 1. Response rate in patients according to WHO response criteria after six weeks of completion of treatment.

Table 2. Overall summary of adverse events.

Symptoms	Group	G1	G2	G3	G4	G5
Acute Toxicity						
Anemia	Arm-A	14	5	0	0	0
	Arm-B	19	9	0	0	0
Neutropenia	Arm-A	11	2	0	0	0
	Arm-B	11	3	0	0	0
Thrombocytopenia	Arm-A	11	5	0	0	0
	Arm-B	11	7	0	0	0
Esophagitis	Arm-A	32	0	0	0	0
	Arm-B	34	0	0	0	0
Pneumonitis	Arm-A	9	0	0	0	0
	Arm-B	13	0	0	0	0
Late Toxicity						
Lung Fibrosis	Arm-A	27	4	0	0	0
	Arm-B	33	4	0	0	0
Cardiac toxicity	Arm-A	13	0	0	0	0
	Arm-B	15	0	0	0	0
Dysphagia	Arm-A	20	0	0	0	0
	Arm-B	26	0	0	0	0

Table 2 displays acute and late toxicities observed during the study, with reported toxic effects limited to grades I and II. Notably, radiation esophagitis emerged as the most prevalent acute toxicity, with grade 1 radiation esophagitis noted in 32 patients in Arm-A and 34 patients in Arm-B, while grade 1 radiation pneumonitis occurred in 9 patients in Arm-A and 13 patients in Arm-B (P=0.9). Additionally, grade 1 lung fibrosis was documented in 27 patients in Arm-A and 33 patients in Arm-B. Grade 1 cardiac toxicity was experienced by 13 patients in Arm-A and 15 patients in Arm-B, with no instances of myelitis reported in either arm. Notably, most of these toxicities exhibited a reduction in severity during the subsequent follow-up period. Figure 2 represents the Progression-free survival in months. Arm-B demonstrated a longer median PFS of 11 months compared to Arm-A's 9 months, with a statistically significant difference denoted by a p-value of 0.047.

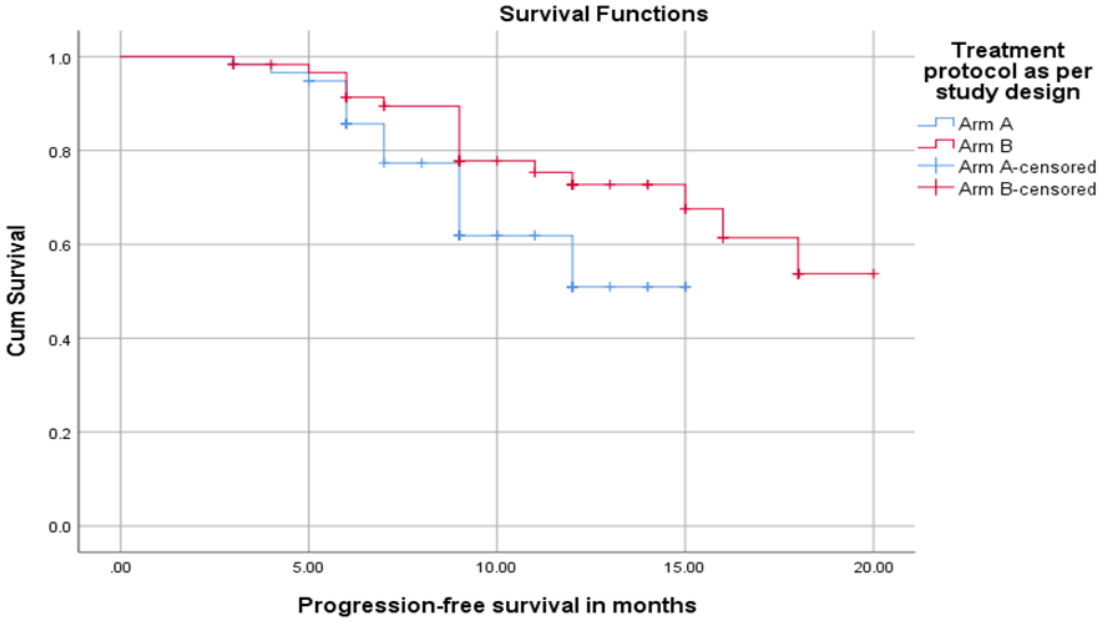

Fig. 1. Progression-free survival.

4. Discussion

In enhancing overall survival among LA-NSCLC patients, the imperative focus lies in achieving robust primary tumor control. Empirical investigations into radical R.T. dose escalation for cases of unresectable or medically inoperable NSCLC have consistently unveiled a compelling dose-response relationship.[5, 6] Furthermore, accelerated treatment regimens, characterized by treatment durations of fewer than six weeks, have demonstrated a potential advantage over protracted conventionally fractionated protocols. This abbreviated treatment schedule holds promise in averting accelerated repopulation of tumor cells during fractionated radiation therapy, consequently bolstering the prospects for local cure.[7] The implementation of accelerated R.T. presents a cost-effective alternative, particularly for patients undergoing sequential chemoradiotherapy (CRT) or radiotherapy alone. It is, therefore, strongly recommended as a curative approach for patients afflicted with unresected NSCLC who do not undergo concurrent chemoradiotherapy.

Patients' characteristics

With a mean age of 56.9 years, the majority of patients in our current study were between the ages of 61 and 70, which is consistent with the known trend that lung cancer primarily affects older people. These findings are consistent with prior studies.[8] Nevertheless, it is worth noting that studies conducted[9] documented higher median ages within the study populations. Male patients exhibited a predominant representation within our study cohort compared to female patients, a pattern consistently observed in other investigations. Furthermore, most of the patients in our study had a KPS of 80%, which is consistent with Prasad et al.[10] findings. The clinical presentation was akin between Arm A and Arm B, with cough as the most common presenting symptom, followed by chest pain, shortness of breath, and hemoptysis, a pattern akin to the observations made by Buchherri et al.[11] In our study, squamous cell carcinoma was diagnosed in 59.3% of patients, with 46.6% presenting with stage IIIA disease and 53.4% with stage IIIB disease. Notably, the two study groups were well-matched, devoid of any statistically significant differences concerning age, stage, or KPS.

Response

In the present study, Arm A revealed a 3.4% complete response rate, and 50.8% of patients had a partial response, resulting in a 54.2% overall response rate. Arm B, on the other hand, indicated a complete response rate of 6.8% and a partial response rate of 66.1% of patients, for a total response rate of 72.9%. These assessments were based on radiological imaging conducted one month after the conclusion of treatment. In terms of disease progression, Arm A reported a rate of 6.8%, accompanied by 39% of patients demonstrating stable disease. In Arm B, 5.1% of patients experienced disease progression, while 22% maintained stable disease status. Notably, the response rate observed in Arm B aligns with a study conducted by Kim Y.H. et al.[9] where patients received concurrent chemoradiation. However, it is important to note that the response rates obtained in both arms of our study fell short of those obtained in the study conducted by Elmesidy et al.[12] In the latter investigation, the response rates were notably higher at 84% in the accelerated concomitant boost arm and 80% in the conventional arm. The utilization of

two cycles of induction chemotherapy may have contributed to these differential results. Our study has demonstrated superior outcomes when compared to the investigation conducted by Izmirli et al.[13] In their study, patients received treatment with a fractionated radiation dose of 1.8 Gy to the large field and 1.8 Gy to the boost field, with a 6-hour interval, reaching a cumulative dose of 63 Gy over 35 fractions. This regimen resulted in a complete response rate of 8% and a partial response rate of 50% among the patients. Notably, several other studies also reported response rates that were comparatively less favorable than those observed in our study.

Toxicity

During the six-week treatment course in our study, toxicity patterns predominantly emerged after the third week of treatment initiation, with grade 1 esophageal and lung toxicities being the most prevalent in both arms. This study reveals a higher incidence of esophagitis compared to the study conducted by Koutaisoff et al,[14] where oesophageal toxicity was observed in 13.5%. However, it is considerably lower than the study conducted by Izmirli et al.,[13] where oesophageal toxicity was reported in 85% of cases. Lung toxicity was reported in 15.3% of patients in Arm A and 22% in Arm B, with all cases presenting as grade 1 toxicity. Importantly, in all instances, these toxicities proved to be reversible within three weeks following the completion of radiation therapy.

Furthermore, hematological toxicities, such as anemia, leucopenia, and thrombocytopenia, were more pronounced among Arm-B patients during the six-week treatment period, with the majority of cases classified as grade 1 toxicity. These observations align with the results reported in the study conducted.[14] This comprehensive study showed that radiation toxicities were more prominent in Arm B, although they remained well-managed and did not compromise the overall treatment course. The occurrence of late side effects, evaluated at 3, 6, and 9 months after treatment completion within a median follow-up period of 12 months, remained within acceptable thresholds, even in the context of accelerated radiotherapy utilization. However, it is imperative to acknowledge that an extended follow-up period is essential for a more accurate assessment of late adverse events. The application of accelerated radiotherapy, by reducing the overall treatment duration while retaining high radiation dosages, represents a viable and practical alternative to conventional treatment regimens. The abbreviated treatment schedule not only potentially intensifies the tumor cell-killing effect but also mitigates prolonged waiting times due to the reduction in the number of treatment fractions. Undoubtedly, accelerated radiotherapy stands as a promising approach that offers significant benefits to patients, facilitating improved local control, and concurrently contributing to the economic efficiency of healthcare systems.

Progression-free survival

The median PFS in Arm A and Arm B closely corresponded to the results reported by Izmirli et al,[13] who observed a median PFS of 13 months, and the findings of Koutaisoff et al,[14] where the median PFS was 10.2 months, with PFS reaching nine months in Arm A and 11 months in Arm B. However, it is important to note that these PFS values were lower when compared to the study conducted by Abrao et al.[15] Our study has certain limitations, including a relatively short follow-up duration, a modest sample size, and the utilization of a 2-D Cobalt-60 teletherapy machine for treatment delivery.

5. Conclusion

Radiation therapy is crucial to the comprehensive treatment of NSCLC. The predominant factor contributing to treatment failure is the lack of local control, consequently leading to compromised overall survival. Therefore, enhancing loco-regional control assumes a critical role in extending patient survival. It has been substantiated that a condensed course of irradiation, preserving high dosage levels, exerts a more potent effect in eradicating tumor cells, primarily by curtailing opportunities for tumor cell proliferation. In our current study, Arm B exhibited superior response rates, albeit with slightly elevated treatment-related toxicities, which remained well-managed. As a result, accelerated fractionated R.T. emerges as a promising and feasible approach for patients with inoperable NSCLC, outperforming conventional fractionation regimens. However, an extended follow-up duration with an expanded sample size and comparative trials is imperative for a conclusive assessment of the long-term response and toxicity profile.

Conflict of Interest

The authors declared that there is no conflict of interest.

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