Research Article

Palliative radiotherapy in locally advanced and metastatic carcinoma of lung with two radiotherapy regimens: A randomized comparative study from tertiary health-care cancer center

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ABSTRACT

Background: Worldwide, leading cause of cancer mortality is lung cancer. Approximately 63,000/year new lung cancer cases reported in India. Around 80–85% of patients of lung cancer is non-small cell histology (non-small cell lung cancer) and over >90% of patients presented locally advanced and metastatic disease. Hence, in these patients, population curative treatment approach with radiotherapy (RT) and chemotherapy in most of the time is non-viable option yielding short survival and relatively poor prognosis. In majority of such cases, the only aim of treatment remains palliative, the main aim is to improve quality of life. Although there are other medical management of symptoms palliation, radiation therapy is the cheapest option, quite effective, time efficient, and well tolerated in providing relief from symptoms. The rate of palliation of symptoms is quite high for chest pain and hemoptysis at 60–80%, whereas cough and dyspnea are improved in only 50–70%. For intrathoracic disease with obstructive symptoms, 30 Gy/10# over 2 weeks are generally recommended. Patients with poor performance status, advanced age, and associated comorbidity at the time of diagnosis, for which daily RT over 2–3 weeks is logistically difficult, 1–2 fractions have been utilized with good results. There are multiple randomized trials showed that both short and long RT course were equally effective for symptoms control. **Aims and Objectives:** The aims of our study are to compare the outcome, symptom control and assess toxicity profile in locally advanced lung cancer patient with 17 Gy/2 fractions (8.5 Gy/fraction, × 2 fractions) only on Saturdays over 2 weeks versus 30 Gy/10 fractions (3 Gy/fraction) over 2 weeks and to compare quality of life. **Materials and Methods:** This study was a single-institutional, prospective, open-labeled, randomized controlled study. Eligible patients were age ≥18 years with histopathologically proven lung carcinoma which was inoperable Stage III or IV disease and too locally advanced to curative concurrent chemoradiation, pulmonary symptoms attributable to the primary tumor, Eastern Cooperative Oncology Group (ECOG) performance status ≤3, and adequate hematologic (hemoglobin >10 g/dl; absolute neutrophil count >1500; platelet count >100,000/ml; and hepatic and renal function calculated creatinine >60 ml/min). Patients with bleeding diathesis, emphysematous bullae, poor respiratory function or reserve, pregnancy, and ECOG performance status >3 were excluded from the study. **Results:** Age, stage, histopathology, and pre-treatment symptoms score between two groups were comparable and statistically not significant. Pain in chest due to lung cancer was decreased in both arms due to treatment (at treatment completion Arm A = 47.62 and Arm B = 38.09). However, at the 2nd follow-up, difference between two arms was statistically significant where Arm A = 27.78 and Arm B = 15.00; $P = 0.005$. Global health status of patients in this study was improved in both arms due to treatment. Physical functioning emotional functioning, role functioning, global health status, cognitive functioning, and social functioning were improved in both arms due to treatment and kept improving during follow-up, but difference between two arms was not significance. **Conclusions:** Although overall symptom palliation, toxicity profile, and quality of life parameters are

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almost equal in both arms, patients with short expected survival, 8.5 Gy × 2 fractions would be preferable, limiting the number of hospital visit to a minimum. On the other hand, 3 Gy × 10 fractions schedule can be chosen for those patients with longer expected survival and better ECOG status, due to prolong duration of palliative response.

KEY WORDS: Radiotherapy; Symptoms; Palliation; Lung Carcinoma; Performance Status

INTRODUCTION

Worldwide, in the year 2018, for all sexes and all ages, carcinoma of lung is the most common cancer with incidence of 2094 million new cases (11.6%). Worldwide, leading cause of cancer mortality is lung cancer, causing 18.4% of all cancer deaths and 1.8 million deaths in the year 2018. Approximately 63,000/year new lung cancer cases reported in India.[1,2] Around 80–85% of patients of lung cancer is non-small cell histology (non-small cell lung cancer [NSCLC]) and over >90% of patients presented locally advanced and metastatic disease. Hence, in these patients, population curative treatment approach with radiotherapy (RT) and chemotherapy in most of the time is non-viable option yielding short survival and relatively poor prognosis.[3-5] In patients with non-metastatic but inoperable lung cancer that is locally too extensive for radical RT and also who have poor performance status, it is important to determine whether thoracic RT should be the minimum that is required to palliate thoracic symptoms or whether treatment should be more intensive, with the aim of prolonging survival.[6] As previously stated, most of the lung cancer patients are coming with a late Stage III, locally advanced and metastatic disease; in majority of such cases, the only aim of treatment remains palliative, the main aim is to improve quality of life.[6-8] Though there are other medical management of symptoms palliation, but radiation therapy is the cheapest, quite effective, time efficient, well tolerated in providing relief from thoracic pain and dyspnea from airway obstruction due to local lung pathology. It also helps to control symptoms like hemoptysis, hoarseness of voice from recurrent laryngeal nerve palsy and superior vena cava obstruction.[9] The rate of palliation of symptoms is quite high for chest pain and hemoptysis at 60–80%, whereas cough and dyspnea are improved in only 50–70%.[10] For intrathoracic disease with obstructive symptoms, 30 Gy/10# over 2 weeks are generally recommended.[10,11] Patients with poor performance status, advanced age, and associated comorbidity at the time of diagnosis, for which daily RT over 2–3 weeks is logistically difficult, 17 Gy in two fractions in 2 weeks, and 8–10 Gy in single fraction have been utilized with good results and patients with average prognosis and performance status 30 Gy/10 fractions/2 weeks have been advocated. The number of patients attending the RT department of our institution is clearly showing a discrepancy between the availability of infrastructure in terms of machinery power and the bulk of patients in need of early radiation treatment for symptoms palliation. There are multiple randomized trials showed that both short (17 Gy/2 fractions) and long course RT (30 Gy/10 fractions/2 weeks) were equally effective for symptoms control.[12-14] Furthermore, hypofractionation may release RT resource and make RT more available for other group of cancer patients. On the basis of above-mentioned published literature, we have treated small number of patients by both the palliative RT regimen, 17 Gy/2 fractions and 30 Gy/10 fractions/2 week, we have limited experience regarding feasibility of both these regimen and we did not compare the effectiveness and toxicity of the regimens. The purpose of the study was to compare the effectiveness of two different regimens of radiation; 8.5 Gy × 2 fractions versus 30 Gy/10 fractions for palliation in locally advanced, metastatic lung carcinoma in terms of symptom relief, toxicity profile, and assessment of quality of life. To conduct the study, we included 50 patients with lung carcinoma in each arm with histological proof, attending our RT Department at NRS Medical College and Hospital, Kolkata. The patients were randomized into two groups, Arm A received 17 Gy in 2 fractions over 2 weeks (1 fraction/week) and Arm B received 30 Gy in 10 fractions in 2 weeks (5 fractions/week).

MATERIALS AND METHODS

This study was a single-institutional, prospective, open-labeled, randomized controlled study. Eligible patients were age ≥18 years with histopathologically proven lung carcinoma which was inoperable Stage III or IV disease and too locally advanced to curative concurrent chemoradiation, pulmonary symptoms attributable to the primary tumor, Eastern Cooperative Oncology Group (ECOG) performance status ≤3, and adequate hematologic (hemoglobin [Hb] >10 g/dl; absolute neutrophil count >1500; platelet count >100,000/ml; and hepatic and renal function calculated creatinine >60 ml/min). Patients with bleeding diathesis, emphysematous bullae, poor respiratory function or reserve, pregnancy, and ECOG performance status >3 were excluded from the study. As it is a prospective randomized study, we have taken approval from institutional ethical committee and after getting formal approval from the institutional ethical committee, we have started patient accrual for our study. After receiving informed consent of the patients random assignment and treatment started.

Treatment Protocol

Treatment protocol depicted Figure 1. After confirming by biopsy, before starting treatment, all patients underwent

complete blood count, complete metabolic profile, bronchoscopy, contrast-enhanced computed tomography (CT) of chest to assess extent of locoregional disease, ultrasonography of whole abdomen, and whole-body fluorodeoxyglucose-positron emission tomography CT scan and bone scan to rule out distant metastasis. Between January 2015 and January 2017, 100 previously untreated patients with locally advanced and metastatic histologically confirmed carcinoma of lung patients were randomly allocated into two arms – Arm A: 50 patients received 17 Gy/2# for 2 weeks (8.5 Gy/#/week, only on Saturdays) and Arm B: 50 patients received 30 Gy/10# for 2 weeks (3 Gy/#, 5#/week; Monday–Friday) and outcomes will be compared between those groups. Patients were positioned in supine with arms immobilized above the head in a comfortable and reproducible position to allow a greater choice of beam angle. Conventional two-dimensional treatment planning was done with the help of anatomical landmarks. Marking was done in skin by marker taking whole of the tumor mass and lymph nodes, as gross tumor volume (GTV) with a 2 cm margin around the GTV. EBRT delivered in Theratron 780E isocentric Co-60 teletherapy machine using anterior-posterior parallel opposed fields. The American Joint Committee on Cancer Tumor, Node, and Metastasis staging system used for staging of lung cancer (7th Edition). Patients were followed at the end of 2nd week, 6th week, and 12th week after completion of treatment and toxicity of the patients was assessed by clinical examination, and laboratory and assessment of quality of life is done by the European Organization for the Research and Treatment of Cancer questionnaire quality of life questionnaire (QLQ)-C30 and QLQ-LC13. Statistical analysis was conducted using IBM SPSS Statistics version 19.0 (SPSS Inc., Chicago, IL). For normally distributed data, the mean values between the two arms were compared for test of significance using unpaired *t*-test. Interarm mean differences were compared for test of significance using paired *t*-test. For comparing proportions of different events in between the two arms, Pearson's Chi-square test was applied as test of significance.

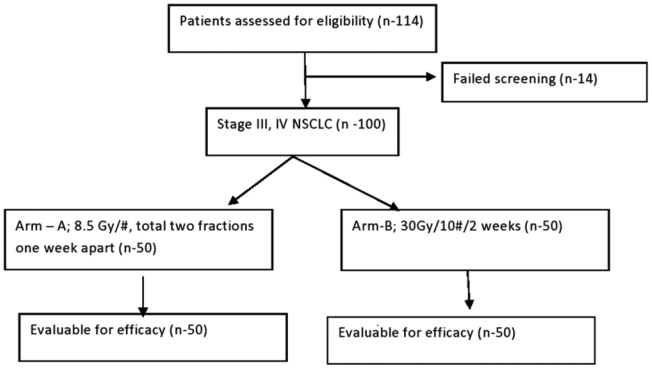

Figure 1: Treatment protocol

Table 1: Age distribution in two treatment arms

Age	Arm		*P* value	Significance
	Arm A	Arm B		
	Mean±Std. deviation	Mean±Std. deviation		
	57.11±7.72	54±6.92	0.119	Not significant

Table 2: Sex distributions between two treatment arms

Sex	Arm (%)		Total (%)	*P* value	Significance
	Arm A	Arm B			
Female	5 (10)	0	5 (5)	0.075	Not significant
Male	45 (90)	50 (100)	95 (95)		
Total	50	50	100		

RESULTS

The mean age of patient enrolled for this study is 55.5 years. Comparing the mean age between two groups by unpaired *t*-test, *P* value was not statistically significant (0.119). Hence, the groups were comparable with respect to age [Table 1]. Sex distribution between two arms was comparable and statistically not significant [Table 2]. 68% of patients have squamous cell carcinoma, 32% have adenocarcinoma. Comparing histopathology reports of two group of population by unpaired *t*-test, *P* value was not statistically significant (0.599). Hence, the two groups were comparable [Table 3]. Almost 54% of patients in the study group were in Stage III B, 31% of patients in the study group were in Stage IIIA, and 15% of patients were in Stage IV [Table 4]. Approximately 61% of the study population in Arm A belongs to ECOG 3 and 75% of the study population in Arm B belongs to ECOG 3 ($P = 0.252$) and rest belongs to ECOG 2. Hence, difference between the two arms is not significant. Baseline Hb, total lung capacity, platelets count, urea, and creatinine between two were comparable and statistically not significant. Pain in chest due to lung cancer was decreased in both arms due to treatment (at treatment completion Arm A = 47.62 and

Table 3: Histopathologic distributions between two treatment arms

Histology	Arm (%)		Total (%)	*P* value	Significance
	Arm A	Arm B			
Adenocarcinoma	15 (30)	17 (33)	32 (32)	0.599	Not significant
Sq. cell carcinoma	35 (70)	33 (67)	68 (68)		
Total	50	50	100		

Arm B = 38.09). However, at the 2nd follow-up, difference between two arms was statistically significant where Arm A = 27.78 and Arm B = 15.00; *P* = 0.005 [Figure 2 and Table 5]. Baseline global health status (QL2; Table 6), functional scales (PF2, RF2, EF, CF, and SF), generalized symptom scales (FA, NV, PA, SL, AP, CO, and FI; Table 7), and lung cancer-specific symptom scales (LCDY, LCCO, LCHA, LCSM, LCDS, LCPN, LCHR, LCPC, LCPA, and LCPO) were comparable between two arms. Global health status (QL2) of patients in this study was improved in both arms due to treatment. Physical functioning emotional functioning, role functioning, global health status, cognitive functioning, and social functioning were improved in both arms due to the treatment and kept improving during follow-up, but difference between two arms was not significance.

DISCUSSION

Age, stage, histopathology, and pre-treatment symptoms score between two groups were comparable and statistically not significant. Pain in chest due to lung cancer was decreased in both arms due to treatment (at treatment completion Arm A = 47.62 and Arm B = 38.09). However, at the 2nd follow-up, difference between two arms was statistically significant where Arm A = 27.78 and Arm B = 15.00; *P* = 0.005. Global health status of patients in this study was improved in both arms due to treatment. Physical functioning emotional functioning, role functioning, global health status, cognitive functioning, and social functioning were improved in both arms due to treatment and kept improving during follow-up, but difference between two arms was not significance.

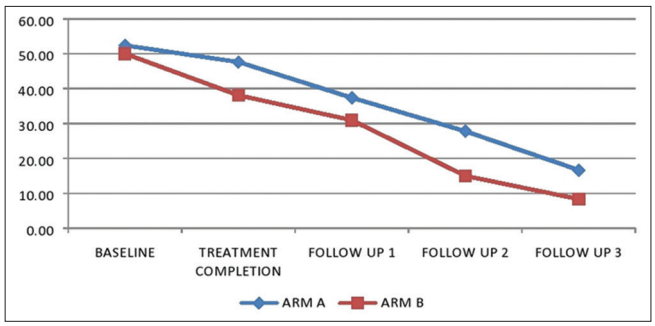

Figure 2: Pain in chest (post-radiation therapy)l

Table 4: Stage-wise distribution of patients between two arms

Stage	Arm (%)		Total (%)	*P* value	Significance
	Arm A	Arm B			
III B	27 (54)	27 (53)	54 (54)	0.767	Not significant
III A	16 (32)	15 (31)	31 (31)		
IV	7 (14)	8 (16)	15 (15)		
Total	50	50	100		

The median age of patients in our study was 55.5 years. According to available literature, the most common age for the development of lung cancer is the 4th–7th decade in India.[1,3] The mean age of our study thus corresponds to the existing data. In the present study, 94.64% of patients were male, indicating that lung carcinoma is more prevalent in male than in female. Carcinoma of the lung is more common malignancies in male, attending our outpatient department, well correlated with published literature.[1-3] The baseline parameters including ECOG performance status, histology, stage, baseline hematological parameters, and gender-wise distribution of the patients were comparable in both treatment arms. Baseline global health status (QL2), functional scales (PF2, RF2, EF, CF, and SF), generalized symptom scales (FA, NV, PA, SL, AP, CO, and FI), and lung cancer-specific symptom scales (LCDY, LCCO, LCHA, LCSM, LCDS, LCPN, LCHR, LCPC, LCPA, and LCPO) were comparable between two arms. Global health status (QL2) of patients in this study was improved in both arms due to treatment. Pain in chest due to lung cancer was decreased in both arms due to treatment. However, this improvement is more prominent in Arm B as compared to Arm A. At the 2nd follow-up, difference between two arms is statistically significant (Arm A=27.8 and Arm B= 14.9; *P* = 0.005). As previously mentioned that patient with locally advanced carcinoma of lung has a very short overall survival in spite of treatment with different newer improved chemotherapeutic agents and other newly discovered targeted molecules, the main goal in most of the terminally ill patients remains palliative due to their poor performance status due to variety of factors such as loss of appetite, significant weight loss, poor pulmonary reserve, and subclinical distant metastasis which becomes overt within a few months of completion of treatment. Our study comparing the efficacy of two different dose fractionation schedules of thoracic radiation

Table 5: Pain in chest (response to treatment)

Pain	Arm		*P* value	Significance
	Arm A	Arm B		
	Mean±Std. deviation	Mean±Std. deviation		
Pain (PA) baseline	50±18.15	52.38±16.8	0.613	Not significant
Pain (PA) treatment completion	38.09±19.7	47.62±20.14	0.079	Not significant
Pain (PA) follow-up 1	30.95±24.73	37.38±20.24	0.292	Not significant
Pain (PA) follow-up 2	15±13.13	27.78±8.2	0.005	Significant
Pain (PA) follow-up 3	8.33±8.91	16.67±0	0.098	Not significant

(17 Gy in 2 fractions in Arm A and 30 Gy in 10 fractions in Arm B) for palliation of symptoms such as chest pain, dyspnea, hemoptysis, and to assess quality of life. In this study, we mainly focused on whether the short fractionation schedule (17/Gy in 2 fractions) is equally effective in relieving symptoms compared to longer fractionation schedules. We observed that both RT regimens are equally effective in respect to symptom control, toxicity profile, and assessment of quality of life, but in the 10 × 3 Gy arm, the palliative benefit of RT persisted longer compared to 2 × 8.5 Gy arm, which was statistically significant. However, there was no statistically significant difference in degree/intensity of pain relief in the two arms. In a landmark trial by Macbeth *et al*.,[12] who also observed that both the RT treatment regimens were equally effective but hypofractionation (8.5 Gy × 2 fractions) resulted in a quicker reduction of symptoms, whereas larger fractionation schedule (39 Gy/13#) resulted in a longer duration of palliation. Our results are consistent with those of above study. An earlier Medical Research Council study[13,14] found no difference in radiological responses, using radiation doses comparable with those used in our study. In a multicenter randomized study by Kramer *et al*.[15] comparing efficacy of 8 Gy × 2 fractions versus 30 Gy/10 fractions/2 weeks in Stage III NSCLC found that both the RT treatment regimens were equally effective but in 30 Gy/10 fractions arm prolonged palliation of symptoms than 8 Gy x 2 fractions arm. The results of our study well correlated with above-mentioned study. Even with higher doses, data about tumor control are conflicting. In a randomized study by Sundstrom *et al*.[16] with respect to symptoms palliation and survival in locally advanced NSCLC, hypofractionated thoracic RT found to be equally effective to that of more protracted higher dose thoracic RT and due to long survival, patients with good PS may benefit more from protected higher dose thoracic RT. Nestle *et al*.[17] and Reinfuss *et al*.[18] also found a tendency of better control with higher radiation doses. This difference in terms of efficacy in the two different fractionation schedules not only because of more total dose or number of fractions but also because of their different biological effective dose. To compare the biological effectiveness of radiation on acutely reacting normal tissue and tumors for each RT schedule, we have used the BED formulation. Comparing the values of BED value of two arm which was in Arm-A 31.5 Gy and in Arm-B 39 Gy, one can understand that Arm B in our study has a more intensive biological effect on the tumor and early reacting tissue since it delivers a total dose of 7.5 Gy more than Arm-A and this translated into treatment better outcome of Arm-B (30 Gy/10#/2 weeks, hyperfractionation) with longer duration of palliation. There are no cardiac toxicities such as acute pericarditis, congestive heart failure, or valvular abnormalities during or after RT in study population. The overall excess risk of cardiac mortality after thoracic RT is low but depends on the dose, volume, and the patient's existing cardiac risk factors.[18] There is also no skin toxicity such as erythema, necrosis, or ulceration in study population during or after treatment. However, on the other hand, symptoms such as fatigue (FA), nausea and vomiting (NV), and appetite loss were increased due to treatment in both arms and then decreased from the 1st follow-up. Radiation-induced FA, nausea, vomiting, and anorexia are well documented in literature. FA remains a major problem for cancer patients even after treatment. RT produced FA typically is short-lived; FA levels initially worsened with RT and returned to baseline after treatment. Large observational studies suggest a worrisome 50–80% overall cumulative incidence rate of some degree of radiation-induced NV among patients undergoing RT.[19]

Limitation of our randomized study is small number of patients and shorter duration of follow-up.

Table 6: Baseline global health status (QL2)

Parameter	Arm A	Arm B	*P* value
Global health status (QL2)	42.76	40.47	0.577
Functional scales			
Physical functioning (PF2)	63.1	70.65	0.339
Role functioning (RF2)	59.52	51.19	0.365
Emotional functioning (EF)	61.9	61.9	1.000
Cognitive functioning (CF)	60.71	62.52	0.710
Social functioning (SF)	39.28	36.9	0.454

CONCLUSIONS

In view of the overall findings in our study, it is obvious that, in patients with short expected survival, 8.5 Gy × 2 fractions can be the treatment of choice as most acute symptoms induced by toxicity can be treated or prevented with steroid, and/or analgesic, limiting the number of hospital visit to a minimum of two to three. On the other hand, although the

Table 7: Generalized symptom (response to treatment) scales

Fatigue	Arm		*P* value	Significance
	Arm A	Arm B		
	Mean±Std. deviation	Mean±Std. deviation		
Fatigue (FA) baseline	45.63±28.59	32.14±30.74	0.095	Not significant
Fatigue (FA) treatment completion	55.14±24.34	46.36±29.13	0.226	Not significant
Fatigue (FA) follow-up 1	47.52±26.17	41.2±16.78	0.286	Not significant
Fatigue (FA) follow-up 2	13.33±16.75	18.47±22.83	0.469	Not significant
Fatigue (FA) follow-up 3	11±11.76	22±0	0.098	Not significant

overall symptom palliation and quality of life parameters are almost equal in both arms, 10 × 3 Gy schedule can be chosen for those patients with longer expected survival and better ECOG status, due to prolong duration of palliative response and should be counseled about dysphagia which is most common toxicity seen in 10 × 3 Gy schedule.

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