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Comparative analysis of hypofractionated vs. conventional radiation therapy with concurrent chemotherapy in advanced inoperable non-small cell lung cancer: a retrospective study

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Abstract

Introduction: Traditional fractionated radiation therapy is commonly used for patients with inoperable stage III non-small cell lung cancer. This study hypothesizes that accelerated hypofractionated radiotherapy could offer comparable effectiveness without increasing toxicity risks.

Materials and methods: This retrospective analysis included patients diagnosed with stage III non-small cell lung cancer between January and September 2020 who were medically or surgically inoperable, free of metastatic disease and did not receive simultaneous chemotherapy. Two treatment arms were compared: Arm A received hypofractionated radiotherapy (55Gy in 20 fractions), and Arm B received conventional fractionation (60Gy in 30 fractions). Both groups adhered to specific dose constraints for critical organs, including the spinal cord, esophagus, heart, and lungs.

Results: The study cohort consisted mainly of individuals aged 56 to 60 years, with a significant smoking history in both groups. The most common symptoms were cough, chest pain, and respiratory distress. Lesions were predominantly located in the right and left upper lobes, and adenocarcinoma was the most common histology. Despite similar performance status, differences in tumour and nodal staging affected treatment response and toxicity profiles. Acute toxicities were comparable across both treatment regimens.

Conclusion: Hypofractionated radiotherapy may be a viable treatment option for patients with inoperable stage III non-small cell lung cancer, especially those with limited performance status. These findings support the need for further research to explore the potential benefits of advanced radiation techniques in this patient population.

Keywords: Accelerated radiotherapy, Lung cancer, Non-small cell lung cancer, Hypofractionated radiotherapy

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Introduction

The most lethal cancer type which kills more people than any other cancer worldwide causing about 1.4 million deaths each year is Lung cancer (1). Many studies on different groups in India show that lung cancer is common in the country. This disease has a significant impact on cancer sickness and death in India (2-4). While lung cancer deaths are going down around the world because fewer people smoke, it seems to be getting more common in India (5, 6). In the year 2012, the Indian Council of Medical Research cancer registry reported 57,795 new lung cancer cases. They think this number will go up to 67,000 new cases a year by 2020 (5). The high death rate from this disease shows it's a significant health problem that needs attention. Only non-small cell lung cancer (NSCLC) accounts for about 80% of the cases. Doctors recommend daily radiation therapy for patients who can't have surgery due to medical reasons. The Radiation Therapy Oncology Group (RTOG) having 7,310 trials (7, 8) shaped this regimen. It involves giving a total radiation dose of 60 Gy split into 2 Gy portions per session.

In India, lung cancer is still a big health problem. Many patients find out they have it when it's already at a late stage - about 86% of cases. Of these around 29% are advanced cases (9), advanced lung cancer includes different types and often means the same thing as stage III lung cancer (10). Right now, we can't cure advanced or metastatic NSCLC (11). This shows we need better ways to screen for and spot lung cancer. If we want to cure it with surgery we must catch it sooner. Even though the numbers look bad, there's some good news. Almost a third of patients with advanced lung cancer might be able to have surgery. Again it emphasizes the importance of quick diagnosis and treatment of lung cancer (12).

The standard treatment for advanced stage III NSCLC combines thoracic radiotherapy (TRT) with chemotherapy (13,14). About 30 years ago, the RTOG, 7301 trial set a radiation dose standard between 60 and 63 gray (Gy) given in 1.8-2.0 Gy fractions. This approach has remained the go-to treatment for this group of patients for over three decades (8).

Even with better treatments, doctors still face problems when trying to get the best results for patients with advanced NSCLC. Tests using higher doses have shown they can help control cancer in the nearby area, but this hasn't helped people live longer once the dose goes above about 60 Gy with conformal radiotherapy (8,15,16). The RTOG 0617 study looked at different radiation doses (60Gy vs. 74Gy) along with chemotherapy (carboplatin + paclitaxel). It didn't find that the higher dose worked better, and it might even cause harm (17). Experts think that longer treatment times let tumour cells grow back more, which could explain why the high-dose group in RTOG 0617 didn't do well (18,19,20). Recent studies have looked at speeding up treatment by using bigger doses once a day instead of smaller doses more than once a day like in hyperfractionation (18, 19).

In recent years, hypofractionation has become a potential way to tackle some of these issues (21). Hypofractionated radiotherapy is made easier by new techniques like volumetric modulated arc therapy (VMAT) when it comes to treatment time, compared to intensity modulated radiation therapy (IMRT) offers a chance to boost the effective dose (BED) without making treatment longer slowing down cancer cell growth (22). Yet, we still don't have many forward-looking randomized studies that compare hypofractionated radiotherapy with concurrent chemotherapy to standard fractionation in these patients. Our study will compare hypofractionated radiotherapy (55 Gy in 20 fractions) with conventionally fractionated radiotherapy (60 Gy in 30 fractions), both administered with concurrent chemotherapy, in the context of locally advanced, inoperable stage III NSCLC. Employing intensity-modulated radiotherapy (IMRT) through volumetric modulated arc therapy (VMAT), it assesses treatment response, acute toxicity, and tolerability to establish if hypofractionation is an equally effective and practical alternative, especially for patients with poor performance status.

Materials and methods

Patient characteristics

Doctors chose patients with inoperable advanced NSCLC to take part in the study. The weekly multidisciplinary tumour board, which included surgeons, radiation oncologists, and medical

oncologists, made these decisions. To be selected, patients needed a confirmed diagnosis and had to qualify for chemotherapy and radiation at the same time.

We looked at the treatment records of lung cancer patients at a major medical centre. This happened in the Department of Radiation Oncology from January 2020 to September 2020 of a tertiary medical facility. We received ethical approval from the institutional ethics committee. The ethics code: (XXXX-IEC-TM-2020-7 dated 16.01.2020). Our criteria led us to include 64 patients in this study.

Inclusion: Patients were included who must have:

- NSCLC was proven by biopsy.
- Cancer at stages IIIA (bulky N2) or IIIB.
- Limited radiation exposure.
- ECOG score less than 2.
- Age between 18 and 70.
- Ability to give consent.
- Meeting physical health standards.

Exclusion: Patients can't take part if they have:

- Had earlier radiotherapy, chemotherapy, or surgery (except biopsy).
- Major health issues alongside cancer.
- Pregnancy or breastfeeding.
- Cancer spreads to distant parts of the body.
- Lack of willingness to participate.
- Small cell lung cancer.
- Age below 18.
- Suitability for surgery or pinpoint radiation.
- Certain lymph node involvement.
- Fluid buildup in the chest due to cancer.
- Serious heart problems.

Study Arm

The study split patients into four groups to test different treatments. These groups got radiation therapy in two ways: at the same time or one after another. They also used two radiation doses: 45 Gy or 60 Gy. This setup helped compare how well each method worked. This setup is focused to find the foremost way to treat these patients. By looking at the results from each group, doctors could figure out which approach had the biggest impact on patients' health.

Treatment and outcomes assessment

We look at a patient's medical history and do a physical exam as part of the pre-treatment check. They also run tests like contrast-enhanced computed tomography (CECT) and blood work. Pulmonary function tests (PFTs) are used to check how well the lungs work. If needed, they might do more imaging studies. This full approach helps doctors to create treatment plans that fit each patient aiming to get the best results.

Radiation Therapy technique

Medical practitioners performed CT simulations on patients using a wide-base 16-slice CT simulator from GE Healthcare USA. They set the cranial limit at the cricoid and the caudal limit at the gastroesophageal junction. To prepare for the simulation medical staff placed patients on their backs and used a vacloc system to keep them still. They aligned lasers over the body to mark three points on the midline and two at the lateral ends. The team put radiopaque ball- bearing stickers (fiducials) near bony landmarks to serve as CT reference points. After completing the CT simulation, they sent the gathered data to the contouring workstation.

Chemotherapy

Admitted patients got chemotherapy on the first day of radiotherapy. Doctors gave Cisplatin 20mg/m2 through IV during fractions 1-4 and 16-19, while they administered Vinorelbine 15mg/m2 on the day of fractions 1, 6, 15, and 20. The first and last weeks of chemoradiotherapy involved inpatient chemotherapy. Four weeks after the concurrent phase ended, patients received outpatient cisplatin (80mg/m2 on day 1) and vinorelbine (25mg/m2 on days 1 and 8) three weeks apart. Standard antiemetic prevention included 16mg of Ondansetron and 16mg of dexamethasone through

IV before chemotherapy followed by oral Ondansetron and Domperidone for 3-5 days after each cycle.

Follow-Up

The research looked at how tumours reacted and the short-term side effects. This included checking for issues with blood (like changes in blood cell numbers), stomach and gut problems (such as feeling sick or having loose stools), skin reactions, and other organ-specific problems.

Statistical Analysis

We collected the research data for this study through random selection and organized it in Microsoft Excel. We then used SPSS version 24 to crunch the numbers further. We analysed and calculated the mean and standard deviation of the data which gives us a full and vivid picture of its central tendency and spread. For distributed continuous data, we summarized baseline characteristics using means and standard deviations. For non-normal data, we used medians and interquartile ranges (IQRs). We presented categorical data as percentages.

We applied the Chi-square test and the Test of Significance to check the difference in proportions to determine the statistical importance of analysing the qualitative data. We determined significance levels by comparing calculated values with tabulated values at specific degrees of freedom, with $P < 0.05$ indicating statistical significance.

Results

RT therapy was administered in the four study arms

The data in the table shows how patients are spread across four treatment groups: "Conc 45 Gy," "Seq 45 Gy, (Conc" is for concurrent chemoradiotherapy, where chemotherapy and radiation therapy are given together, and "Seq" is for sequential treatme nt, where chemotherapy is followed by radiation.)" "Conc 60 Gy," and "Seq 60 Gy." The "Conc 45 Gy" group has 16 patients, which is 24.6% of all patients. The "Seq 45 Gy" group also has 15 patients making up 24.6% of the total. Another 16 patients, or 24.6% of the group, are in the "Conc 60 Gy" arm. The "Seq 60 Gy" group has 17 patients, which is 26.2% of all patients in the study. This even distribution of patients among the treatment groups allows researchers to compare the results of different radiation doses and methods for treating NSCLC.

Demographic and clinical details showed a predominance of female patients, a high rate of smoking, and upper lobe lesion distribution. Cough was the most common presenting symptom. Detailed frequencies are summarized in Table 1.

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Table 1. Demographic characteristics of the patients.

		Number	Percentage
Gender	Male	12	20
	Female	52	80.0
Addiction	Smoker	45	69.2
	Non-smoker	19	30.7
Symptom			
	Cough	30	47.7
	Chest pain	18	27.7
	Respiratory distress	7	10.8
	Hemoptysis	9	13.8
Site of Lesion			
	Right upper lobe	18	27.7
	Right middle lobe	13	21.5
	Right lower lobe	8	12.3
	Left upper lobe	17	26.2
	Left lower lobe	8	12.3

Exploration of ECOG status, Tumour T status, and lymph node involvement within the patient cohort.

The dataset offers key numbers to help cancer research. A look at ECOG status shows that 29.2% of patients have an ECOG score of 0, 47.7% are ECOG 1, and 23.1% are ECOG 2. This shows how well patients can function varies. Tumour T status points to advanced local disease. 56.9% are T3, 18.4% are T2, and 24.6% are T4. This means many tumours have spread a lot. Looking at positive lymph nodes, we see that 44.6% of patients have more than one positive node. 24.6% have

3 positive nodes (**Table 2).** This suggests the cancer might spread and get worse. Using these exact numbers can improve treatment plans and help predict outcomes better in cancer care.

Events for Disease-free Survival	44 (67.7%)	20 (32.3%)	N/A	64

Table 2. Spatial pattern of pathology.

Toxicity Type	Grade 0 Frequency	Grade 1 Frequency	Grade 2 Frequency	Total Frequency
Acute Hematological Toxicity	29 (44.6%)	26 (41.5%)	9 (13.8%)	64
Acute Lung Toxicity	42 (64.6%)	16 (24.6%)	6 (10.7%)	64
Acute Esophageal Toxicity	46 (72.3%)	12 (18.5%)	6 (9.2%)	64
Acute Cardiac Toxicity	53 (83.0%)	11 (16.9%)	N/A	64
Acute Skin Toxicity	53 (83.0%)	11 (16.9%)	N/A	64

Our data from ARM 1 shows that Grade 0 toxicity dominates all observed parameters, from 62.5% to 81.3%. This points to a good treatment response with few side effects. Grade 1 toxicities also appear, but less often, from 18.8% to 31.3%. These show manageable bad reactions, but we need to watch them and step in if needed. Grade 2 toxicities happen less (from 6.3% to 12.5%) (**Table 3)**, but they show more serious side effects that need attention. These detailed patterns highlight how treatment effectiveness and side effects interact in complex ways showing we need to tailor how we manage each patient. ARM 2 ARM 3, and ARM 4 show similar trends confirming that treatment responses vary and we need to customize care for each patient to get the best results (**Table 3)**.

Table 3. Distribution of toxicity grades and events for disease-free survival across treatment arms.

	Acute Hematological Toxicity Grade	Acute Lung Toxicity Grade	Acute Esophageal Toxicity Grade	Acute Cardiac Toxicity Grade	Acute Skin Toxicity Grade	Events for Disease-free Survival
ARM 1						
0	10 (62.5%)	9 (56.3%)	12 (75.0%)	13 (81.3%)	13 (81.3%)	13 (81.3%)
1	5 (31.3%)	5 (31.3%)	3 (18.8%)	3 (18.8%)	3 (18.8%)	3 (18.8%)
2	1 (6.3%)	2 (12.5%)	1 (6.3%)	N/A	N/A	N/A
Total	16	16	16	16	16	16
ARM 2						
0	4 (26.7%)	11 (73.3%)	13 (86.7%)	13 (81.3%)	13 (86.7%)	8 (53.3%)
1	7 (46.7%)	4 (26.7%)	2 (13.3%)	3 (18.8%)	2 (13.3%)	7 (46.7%)
2	4 (26.7%)	0 (0.0%)	0 (0.0%)	N/A	N/A	4 (26.7%)
Total	15	15	15	16	15	15
ARM 3						
0	9 (56.3%)	10 (62.5%)	12 (75.0%)	13 (81.3%)	14 (87.5%)	12 (75.0%)
1	7 (43.8%)	4 (25.0%)	1 (6.3%)	3 (18.8%)	2 (12.5%)	4 (25.0%)

2	0 (0.0%)	2 (12.5%)	3 (18.8%)	N/A	N/A	N/A
Total	16	16	16	16	16	16
ARM 4						
0	6 (35.3%)	12 (70.6%)	9 (52.9%)	14 (82.4%)	13 (76.5%)	11 (64.7%)
1	7 (41.2%)	3 (17.6%)	6 (35.3%)	3 (17.6%)	4 (23.5%)	6 (35.3%)
2	4 (23.5%)	2 (11.8%)	2 (11.8%)	N/A	N/A	N/A
Total	17	17	17	17	17	17
Total (Toxicity Grade)	64 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)	64 (100.0%)

The dataset analysis showed several number-based findings across different factors. The acute hematological toxicity grade had significant test stats, with a Pearson Chi-Square of 9.236 and a Likelihood Ratio of 11.243. This suggests possible links in the data. On the other hand, lung toxicity grades didn't show important relationships. Its Pearson chi-square was 2.915 and its likelihood ratio was 4.310. Oesophageal toxicity grade also lacked significant connections, with a Pearson chi-square of 8.574 and a Likelihood ratio of 9.691. Cardiac and skin toxicity grades weren't significant either. Their Pearson chi-square values were 0.214 and 0.911. , events for disease-free survival had unimportant results, with a Pearson chi-square of 3.243 (**Table 4)**. These numbers give key insights into the relationships and importance levels among the factors we looked at. They highlight how complex treatment results and toxicity profiles are in the dataset.

Table 4. Statistical results from various tests examine associations between toxicity grades and disease-free survival events.

Test	Pearson Chi-Square	Likelihood Ratio	Fisher's Exact Test	Linear-by-Linear Association
Acute Hematological Toxicity Grade	9.236 (df=6)	11.243 (df=6)	9.044	1.063 (df=1)
Acute Lung Toxicity Grade	2.915 (df=6)	4.310 (df=6)	3.257	0.097 (df=1)
Acute Esophageal Toxicity Grade	8.574 (df=6)	9.691 (df=6)	7.789	2.437 (df=1)
Acute Cardiac Toxicity Grade	0.214 (df=3)	0.223 (df=3)	0.413	0.002 (df=1)
Acute Skin Toxicity Grade	0.911 (df=3)	0.903 (df=3)	0.989	0.113 (df=1)
Events for Disease-free Survival	3.243 (df=3)	3.260 (df=3)	3.148	0.315 (df=1)

Discussion

The study divided patients into four treatment arms: each made up 24.6% to 26.2% of the group allowing for a solid comparison of treatment results in NSCLC. This even split reduces biases and makes the differences seen due to treatments more reliable rather than due to demographic or clinical differences. In terms of demographics, the group had female patients (80%) pointing to possible gender-specific patterns in

NSCLC occurrence or diagnosis in the studied population, which matches some earlier reports (23). A high number of smokers (69.2%) highlight the known link between smoking and lung cancer stressing the need to target smoking cessation efforts (23, 24).

For symptoms, cough was the most common (47.7%) then chest pain (27.7%) coughing up blood (13.8%), and trouble breathing (10.8%), which lines up with typical NSCLC signs and helps guide diagnostic tests. In the upper lobes of the lungs, in the right upper lobe (27.7%) and left upper lobe (26.2%) lesions were found more often, which affects diagnostic imaging plans and targeted treatment approaches. ECOG status showed different levels of functional impairment, with 29.2% of patients having an ECOG score of 0 meaning full activity, while 47.7% were ECOG 1, and 23.1% were ECOG 2 requiring tailored treatment plans to get the best results. Analysis of tumour T status showed advanced disease, with 56.9% classified as T3, 18.4% as T2, and 24.6% as T4 suggesting big advanced or invasive tumours at diagnosis, which is the key for staging and treatment planning. A high rate of positive lymph nodes (44.6% with multiple positive nodes) further highlighted the spread potential and challenges in managing advanced NSCLC.

Looking at treatment arms showed Grade 0 toxicities in ARM 1 ranging from 62.5% to 81.3%, suggesting minimal side effects and good tolerance to radiation therapy. Grade 1 toxicities were seen in smaller amounts (18.8% to 31.3%) representing manageable side effects, while Grade 2 toxicities (6.3% to 12.5%) showed the need to watch and step in for more significant side effects. Similar toxicity trends across ARM 2 ARM 3, and ARM 4 underlined the variety in individual treatment responses emphasizing the importance of personalized strategies to get the best patient outcomes.
Our results correlate with earlier literature where hypo fractionated
radiotherapy has produced equivalent tumor control with acceptable toxicity in locally advanced NSCLC. Laine et al (2016) provided better BED without prolonged treatment time, and the CHART trial by Saunders et al also established better local control with modulated fractionation (19, 21). In contrast to RTOG 0617, which demonstrated no survival advantage with increased doses
and more toxicity, our findings favor moderate hypofractionation as
a viable alternative, particularly for patients with poor tolerance.

Statistical analysis showed significant links for acute blood toxicity (Pearson chi-square = 9.236, Likelihood ratio = 11.243) suggesting notable correlations, while lung toxicity (Pearson chi-square = 2.915, Likelihood ratio = 4.310) esophageal toxicity (Pearson chi-square = 8.574, Likelihood ratio = 9.691), heart toxicity (Pearson chi-square = 0.214), skin toxicity (Pearson chi-square = 0.911), and disease-free survival events (Pearson chi-square= 3.243) showed no meaningful links. These results shed light on how complex treatment results and side effect patterns are in managing NSCLC. While blood-related side effects have strong connections other types of side effects and survival rates don't, which shows how varied treatment responses can be. This points to the need for more studies to understand these relationships better.

This study offers a full look into how NSCLC patients are spread out, what their symptoms are like, and how they react to different types of radiation therapy. It shows why it's crucial to tailor treatments to each person. This approach helps make the therapy work better and keeps side effects in check. The study also points out that future research should try to understand why some treatments work differently for different people. It gives us a clear suggestion that we must fine-tune our methods to help patients with NSCLC get the best results. These results confirm hypofractionated radiotherapy as a safe
and functional substitute to standard fractionation
for carefully chosen inoperable stage III NSCLC patients, especially with poor performance status. The reduced, tolerable course of therapy can
enhance compliance and utilization. The findings also call for large prospective trials to confirm and fine-
tune advanced methods such as IMRT and VMAT. Our study has limits due to its backward-looking nature and clear differences in treatment groups that come with observational studies. Some patients didn't follow up well so the disease might have come back more often than we reported. Still, our study has strong points. We looked at a pretty big group of patients (62)

who got a short intense radiation therapy. These patients couldn't have handled a longer treatment. We compared them to patients who got over 60 Gy without chemo at the same time. Even with its limits, we think this comparison helps answer questions about dose better. It also removes the tricky issue of picking patients for chemo at the same time as radiation.

We think our reported experience showed this treatment plan was tolerable and worked pretty well. Right now, doctors use chemo and radiation together as the main way to treat advanced NSCLC that hasn't spread. This is based on the results of a big study called RTOG 9410 that came out not long ago. This approach helped patients live about 3 months longer compared to giving chemo first and then regular radiation treatments.

This treatment plan, however, brings with it much higher grade 3 or worse non-hematologic acute side effects, like esophagitis and mucositis. To cut down on this extra toxicity, doctors could limit the use of chemotherapy alongside radiotherapy. Since distant metastatic disease remains the main failure pattern for advanced NSCLC, a treatment using high-dose systemic chemotherapy sandwiched between short courses of effective local therapy might lead to better disease outcomes while cutting down on treatment-related side effects.

Conclusion

This study shows how well different radiation therapy plans work for NSCLC and how easy they are to handle stressing the need to customize treatment for each patient. Fast high-dose radiotherapy had very few side effects making it a good choice for patients who can't handle longer treatments. The study found strong links to quick blood-related side effects, but other side effects didn't show clear connections pointing to varied responses to treatment. Because cancer often spreads to distant parts of the body, combining high-dose chemo with good local therapy might lead to better results and fewer side effects. Even though this study looked back at past data, it backs up the idea that we need to tailor our approach when treating advanced NSCLC.

Author contribution

SC conceived the study design, developed the methodology, and conducted the formal analysis. He wrote the original draft and provided overall supervision. **AR** led the investigation and data curation, ensuring data validity, and contributed to writing the original draft as well as reviewing and editing the manuscript. **SR** managed resources and project administration, played a key role in data visualization, and contributed to writing and reviewing the manuscript. **TM** developed and implemented software tools, validated results, and contributed to writing and reviewing the manuscript. All authors reviewed the manuscript.

Conflict of interest

There is no Conflicts of interest.

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