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Research Article

Exploring the Value of Sequential Chemoradiotherapy in Locally Advanced Non-Small Cell Lung Cancer: Insights from a Single Institution's Retrospective Analysis

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Abstract

Introduction: The management of locally advanced non-small cell lung cancer (NSCLC) typically involves definitive chemoradiotherapy, a well-established and safe treatment method across various therapeutic protocols. Even with specific patient subpopulations, there may be better candidates for this approach, leading to ongoing debates in the scientific literature regarding the potential benefits of sequential chemoradiotherapy for these individuals. By examining the effects of sequential chemoradiotherapy in patients with locally advanced NSCLC who are declared ineligible for definitive chemoradiotherapy, this study seeks to add to the conversation.

Methods: Researchers retrospectively analyzed NSCLC cases spanning a decade at a tertiary care center. Patients who underwent sequential chemotherapy as an essential component of their treatment plan made up the study population. Researchers analyzed patient demographics, treatment features, and important outcome metrics like overall and progression-free survival.

Results: The findings revealed a median overall survival of 18.8 months (95% confidence interval [CI], 15.7-22.6). The overall survival probabilities were 78% in one year, 19% in three years, and 4% at five years. Additionally, it was shown that the median progression-free survival was 13.4 months (95% CI, 11.7-15.5). The associated progression-free survival probabilities at one year, three years, and five years were 59%, 9%, and 1%, respectively.

Conclusion: According to the results of the retrospective analysis, individuals with non-small cell lung cancer who are ineligible for concurrent chemoradiotherapy may benefit from sequential

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chemoradiotherapy. These results support previously published data, suggesting that sequential chemotherapy may be a workable alternative treatment for this patient population.

Keywords: Locally advanced NSCLC; Chemoradiotherapy; Concurrent; Sequential; Survival.

Introduction

In 2020, lung cancer emerged as the second most prevalent neoplasm globally, constituting 11.4% of all newly identified cancer instances [1]. Comprising adenocarcinoma, large cell carcinoma, and squamous cell carcinoma, non-small cell lung cancer (NSCLC) accounts for 75-85% of all lung cancer occurrences [2].

The lung cancer TNM staging system, devised by the International Association for the Study of Lung Cancer (IASLC), has gained widespread acceptance [3]. Approximately 50% of NSCLC cases are detected at the inoperable stages IIIB or IV. While the 5-year survival rate for localised lung tumours reaches up to 59%, it plummets to a scant 6% for extensive-stage disease. Notably, between 2001 and 2016, the 2-year relative survival for advanced-stage NSCLC cases experienced a two-fold increase, from 10% to 20% [4].

In instances of locally advanced, non-resectable malignancies, the prevailing therapeutic modality includes concurrent chemoradiotherapy (cCRT), integrating radiotherapy with predominantly platinum-based chemotherapy agents, such as cisplatin or carboplatin, in conjunction with pharmaceuticals like etoposide, vinorelbine, gemcitabine, and paclitaxel. Furthermore, incorporating adjuvant or consolidation immunotherapy following chemoradiation has significantly improved survival outcomes, as evidenced by the PACIFIC trial [5].

Curran, et al.'s phase III clinical trial examined 610 patients with stage II, III A, or III B non-small cell lung cancer (NSCLC), who were randomised to receive either concurrent or sequential chemoradiotherapy regimens [6]. The study demonstrated a statistically significant enhancement in five-year survival rates for patients undergoing concurrent treatment relative to those receiving sequential therapy, albeit with a greater incidence of acute grade 3-5 non-hematologic toxic events in the sequential therapy group. A meta-analysis by Auperin, et al., corroborated these findings, indicating a significant survival advantage for cCRT over sCRT, with a hazard ratio (HR) of 0.84 (P=0.004) [7].

The phase III PACIFIC trial investigated the efficacy of adding durvalumab to the treatment of patients with unresectable, stage III NSCLC who exhibited no disease progression following cCRT. Consolidation treatment with durvalumab significantly improved overall survival (OS) and progression-free survival (PFS) primary endpoints. Updated median OS and PFS values were 47.5 and 16.9 months for durvalumab-treated patients, respectively, versus 29.1 and 5.6 months for the placebo group. The estimated 5-year OS and PFS rates were 42.9% and 33.1% for durvalumab, and 33.4% and 19.0% for placebo, respectively.

Nevertheless, a recent extensive study in England employing National Lung Cancer Audit data disclosed that merely 34% of stage

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III NSCLC patients undergoing chemoradiotherapy received concurrent treatment. In comparison, 66% were administered a sequential regimen [8].

In certain instances of locally advanced lung cancer, the extensive nature of the disease renders implementing a radical concurrent treatment protocol unfeasible. Sequential chemoradiotherapy (sCRT) is an alternative method to augment local and systemic control for this subset of patients. In their exhaustive meta-analysis, Xiao, et al., scrutinised the efficacy and safety of concurrent and sequential chemoradiotherapy for patients with advanced non-small cell lung cancer (NSCLC) [9].

The study demonstrated that concurrent chemoradiotherapy was associated with enhanced treatment response rates and extended progression-free survival. In contrast, sequential chemoradiotherapy was linked to decreased occurrences of acute toxicity and treatment-related mortality. Notably, the analysis did not detect a significant difference in overall survival between the two treatment approaches. This research highlights the imperative of personalising treatment strategies for patients with advanced NSCLC, considering individual patient factors and treatment goals. Healthcare professionals may need to consider patient age, comorbidities, and tumour characteristics when deciding between concurrent and sequential chemoradiotherapy.

Attaining the best treatment results for NSCLC patients requires a delicate balance between improving survival rates and reducing toxicities. In modern medicine, patient-focused and interdisciplinary methods are increasingly recognised as essential for successful treatment plans. Sharing real-world experiences in managing NSCLC patients can offer invaluable guidance for clinical oncologists, helping them advise patients and peers on the most appropriate therapeutic choices. In this study, researchers report the outcomes of patients diagnosed with inoperable NSCLC who received sequential chemoradiotherapy at a single-centre tertiary institution in the United Kingdom. Researchers aim to enrich the existing knowledge base by presenting the findings and insights, thus promoting evidence-based decision-making in clinical practice.

Methods

This retrospective study was conducted at the tertiary centre, Royal Stoke Hospital, to assess the effectiveness of sequential chemoradiotherapy (sCRT) for non-small cell lung cancer (NSCLC) patients who were ineligible for surgery or concurrent chemoradiotherapy (cCRT). The study population comprised patients from when sCRT was a standard treatment approach. Researchers retrospectively examined clinical documentation and records for NSCLC patients diagnosed between 2007 and 2019. All patients had histologically verified diagnoses and were staged according to the TNM classification system. Following initial diagnostic and staging evaluations, patients started chemotherapy treatment. After completing the third or fourth chemotherapy cycle, the patients underwent assessment CT

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scans and subsequently began radiotherapy. Patients were excluded from the final analysis if they had yet to finish at least three combination chemotherapy cycles or received less than 50 Gray in 20 fractions of external beam radiotherapy.

The chemotherapy regimen included either Cisplatin or Carboplatin combined with Gemcitabine (n=65), Vinorelbine (n=20), Pemetrexed (n=31), or Docetaxel (n=1). Administered radiotherapy doses ranged from 50 to 55 Gray in 20 fractions, delivered using conformal or intensity-modulated radiotherapy techniques. After treatment, patients were monitored regularly until disease progression, death, or cessation of clinical follow-up at five years. During this time, some patients were lost to follow-up.

Gender	Number	Percentage
Male	82	70
Female	35	30
Age		
≤60	23	20
>60	94	80
Performance status		
0	48	41
1	50	43
2	19	16
Smoking status		
Ex-Smoker	59	50
Current Smoker	43	37
Never Smoked	8	7
Smoking status unknown	7	6
Cancer Type		
Adenocarcinoma	37	32
Squamous cell carcinoma	62	53
NOS	18	15
Cancer stage		
II	12	10.2
III A	28	23.9
III B	61	52.1
III C	5	4.3
IV	11	9.4

Table 1: Participant and Cancer Characteristics.

Statistical analyses

The statistical analysis for this study was carried out using IBM SPSS software (version 26). Time variables were measured from the date of diagnosis to the event of interest. The primary outcome measures evaluated in this study included Overall Survival (OS) and Progression-Free Survival (PFS). Secondary

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outcomes involved the incidence of treatment-related toxicities. A Cox proportional hazards regression model was applied to determine the significance of differences between events. A p-value of 0.05 or less was deemed statistically significant for this analysis. These statistical tests' results contributed to a thorough understanding of sequential chemoradiotherapy's efficacy and safety profile in managing non-small cell lung cancer patients not eligible for surgery or concurrent chemoradiotherapy.

Results

Table 1 displays the demographic and clinical characteristics of the 117 patients included in the final analysis based on the defined inclusion criteria. The median age of the patients was 69 years, ranging from 44 to 83 years, with a majority being male (82, 70%). A considerable proportion of patients were above 60 years of age at the time of diagnosis. Most patients (97, 83%) had a history of smoking, either as former or current smokers, averaging 43 pack-years. Squamous cell carcinoma was the most prevalent histological subtype (62, 53%), with stage III B being the most common stage at diagnosis (61, 52%).

The average duration from diagnosis to the initial oncology clinic evaluation was 36.2 days (1-133), while the average interval between the first assessment and chemotherapy completion was 95.2 days (7-281). Furthermore, the average time from the initial oncology clinic visit to radiotherapy initiation was 133 days (91-329). Notably, an average gap of 38.5 days (range: 10-151) existed between the chemotherapy conclusion and subsequent radiotherapy commencement. After the post-sCRT evaluation, 81 patients (69%) showed a partial response, 16 patients (14%) exhibited stable disease, and six patients (5%) had progressive disease. For patients with progressive disease after treatment, the average duration between diagnosis and progression was 17.8 months, ranging from 4 to 60 months. Progression sites included: 1 adrenal, six bone, nine brains, one cutaneous deposit, 23 ipsilateral lungs, one supraclavicular fossa, three liver, 29 further progressions of the original primary tumour, three mediastinum, two cervical lymph nodes, and 4 cases with unrecorded locations. The median follow-up period was 15.8 months, ranging from 0.2 to 110 months.

Figures 1 and 2 display the Kaplan-Meier curves illustrating the median overall survival (OS) and progression-free survival (PFS). The median OS was 18.8 months (95% CI: 15.7-22.6), with OS probabilities of 78%, 19%, and 4% at the 1-year, 3-year, and 5-year time points, respectively.

The median PFS was also determined to be 13.4 months (95% CI: 11.7-15.5), with progression-free probabilities of 59%, 9%, and 1% at the corresponding 1-year, 3-year, and 5-year intervals, respectively. In the study population, 32% of patients experienced treatment-related adverse events of varying severity. The most common toxicity observed was myelosuppression, affecting 16% of individuals, while gastrointestinal toxicity occurred in 6% of cases. The remaining 10% of adverse events included manifestations, such as renal impairment, fatigue, dermatological manifestations, and thromboembolic occurrences.

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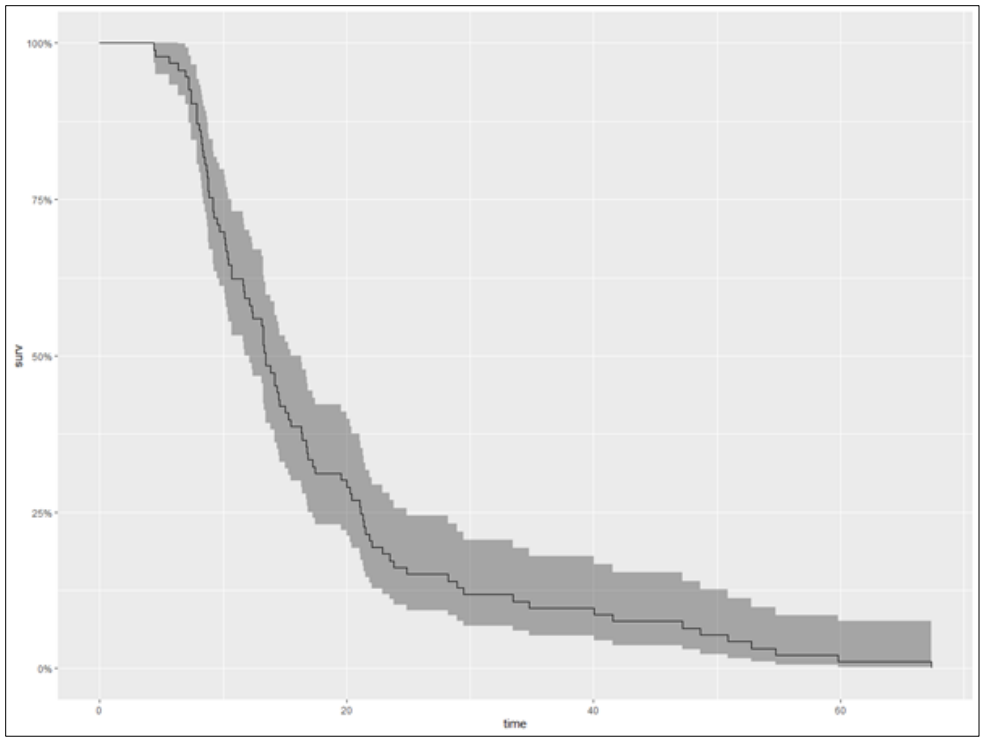

Figure 1: Kaplan-Meier curve of progression-free survival.

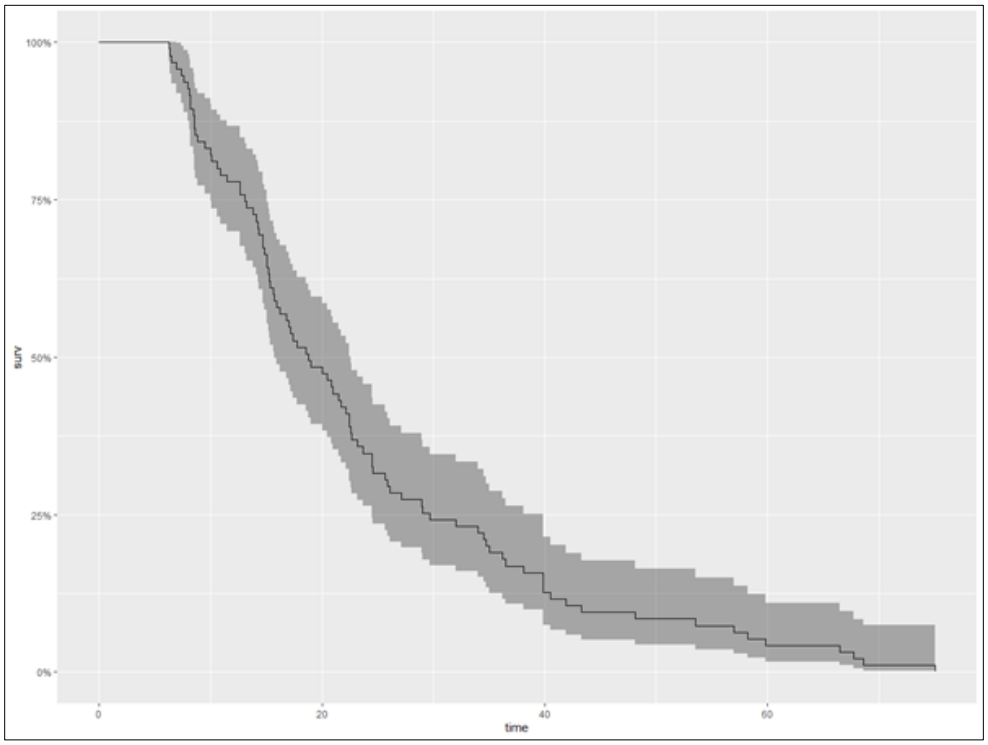

Figure 2: Kaplan-Meier curve of overall survival.

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Discussion

In the ground-breaking meta-analysis, Auperin, et al., meticulously examined individual patient data from seven randomised controlled trials to assess the comparative efficacy of concurrent chemoradiotherapy (cCRT) and sequential chemoradiotherapy (sCRT) for locally advanced NSCLC [7]. The investigation revealed a significant enhancement in overall survival (HR 0.84, 95% CI 0.74 to 0.95) and locoregional control (HR 0.77, 95% CI 0.62 to 0.95) associated with cCRT compared to sCRT. The absolute survival advantage of cCRT was 5.7% at three years and 4.5% at five years.

Nevertheless, cCRT led to an elevated risk of acute oesophageal toxicity (RR 4.9, 95% CI 3.1 to 7.8). The authors surmised that cCRT represents a more effective treatment alternative for locally advanced NSCLC, albeit with manageable acute oesophageal toxicity.

Another comprehensive systematic review and meta-analysis by Xiao, et al., incorporated 14 RCTs with a cumulative total of 2,634 patients diagnosed with NSCLC. The findings demonstrated that cCRT considerably augmented the 2–5-year survival rates compared to Scrt [9].

Furthermore, cCRT decreased the risk of locoregional recurrence and yielded favourable outcomes in overall response rates but escalated the risk of grade 3 (or higher) adverse events such as esophagitis, nausea/vomiting, and diminished leukocyte and platelet counts. The authors deduced that cCRT might confer significant benefits in terms of prolonged survival and locoregional relapse, albeit with an increased risk of adverse events.

In the meta-analysis, Viani, et al., assessed the efficacy and safety of chemotherapy in conjunction with hypo-fractionated radiotherapy (HYPO-RT) for locally advanced NSCLC patients while indirectly contrasting the outcomes with conventional fractionation radiotherapy (CONV-RT) derived from prior studies [10]. The meta-analysis encompassed two randomised controlled trials (RCTs) with 288 patients.

The results indicated that HYPO-RT, alongside chemotherapy, exhibited comparable overall mortality, local failure, and disease progression rates relative to sequential chemotherapy, succeeded by HYPO-RT. Moreover, there was no significant difference between HYPO-RT cohorts in late-grade three pneumonitis and esophagitis. The authors suggested that HYPO-RT could be contemplated as an experimental arm in forthcoming clinical trials for locally advanced NSCLC patients.

In the systematic review, Liang, et al., compared cCRT and sCRT across 11 trials involving an aggregate of 2,043 patients [11]. The authors concluded that cCRT correlated with a statistically significant augmentation in median survival time, response rate, and tumour-relapse control compared to sCRT. Nonetheless, cCRT was also linked to intensifying haematological and non-haematological toxicity. Subgroup analyses revealed that concurrent CT-RT was predominantly connected with improved locoregional control. The authors inferred that this study evinces the superiority of the

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concurrent approach over the sequential modality in the treatment of advanced NSCLC.

Toxicity related to concurrent and sequential regimes was also considered. In one analysis, concomitant radiotherapy significantly increased the risk of acute grade 3 to 4 oesophageal toxicity (from 4 to 18%, RR 4 (95% CI 3.1-7.8, P<0.001) [7]. In another, the only toxicities that were significantly worsened with concurrent chemotherapy were leukocyte count RR: 2.17; 95% CI: 1.44-3.26; P<0.001), platelet count (RR: 1.96; 95% CI: 1.24-3.09; P=0.004); moreover, it was associated with esophagitis (RR: 3.85; 95% CI: 2.39-6.21; P<0.001) and nausea/vomiting (RR: 1.44; 95% CI: 1.05-1.97; P=0.024) [9].

To enhance treatment outcomes for patients with stage III non-NSCLC who exhibited no progression following cCRT, the PACIFIC trial assessed the efficacy of consolidation durvalumab [5]. The study determined that durvalumab substantially improved overall and progression-free survival compared to a placebo. This updated exploratory outcome analysis offers compelling evidence that durvalumab consistently delivers robust, long-lasting benefits in terms of overall survival and durable progression-free survival. Remarkably, an estimated 42.9% of patients treated with durvalumab were still alive at the 5-year mark, setting a new standard of care within this context.

Our findings align with those previously reported in the literature for sCRT patients, demonstrating a mean overall survival (OS) of 18.8 months (95% confidence interval [CI] 15.7 – 22.6) and OS probabilities of 78%, 19%, and 4% at one, three, and five years, respectively. Moreover, the study exhibited superior progression-free survival rates compared to specific earlier investigations, with values of 59%, 9%, and 1% at one, three, and five years, respectively.

In cases of the large-volume disease, the data propose that sequential chemoradiotherapy (CRT) represents a feasible alternative consonant with the existing body of research.

Moreover, the potential advantages of implementing consolidation immunotherapy after sequential chemoradiotherapy (sCRT) to further enhance treatment outcomes is being explored. The Phase 2 PACIFIC-6 trial aimed to evaluate the safety and tolerability of durvalumab following platinum-based sCRT in patients diagnosed with stage III, unresectable non-small-cell lung cancer (NSCLC) who demonstrated no disease progression [12].

Durvalumab was administered every four weeks for a maximum of 24 months, with primary outcomes being the incidence of grade 3 or 4 adverse events. Secondary outcomes included investigator assessed PFS and OS.

A recent update revealed that 117 patients participated in the trial, with a median treatment duration of 32.0 weeks. At the time of data cut-off, 37.6% of patients continued the treatment. Grade 3 or 4 adverse events were observed in 18.8% of patients. Although survival data maturity was limited, the reported median PFS was 10.9 months, and the 12-month PFS and OS rates were 49.6% and 84.1%, respectively.

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Conclusion

In conclusion, the evidence supports using concurrent chemoradiotherapy followed by consolidation immunotherapy to manage unresectable locally advanced non-small cell lung cancer (NSCLC) as standard. In patients where concurrent chemoradiotherapy is not feasible, sequential chemoradiotherapy may serve as an alternative approach, incorporating consolidation immunotherapy to enhance treatment outcomes further. The findings will contribute to the expanding corpus of literature aimed at informing and refining the therapeutic strategies for this malignancy.

Conflicts of interest

The authors have no conflicts of interest to declare. All co-authors have seen and agreed with the contents of the manuscript and there is no financial interest to report.

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