

## Clinical and Epidemiological Profile of Lung Cancer in a Tertiary Care Setting: Findings from a Prospective Observational Study

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### Abstract

**Introduction:** Lung cancer is the leading cause of cancer-related morbidity and mortality worldwide, accounting for 11.6% of all cancers and 18.4% of cancer-related deaths. In India, approximately 67,795 new cases were reported in 2018, with an estimated 63,475 deaths. Epidemiological patterns vary geographically, with smoking remaining the predominant risk factor. Recent trends indicate an increasing prevalence of adenocarcinoma, particularly among non-smokers and females, and late-stage presentation remains common, contributing to poor survival outcomes. This study aimed to evaluate the demographic, clinical, histopathological, and molecular characteristics of lung cancer patients in a tertiary care hospital.

**Materials and Methods:** A prospective observational study was conducted at SMS Medical College and Hospital, Jaipur, enrolling 144 adult patients with histopathologically confirmed primary lung carcinoma. Demographic, clinical, histological, and molecular data, including ALK, EGFR, and PD-L1 status, were collected using a structured case record form. Continuous variables were expressed as mean  $\pm$  SD or median with range, and categorical variables as frequencies and percentages.

**Results:** The mean age of participants was 56.9 years, with the majority aged 60–69 years (36.11%). Male patients predominated (75%), and 61.8% were smokers. Adenocarcinoma was the most common histological subtype (79.9%), followed by squamous cell carcinoma (19.4%). Molecular profiling showed ALK positive in 16.4% and EGFR positivity in 26% of cases. PD-L1 expression was mostly low (<1%) or negative (67.8%), while high expression ( $\geq 50\%$ ) was observed in 4.1% of participants.

**Conclusion:** Lung cancer in this cohort primarily affected elderly male smokers, with adenocarcinoma as the dominant histological type. Actionable molecular alterations were limited, and PD-L1 expression was predominantly low, underscoring the importance of early diagnosis, tobacco cessation, and molecular testing to guide personalized therapy.

**Keywords:** Lung cancer, Adenocarcinoma, Smoking, EGFR, PD-L1.

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### Introduction

Lung cancer is the leading cause of cancer-related morbidity and mortality worldwide, accounting for approximately 11.6% of all cancers and 18.4% of cancer-related deaths globally [1]. According to GLOBOCAN 2018, about 67,795 new cases of lung cancer were reported in India, contributing to 5.9% of all cancers, with an estimated 63,475 deaths, reflecting a high disease-attributable mortality burden [2].

The epidemiology of lung cancer demonstrates considerable geographic variation with respect to incidence, histological patterns, and risk factors. Cigarette smoking remains the predominant risk factor, particularly among men, with the risk increasing proportionally with smoking intensity and duration [3].

However, in India, a significant subset of patients, particularly women and younger individuals, present

without a smoking history, highlighting the contribution of other risk factors such as biomass fuel exposure, passive smoking, genetic susceptibility, and environmental pollutants [4,5]. Histological patterns have also evolved over time. Squamous cell carcinoma (SCC) was historically the most common subtype; however, recent Indian and global data show a rising trend in adenocarcinoma (ADC), which is now the predominant histological type, especially among non-smokers and females [6,7]. This shift may be related to changing smoking patterns, improved histopathological classification, and wider application of immunohistochemistry and molecular diagnostics [7].

Another important concern is the stage at presentation. More than two-thirds of Indian patients are diagnosed at an advanced stage (Stage III or IV), limiting curative treatment options and contributing to poor survival outcomes [6,7]. Despite the availability of newer modalities, including targeted therapy and immunotherapy, survival outcomes in India remain significantly lower compared to Western countries, largely due to late presentation and limited access to comprehensive oncology care [7,8]. Given these challenges and the paucity of long-term multicentric data in India, further regional studies are required to understand the clinical and epidemiological patterns of lung cancer. This study aims to evaluate the demographic, clinical, and pathological characteristics of lung cancer patients in a tertiary care hospital through a prospective observational design.

## Materials and Methodology

**Study Design and Setting:** The present study was designed as a prospective observational study conducted at the Department of Respiratory Medicine in SMS Medical college and Hospital, Jaipur, Rajasthan. The study period extended over two years, during which all eligible patients diagnosed with primary lung carcinoma were enrolled. Ethical approval was obtained from the Institutional Ethics Committee, and written informed consent was secured from all participants prior to inclusion in the study.

**Study Population:** All adult patients ( $\geq 18$  years) with a histopathologically or cytologically

confirmed diagnosis of primary lung carcinoma were included.

Patients with recurrent lung cancer, metastatic disease from extrapulmonary primaries, or incomplete clinical/molecular data were excluded.

**Data Collection:** A structured case record form (CRF) was used to capture demographic, clinical, radiological, histopathological, and molecular information. The following parameters were recorded:

- Demographic details: Age, gender.
- Lifestyle risk factors: Smoking history (smoker vs. non-smoker).
- Histological subtype: Adenocarcinoma, squamous cell carcinoma, or NSCLC (not otherwise specified), confirmed by biopsy.

## Molecular Profiling

1. ALK status (positive/negative) determined by immunohistochemistry (IHC).
  2. EGFR mutation analysis performed using PCR-based molecular assays.
  3. PD-L1 expression evaluated by IHC and categorized as negative (0%), low ( $<1\%$ ), intermediate (1–49%), or high ( $\geq 50\%$ ).
- Combined molecular status: Patients were stratified according to combined ALK and EGFR profiles.

**Sample Size:** A total of 144 patients were included in the study, based on consecutive sampling during the study period.

**Data Analysis:** All data were entered into Microsoft Excel and subsequently analyzed using GraphPad version 8.

Continuous variables such as age were summarized as mean  $\pm$  standard deviation (SD) or median with range, while categorical variables such as gender, smoking status, histological subtype, and biomarker status were presented as frequencies and percentages. Comparative analysis with published studies was performed to contextualize findings.

## Result

**Table 1: Age distribution of study participants**

Age Group (years)	Number (%)
<30	2 (1.39%)
30–39	11 (7.61%)
40–49	18 (12.5%)
50–59	45 (31.25%)
60–69	52 (36.11%)
70–79	15 (10.42%)
80+	1 (0.69%)

The age distribution of study participants (Table 1) demonstrated that the majority of patients were in the 60–69 years age group (36.11%), followed by those aged 50–59 years (31.25%). A smaller proportion of participants belonged to the younger age groups, with only 9% below 40 years, indicating that lung cancer was more common in the elderly population. Mean age of the present study participants was 56.9 years.

**Table 2: Gender distribution of study participants**

Gender	Number (%)
Male	108 (75.0%)
Female	36 (25.0%)

With respect to gender distribution (Table 2), a clear male predominance was observed, with 75% males and 25% females, reflecting the established male preponderance in lung cancer epidemiology.

**Table 3: Smoking status distribution of study participants**

Smoking Status	Number (%)
Smoker	89 (61.8%)
Non-Smoker	55 (38.2%)

Smoking status analysis (Table 3) revealed that 61.8% of participants were smokers, highlighting tobacco use as a significant risk factor in the study population.

**Table 4: Distribution of study participants according to type of Lung cancer**

Type	Number (%)
Adenocarcinoma	115 (79.9%)
Squamous Cell Carcinoma	28 (19.4%)
NSCLC (NOS)	1 (0.7%)

Histological sub typing (Table 4) showed that adenocarcinoma was the most common variant (79.9%), followed by squamous cell carcinoma (19.4%), whereas NSCLC not otherwise specified (NOS) accounted for only 0.7%, consistent with global trends in lung cancer histology.

**Table 5: Distribution of study participants according to ALK status**

Result	Number (%)
Negative (N)	122 (83.6%)
Positive (P)	19 (13.0%)
Missing / NaN	5 (3.5%)

Molecular testing outcomes demonstrated that ALK negativity was predominant (83.6%), with only 13% showing ALK positivity (Table 5). Similarly, EGFR mutations were positive in 26% of cases, while the majority (69.9%) were negative (Table 6).

**Table 6: Distribution of study participants according to EGFR status**

Result	Number (%)
Negative (N)	102 (69.9%)
Positive (P)	38 (26.0%)
Missing / NaN	6 (4.1%)

**Table 7: Distribution of study participants according to ALK and EGFR status**

ALK \ EGFR	Negative (N)	Positive (P)	Missing	NaN
Negative	85	36	0	1
Positive	17	2	0	0
Missing	2	0	0	0
NaN	0	0	3	0

Combined analysis of ALK and EGFR status (Table 7) indicated that the largest subgroup consisted of ALK-negative/EGFR-negative patients (85 cases), followed by ALK-negative/EGFR-positive cases (36 cases). ALK positivity was relatively uncommon, with only 19 patients overall, of which 17 were EGFR-negative and 2 were EGFR-positive.

**Table 8: Distribution of study participants according to PD-L1 Expression status**

Category	Number (%)
Negative (0%)	37 (25.3%)
Low (<1%)	62 (42.5%)
Intermediate (1–49%)	27 (18.5%)
High (≥50%)	6 (4.1%)
Missing / NA	14 (9.6%)

Regarding PD-L1 expression (Table 8), the largest proportion of patients exhibited low expression (<1%) at 42.5%, followed by negative expression at 25.3% and intermediate expression (1–49%) at 18.5%. Only a small fraction (4.1%) demonstrated high expression (≥50%), whereas 9.6% had missing data.

Overall, these findings indicate that the study population was predominantly elderly male smokers, with adenocarcinoma as the leading histological type. From a molecular standpoint, ALK negativity, EGFR negativity, and low to absent PD-L1 expression were the most common features, which may have implications for the choice of targeted and immunotherapeutic strategies.

### Discussion

In the present study, the majority of participants belonged to the 60–69 years age group (36.11%), followed by those aged 50–59 years (31.25%) with mean age of 56.9 years. This is consistent with findings from Raghavendra et al., who reported a mean age of 57.8 years with most cases between 40–60 years. [9] Similarly, Mehta et al. observed a median age of 64 years with the largest proportion in the 60–69 years category, closely aligning with our results. [10] Chowdhary et al. also reported a mean age of 61.5 years, further confirming lung cancer as a disease predominantly affecting older adults. [11] Gender distribution in our study revealed a marked male predominance (75%), which is comparable to the studies by Raghavendra et al. (70.1% males) and Chowdhary et al. (80% males). [9,11]

However, Mehta et al. highlighted a declining male-to-female ratio, with female cases rising from 20.1% to 28.4% over a 15-year period. [10] This trend suggests evolving risk profiles, particularly among women, potentially due to environmental and non-tobacco exposures. In relation to smoking status, our study found that 61.8% were smokers, which closely parallels the 67.3% smokers reported by Raghavendra et al. and the predominance of smoking-related cases in the Chowdhary cohort. [9,11] The persistence of a significant smoker population underscores the continued role of tobacco as a primary etiological factor, though increasing recognition of non-smoking-related lung cancer, particularly adenocarcinoma, warrants further attention.

Histological distribution in our study showed adenocarcinoma as the predominant subtype (79.9%), followed by squamous cell carcinoma (19.4%). This is in agreement with Raghavendra et al., who reported 76% adenocarcinoma, and Mehta et al., who documented a rising prevalence of adenocarcinoma, particularly among women, increasing from 32% to 55% over 15 years. [9,10] In contrast, Chowdhary et al. reported a relatively lower adenocarcinoma prevalence (45%) with a higher proportion of squamous cell carcinoma (35%), suggesting possible regional or population-specific variations. [11]

With respect to molecular profiles, our findings demonstrated ALK negativity (83.6%) and EGFR positivity in 26% of cases. While the referenced studies did not systematically evaluate molecular markers, Mehta et al. emphasized the growing importance of molecular and immunohistochemical profiling in refining histological classification and therapeutic strategies. [10] The predominance of EGFR-negative cases in our study is consistent with broader epidemiological data, where actionable driver mutations are present only in a subset of patients.

Regarding immune marker expression, we observed that most patients had low or absent PD-L1 expression, with only 4.1% demonstrating high (≥50%) positivity. Although direct comparisons are limited by the absence of PD-L1 reporting in the uploaded studies, these findings align with international data showing that high PD-L1 expression occurs in a minority of non-small cell lung cancers. This has direct implications for the eligibility of patients for immune checkpoint inhibitor therapy. Overall, our study corroborates prior Indian literature in identifying adenocarcinoma as the dominant histological subtype, a male preponderance, and smoking as a key risk factor, while also contributing additional insight into the molecular landscape, including ALK, EGFR, and PD-L1 status, which were not comprehensively addressed in earlier regional studies. The integration of such molecular and immunological markers is increasingly relevant for guiding personalized therapy and improving patient outcomes.

### Conclusion

The present study highlights the clinicopathological and molecular profile of lung cancer in a tertiary care setting, showing that the disease predominantly

affects older adults, with a mean age of 58.4 years, and demonstrates a clear male predominance with strong association to smoking. Adenocarcinoma emerged as the most common histological subtype, consistent with recent epidemiological shifts in India and globally.

On molecular profiling, due to increasing number of target mutations testing, number of EGFR and ALK positive are rising, while PD-L1 expression was largely low or absent, suggesting limited eligibility for immunotherapy. Overall, the findings emphasize that lung cancer in the Indian population is increasingly characterized by adenocarcinoma among elderly male smokers, but with few targetable molecular alterations, underscoring the importance of early diagnosis, robust tobacco cessation initiatives, and wider access to molecular testing to guide precision-based management and improve clinical outcomes.

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