

Clinicopathological Landscape in ALK+ NSCLC: A 10-Year Study from AIIMS, New Delhi, India

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INTRODUCTION

- Anaplastic Lymphoma Kinase (ALK) gene rearrangements drive 3–11.4% of Non-Small Cell Lung Cancer (NSCLC) cases in Asian populations.
- ALK tyrosine kinase inhibitors (TKIs) are approved and widely used in India, but real-world data on long-term survival and treatment patterns remain limited.
- Sequential TKI therapy across lines is central to disease control once resistance emerges.
- This 10-year, single-center study evaluates real-world treatment patterns and survival outcomes among ALK+ NSCLC patients at a tertiary care center in India.

METHODS

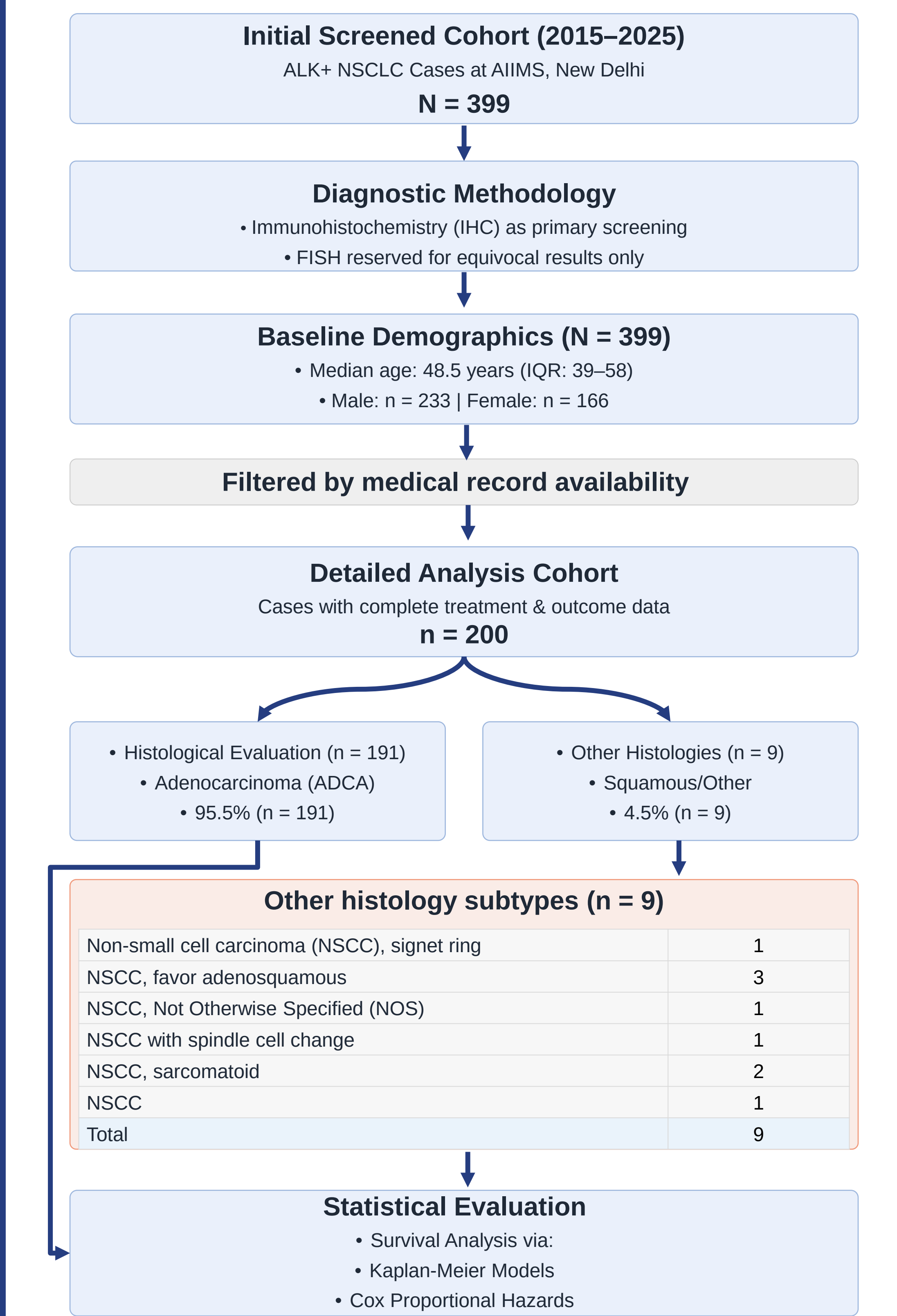


Figure 1. Case selection and analytic pipeline. ALK-positive NSCLC cases (2015–2025, AIIMS New Delhi) were screened by IHC, with FISH for equivocal cases (N = 399), then filtered by medical record availability to a detailed analysis cohort (n = 200). Histology: adenocarcinoma, 191 (95.5%); other subtypes, 9 (4.5%). Survival analyzed via Kaplan-Meier and Cox proportional hazards.

RESULTS

Table 1: Baseline characteristics

Clinical characteristic	Overall cohort (N = 200)
Age, years, median (range)	47 (20–83)
Sex, n (%)	
Male	120 (60)
Female	80 (40)
Outcome status, n (%)	
Deaths	50 (25)
Alive at last follow-up	82 (41)
Lost to follow-up	68 (34)
Follow-up, months, median (95% CI)	20 (17–25) *

*Median follow-up was estimated using the reverse Kaplan-Meier method.

Table 2 : Overall Survival by TKI Receipt in Treated Metastatic Patients

Treatment group	n	Events	Median OS, mo	HR (95% CI)	p
No TKI (other active therapy)*	35	13	19.8	1.00 (ref)	—
TKI received (any line)	112	15	121.0	0.14 (0.07–0.31)	<0.0001

*Restricted to metastatic ALK-positive NSCLC patients who received some form of active treatment (surgery, radiotherapy — predominantly palliative — and/or chemotherapy) but never a TKI. Patients who received no treatment of any kind (n=26) were excluded from both groups. TKI-received group includes TKI given at any line (first-line or later), given with or without sequential chemotherapy/palliative RT. Metastatic status defined as Stage IV (any variant) or presence of any distant/regional metastatic site. HR and 95% CI from univariable Cox proportional hazards regression; OS measured from date of registration/diagnosis. n = 173 metastatic patients evaluable for survival; 147 remained after excluding untreated patients

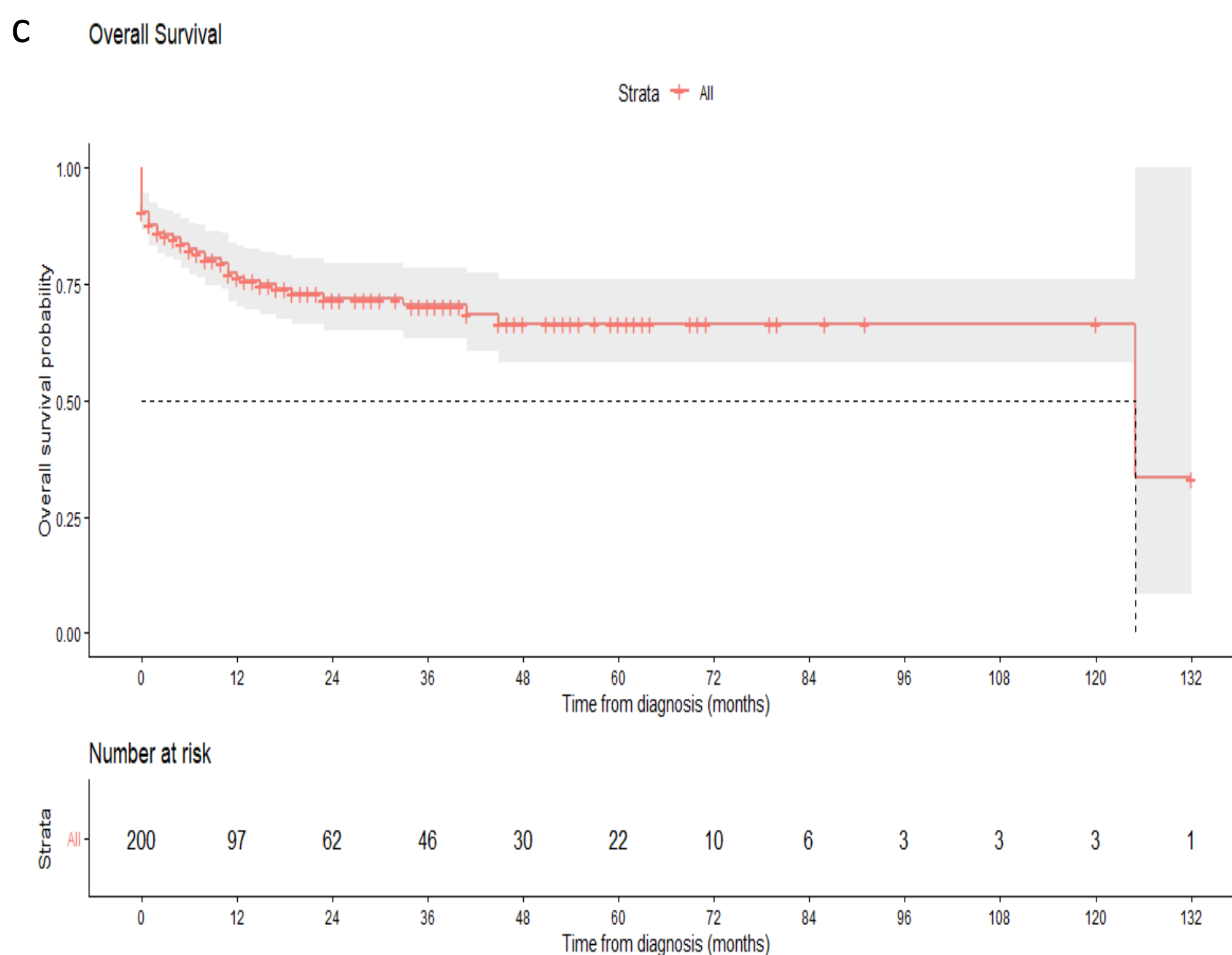
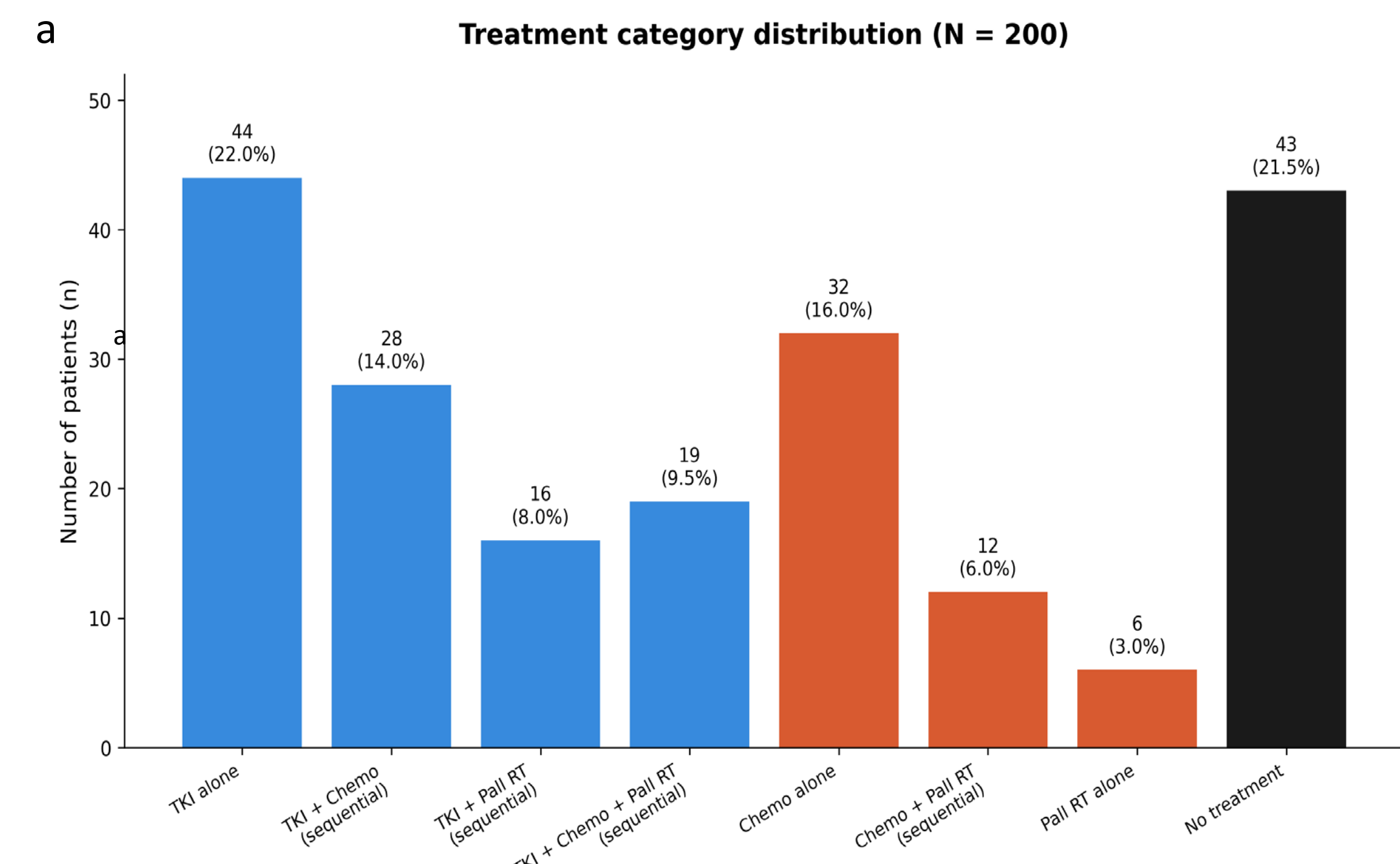
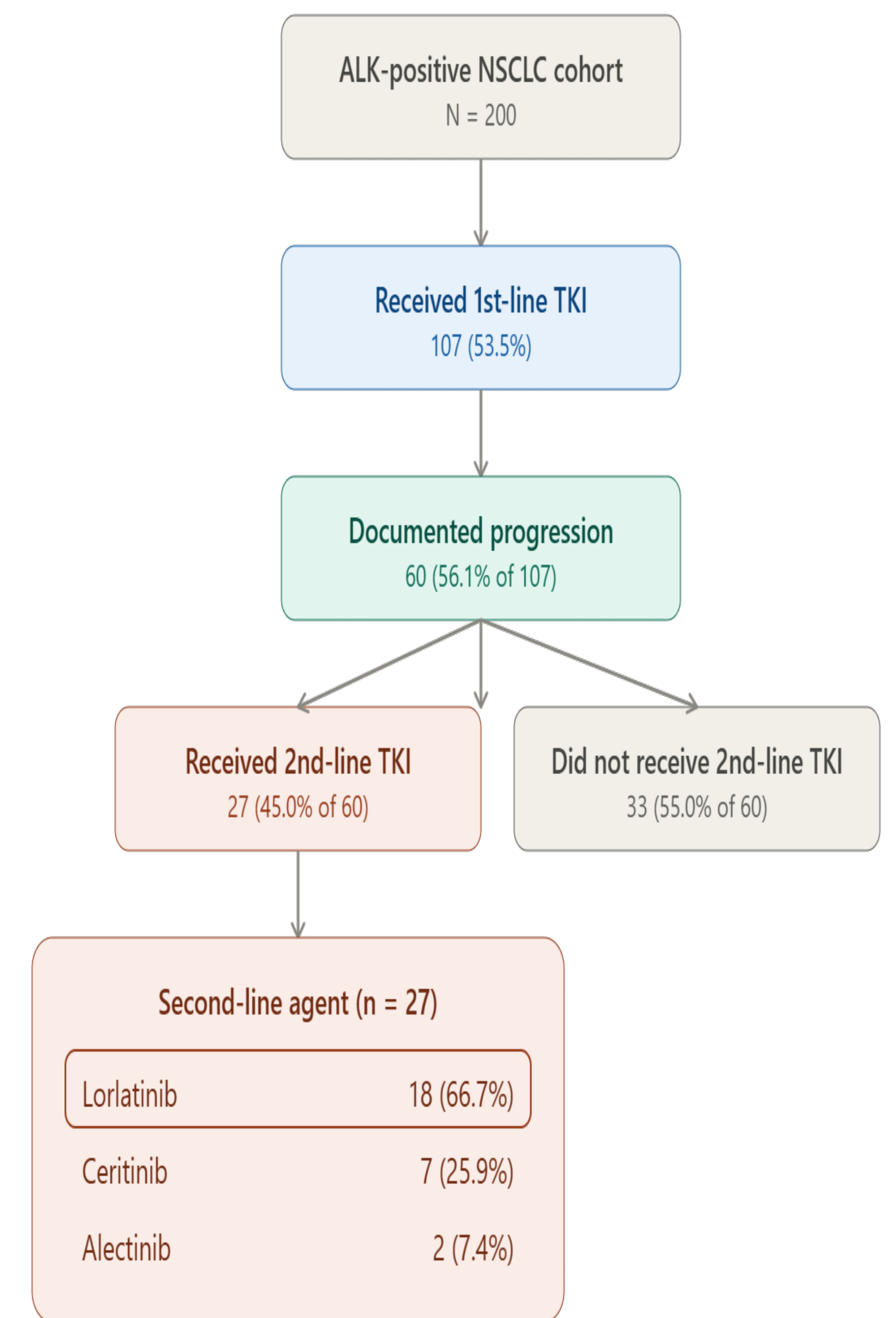


Figure 2. (a) Distribution of treatment categories received across the full cohort (N = 200). **(b)** Treatment attrition pathway from first-line TKI initiation through second-line TKI selection; percentages are calculated against the denominator at the immediately preceding stage. **(c)** Overall survival (Kaplan-Meier), with number-at-risk table shown below.



*"Sequential" indicates the modalities were received at different times, not concurrently; order of administration varied by patient.

b Treatment attrition pathway



RESULTS

- **Cohort:** 200 patients with ALK-positive NSCLC (**Table 1**); median follow-up 20 months (95% CI, 17–25) — 50 (25%) deaths, 82 (41%) alive, 68 (34%) lost to follow-up.
- **Treatment landscape:** 53.5% (107/200) received TKI-based therapy (with or without sequential chemotherapy and/or palliative radiotherapy), 22.0% (44/200) chemotherapy-based therapy without a TKI, and 24.5% (49/200) no systemic therapy (Fig. 2a).
- **Treatment pathway:** 107 (53.5%) received first-line TKI; among 60 with documented progression, only 27 (45.0%) went on to a second-line TKI — predominantly lorlatinib (18/27, 66.7%) (**Fig. 2b**).
- **Overall survival:** Early decline over the first 12–24 months, then stabilization with a long-term right-censored tail extending beyond 120 months (**Fig. 2c**).
- **Survival by treatment group :** Among metastatic patients who received active treatment, TKI-based therapy (given at any line, sequentially with or without chemotherapy/palliative RT) was associated with markedly better overall survival than other active therapy without a TKI — median OS 121.0 vs. 19.8 months (HR 0.14, 95% CI 0.07–0.31, p <0.0001) (Table 2). Patients who received no treatment of any kind were excluded from this comparison (n=26); many of these had died before diagnostic workup — and ALK testing — could be completed.

DISCUSSION

- **Younger disease profile:** Median age 47 years, younger than reported in many Western ALK-positive NSCLC cohorts.
- **Treatment attrition:** Only 53.5% received first-line TKI; among those with documented progression, 45.0% received a documented second-line TKI.
- **Survival association:** Among treated metastatic patients, TKI receipt was associated with substantially longer OS (121.0 vs 19.8 months; HR 0.14, 95% CI 0.07–0.31; p<0.0001).
- **Diagnostic and follow-up gaps:** 34% were lost to follow-up, while some patients died before ALK confirmation, highlighting the need for faster diagnosis and improved longitudinal care.

CONCLUSION

- This 10-year real-world experience demonstrates a strong association between ALK-TKI receipt and longer survival among treated metastatic patients, while highlighting substantial attrition across the diagnostic and sequential treatment pathway.
- Strengthening diagnostic pathways, TKI access, and structured long-term follow-up is needed to improve real-world outcomes.

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