Poster 1025P

A Multicenter, Real-World Study of Treatment Patterns and Clinical Outcomes of Later-Line Therapy in Chinese Patients with Advanced Non-Small Cell Lung Cancer Harboring Non-Actionable Genomic Alterations (RECAP Study)

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Introduction

- Lung cancer remains the leading cause of cancer-related mortality worldwide. Non-small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancer diagnoses[1]. Approximately 40–60% of patients with advanced NSCLC lack known actionable genomic alterations (non-AGA), making them ineligible for targeted agents[2].
- The emergence and widespread adoption of immunotherapy have significantly expanded treatment options for non-AGA NSCLC and are now established as first-line (1L) therapy. For patients with non-AGA receiving second- or third-line therapy after disease progression, guideline-recommended options remain limited and often nonspecific[3].
- Clinical decision-making in later lines is further complicated by considerable heterogeneity in patient characteristics and treatment practices. However, real-world evidence remains limited regarding how post–first-line treatment patterns and these heterogeneity factors affect clinical outcomes in non-AGA advanced NSCLC.

Objective

- To address these gaps, we conducted the RECAP study to evaluate clinical outcomes associated with second- and third-line treatment strategies in patients with non-AGA advanced NSCLC. The study also offers a descriptive analysis of treatment patterns and outcomes across key sources of clinical heterogeneity, including histological subtype.

Methods

Study design :

- The RECAP study is a multicenter, retrospective, real-world study (NCT06617390) conducted at six centers across China. Patients diagnosed with advanced NSCLC on or after January 1, 2018, and who initiated second- (2L) or third-line (3L) systemic therapy between September 1, 2019, and December 31, 2022, were eligible for inclusion.
- In the non-AGA cohort, patients were categorized based on the line of therapy they were receiving at the time of study enrollment into the second-line (2L-enrolled) or third-line (3L-enrolled) groups.

Patient Selection:

- Age of 18 years or older at enrollment; Stage IV NSCLC confirmed by histological or cytological examination; Had received prior immunotherapy in the first- or second-line setting.

Variables:

- Regimens were categorized into six groups—immunotherapy (I), immunotherapy-based combinations (I+), chemotherapy monotherapy (C+), chemotherapy-based combinations without immunotherapy agents (C+), anti-angiogenic monotherapy (A), and other regimens (O).

Outcomes:

- The primary outcome was the real-world distribution of different treatment options in NSCLC patients with non-AGA in 2L+ setting. Secondary outcomes included biomarker testing patterns (including timing, proportion, methods, and specimen types associated with biomarker detection) and clinical outcomes (including real-world effectiveness and safety profiles). Real-world effectiveness included real-world progression-free survival (rwPFS), time to treatment discontinuation (rwTTD), time to next treatment or death (rwTTNT), and real-world overall survival (rwOS).

Results

- The full analysis set of the non-AGA cohort included 383 patients with NSCLC, all of whom were also included in the efficacy analysis set and safety set (Figure 1).
- The mean age was 61.11 ± 9.94 years. Female patients accounted for 62 (16.2%) cases. Comorbidities were present in 256 (66.8%) patients.
- Surgical resection of the primary tumor had been performed in 40 (10.4%) patients, and 141 (36.8%) had received radiotherapy (Table 1).

Figure 1. Patient flowchart

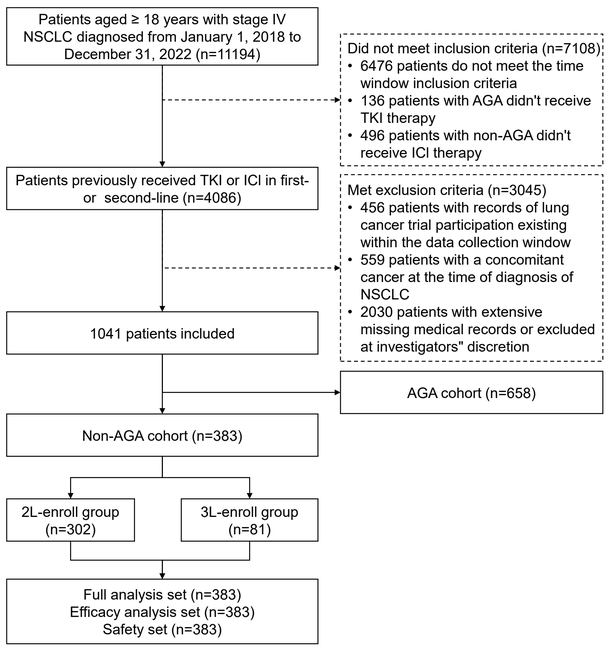
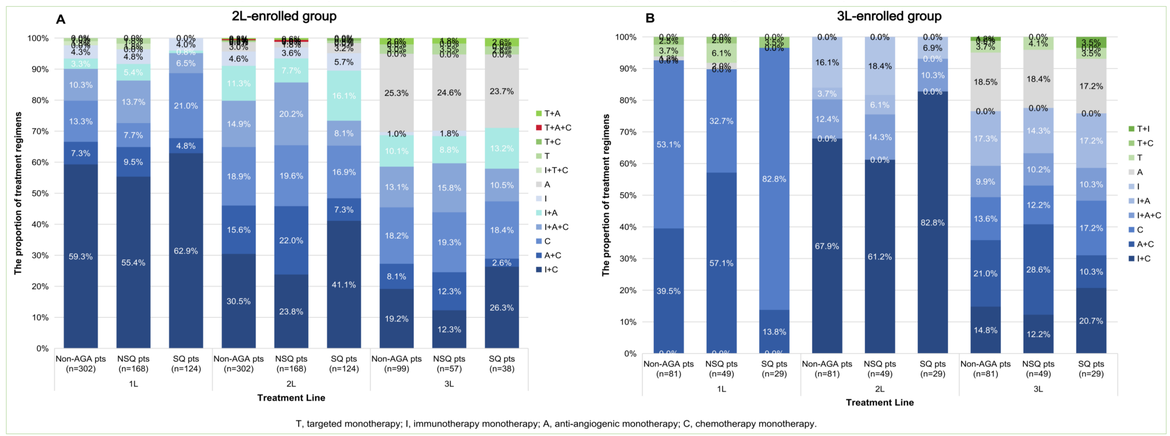


Table 1. Baseline characteristics of patients

Characteristic	All (N=383)
Age, years, mean±SD	61.1±9.9
Age at first diagnosis of advanced NSCLC, years, mean±SD	60.7±9.7
Sex, *n* (%)	
Male	321 (83.8)
Female	62 (16.2)
Family history of lung cancer, *n* (%)	28 (7.3)
Smoking history, *n* (%)	
Yes	229 (59.8)
No	143 (37.3)
Unknown	11 (2.9)
Treatment line at enrolment, *n* (%)	
Second-line	302 (78.9)
Third-line	81 (21.1)
Use of docetaxel in second-line at enrolment, *n* (%)	46 (15.2)
Pathological subtype, *n* (%)	
Squamous cell carcinoma	153 (39.9)
Non-squamous cell carcinoma	217 (56.7)
Adenosquamous carcinoma	4 (1.0)
Other	2 (0.5)
Unknown	7 (1.8)
ECOG performance status, *n* (%)	
0	33 (8.6)
1	113 (29.5)
2	15 (3.9)
3	4 (1.0)
4	0 (0.0)
Unknown	218 (56.9)
Presence of intracranial metastasis, *n* (%)	124 (32.4)
Presence of other distant metastases, *n* (%)	377 (98.4)
Comorbidities, *n* (%)	256 (66.8)
Previous tumor surgery, *n* (%)	40 (10.4)
Previous tumor radiotherapy, *n* (%)	141 (36.8)

Figure 2. Treatment patterns.

- Among patients enrolled in second-line therapy, the most common first-line regimen was immunotherapy plus chemotherapy (I+C) (179 patients, 59.3%) (Figure 2A). Among patients enrolled in third-line therapy, first-line treatment most commonly was C (43 patients, 53.1%) (Figure 2B).
- In patients who were enrolled in 2L and 3L treatment, the proportion of non-squamous patients receiving I+C was consistently lower than that of squamous patients from 1L to 3L setting. Conversely, the use of regimens containing A was less frequent in squamous patients than in non-squamous patients (Figure 2A, 2B).



T, targeted monotherapy; I, immunotherapy monotherapy; A, anti-angiogenic monotherapy; C, chemotherapy monotherapy.

Results

Figure 3. Sankey diagrams of treatment sequences among 2L-enrolled patients.

- Immunotherapy demonstrated notable cross-line utilization, with a substantial proportion of squamous and non-squamous NSCLC patients receiving I-based regimens (I+) across 1L, 2L, and 3L treatments (Figure 3A, 3B).
- Among patients with non-squamous NSCLC, 128 (76.2%) received I+ therapy in the 1L setting. Of these, 87 (51.8%) continued I+ therapy in 2L (Figure 3A).
- Among patients with squamous NSCLC, 87 (70.2%) received I+ therapy as their 1L regimen, with 81 (65.3%) continuing I+ therapy in 2L and 19 (15.3%) of them received I+ therapy again in 3L (Figure 3B).

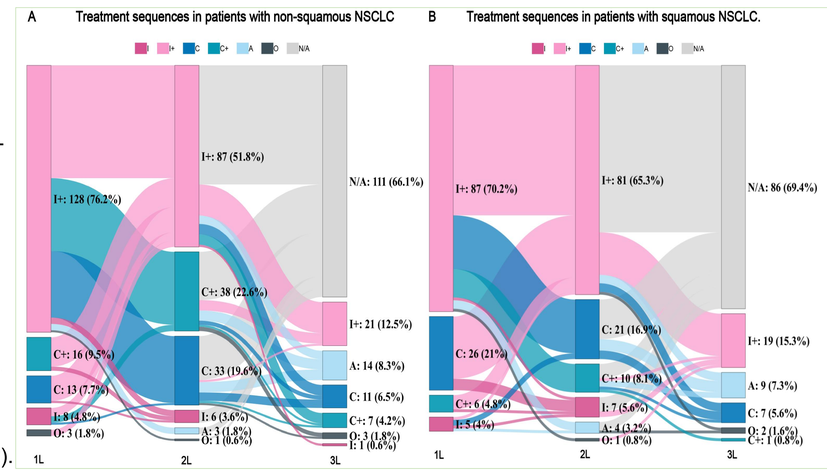


Figure 4. Median rwPFS by pathological subtype in second-line therapy for 2L-enrolled patients.

- The median follow-up duration for the overall cohort was 5.7 months (IQR: 2.4–10.6), during which 6 deaths (1.6%) were recorded.
- Among 2L-enrolled patients receiving second-line treatment, the disease progression rate was 42.3%, with a median rwPFS of 7.0 months (95% CI: 5.9–9.6).
- Among 2L-enrolled patients receiving second-line treatment, those with non-squamous NSCLC had a median rwPFS of 7.4 months (95% CI: 6.1–12.9), while those with squamous NSCLC had a median rwPFS of 6.5 months (95% CI: 4.3–10.2) (Figure 4).

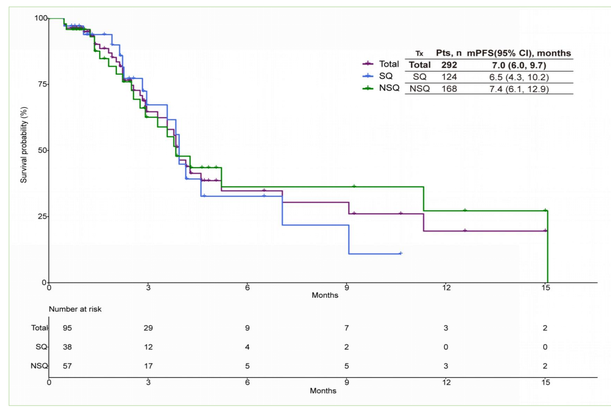


Figure 5. Median rwPFS by treatment regimen in 2L-enrolled patients, stratified by histological subtype.

- For I-based regimens, the median rwPFS was 11.8 months in non-squamous NSCLC (Figure 5A) and 9.7 months in squamous NSCLC (Figure 5B).
- For C-based regimens, median rwPFS was 6.5 months in non-squamous NSCLC (Figure 5A) and 3.0 months in squamous NSCLC (Figure 5B).

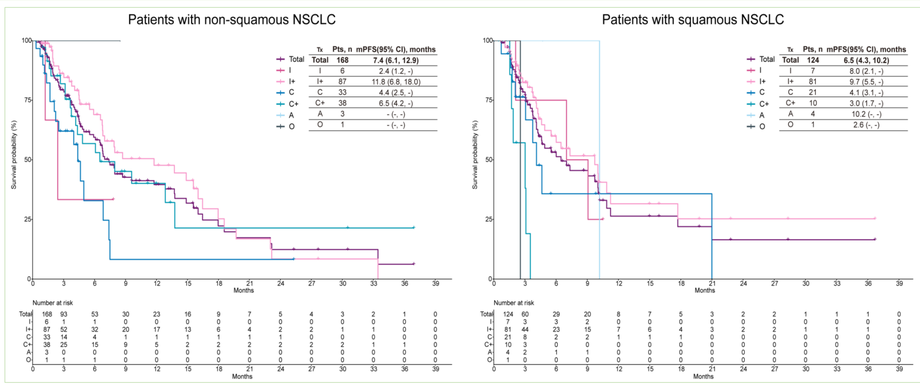


Figure 6. Median rwPFS in patients with non-squamous or squamous NSCLC, stratified by enrollment line.

- Among 2L-enrolled non-squamous patients, the median rwPFS of third-line treatment was 3.8 months (95% CI: 2.9–not available [NA]) (Figure 6A) ; for 3L-enrolled non-squamous patients, it was 5.8 months (95% CI: 4.7–NA) (Figure 6B) .
- Among 2L-enrolled squamous NSCLC patients, median rwPFS was 3.9 months (95% CI: 3.6–NA) (Figure 6C) ; and for 3L-enrolled squamous patients, median rwPFS was 9.0 months (95% CI: 4.8–NA) (Figure 6D).

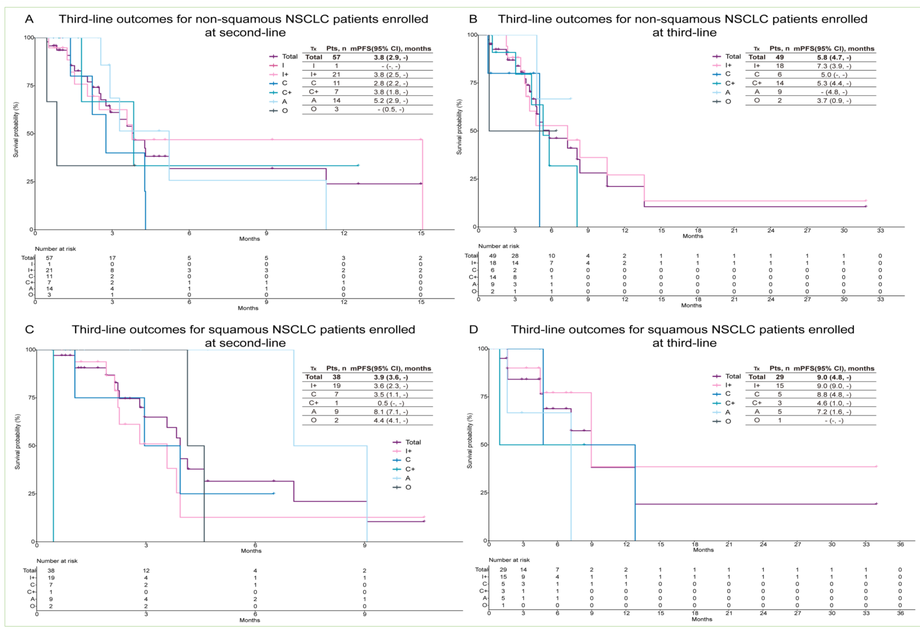


Table 2. Summary of adverse events (AEs).

- During the study period, 50 patients (13.1%) experienced at least one AE, with a total of 94 AEs recorded.
- AEs led to treatment discontinuation in 12 patients (3.1%), treatment interruption in 4 (1.0%), and dose modification in 4 (1.0%).
- It is important to note that the incidence of AEs was likely underreported due to incomplete documentation by clinicians.

Variables	Number of events, *n*	Number of cases, *n* (%)
Any AE	94	50 (13.1)
AE severity		
Grade 1	11	6 (1.6)
Grade 2	14	13 (3.4)
Grade 3	11	9 (2.4)
Grade 4	4	4 (1.0)
Unknown	54	33 (8.6)
Impact of AEs on treatment		
No impact	62	32 (8.4)
Treatment discontinuation at current line	12	12 (3.1)
Treatment interruption	12	4 (1.0)
Dose adjustment	5	4 (1.0)
Unknown	3	2 (0.5)

Variables	Number of events, *n*	Number of cases, *n* (%)
Common AEs		
Myelosuppression	32	25 (6.5)
Gastrointestinal reactions	21	21 (5.5)
Skin and mucosal abnormalities	7	7 (1.8)
Fatigue	4	4 (1.0)
Infection	10	9 (2.4)
Anemia	4	4 (1.0)
Cardiac dysfunction	3	3 (0.8)
AE outcome		
Remission	44	26 (6.8)
No change	3	2 (0.5)
Unknown	47	31 (8.1)

Conclusion

- The RECAP study characterized treatment distribution and effectiveness across therapy lines, revealing that I+C was most frequently used in the second-line setting, whereas A+C predominated in third-line treatment.
- Immunotherapy was commonly administered across treatment lines in this population. Immune-based combination therapies may confer greater clinical benefit in both second-line and third-line settings.

Abbreviations:

1L,first-line; 2L, second-line; 3L, third-line; AE, adverse event; AGA, actionable genomic alterations; ECOG, eastern cooperative oncology group; NA, not available; NSCLC, non-small-cell lung cancer; rwOS, real-world overall survival; rwPFS, real-world progression-free survival; rwTTD, time to treatment discontinuation; rwTTNT, time to next treatment or death; TKIs, tyrosine kinase inhibitors.

Disclosures:

All authors declare no competing interests. Leilei Ma is employed by Daiichisankyo (China) Holdings Co., Ltd.

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