

Real-World Burden of Illness in Patients With Metastatic NSCLC and PD-L1 TPS ≥50%

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Conclusions

- The majority of patients with mNSCLC in this real-world study received 1L IO + chemotherapy or IO monotherapy with pembrolizumab. Patients who received 1L IO + chemotherapy were younger, more likely to have non-squamous histology, and had higher rates of brain metastases and Stage 4 disease at diagnosis
- Real-world outcomes were poor, characterized by short 1L treatment duration, limited rwPFS, and rwOS less than 2 years
- There was no significant difference in risk of death between patients with squamous vs non-squamous histology or between those with very high or high PD-L1 expression
- rwPFS demonstrated similar trends to rwOS, however squamous histology was associated with slightly higher risk of progression than non-squamous histology
- This real-world study highlights the need for more effective 1L treatment options to prolong survival and maintain eligibility for subsequent therapy in patients with mNSCLC with PD-L1 TPS ≥50% and no *EGFR*, *ALK*, or *ROS-1* aberrations

Plain Language Summary

This real-world study describes characteristics, treatment patterns, and survival outcomes in patients with previously untreated non-small cell lung cancer that has spread to other parts of the body and has high levels of a protein called PD-L1. These patients also did not have certain genetic changes that are found in lung cancer. Most patients were treated with immunotherapy alone or in combination with chemotherapy. The results showed that real-world outcomes were poor. Many patients did not stay on their treatment for long, with most living less than 2 years. This study shows that better first-line treatments are still needed to help patients with lung cancer live longer.

References: 1. Hendriks LEL, et al. *Ann Oncol*. 2025;36(10):1223-1227. 2. NCCN Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer, Version 3, 2026. 3. Owen DH, et al. *J Clin Oncol*. 2025;43(24):e45-e58. 4. Wang K, et al. *Explor Target Antitumor Ther*. 2024;5:1297-1320. 5. Passaro A, et al. *Cancers (Basel)*. 2021;13(12):2935. 6. Azoulay L. *Oncologist*. 2022;27(9):e731-e738.

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Introduction

- For patients with metastatic non-small cell lung cancer (mNSCLC), programmed cell death ligand 1 (PD-L1) tumor proportion score (TPS) ≥50%, and no actionable genomic aberrations, first-line (1L) treatment with a PD-(L)1 inhibitor alone or with chemotherapy is current standard of care¹⁻³
- Despite significant progress with immuno-oncology (IO)-based treatments, most patients eventually progress and develop therapeutic resistance⁴
- Further, outcomes observed in clinical trials may not fully translate to routine practice, with real-world populations demonstrating greater heterogeneity and variability in treatment benefit^{5,6}
- As such, there remains a need for additional real-world evidence to better characterize the patient burden, clinical outcomes, and benefits from available treatment regimens
- The aim of this study was to characterize real-world treatment patterns as well as demographics, characteristics, and outcomes in patients with previously untreated mNSCLC with PD-L1 TPS ≥50% who were negative for *EGFR*, *ALK*, or *ROS-1* aberrations

Methods

- This retrospective, observational study used de-identified data from the Tempus AI multimodal database, sourced from geographically diverse oncology practices across the United States
- The index date was the date of initiation of treatment line of interest in the metastatic setting, and the follow-up period was ≥3 months from index date until death, loss to follow-up, or study end
- Eligible patients were between 18 and 89 years of age; were diagnosed with mNSCLC between January 1, 2016, and September 15, 2025; had initiated systemic therapy for mNSCLC; had PD-L1 TPS ≥50%; and had an absence of *EGFR*, *ALK*, and *ROS-1* aberrations
- Patients were excluded if they were enrolled in a clinical trial during the study period or if they had another prior primary cancer (excluding non-melanoma of the skin)
- Patient demographics, clinical characteristics, and treatment patterns were analyzed descriptively
- Outcomes included (estimated by Kaplan-Meier method)
 - Real-world overall survival (rwOS): the time from index date to the date of death from any cause
 - Real-world progression-free survival (rwPFS): the time from index date to the first recorded date of disease progression, recurrence, metastases, or death from any cause
 - Real-world time on treatment (rwTOT): the time from index date to the date of last administration, including treatment interruptions, permanent treatment discontinuation, or death from any cause
- All time-to-event analyses were performed using risk-set adjustment (RSA) to correct for left truncation, assuming no violation of the independent delayed entry assumption. If the independent delayed entry assumption was not satisfied, a prospective adjustment method was used
 - The independent delayed entry assumption states that time of entry into a study for a patient is independent of their underlying time-to-event or prognosis
 - The prospective adjustment method refers to planning study design modifications before data collection is completed, such as re-estimation of study sample size

Results

Baseline Demographic and Disease Characteristics

- At end of study (December 15, 2025), 480 patients with mNSCLC were included in the analysis
- Patients were median age 68 (range, 36–89) years, 55% were male, 77.3% had non-squamous histology, 76.7% were Stage 4 at diagnosis, 54.6% had an Eastern Cooperative Oncology Group performance status score of 0 or 1, and 74.2% were seen at non-academic centers (**Table 1**)
- The percentage of Asian patients, and also the percentage of patients with squamous histology are lower than what may be observed in global randomized trials

Table 1. Baseline Demographics and Disease Characteristics

Characteristic	Overall (N=480)	IO Monotherapy (n=195)	IO + Chemo (n=199)
Median age (range), y	68.0 (36.0–89.0)	72.0 (45.0–89.0)	65.0 (41.0–86.0)
Male, n (%)	264 (55.0)	110 (56.4)	109 (54.8)
Race, n (%)			
Asian	10 (2.1)	5 (2.6)	3 (1.5)
Black or African American	49 (10.2)	22 (11.3)	16 (8.0)
White or Caucasian	331 (69.0)	134 (68.7)	145 (72.9)
Other race	21 (4.4)	9 (4.6)	7 (3.5)
Unknown	69 (14.4)	25 (12.8)	28 (14.1)
Ethnicity, n (%)			
Hispanic or Latino	18 (3.8)	9 (4.6)	5 (2.5)
Non-Hispanic or Latino	318 (66.3)	130 (66.7)	139 (69.8)
Unknown	144 (30.0)	56 (28.7)	55 (27.6)
Geographic region, n (%)			
Northeast	21 (4.4)	10 (5.1)	9 (4.5)
Midwest	241 (50.2)	105 (53.8)	98 (49.2)
South	147 (30.6)	59 (30.3)	59 (29.6)
West	54 (11.3)	18 (9.2)	25 (12.6)
Unknown	17 (3.5)	3 (1.5)	8 (4.0)
Practice type, n (%)			
Ever academic ^a	123 (25.6)	48 (24.6)	44 (22.1)
Non-academic	356 (74.2)	146 (74.9)	155 (77.9)
Unknown	1 (0.2)	1 (0.5)	0
Insurance type, n (%)			
Commercial	124 (25.8)	29 (14.9)	73 (36.7)
Medicare	290 (60.4)	139 (71.3)	99 (49.7)
Medicaid	55 (11.5)	22 (11.3)	23 (11.6)
Other	3 (0.6)	1 (0.5)	2 (1.0)
Unknown	8 (1.7)	4 (2.1)	2 (1.0)
Tumor histology, n (%)			
Squamous	89 (18.5)	50 (25.6)	32 (16.1)
Non-squamous	371 (77.3)	134 (68.7)	158 (79.4)
Not otherwise specified	20 (4.2)	11 (5.6)	9 (4.5)
PD-L1 score, n (%)			
High (50%–90%)	359 (74.8)	145 (74.4)	151 (75.9)
Very high (≥90%)	121 (25.2)	50 (25.6)	48 (24.1)
Harmonized ECOG PS and Karnofsky score, n (%)			
0	96 (20.0)	37 (19.0)	45 (22.6)
1	166 (34.6)	70 (35.9)	67 (33.7)
≥2	66 (13.8)	35 (17.9)	22 (11.1)
Unknown	152 (31.7)	53 (27.2)	65 (32.7)
Modified CCI 12 mo before index date, n (%)			
0	1 (0.2)	0	1 (0.5)
>0–1	7 (1.5)	2 (1.0)	4 (2.0)
>1–2	124 (25.8)	50 (25.6)	58 (29.1)
>2–3	98 (20.4)	34 (17.4)	51 (25.6)
≥3	161 (33.5)	82 (42.1)	49 (24.6)
Unknown	89 (18.5)	27 (13.8)	36 (18.1)
Smoking history, n (%)			
Current smoker	73 (15.2)	32 (16.4)	31 (15.6)
Ex-smoker	243 (50.6)	100 (51.3)	102 (51.3)
Never smoker	36 (7.5)	8 (4.1)	15 (7.5)
Unknown	128 (26.7)	55 (28.2)	51 (25.6)
Metastatic sites, n (%)			
Brain	122 (25.4)	42 (21.5)	54 (27.1)
Liver	62 (12.9)	22 (11.3)	29 (14.6)
Metastatic sites at index date, n (%)			
1	246 (51.3)	104 (53.3)	99 (49.7)
2	117 (24.4)	50 (25.6)	49 (24.6)
≥3	79 (16.5)	25 (12.8)	37 (18.6)
Unknown	38 (7.9)	16 (8.2)	14 (7.0)
Tumor grade at index date, n (%)			
Grade X	1 (0.2)	1 (0.5)	0
Grade 1	2 (0.4)	2 (1.0)	0
Grade 2	35 (7.3)	15 (7.7)	13 (6.5)
Grade 3	192 (40.0)	71 (36.4)	90 (45.2)
Grade 4	2 (0.4)	0	1 (0.5)
Unknown	248 (51.7)	106 (54.4)	95 (47.7)
Disease stage at diagnosis, n (%)			
Stage 1	33 (6.9)	14 (7.2)	14 (7.0)
Stage 2	9 (1.9)	6 (3.1)	1 (0.5)
Stage 3	29 (6.0)	13 (6.7)	13 (6.5)
Stage 4	368 (76.7)	139 (71.3)	162 (81.4)
Unknown	41 (8.5)	23 (11.8)	9 (4.5)

CCI, Charlson Comorbidity Index; Chemo, chemotherapy; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-L1, programmed cell death ligand 1.
^aPatients seen at both academic and non-academic institutions.

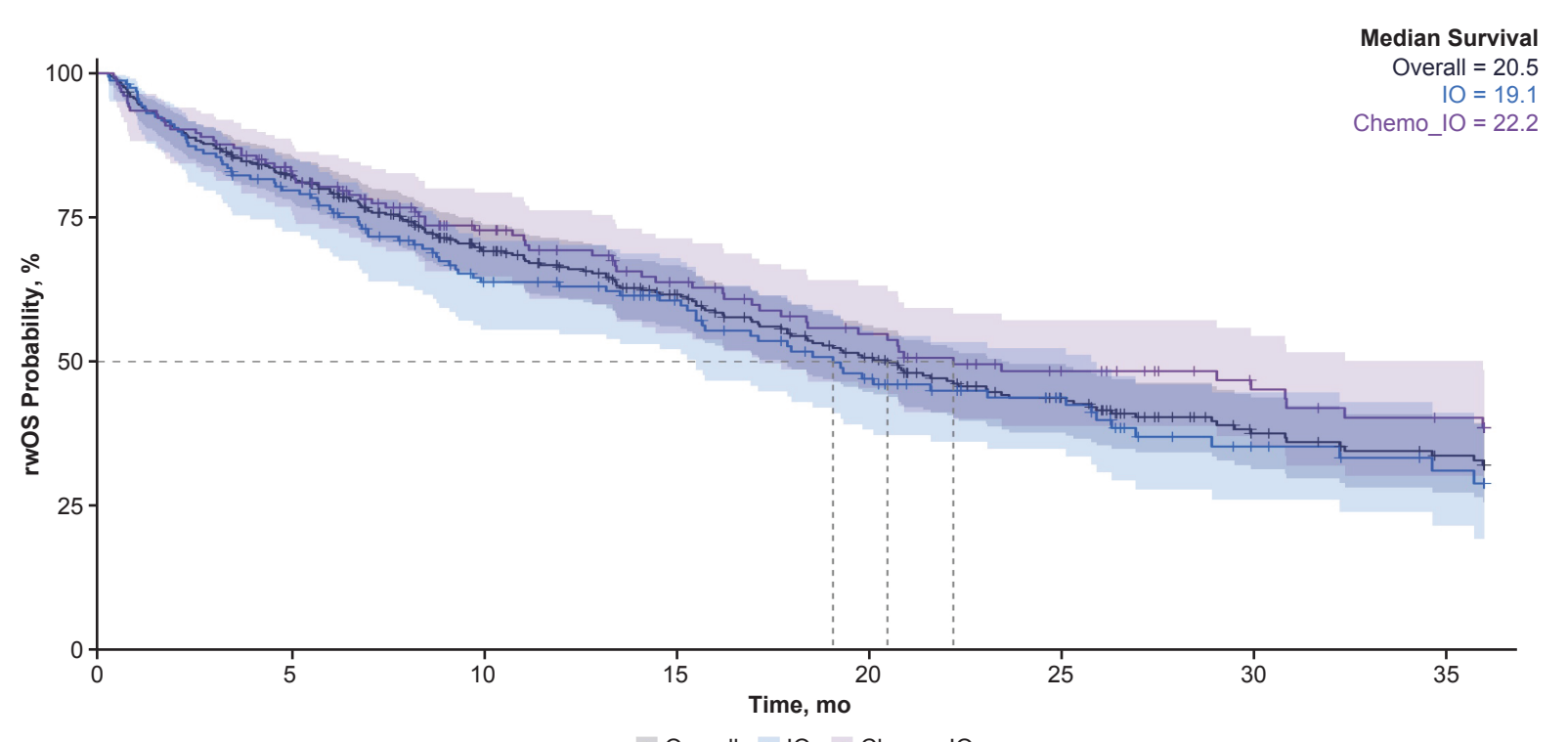
Treatment Distribution

- An IO-based regimen (IO monotherapy [40.6%] or IO + chemotherapy [41.5%]) was received by 82.1% of patients as 1L treatment, with 87.1% receiving pembrolizumab-based regimens

Outcomes

- In the overall cohort, median rwOS (prospective-adjusted) was 20.5 months
- When stratified by 1L treatment, median rwOS was shorter among patients receiving IO monotherapy (19.1 months) than among those receiving IO + chemotherapy (22.2 months), although the difference was not statistically significant (**Figure 1**)

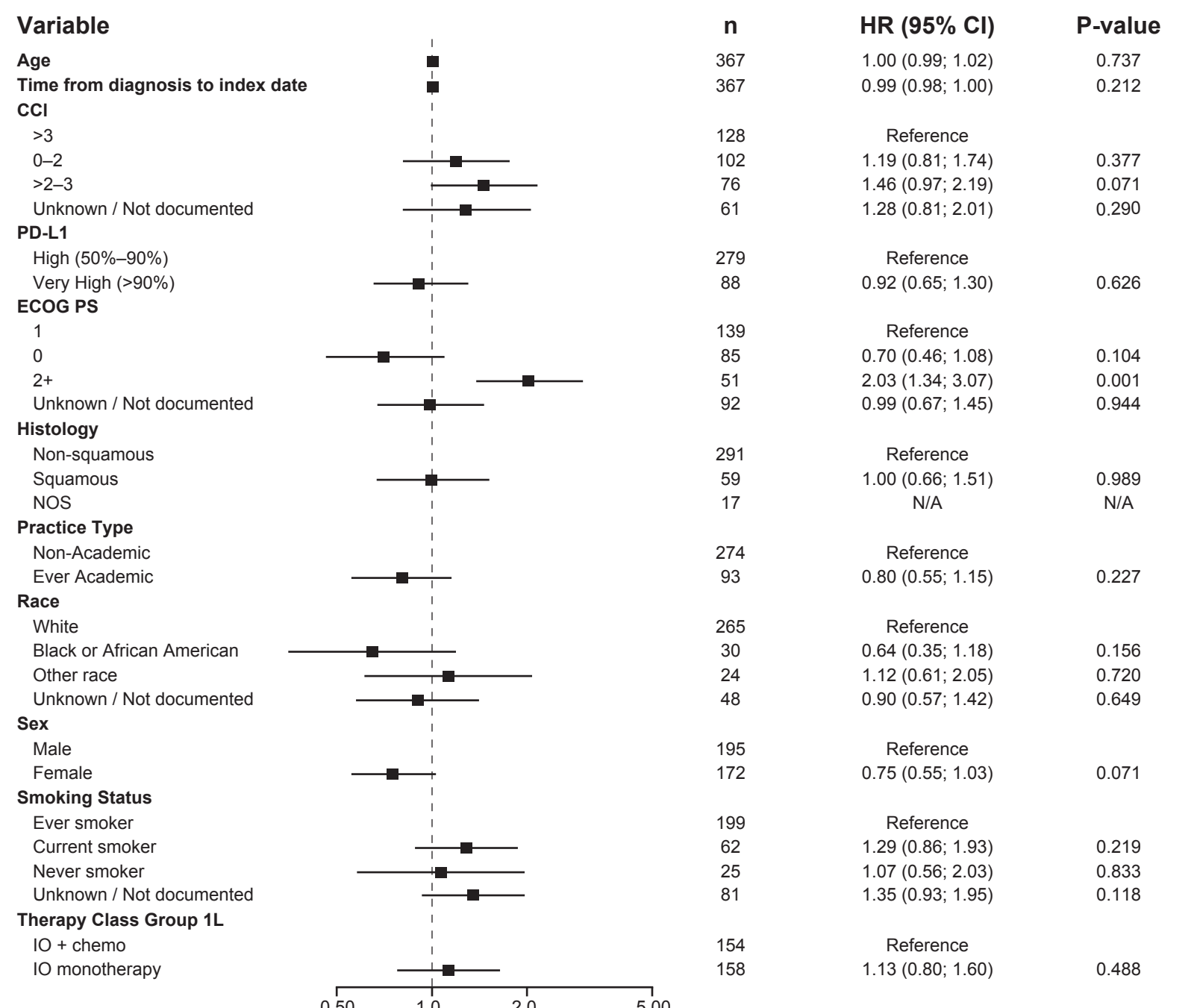
Figure 1. Prospective Adjusted rwOS^a



Outcome	1L treatment	n	Median (95% CI), mo	6-mo rate (95% CI)	12-mo rate (95% CI)	24-mo rate (95% CI)	36-mo rate (95% CI)
rwPFS	Overall	394	8.71 (7.53; 10.49)	60.54 (55.06; 65.56)	40.03 (34.21; 45.78)	26.13 (20.19; 32.45)	19.82 (13.13; 27.52)
	IO + chemo-therapy	167	10.29 (7.92; 13.74)	65.23 (56.94; 72.31)	44.21 (35.34; 52.69)	29.19 (20.45; 38.47)	27.37 (18.61; 36.83)
	IO monotherapy	167	7.96 (5.62; 8.91)	54.8 (46.27; 62.54)	37.33 (28.92; 45.73)	25.33 (16.74; 34.83)	15.83 (9.54; 21.57)
rwOS	Overall	368	20.52 (17.75; 23.67)	79.93 (75.43; 83.70)	66.38 (61.06; 71.15)	43.71 (37.70; 49.56)	32.05 (25.64; 38.62)
	IO + chemo-therapy	154	22.22 (17.19; 35.97)	80.31 (73.06; 85.80)	69.31 (60.91; 76.25)	48.34 (38.83; 57.21)	38.51 (28.39; 48.53)
	IO monotherapy	159	19.1 (15.55; 25.81)	77.06 (69.65; 82.89)	63.02 (54.73; 70.21)	43.77 (34.86; 52.32)	28.87 (19.25; 39.19)

- 1L, first-line; chemo, chemotherapy; IO, immuno-oncology; OS, overall survival; rwOS, real-world overall survival.
- ^aThe overall population includes patients who were treated with chemotherapy alone, and other therapies.
- In multivariate Cox models, prospective hazard ratios (HRs) indicate that only Eastern Cooperative Oncology Group performance status ≥2 is associated with a significantly higher risk of death (HR, 2.03; P=0.001) (**Figure 2**)

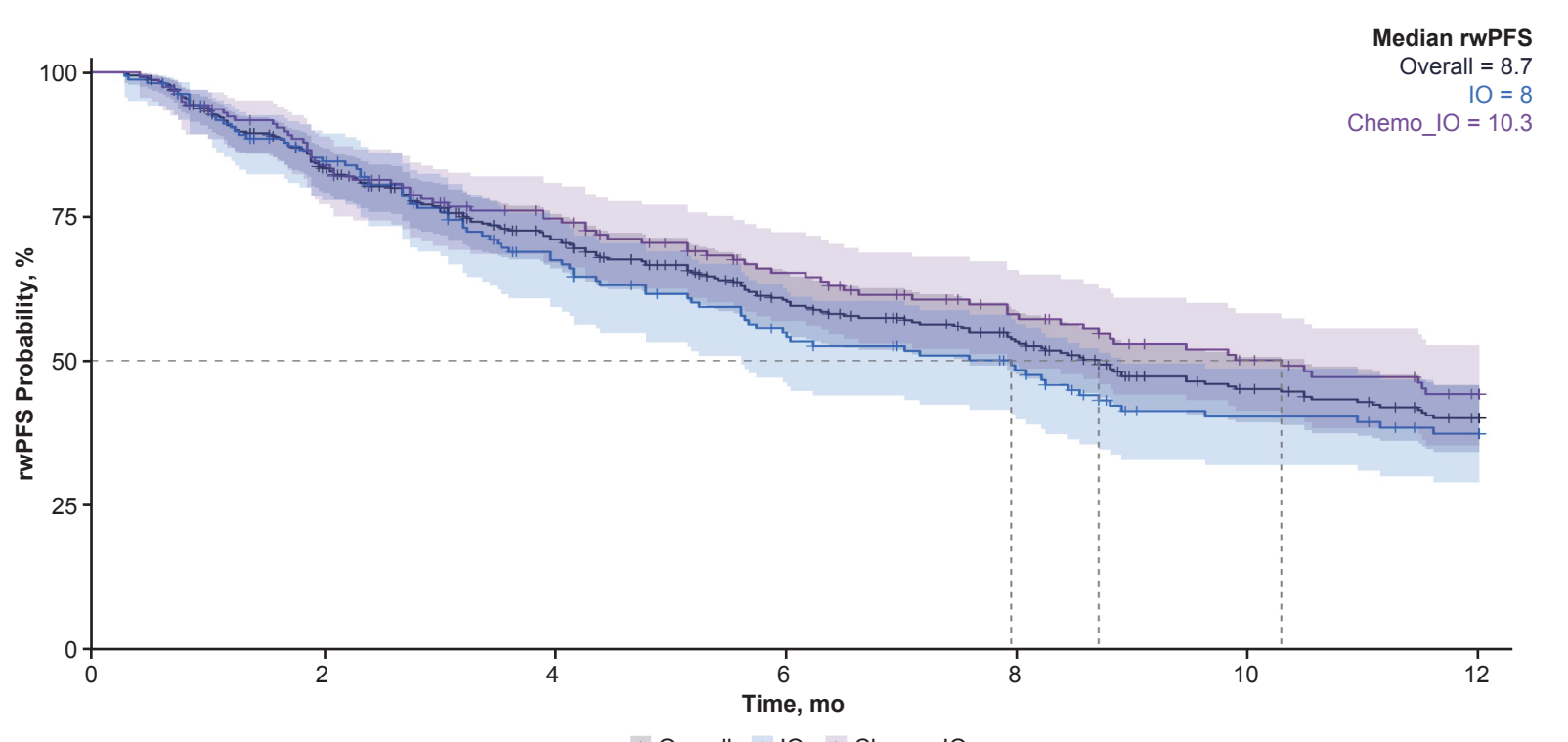
Figure 2. Prospective Hazard Ratios for rwOS by 1L Treatment



1L, first-line; chemo, chemotherapy; CCI, Charlson Comorbidity Index; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IO, immuno-oncology; N/A, not available; NOS, not otherwise specified; NSCLC, non-small cell lung cancer; PD-L1, programmed cell death ligand 1; rwOS, real-world overall survival.

- Among all patients, median rwPFS (RSA) was 8.7 months
- Similar to the trend seen for rwOS, rwPFS was shorter in patients who received IO monotherapy (7.96 months) vs IO + chemotherapy (10.29 months), although the difference was not statistically significant (**Figure 3**)

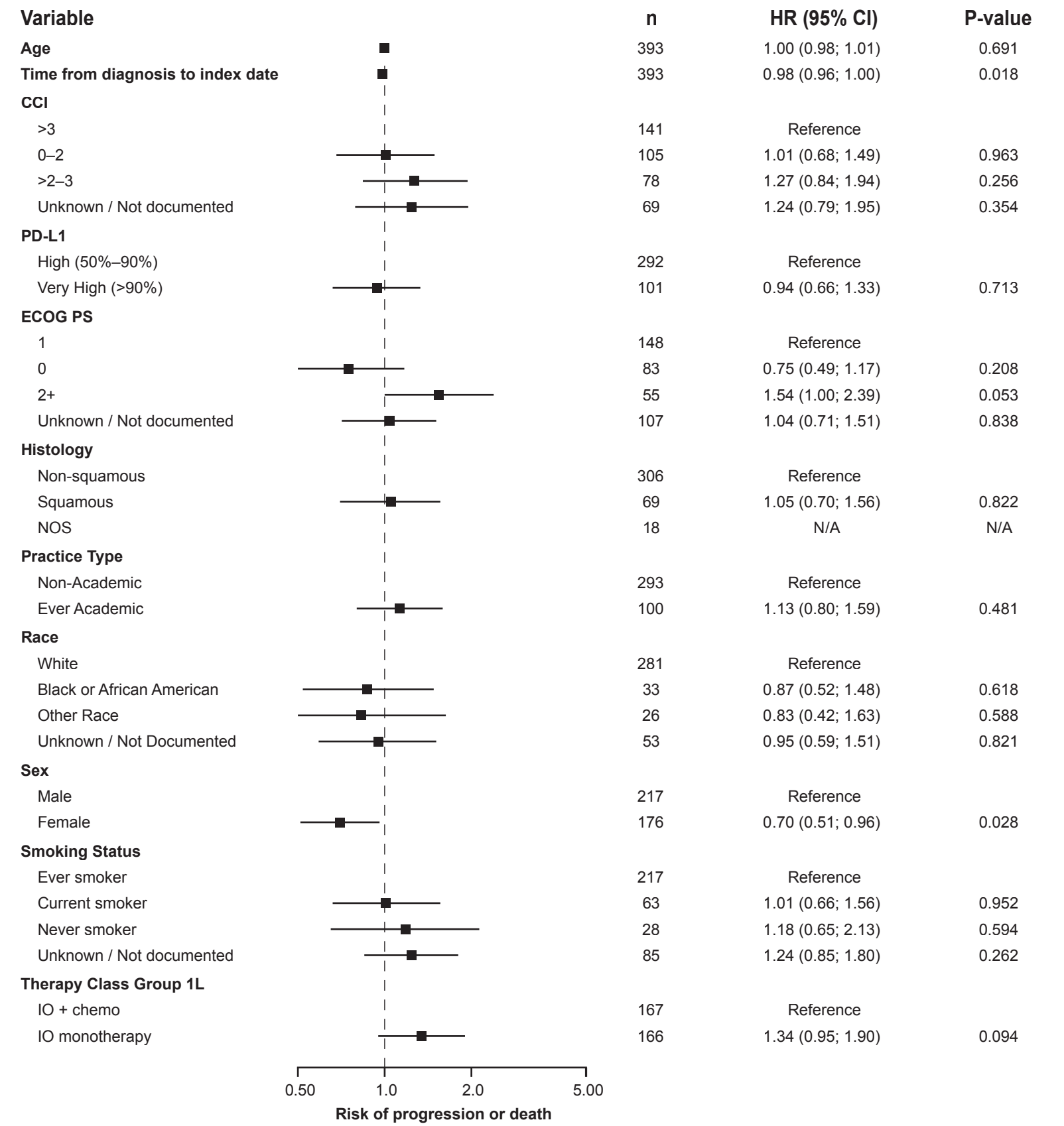
Figure 3. Risk-Set Adjusted rwPFS^a



Outcome	1L treatment	n	Median (95% CI), mo	6-mo rate (95% CI)	12-mo rate (95% CI)	24-mo rate (95% CI)	36-mo rate (95% CI)
rwPFS	Overall	394	8.71 (7.53; 10.49)	60.54 (55.06; 65.56)	40.03 (34.21; 45.78)	26.13 (20.19; 32.45)	19.82 (13.13; 27.52)
	IO + chemo-therapy	167	10.29 (7.92; 13.74)	65.23 (56.94; 72.31)	44.21 (35.34; 52.69)	29.19 (20.45; 38.47)	27.37 (18.61; 36.83)
	IO monotherapy	167	7.96 (5.62; 8.91)	54.8 (46.27; 62.54)	37.33 (28.92; 45.73)	25.33 (16.74; 34.83)	15.83 (9.54; 21.57)

- 1L, first-line; chemo, chemotherapy; IO, immuno-oncology; PFS, progression-free survival; rwPFS, real-world progression-free survival.
- ^aThe overall population includes patients who were treated with chemotherapy alone, and other therapies.
- In multivariate Cox models, risk-set adjusted HRs indicate that female sex is associated with a significantly lower risk of progression or death, (HR, 0.70; P=0.028) (**Figure 4**)

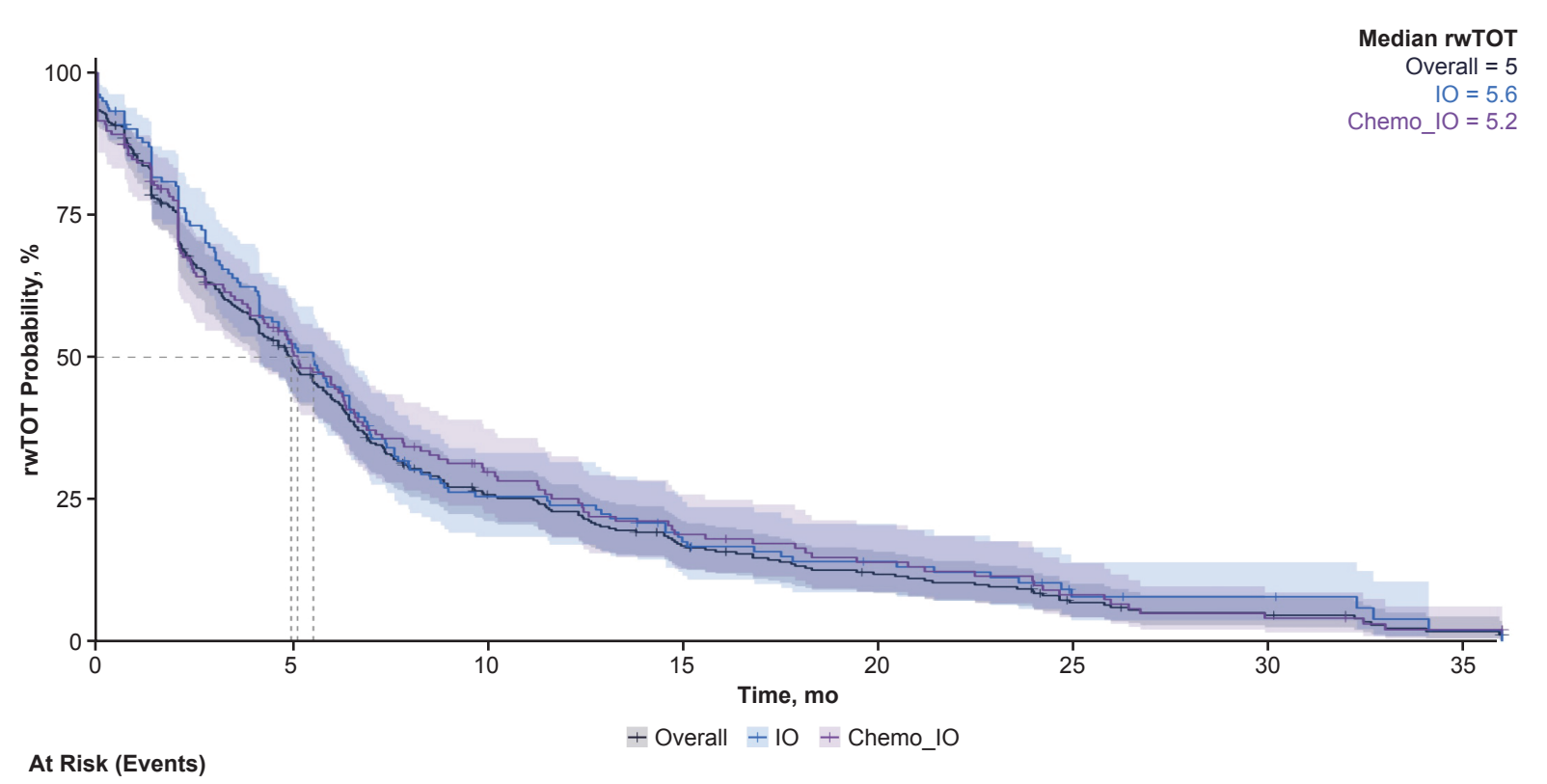
Figure 4. Risk-set Adjusted Hazard Ratios for rwPFS by 1L Treatment



1L, first-line; chemo, chemotherapy; CCI, Charlson Comorbidity Index; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IO, immuno-oncology; N/A, not available; NOS, not otherwise specified; NSCLC, non-small cell lung cancer; PD-L1, programmed cell death ligand 1; rwPFS, real-world progression-free survival.

- Median rwTOT (RSA) for the overall population was 5.0 months
- Patients who received IO monotherapy had median rwTOT very similar to patients who received IO + chemotherapy (5.55 months vs 5.16 months) (**Figure 5**)

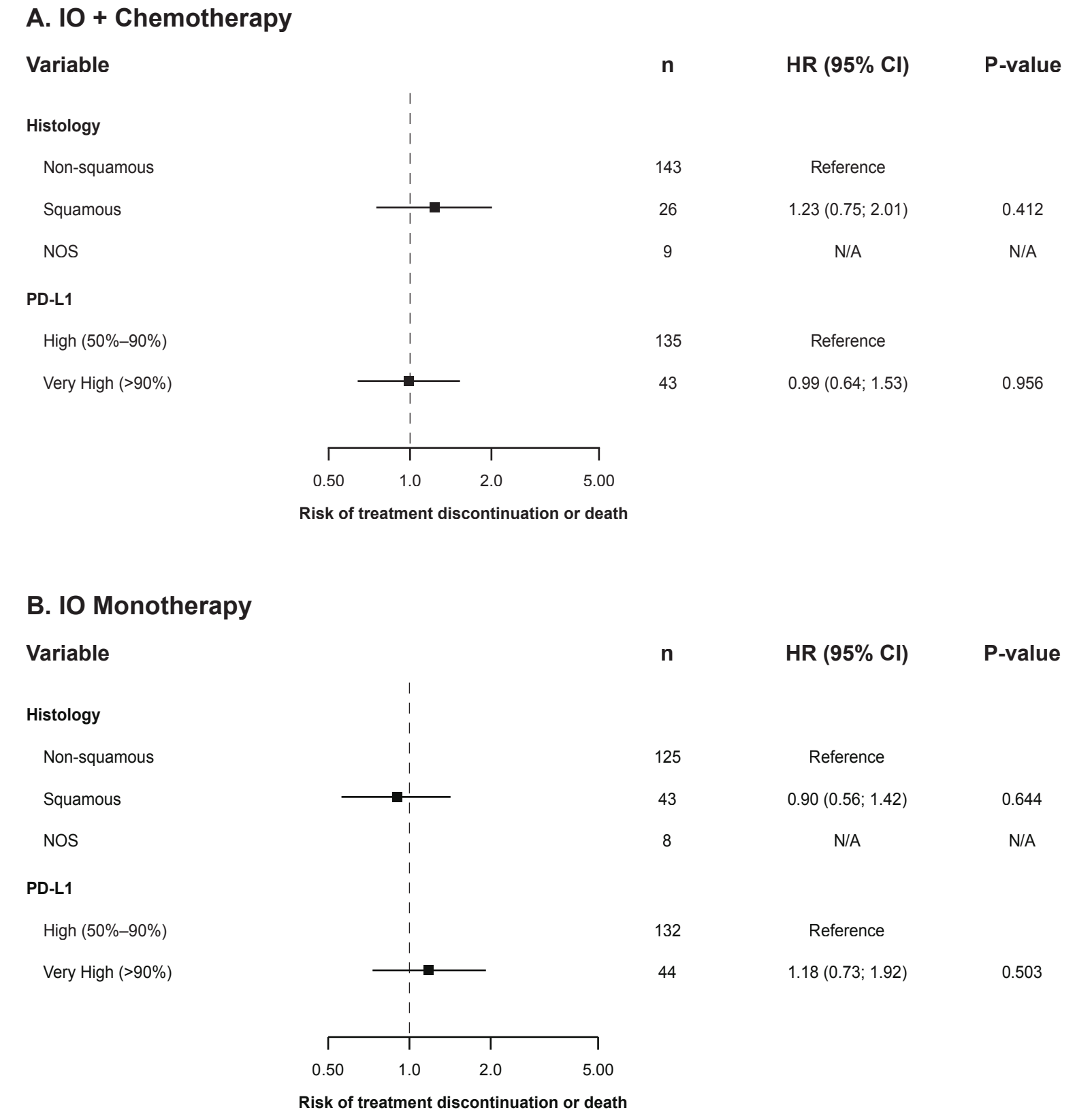
Figure 5. Risk-Set Adjusted rwTOT^a



Outcome	1L treatment	n	Median (95% CI), mo	6-mo rate (95% CI)	12-mo rate (95% CI)	24-mo rate (95% CI)	36-mo rate (95% CI)
rwTOT	Overall	427	4.99 (4.17; 5.68)	43.44 (38.01; 48.73)	22.83 (18.37; 27.6)	8.84 (5.93; 12.45)	1.15 (0.25; 3.61)
	IO + chemo-therapy	178	5.16 (3.94; 6.37)	46.6 (38.37; 54.41)	25.08 (18.2; 32.53)	10.65 (6.08; 16.69)	2.05 (0.44; 6.17)
	IO monotherapy	177	5.55 (4.17; 6.47)	44.75 (36.16; 52.97)	23.93 (17.01; 31.52)	10.3 (5.67; 16.53)	N/A

- 1L, first-line; chemo, chemotherapy; IO, immuno-oncology; N/A, not available; rwTOT, real-world time on treatment.
- ^aThe overall population includes patients who were treated with chemotherapy alone, and other therapies.
- Among patients treated with either IO + chemotherapy or IO monotherapy, time on treatment was similar between those with very high PD-L1 expression (>90%) and those with PD-L1 expression of 50%–90%, as indicated by risk-set adjusted HRs from multivariate Cox models (**Figure 6**). Likewise, the difference in rwTOT for patients with squamous and those with non-squamous tumor histology was not statistically significant for either therapy group (**Figure 6**)

Figure 6. Risk-set Adjusted Hazard Ratios for rwTOT by 1L Treatment



HR, hazard ratio; IO, immuno-oncology; N/A, not applicable; NOS, not otherwise specified; PD-L1, programmed cell death ligand 1.