

P1.11: Analysis of Immune-Related Adverse Events in a Diverse Patient Population with Advanced Non-Small Cell Lung Cancer

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INTRODUCTION

- Lung cancer is the leading cause of cancer death in the U.S.; NSCLC accounts for ~85% of diagnoses, and 5-year survival in advanced disease is 5-10%.^{1,2}
- Guidelines recommend ICIs, primarily PD-1 or PD-L1 inhibitors, alone or with chemotherapy, as standard first-line and adjuvant treatment for most patients with NSCLC.³
- Under-representation of minority groups in pivotal ICI trials may contribute to observed disparities in the incidence and presentation of irAEs among these populations.⁴

OBJECTIVES

- Evaluate the incidence of irAEs in patients treated with frontline ICIs for advanced NSCLC.
- Evaluate differences in the incidence of irAEs by race and ethnicity.
- Evaluate the management of irAEs.

METHODS

Single-center retrospective chart review conducted between January 1st, 2021 and December 31st, 2024 at Memorial Cancer Institute.

irAEs were identified by manual chart review and graded using CTCAE criteria. Approved by the Memorial Healthcare System Institutional Review Board.

Patient Population

- Adults aged 18 to 89 years
- Advanced NSCLC diagnosis receiving immunotherapy in the frontline setting

Statistical Methods

- Descriptive statistics: patient demographics, incidence, type, and management of irAEs
- Continuous variables: medians with IQR; categorical variables: frequencies and percentages
- Group comparisons: OR with 95% CI from 2x2 tables; Fisher exact test where expected cell counts were <5
- No adjustment was made for multiple comparisons or for baseline covariates and duration of ICI exposure; reported p-values are nominal and findings are hypothesis-generating

RESULTS

Table 1. Patient Baseline Characteristics

Characteristics	Did Not Experience irAEs (n = 24)	Experienced irAEs (n = 102)
Median age – years (IQR)	68.5 (62-75.75)	69.5 (63-77.75)
Sex – no. (%)		
Male	17 (71)	49 (48)
ECOG PS – no. (%)		
0	16 (67)	63 (62)
1	6 (25)	26 (25)
2	2 (8)	11 (11)
3	0	2 (2)
Ethnic representation – no. (%)		
White non-Hispanic	7 (29)	50 (49)
White Hispanic	10 (42)	24 (24)
Black non-Hispanic	6 (25)	24 (24)
Middle Eastern	1 (4)	2 (2)
Asian	0	1 (1)
Other	0	1 (1)
ICI received – no. (%)		
Pembrolizumab	21 (88)	96 (94)
Atezolizumab	1 (4)	3 (3)
Nivolumab + ipilimumab	2 (8)	1 (1)
Durvalumab + tremelimumab	0	2 (2)
Autoimmune disorder – no. (%)	4 (17)	23 (23)

Table 2. Management of irAEs

Management Strategy – no. (%)	irAEs (n = 204)
Self-Limiting	128 (63)
Dose Interruption	8 (4)
Systemic Steroids	35 (17)
Levothyroxine	11 (5)
Supportive care	3 (1)
Not Documented	19 (9)

Percentages are of all 204 irAEs. One management strategy was recorded per event.

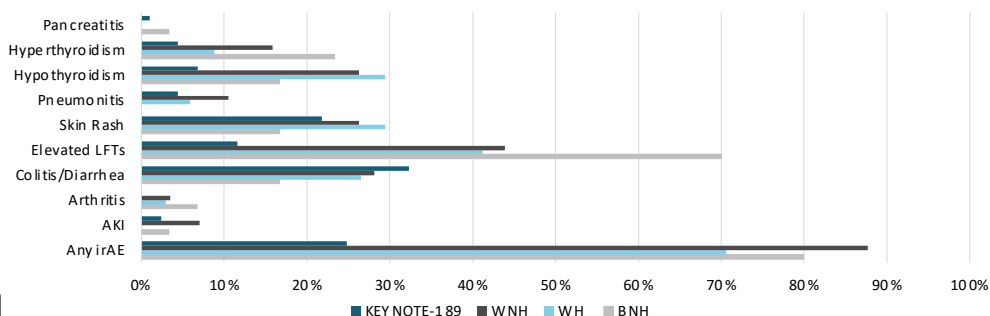
Table 3. Severity of irAEs

Severity of irAEs – no. (%)	irAEs (n = 204)
Grade 1	107 (52)
Grade 2	20 (10)
Grade 3	2 (1)
Grade 4	1 (<1)
Not Reported	74 (36)

Graded using CTCAE criteria; grade was not documented for 74 of 204 events (36%).

Figure 1. Incidence of irAEs by Race/Ethnicity Compared with KEYNOTE-189

A caution on comparability. KEYNOTE-189 events were prospectively adjudicated per protocol; events here were abstracted retrospectively from the chart. The two are not directly comparable, and the rate difference likely reflects ascertainment.

**Table 4. Incidence of irAEs by Race/Ethnicity. Interpretation.** OR = odds of the event in WNH relative to the comparator (reference) group. p-values are unadjusted for 14 comparisons; highlighted values are nominally significant only.

Adverse Events	WNH (n = 57) vs BNH (n = 30) OR (95% CI)	p-value	WNH (n = 57) vs WH (n = 34) OR (95% CI)	p-value
Any irAEs	1.79 (0.54-5.89)	0.337	2.98 (1.01-8.78)	0.043
Elevated LFTs	0.34 (0.13-0.86)	0.02	1.12 (0.47-2.64)	0.802
Skin rash	1.79 (0.58-5.51)	0.309	0.86 (0.33-2.2)	0.749
Colitis/Diarrhea	1.95 (0.64-5.98)	0.237	1.08 (0.42-2.82)	0.869
Hypothyroidism	1.79 (0.58-5.51)	0.309	0.86 (0.33-2.2)	0.749
Hyperthyroidism	0.62 (0.2-1.86)	0.388	1.94 (0.49-7.72)	0.524
Pneumonitis	—	0.089	1.88 (0.36-9.9)	0.705

LIMITATIONS

- Single-center, retrospective design; irAE attribution and grading were limited by clinical documentation.
- No adjustment for multiple comparisons or for duration of ICI exposure and time at risk.
- Race and ethnicity were self-reported and abstracted from the electronic health record.
- The overall irAE rate exceeds that of prospective trials, likely reflecting differences in ascertainment rather than in true toxicity.

DISCUSSION & CONCLUSION

- In this real-world analysis, BNH (24%) and WH (27%) patients were far better represented than in KEYNOTE-189, which enrolled >94% WNH patients, providing insight into the irAE profile of ICIs in a more diverse population.⁵
- The most frequently documented irAEs were elevated LFTs, skin rash, colitis/diarrhea, and hypothyroidism. Grade 1 events accounted for 52% of all events, although grade was not documented for a further 36%.
- Nominally significant differences were observed for elevated LFTs (WNH vs BNH) and for any irAE (WNH vs WH). These p-values are unadjusted for 14 comparisons and would not remain significant after correction.
- No other differences reached nominal significance. The remaining between-group differences should be regarded as trends only.
- The overall irAE rate (81%) substantially exceeds rates reported in prospective trials, most plausibly reflecting differences in ascertainment and attribution inherent to retrospective chart review rather than a true excess of toxicity.
- Conclusion:** irAE patterns may differ across racial and ethnic groups, but these findings are hypothesis-generating. Larger, multicenter cohorts with prospectively adjudicated events and adjustment for exposure time are needed to confirm them.

REFERENCES & DISCLOSURES

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Scan here for references
and team details



Abbreviations:

AKI, acute kidney injury; BNH, Black non-Hispanic; CI, confidence interval; CTCAE, Common Terminology Criteria for Adverse Events; ECOG PS, ECOG performance status; ICI, immune checkpoint inhibitor; irAE, immune-related adverse event; IQR, interquartile range; LFT, liver function test; NSCLC, non-small cell lung cancer; OR, odds ratio; WH, White Hispanic; WNH, White non-Hispanic.