THE RISK OF MYOCARDIAL INFARCTION AND STROKE WITH IMMUNE CHECKPOINT INHIBITORS: A FDA ADVERSE EVENT REPORTING SYSTEM (FAERS) DATABASE ANALYSIS

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INTRODUCTION

- Immune checkpoint inhibitors (ICIs) have revolutionized the treatment of solid tumor, however, only are of modest use in hematological malignancies
- Currently improved for relapsed or refractory Hodgkin lymphoma
- It is well established that ICIs are associated with accelerated atherosclerosis
- However, their impact on clinical outcomes such as myocardial infarction (MI) and stroke remains unclear

OBJECTIVE

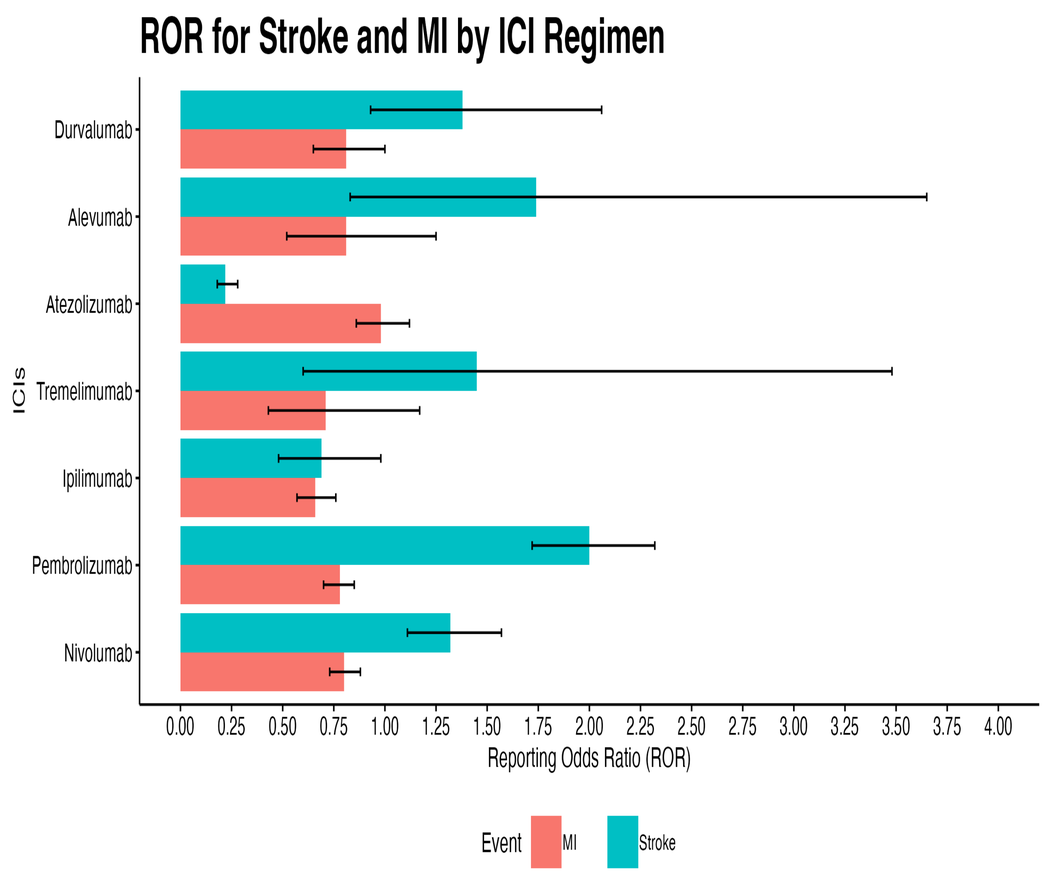
- Our study aims to evaluate the risk of MI and stroke with ICIs using data from the FDA Adverse Event Reporting System (FAERS)

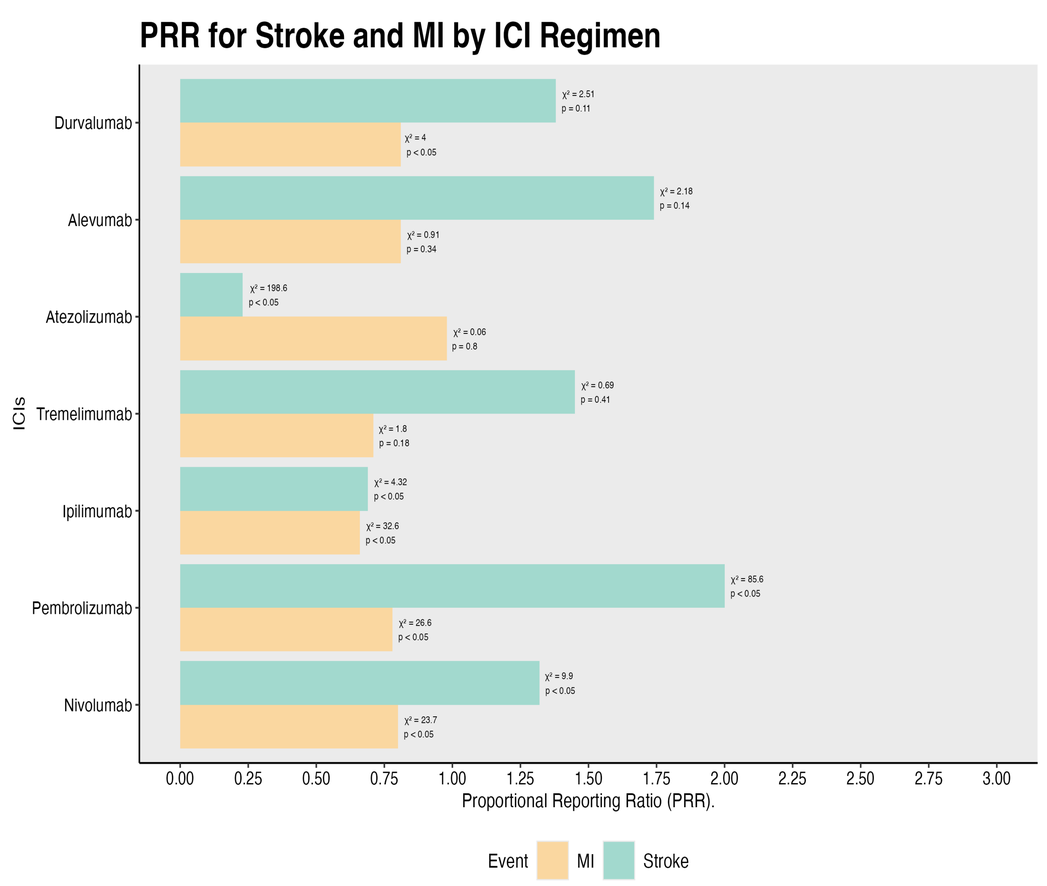
METHODS

- The FDA FAERS (Federal Adverse Event Reporting System) is a database that collects and analyzes adverse event reports related to FDA-approved drugs and biologics
- A retrospective analysis of FAERS was conducted up to December 2024
- We investigated the association between 7 commonly used ICIs use and the risk of MI and stroke
- Following ICIs were included:
  - PD1-inhibitors (pembrolizumab and nivolumab)
  - PDL1-inhibitors (atezolizumab, alevumab and durvalumab)
  - CTLA4-inhibitors (ipilimumab and remelimumab)
- Disproportionality analysis was performed using the reporting odds ratio (ROR) and proportional reporting ratio (PRR)

RESULTS

ICIs	Stroke		MI	
	ROR (95% CI)	PRR (chi square, p-value)	ROR (95% CI)	PRR (chi square, p-value)
Nivolumab	1.32 (1.11-1.57)	1.32 (9.9, < 0.05)	0.8 (0.73-0.88)	0.80 (23.7, < 0.05)
Pembrolizumab	2 (1.72-2.32)	2 (85.6, < 0.05)	0.78 (0.70-0.85)	0.78 (26.6, < 0.05)
Ipilimumab	0.69 (0.48-0.98)	0.69 (4.32, < 0.05)	0.66 (0.57-0.76)	0.66 (32.6, < 0.05)
Tremelimumab	1.45 (0.60-3.48)	1.45 (0.69, 0.41)	0.71 (0.43-1.17)	0.71 (1.8, 0.18)
Atezolizumab	0.22 (0.18-0.28)	0.23 (198.6, < 0.05)	0.98 (0.86-1.12)	0.98 (0.06, 0.8)
Alevumab	1.74 (0.83-3.65)	1.74 (2.18, 0.14)	0.81 (0.52-1.25)	0.81 (0.91, 0.34)
Durvalumab	1.38 (0.93-2.06)	1.38 (2.51, 0.11)	0.81 (0.65-1)	0.81 (4, < 0.05)





CONCLUSIONS

- Our analysis showed significantly increased reporting risk of stroke with:
  - Pembrolizumab
    - ROR (95% CI): 2 (1.72-2.32)
    - PRR (Chi-Square, p-value): 2 (85.6, < 0.05)
  - Nivolumab
    - [ROR (95% CI): 1.32 (1.11-1.57)
    - PRR (Chi-Square, p-value): 1.32 (9.9, < 0.05)
- However, no significant risk was observed for stroke or MI with other ICIs

FUTURE STEPS

- Our results suggest that PD1 inhibitors are associated with a higher risk of stroke while other ICIs were not associated with a higher risk of MI or stroke
- As PD-1 inhibitors are currently the only ICIs approved for use in Hodgkin lymphoma—specifically in relapsed or refractory settings—these findings may have important clinical implications for this patient population.
- Further prospective studies are warranted to confirm these associations and inform risk-benefit assessments in Hodgkin lymphoma patients receiving immunotherapy.