

Association of Immune Checkpoint Inhibitors (ICIs) with Sarcoidosis: Analysis of the FDA Adverse Event Reporting System (FAERS)

Arifa Bibi¹, Saeed Khan², Aneeta Channar³, Saeed Anwar⁴, Bireera Muzaffar¹, Farzana Khan⁵, Aminah Tayyab¹.

¹University of Oklahoma, Oklahoma City, OK; ²Ghurki Trust Teaching Hospital, Lahore, Punjab; ³Rutgers-Jersey City Medical Center, Jersey City, NJ; ⁴Loralai Medical College, Loralai, Balochistan; ⁵Bolan University of Medical and Health Sciences, Quetta, Balochistan.



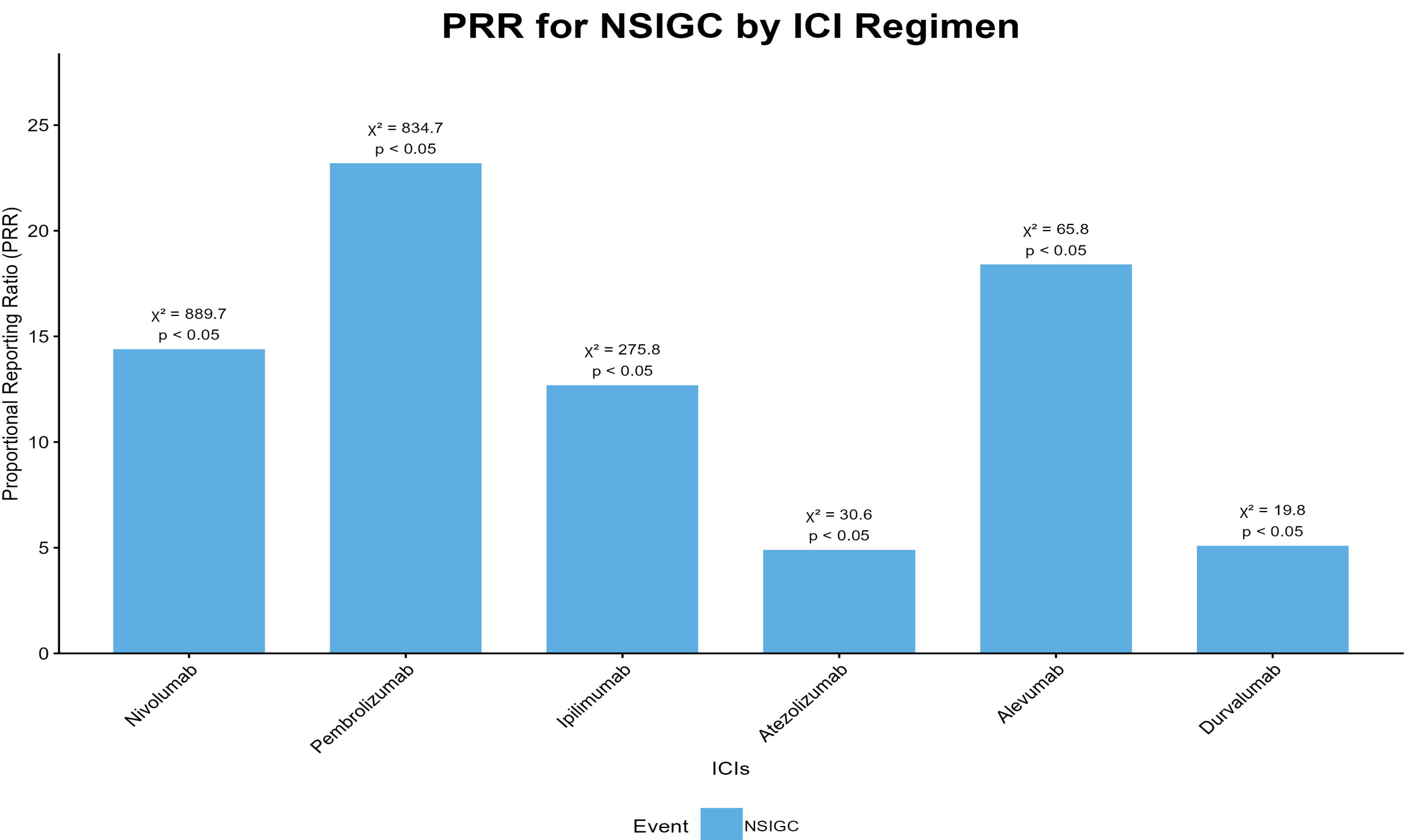
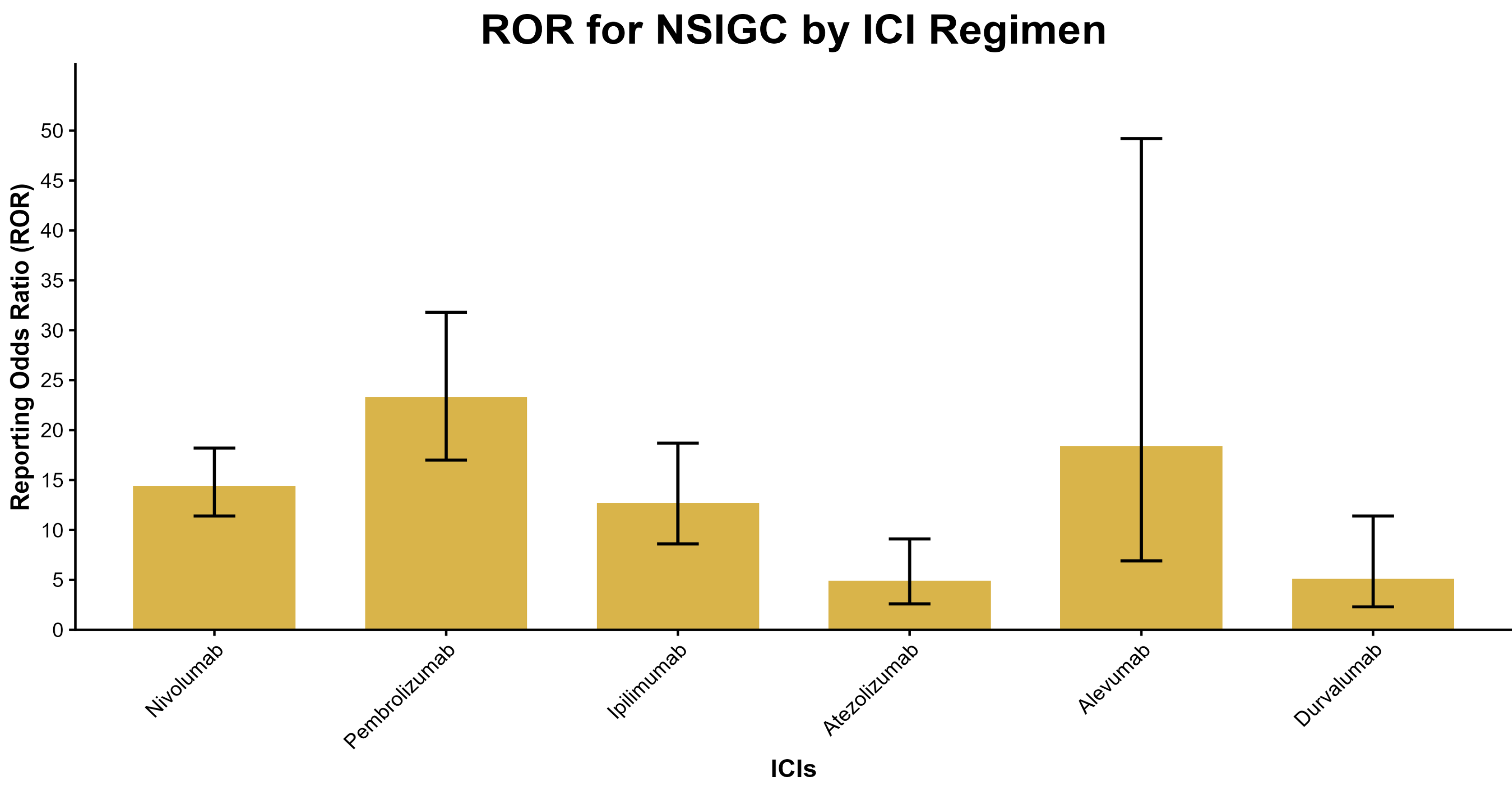
Background

- ICIs have transformed the treatment landscape of several solid tumors and have gained FDA approval for relapsed or refractory Classical Hodgkin Lymphoma and Primary Mediastinal Large B-Cell Lymphoma.
- While their role in most other hematologic malignancies remains largely investigational.
- With the increasing use of ICIs, a wider spectrum of immune-related adverse events (irAEs) has been recognized, including rare toxicities.
- However, sarcoidosis remains poorly characterized in this setting, with limited data on its true association with ICIs.
- We aimed to evaluate the association between ICIs and sarcoidosis using the FAERS database.

Methods

- A retrospective pharmacovigilance analysis was performed using the FAERS database through December 2024 to evaluate the association between ICIs and sarcoidosis.
- Sarcoidosis cases encompassed a broad spectrum of manifestations, including pulmonary, cardiac, ocular, and neurologic involvement, as well as sarcoid-like reaction and lymph node sarcoidosis.
- The ICIs analyzed included PD-1 inhibitors (pembrolizumab and nivolumab), PD-L1 inhibitors (atezolizumab, avelumab, and durvalumab), and CTLA-4 inhibitors (ipilimumab and tremelimumab).
- Disproportionality analysis was conducted using both the reporting odds ratio (ROR) and proportional reporting ratio (PRR) to assess signal strength.

Results



Results

- A total of 160 cases of sarcoidosis were identified in association with ICIs.
- Among these, pulmonary sarcoidosis was the most frequently reported manifestation (47.5%), followed by sarcoid-like reaction (36.9%).
- Less common presentations included lymph node (6.9%), neurosarcoidosis (3.1%), cardiac sarcoidosis (3.1%), and ocular sarcoidosis (2.5%).
- Among ICIs, the strongest disproportionality signals for sarcoidosis were observed with pembrolizumab (ROR: 23.3; PRR: 23.2, $\chi^2=834.7$, $p<0.05$), followed by avelumab (ROR: 18.4; PRR: 18.4, $\chi^2=65.8$, $p<0.05$) and nivolumab (ROR: 14.4; PRR: 14.4, $\chi^2=889.7$, $p<0.05$).
- Significant associations were also observed with ipilimumab, atezolizumab, and durvalumab, whereas no signal was detected with tremelimumab.

Conclusions

- Our findings indicate that ICIs, particularly PD-1 and PD-L1 inhibitors, are associated with an increased risk of sarcoidosis.
- This entity remains underrecognized in literature and is often misinterpreted as disease progression, which may lead to inappropriate discontinuation of therapy.
- Therefore, it is important for clinicians to maintain a high index of suspicion for sarcoidosis in patients receiving ICIs, as timely recognition can support accurate diagnosis and optimize treatment decisions without unnecessarily interrupting effective cancer therapy.

Contact Information

Email: Arifa-Bibi@ou.edu

Twitter: @arifabibi5