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BEYOND EFFICACY: REAL-WORLD EVALUATION OF IMMUNE-RELATED TOXICITIES IN MELANOMA PATIENTS RECEIVING IPILIMUMAB–NIVOLUMAB COMBINATION

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BACKGROUND AND IMPORTANCE

The ipilimumab–nivolumab combination improves survival in advanced melanoma but carries a high incidence of immune-related adverse events (**irAEs**), requiring early identification and coordinated management

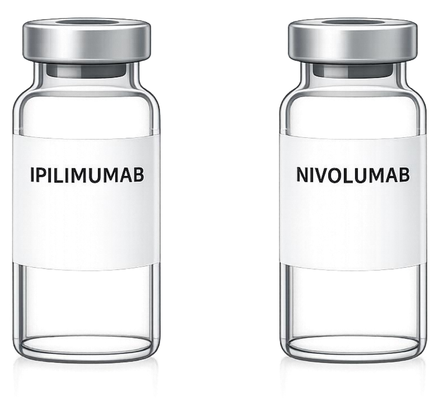
AIM AND OBJECTIVE

To characterize the **incidence, type, severity, and management** of irAEs in melanoma patients receiving ipilimumab–nivolumab therapy.

MATERIALS AND METHODS

STUDY DESIGN

Retrospective observational study of melanoma patients receiving ipilimumab (3 mg/kg) + nivolumab (1 mg/kg) between Jan 2021–Jul 2025.

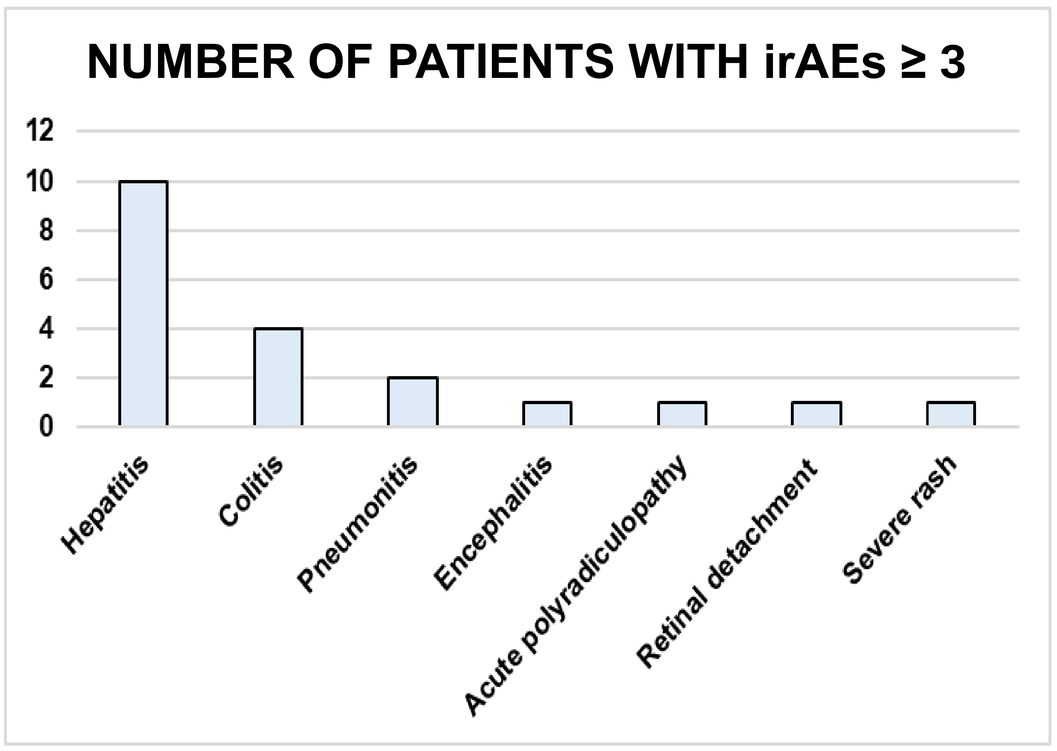


DATA COLLECTION

Electronic health records were used to collect demographic, clinical, treatment and toxicity data (CTCAE v5.0); results expressed as median (IQR).

RESULTS

- 36 patients were included (58.3% male; median age 57.5 [48–69.5] years; median body weight 66.4 [57–73.5] kg). Median disease stage IV (4–4), first-line treatment (1–1), median 2 cycles (1–4), and ECOG 1 (1–2).
- Overall, 66.7% (n=24) developed at least one irAE, and 55.6% (n=20) developed grade ≥3 toxicity. Median onset time was 4 weeks (2.75–8.25).



- 20 patients required corticosteroids; 3 mycophenolate mofetil, 3 infliximab, 1 vedolizumab, and 1 tocilizumab.
- Treatment interruption occurred in 20 patients due to irAE and 4 due to non-irAE causes:
  - 12 switched to nivolumab monotherapy
  - 8 underwent regimen changes.
- 25 hospitalizations were recorded, 20 (80%) irAE-related.
- Most events resolved with immunosuppressive therapy, with no treatment-related deaths.

CONCLUSION AND RELEVANCE

Ipilimumab–nivolumab combination in real-world practice was associated with a high incidence of irAEs. Early recognition and appropriate multidisciplinary management are essential to optimize therapeutic outcomes.
Further multicenter studies are warranted to consolidate these findings and to develop evidence-based strategies for toxicity prevention and monitoring.

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