

IMMUNE-MEDIATED HEPATITIS AND ENCEPHALITIS WITH IPILIMUMAB/NIVOLUMAB IN CLEAR CELL CARCINOMA AFTER A SINGLE DOSE: A CASE REPORT

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BACKGROUND AND IMPORTANCE

Ipilimumab/nivolumab is the first-line treatment for advanced clear-cell renal carcinoma at intermediate/high risk. This case reports severe immune-mediated toxicity (hepatitis and encephalitis) in a stage IV patient after a single dose (ipilimumab 1 mg/kg; nivolumab 3 mg/kg). Causality was assessed using the Naranjo algorithm.

AIM AND OBJECTIVES

To highlight the risk of life-threatening immune-mediated adverse reactions and demonstrate how early identification of hepatic and neurological alterations optimizes corticosteroid therapy and improves patient safety.

RESULTS

- 14/08/25: Post-infusion fever; no infection source found.
- 20/08/25: Fever, CRP 8.9 mg/dL, and bilateral infiltrates. Suspicion of atypical pneumonia.
- 24/08/25: Grade 1 non-pruritic rash.
- 26/08/25: Grade 2 pneumonitis (CT) and Grade 3 hepatitis (ALT 615). Started Prednisone 0.5 mg/kg.
- 18/09/25: Grade 3–4 encephalitis (partial seizure), acute hepatitis, and stage 2 AKI. Treated with methylprednisolone pulses (1 g/5 days) and levetiracetam.
- 06/10/25: Asymptomatic; stabilizing labs (Cr 1.32 mg/dL, Bilirubin 2.42 mg/dL).
- Causality: Naranjo score of 7 (Probable).

MATERIAL AND METHODS

Clinical record review of a single patient case. Toxicities were graded and managed according to ASCO guidelines. Causality was evaluated via the Naranjo algorithm.

CONCLUSION AND RELEVANCE

Severe multi-organ toxicity occurred after a single cycle. Early onset and positive corticosteroid response confirmed an autoimmune mechanism. Full recovery was achieved through immunotherapy discontinuation and prompt steroid therapy. Key recommendations: strengthen pharmacovigilance, train teams in early recognition, and carefully evaluate immunotherapy continuation after \geq Grade 3 events.

