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Real-World Outcomes of Adjuvant Pembrolizumab in Renal Cell Carcinoma: A Single-Centre Experience

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Background:

The KEYNOTE-564 trial demonstrated that adjuvant Pembrolizumab significantly improved disease-free survival (DFS) in patients with high-risk renal cell carcinoma (RCC) following nephrectomy. The objective of this study is to evaluate real-world outcomes of adjuvant pembrolizumab and compare them with clinical trial data.

Methods:

This was a retrospective, single-centre analysis of patients with RCC treated with adjuvant pembrolizumab following nephrectomy from December 2022 to October 2025, with censoring date of 15th May 2026. Data collected included baseline demographics, tumour characteristics, treatment exposure, and immune-related adverse events (irAEs). Time to event analyses were calculated from day 1 of cycle 1 to date of event or censoring date.

Results:

A total of 57 patients were included, with a median age of 63 years (range 39–80), and 68.4% were male. All patients had an ECOG performance status of 0 or 1. Disease was predominantly locally advanced, with 86.1% of patients having pT3 tumours. There was a near-equal distribution between Leibovich's high-risk (49.1%) and intermediate-risk (49.2%) disease.

At a median follow-up of 23.8 months, median disease-free survival (DFS) was not reached, and 78.7% of patients remained disease-free. Treatment-related toxicity was observed in 64.9% of patients, and grade ≥3 adverse events reported in only 14%. The most common irAEs were hypothyroidism (19.2%), skin rash (17.3%), pneumonitis (11.5%), colitis (7.7%), and adrenal insufficiency (7.7%). 49.1% of patients completed planned course of treatment at the time of analysis. 29.9% discontinued due to toxicity, 12.2% due to disease progression, and only 8.8% of patients had ongoing treatment at the time of censoring.

In the pembrolizumab arm of the KEYNOTE 564 trial, 78.2% were disease free at 24 months, 79.1% had any grade iRAEs, 18.6% had grade ≥3 iRAEs, and 21.1% discontinued therapy due to adverse event of any cause.

Conclusion:

This study demonstrated comparable efficacy and safety of adjuvant pembrolizumab in routine clinical setting with the KEYNOTE 564 trial. Longer follow-up and larger sample sizes are required to evaluate overall survival benefit, and the long-term impact of iRAEs in this group of patients.