**Background and Importance**

- The most frequent renal cell tumor is the clear cell renal carcinoma (ccRCC) which represents 80% of malignant renal tumors in adults.
- Pembrolizumab, in combination with axitinib, is indicated for the first-line treatment of advanced renal cell carcinoma (RCC) in adults.

**Aim and Objectives**

- To describe and analyze the effectiveness and safety of pembrolizumab and axitinib in a tertiary hospital clinical practice.

**Materials and Methods**

- **Retrospective observational study** from March 2019 to October 2020
- **Data sources**: electronic medical records
- **Variables analyzed**: sex, age, PDL-1, prior lines treatments, IMDC risk and presence of metastasis at starting therapy, duration of treatment and interruption causes, grade and type of toxicities and best TAC response.

**Results**

- 13 patients
  - 76.9% men
  - 60.4 ± 8.8 years old
  - PDL-1 score ≥1 in 3/4 patients
- Previous treatments
- IMDC risk classification: 7.7% favorable, 53.8% intermediate and 38.5% poor risk
- Lung (7/13) bone (5/13) ganglionar (2/13) cerebral (1/13) unknown (2/13)

**Pembro 200 mg/3 weeks + axi 5 mg/12h**

- Mean duration: 28.7 weeks
- 46% continue with active treatment
- Best TAC response obtained: 50% stable disease, 25% partial response and 12.5% progressive disease
- Discontinuation
  - Progression
  - Unacceptable toxicity
  - Death

**Adverse events (N=3)**

- asthenia G1-3 (N=11)
- anorexia G1-2 (N=6)
- hyperthyroidism G1-3 (N=3)
- diarrhea G1-4 (N=5)
- palmar plantar erythrodysesthesia G2-3 (N=2)
- pruritus G1 (N=1)
- liver alterations G1-3 (N=3)
- abdominal pain G1-2 (N=3)
- thrombopenia G2 (N=1)
- arthralgias G1 (N=1)
- dizziness and paresthesia G1 (N=1)
- vomiting G1 (N=1)

**Conclusion and Relevance**

- The effectiveness in our patients resulted a higher objective response rate than for KEYNOTE-426 trial.
- The combination treatment is well tolerated.
- In order to rationalize novel medicines use and optimize efficiency, measuring health results is crucial.