EFFICACY AND SAFETY OF NIVOLUMAB IN A TERTIARY HOSPITAL: EARLY ACCESS PROGRAM

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OBJECTIVES
To evaluate the efficacy and safety of all patients treated with nivolumab in our hospital in real world data.

METHODS
It is a retrospective and observational study of all patients included in the nivolumab early access program. Different measure variables were analyzed: sociodemographics (age, sex), related to the disease (diagnosis, disease stage, ECOG) and related to treatment (number of cycles of nivolumab, prior lines of treatment, objective response and adverse effects).

RESULTS
A total of 8 patients were included (7 men) with a median age 68.5 years (52-74). The ECOG was 1 for the 66.7% and 2 for the 33.3%. The results can be seen in the following tables:

- **Diagnosis**
  - Squamous cell carcinoma: 25%
  - Lung Adenocarcinoma: 25%
  - Renal-cell carcinoma: 50%

- **Effectiveness**
  - Stable disease (SD): 37.5%
  - Progression: 25%
  - Without evaluation (clinical improvement): 12.5%

- **Number of previous treatments**
  - 2: 25%
  - 3: 12.5%
  - 4: 12.5%
  - 5: 12.5%
  - 7: 12.5%

- **Side effects reported**
  - Decrease appetite: 25%
  - Hepatotoxicity: 12.5%
  - Anemia: 12.5%
  - Respiratory infection: 12.5%
  - Myalgia: 12.5%
  - Hypertension: 12.5%
  - Poor performance status: 12.5%
  - Abdominal pain: 25%
  - Nausea: 12.5%
  - Constipation: 12.5%
  - Diarrhea: 12.5%
  - Anorexia: 25%
  - Colitis: 25%

DISCUSSION
The effectiveness in terms of ORR was lower than that reported in the literature. The tumor response rate has been limited to the SD. Treatment-related AEs are similar to those described in other studies, mostly grades 1-2.

CONCLUSIONS
To evaluate the efficacy and long term safety is required a longer monitoring period. It is essential to measure the health outcomes of new and expensive drugs to rationalize their use and optimize efficiency in the oncology area.