DGI009

# EFFICACY AND SAFETY STUDY OF CETUXIMAB ASSOCIATED RADIATION THERAPY IN ADVANCED CARCINOME OF THE HEAD-NECK

T. Roldan Sevilla[1], G. Casado Abad[1], B. Benitez Garcia[1], E. Capilla Santamaria[1], A. Herrero Ambrosio[1].
[1]HOSPITAL DE LA PAZ, Hospital Pharmacy, Madrid, Spain.

**Background:** The current approach to advanced head and neck squamous cell carcinome (AHNSCC) is based on the combination of radiotherapy (RT) and chemotherapy. Recent introduction of monoclonal antibody cetuximab as a radiosensitizer agent has made a significant advance in the treatment of this pathology.

**Purpose:** To evaluate the efficacy and safety of cetuximab in combination with RT in the treatment of AHNSCC and compare our results with those reported in the pivotal trial.

## Materials and Methods:

Observational, descriptive and retrospective study.

Study period: October 2010-Febrero 2011

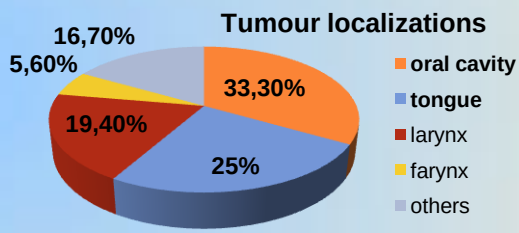
We reviewed the medical records of patients with AHNSCC who started treatment with cetuximab from 2007-2010 in our center.

We collected variables related to:

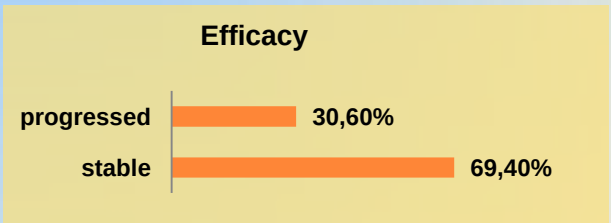
- Patient: gender, age, diagnosis and tumor stage.
- Drug therapy: line of treatment, number of administrations, time to progression (TTP) and adverse events.

## Results:

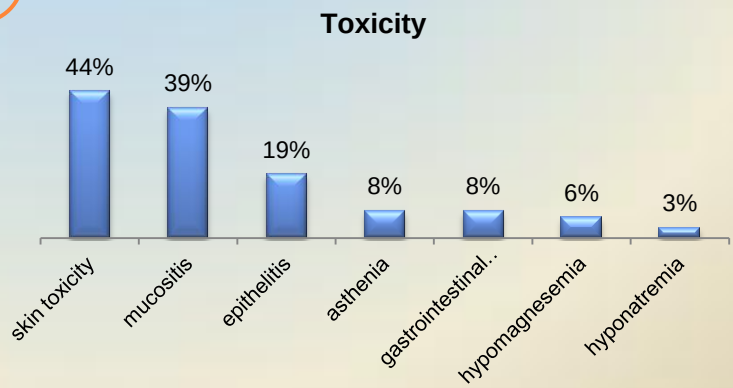
We reviewed **36 patients,** 27 men (75%) and 9 women (25%), with an average age at baseline of 66 years (range 35-85).




- Of all patients, 20 (55.5%) underwent surgery prior to treatment.
- Patients received a median of **5 administrations** (range 1-10) for 38 days (range 1-77).
- The stage at the start of chemoradiotherapy was **24 (66.7%) cases advanced disease** and 8 (22.2%) metastasic disease.
- Median TTP: **5.1 months.**




- Respect to the toxicity associated with cetuximab-RT, **25 patients (69%) developed s**ome adverse events.
- 7 (19%) patients we had to discontinue treatment and **3 (8%) required hospitalization**.




## Conclusions:

- The results obtained are similar to those of the pivotal trial. In our case we got worse results in TTP. This may be because the ideal conditions of clinical trials differ from clinical practice. Likewise, the median cycles which received cetuximab in the pivotal trial were over, which could also influence the therapeutic efficacy.
- The percentage of patients with side effects is high, but it was only necessary to discontinue treatment in a small number of them.