The combination of platinum-based chemotherapy (PT), 5-fluorouracil and cetuximab (EXTREME regimen) remains as a standard of care for advanced squamous cell carcinoma of head and neck (SCCHN). However, some patients (pts) may be frail and cannot use PT. Results from a Phase II trial showed efficacy of cetuximab plus weekly paclitaxel (ERBITUX scheme) as first line (1L) in SCCHN who are unfit for PT. This study aimed to validate the efficacy and safety of the proposed combination as 1L treatment for recurrent/metastatic SCCHN pts in the real world.

OBJECTIVES
- Primary objectives:
  - To estimate the PFS of ERBITUX scheme as 1L for recurrent and/or metastatic SCCHN.
- Secondary objectives:
  - Efficacy by means of best overall response (BOR), objective response rate (ORR), disease control rate (DCR), duration of response (DoR), and OS.
  - To determine potential prognostic factors associated to survival.
  - Safety profile by means of treatment compliance, and toxicities.

METHODS

This study was a retrospective, non-interventional study in 16 centers in Spain. The study used data collected from the medical records of 526 SCCHN pts. The trial included pts with histologically confirmed SCCHN from oral cavity, oropharynx, hypopharynx and larynx; aged 18 years old; and ineligible to non-platinum chemotherapy (PT) due to performance status (PS) ≥ 2.

The enrolled pts had received between 2012-2018 according to standard clinical practice at least one starting dose of both weekly paclitaxel 80 mg/m² and cetuximab (400 mg/m² loading dose, and then 250 mg/m²).

RESULTS

The study enrolled 531 pts (Fig.2/Table 1). Among those with primary location in the oropharynx, 16 were Pts-L1 in 121 pts, being positive (PD-L1 >1) in 26 (21.5%) of them.

With a median follow-up of 8.7 months (95% CI: 7.7-10.2), the median PFS was 4.5 months (95% CI: 3.9-5.5) (Fig.3). Median OS was 8.9 months (95% CI: 7.8-10.4) (Fig.4) for the full dataset. PFS by subgroups is shown in Fig.5 and OS by subgroups is shown in Fig.6.

The median duration of treatment was 3.5 months (95% CI: 3.4-4.2) for cetuximab and 2.8 months (95% CI: 2.7-3.2) for paclitaxel. Response rate was 37.7%, with a median duration of 8.9 months (95% CI: 7.8-10.3) (Fig.2).

The study confirmed the PFS of cetuximab plus paclitaxel as 1L treatment in non-selected patients with recurrent/metastatic SCCHN in the real world.

ECOG was the most important prognostic factor according to the stratified analysis. ECOG was worse in patients who achieved better response after treatment with CT-PX showed promising survival in line with previous reports.

CONCLUSIONS


REFERENCES

The presenting author Dr. Beatriz Ciraqui Ciraqui. Medical Oncology Department. Institut Català d’Oncologia Badalona, B-ARGO Group, 08918, Badalona, Spain e-mail: bciraqui@nclatalon.com

This work was financially supported by Merck S.L.U. Madrid.