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Real World Evidence of First-line Cetuximab (CX) plus Paclitaxel (PX) in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) - TTCC-2019-02

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GRUPO ESPAÑOL DE TRATAMIENTO DE TUMORES DE CABEZA Y CUELLO

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BACKGROUND

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).[1] However, some patients (pts) may be frail and considered unfit for PT. Results from a Phase II trial showed efficacy of cetuximab plus weekly paclitaxel (ERBITAX scheme) as first line (1L) in pts with SCCHN who are medically unfit for PT.[2]

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 objective:
  - To estimate the PFS of ERBITAX 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 secondary data retrieved from the medical records.

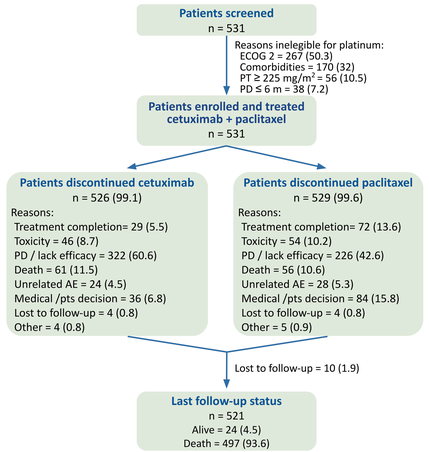


Figure 1. Study patient flowchart

The trial included pts with histologically confirmed SCCHN from oral cavity, oropharynx, hypopharynx and larynx; aged ≥18 years old; and ineligible to platinum-based chemotherapy (PT) due to:

- Performance status (PS) ≥2
- Comorbidities
- High accumulated dose of PT
- Early disease progression after PT.

The enrolled pts had received between 2012-2018 according to standard clinical practice at least one starting dose of both weekly paclitaxel 80 mg/m^2 and cetuximab (400mg/m^2 loading dose, and then 250 mg/m^2).

REFERENCES

1. Vermorken JB, Mesia R, Rivera F, et al. Platinum-based chemotherapy plus cetuximab in head and neck cancer. N Engl J Med 2008;359:1116-27.
2. Hitt R, Irigoyen A, Cortes-Funes H, et al. Phase II study of the combination of cetuximab and weekly paclitaxel in the first-line treatment of patients with recurrent and/or metastatic squamous cell carcinoma of head and neck. Ann Oncol. 2012 Apr;23(4):1016-22.

RESULTS

The study enrolled 531 pts (***Fig.1***)(***Table 1***). Among those with primary location in the oropharynx, 16 were P16 positive and 11 were HPV positive. PD-L1 was determined in 121 pts, being positive (PD-L1 >1) in 26 (21.5%) of them.

Characteristics; unit		TTCC-2019-02 N = 531
Median age (range); years		66 (35-92)
Sex, n (%)	Male	439 (82.7)
	Female	92 (17.3)
Tumor location, n (%)	Oral cavity	192 (36.2)
	Oropharynx	102 (19.2)
	Larynx	164 (30.9)
	Hypopharynx	73 (13.7)
ECOG PS; n (%)	0	18 (3.4)
	1	246 (46.3)
	2	267 (50.3)
Stage at diagnosis; n (%)	I-II	64 (12.1)
	III	89 (16.8)
	IVa-b	313 (58.9)
	IVc	55 (10.4)
	UK	10 (1.9)
Smoker or tobacco use; n (%)	never smoker	60 (11.3)
	Former	226 (42.6)
	Current smoker	217 (40.9)
	UK	28 (5.3)
Alcoholic use; n (%)	never	122 (23)
	Former	121 (22.8)
	Current	210 (39.5)
	UK	78 (14.7)
Previous treatments; n (%) *pts may have >1 therapeutic approach previously*	Surgery	296 (55.7)
	Radiotherapy	426 (80.2)
	Chemotherapy	333 (62.7)

Table 1. Baseline characteristics

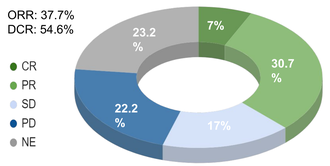


Figure 2. Response rates to study treatment

Most frequent TRAEs; n (%)	Grade ≥ 3	Leading to discont.	TTCC-2019-02 N = 531
Rash acneiform	47 (8.9)	18 (3.4)	108 (20.3)
Oral mucositis	8 (1.5)	8 (1.5)	36 (6.8)
Fatigue	11 (2.1)	9 (1.7)	26 (4.9)
Peripheral sensory neuropathy	5 (0.9)	12 (2.3)	25 (4.7)
Neutrophil count decreased	7 (1.3)	1 (0.2)	16 (3)
Diarrhea	1 (0.2)	1 (0.2)	13 (2.5)
Nail toxicity	6 (1.2)	0 (0)	11 (2.1)
Anemia	2 (0.4)	2 (0.4)	11 (2.1)

Table 2. Most frequent treatment adverse events (TRAEs) occurring in at least 2%
Only reported toxicities leading to discontinuation / dosage reduction, or grade ≥ 3.

The median duration of treatment was 3.5 m (95% CI: 3-4.1) for cetuximab and 2.8 m (95% CI: 2.7-3.2) for paclitaxel. Response rate was 37.7%, with a median duration of response of 5.6 m (95% CI: 4.8-6.6)(***Fig.2***).

With a median follow-up of 8.7 m (95% CI: 7.7-10.2), the median PFS was 4.5 m (95% CI: 3.9-5)(***Fig.3***), and median OS was 8.9 m (95% CI: 7.8-10.3)(***Fig.4***) for the full dataset. PFS by subgroups is shown in ***Fig.5***. OS by subgroups is shown in ***Fig.6***. Most common toxicities are shown in ***Table 2***.

Figure 3. PFS full dataset

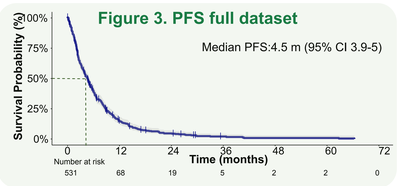


Figure 4. OS full dataset

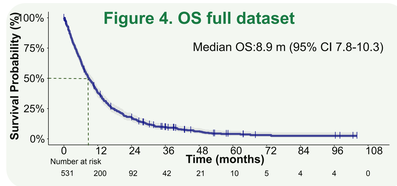


Figure 5. Stratified PFS

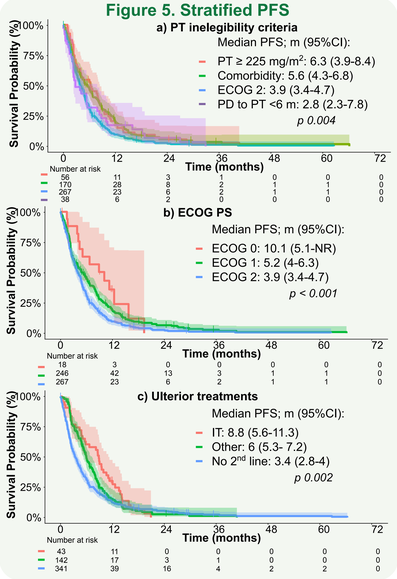
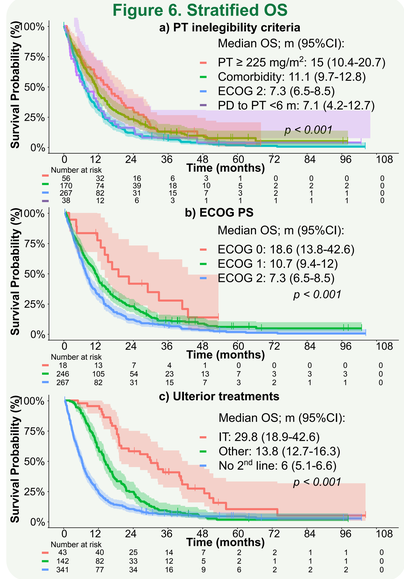


Figure 6. Stratified OS



CONCLUSIONS

- This study confirmed the efficacy and tolerability of cetuximab plus paclitaxel as 1L treatment in non-selected patients with recurrent / metastatic SCCHN in the real world.
- ECOG was of the most important prognostic factor according to the stratified analysis of efficacy.
- Patients who received immunotherapy after treatment with CX-PX showed remarkable promising survival in line with previous reports.

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