head and neck cancer

RESULTS OF TPEX (DOCETAXEL, CISPLATIN, CETUXIMAB) REGIMEN USE IN FIRST LINE PATIENTS WITH RECURRENT/ METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (R/M SCCHN) IN A SINGLE INSTITUTION

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Aim: According to the ESMO guidelines, 5FU, platinum and cetuximab is the standard in first line for patients (pts) with R/M SCCHN (PFEx; Vermorken, 2008). In 2012, the multicenter phase II TPEx GORTEC 2008-03 evaluating TPEx (4 cycles (cy) and maintenance with cetuximab every 2 weeks in case of response or stable disease) demonstrated that this regimen is effective and might be a relevant substitute for PFEx in fit pts (Guigay, ASCO, 2012). We report here the retrospective analysis of pts treated with TPEx at Gustave Roussy.

Methods: Thirty patients with R/M SCCHN were treated between February 2011 and October 2013 in first line chemotherapy with TPEx (docetaxel : 75mg/m²/3 weeks, cisplatin : 75mg/m²/3 weeks and cetuximab 400mg/m² on day 1 cy 1 then 250 mg/m² weekly). G-CSF support was delivered as primary prophylaxis.

Results: Population included 20 male/10 female, median age 56.8 years [range 33-76], PS 0 or 1 except 1 pt (PS = 2), with oral cavity, oropharynx, larynx, hypopharynx localization (n= 10, 11, 7, 2 respectively). Pts received a median of 4 [1-7] cy. TPEx was modified in 18 pts mainly for toxicity; dose-intensity/cy was 94.6% for cisplatin, 90.9 % for docetaxel and 93% for cetuximab. We reported Gr 3 vomiting (n = 1), Gr 3 mucositis (n = 1), Gr 3 skin rash (n = 1), Gr 3 diarrhea (n = 1), Gr 2 neuropathy (n = 6), Gr 4 neutropenia (n = 3), Gr 3 hypersensitivity to cetuximab at cy 1 (n = 1). 25 pts received a maintenance (cetuximab every 2 weeks (n = 18), docetaxel and cetuximab (n = 2), carboplatin and cetuximab (n = 4), docetaxel (n = 1)). The median duration of maintenance was 2.8 months [maximum 9 months]; 3 pts are still in maintenance (after 1.3 and 5 months respectively). 5 pts did not receive maintenance (because of progression (n = 3); hypersensitivity to cetuximab (n = 1); death (n = 1)). Best response was complete response (n = 6), partial response (n = 20), stable disease (n = 2), progressive disease (n = 1), 1 pt (PS = 2) was not evaluated because she died from infectious pneumonia after cy 1. The objective response rate was 87%, the median PFS and OS were 6.0 and 13.6 months respectively with a median follow-up of 21.3 months [range 5.6-26.5].

Conclusions: In real life, TPEx is effective with an 87% ORR and an OS > 13 months. These data confirm the results of the phase II, with tolerable side effects in fit pts. A GORTEC multicentric randomized phase III trial (TPEx vs PFEx) will be conducted.

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