The prognosis for recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) of patients undergoing combination treatment with cisplatin, 5-FU and cetuximab (PCE) is limited.

This regimen requires hospitalization to ensure proper hydration and continuous infusion of 5-FU, and causes severe nausea and anemia. We evaluated the efficacy and safety of paclitaxel, carboplatin and cetuximab (PCE) as a first-line treatment in patients with R/M SCCHN.

Methods: Eligible patients were 25 patients who were 18 to 75 years of age, had a Karnofsky performance status of 70 or greater, had measurable squamous cell carcinoma of the head and neck, and had an adequately recovered organ function; no suitable local therapy for R/M SCCHN; and no prior systemic chemotherapy and/or radiotherapy. The primary end point was overall response rate (ORR). Secondary endpoints included progression-free survival, overall survival, and clinical benefit rate (CBR).

Results: Out of 25 patients, 14 were male and 11 were female; the median age was 63 years; 17 patients were current or recent smokers. The primary lesions included the larynx (n=6), oropharynx (n=10), hypopharynx (n=3), and oral cavity (n=6). The primary histology was SCC in 21 patients and adenoid cystic carcinoma in 4 patients. Treatment consisted of 1 cycle of paclitaxel (80mg/m²), carboplatin at area under the curve of 6, and cetuximab (400mg/m²) on days 1, 8, 15, and 22 of each treatment cycle. The median number of cycles was 6 (range, 1–12).

The primary end point was met with ORR of 40.0% (95% exact CI, 25.7–56.0). Grade 3 or 4 adverse events included neutropenia (68%), skin reaction (15%), anemia (13%), neutropenic fever (8%), and thrombocytopenia (3%). A potential treatment-related death occurred in one patient with intestinal pneumonia.

Conclusions: The PCE regimen shows promising activity with acceptable toxicity, and can be provided in the outpatient clinic. Further studies are needed to compare PCE with PFE in this population.

Background

The primary end point was overall response rate (ORR). Secondary endpoints included progression-free survival, overall survival, and clinical benefit rate (CBR).

Methods

The standard of care for first-line treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) is limited. A randomized phase III study of combination treatment with cisplatin, 5-FU and cetuximab (PCE) is now considered to be standard treatments for first-line treatment of R/M SCCHN. However, this regimen requires hospitalization to ensure proper hydration and continuous infusion of 5-FU, and causes severe nausea and anemia. We evaluated the efficacy and safety of paclitaxel, carboplatin and cetuximab (PCE) as first-line treatment in patients with R/M SCCHN.

The objective of primary analysis is to confirm whether response rate of PCE is non-inferior compared with that of PFE. Additionally, we also evaluated the primary end point in the subgroup of patients with non-smokers (PO). The primary end point was overall response rate (ORR). Secondary endpoints included progression-free survival, overall survival, and clinical benefit rate (CBR).

Conclusions: The PCE regimen shows promising activity with acceptable toxicity, and can be provided in the outpatient clinic, with weekly adjustment of dosages according to toxicity. Further studies are needed to compare PCE with PFE in this population.

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