1063P A multicenter phase II trial of paclitaxel, carboplatin and cetuximab (PCE) followed by chemoradiotherapy in patients with unresectable locally advanced squamous cell carcinoma of the head and neck (SCCHN)


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Background: Induction chemotherapy (IC) often compromises the compliance of following chemoradiotherapy (CRT) in LA-SCCHN. In particular, impaired compliance of cisplatin (CDDP) during CRT negatively affects outcomes. Here, we aimed to assess the feasibility and efficacy of paclitaxel (PTX), carboplatin (CBDCA), and cetuximab (Cmab) as IC for unresectable LA-SCCHN.

Methods: Patients with biopsy-proven, unresectable LA-SCCHN were enrolled. IC consisted of CBDCA AUC = 1.5, PTX 80mg/m² and Cmab with an initial dose of 40mg/m² followed by 250mg/m² administered weekly for 8 weeks. Following IC, CDDP (20mg/m², 4 days x 3 cycles) and concurrent radiotherapy (70Gy/35fr) were started. Primary endpoint was the rate of CRT completion, defined by (1) completion of planned CDDP relative dose intensity (RDI) > 80%, and (2) completion of radiotherapy within 2 weeks after planned completion date. PCE was planned to be deemed effective if the Bayesian posterior probability (PP) that the rate of CRT completion was > 65% exceeded 84%.

Results: 35 patients were eligible and received study treatment. Cases were hypopharynx/oropharynx/larynx in 17/17/1 patients, all Stage IV (stage IVA: 24, stage IVB: 11). Of 35 patients, 34 (97%) completed IC and 32 received CRT (FAS). Of 32 FAS cases, the rate of CRT completion was 96.9%, and the study’s primary endpoint was therefore met (PP = 99.9% > 84%). Mean cumulative dose and RDI of CDDP in CRT was 232.5mg (160-240mg) and 100% (66.7-100%), respectively. Response rate was 88.6% in the IC phase and 93.8% in the CRT phase. 2-year rates of local progression, distant metastasis, event-free survival and overall survival were 34.9%, 16.7%, 55.1% and 83.5%, respectively. Main grade 3 toxicities included neutropenia (11%), skin rash (6%), and anemia (6%) in the IC phase; and oral mucositis (31%), neutropenia (13%), and radiation dermatitis (13%) in the CRT phase. No grade 4 toxicity or treatment-related death was seen.

Conclusions: PCE as IC was feasible, with promising efficacy and no effect on compliance of following CRT in unresectable LA-SCCHN. A Phase III comparison with CRT alone is warranted.

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