head and neck cancer

**INDUCTION CHEMOTHERAPY (IC) WITH DOCETAXEL, CISPLATIN AND 5-FLUOROURACIL (TPF) FOLLOWED BY CHEMORADIOTherapy (CRT) CONCURRENT WITH FRACTIONATED ADMINISTRATION OF HIGH-DOSE CISPLATIN FOR PATIENTS WITH LOCALLY ADVANCED SCCHN: RESULTS OF A MULTICENTER PHASE 2 FEASIBILITY STUDY**

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**Aim:** TPF followed by high-dose cisplatin CRT is not recommended due to concerns over toxicity. The aim of this study was to evaluate the feasibility of TPF as IC and fractionated administration of high-dose cisplatin CRT for the treatment of locally advanced SCCHN.

**Methods:** Key eligibility criteria included histologically proven SCCHN with previously untreated stage 3 or 4, PS 0-1, age 20 to 75 years, adequate organ function. IC consisted of a maximum of 3 cycles of docetaxel at a dose of 70 to 75 mg/m² on day 1, cisplatin at 70 to 75 mg/m² on day 1, and 5-fluorouracil at 750 mg/m² days 1 to 5, repeated every 3 weeks. Patients received a total of 70 Gy of radiotherapy concomitant with fractionated administration of high-dose cisplatin at a dose of 20 mg/m² on days 1 to 4, repeated every 3 weeks. Primary endpoint was the treatment completion rate of IC, which was defined as completion of 3 cycles IC. Sample size was calculated using Simon’s two-stage design.

**Results:** From 2009 to 2014, 48 patients (pts) were accrued. Patient backgrounds were: median age 61 years, ECOG PS 0/1 (41/7) and oropharynx/hypopharynx/larynx (26/19/3). The treatment completion rate of IC was 91.6%. Grade 3 or 4 toxicities of TPF were neutropenia (83.3%) and febrile neutropenia (20.8%), anorexia (14.6%), mucositis (6.3%). 38 pts (79.1%) achieved response after IC. Forty-one pts subsequently received CRT and four received radiation alone. Thirty-four pts (70.8%) completed the three planned cycles of fractionated administration of high-dose cisplatin, but six (12.5%) did not because of hematological toxicity (n = 1) and acute renal failure (n = 1) and others (n = 4). Grade 3 or 4 toxicities of CRT were mucositis (51.2%) and dysphagia (31.7%), dermatitis (8.3%), 24 pts (50%) achieved complete response. With a median follow-up of 36.1 months, 3-year overall survival was 75.4% (95% CI: 55.4-87.4).

**Conclusions:** TPF followed by fractionated administration of high-dose cisplatin CRT was tolerable with acceptable toxicities for pts with locally advanced SCCHN.

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