

Conclusions: The first analysis of this phase III trial revealed that the compliance to the combination of AFX-C and concurrent cisplatin was high and that this regimen did not result in higher acute toxicity or subacute morbidity relative to SFX plus cisplatin. The efficacy analysis will take place when the predetermined number of cancer related events is reached.

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22 Phase II Randomized Trial of Surgery Followed by Chemoradiation Plus Cetuximab for High-Risk Squamous Cell Carcinoma of the Head and Neck (RTOG 0234)

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Purpose/Objective(s): The RTOG has completed enrollment in a randomized phase II trial to examine the safety and feasibility of combining concurrent chemoradiation with cetuximab (anti-EGFR mAb) in the postoperative treatment of H&N cancer patients with high-risk pathologic features. Patients received 60 Gy and weekly cetuximab over 6 weeks with either weekly cisplatin (30 mg/m²) or weekly docetaxel (15 mg/m²).

Materials/Methods: This trial enrolled 238 subjects between April 2004 and December 2006 for an average monthly accrual of 7.6. To ensure a minimum of 6 month follow up beyond treatment completion, only those subjects enrolled on or before June 30, 2006 were included for this report yielding a total of 147 evaluable cases. All subjects had pathologic stage III or IV squamous cell carcinoma of the H&N with high-risk pathologic features following gross total resection including either microscopically positive resection margins, two or more metastatic neck nodes, or extracapsular tumor extension.

Results: Adverse events and treatment delivery parameters were reviewed. One patient (1.5%) on the cisplatin arm died of treatment-related causes. Seven patients (10.6%) on the cisplatin arm and 8 patients (9.9%) on the docetaxel arm experienced Grade 4 adverse events. Grade 3–4 mucositis of the oral cavity, pharynx, or larynx was experienced by 36.4% of patients on the cisplatin arm and 32.1% of patients on the docetaxel arm. The acute grade 4/5 non-hematologic toxicity rate (within 90 days from start of RT) was 10.6% on the cisplatin arm and 6.2% on the docetaxel arm. Study chair review of radiation therapy has been completed for 133 of 147 (90.5%) subjects with 95.5% scored as acceptable or minor variation. Study chair review of systemic treatment has been completed for 139 of 147 (94.6%) subjects with 87.1% scored as per protocol. Tolerable treatment was defined as receiving $\geq 90\%$ of the protocol radiation dose; $\geq 95\%$ of the cetuximab loading dose; ≥ 4 weeks of cetuximab with at least 95% of protocol dose and ≥ 4 weeks of cisplatin or docetaxel with at least 95% of protocol dose. Forty-six of 66 patients (69.7%) on the cisplatin arm, and 66/81 (81.5%) on the docetaxel arm met all of these criteria.

Conclusions: RTOG 0234 is the first completed randomized study to examine the safety and feasibility of two distinct H&N chemoradiation regimens combined with cetuximab. This preliminary review of treatment toxicity and tolerance suggests that concurrent triple therapy (radiation, cisplatin or docetaxel, and cetuximab) is safe and feasible under the conditions tested. Indeed, the Grade 4–5 non-hematologic acute toxicity rate of up to 10.6% compares favorably with the estimated rate of approximately 15% from RTOG prior experience in the same H&N patient setting using radiation plus high-dose cisplatin (RTOG 9501). Additional follow up data will be available for the 2007 ASTRO meeting.

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23 Phase II Multi-Institutional Study of IMRT \pm Chemotherapy for Nasopharyngeal Carcinoma (RTOG 0225): Preliminary Results

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Purpose/Objective(s): To assess the feasibility/toxicity of a multi-center trial of IMRT \pm chemotherapy (CTH) for nasopharyngeal cancer (NPC).

Materials/Methods: Patients with NPC, WHO I-III, stages I-IVB requiring radiation (RT) were eligible. Patients having $>T2a$ disease and/or + node(s) also received concurrent + adjuvant CTH. Target definition/delineation, dose prescription, and dose volume constraints for both targets/critical tissues were described in the protocol. The doses delivered to the planning target volumes of primary tumor/involved nodes (PTV₇₀) and subclinical disease (PTV_{59.4}) were 70 Gy and 59.4 Gy, delivered simultaneously in 33 fractions. Central quality assurance (Q/A) was performed for all centers and all patient treatment plans. Primary endpoint was to determine the ability to implement IMRT for NPC across multi-centers (defined as ≤ 9 major variations of the first 57 patients); secondary endpoints were to assess the acute/late toxicities + the rate of xerostomia at one year, and to test the hypothesis that a potential reduction of RT side effects on salivary flow will increase patient compliance to combined therapy.