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**Esophageal/Gastric Cancer**

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**Erlotinib and Radiation Therapy for Elderly Patients With Esophageal Cancer: Clinical and Correlative Results From a Prospective Multicenter Phase II trial**

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**Background:** Elderly patients (pts) with comorbidities have limited treatment options for localized esophageal cancer (EC). High EGFR expression correlates with poor response to radiation therapy (RT). We examined the safety and efficacy of erlotinib, an oral EGFR tyrosine kinase inhibitor with RT in these pts.

**Methods:** Pts older than 65 years, ineligible for platinum based treatment with carcinoma of the thoracic esophagus or gastroesophageal junction received erlotinib 150 mg PO QD for one year starting D1 of RT (50.4 Gy D1-28 (M-F) at 1.8 Gy per fraction). Assessments - mucosal response by upper endoscopy 4-8 wks post RT; RECIST response by CT q3mo. Endpoints: Primary - overall survival (OS), secondary - quality of life (QOL) using the FACT-E QOL tool, progression free survival (PFS) and toxicity; correlative - pretreatment tumor EGFR and pEGFR expression by immunohistochemistry (IHC).

**Results:** The study was closed after 17 of planned 35 pts were included due to poor accrual. Baseline characteristics: median age 78 yrs (66-91); gender M/F: 11/6; ECOG performance scale 0/1/2 in 2, 12, and 3 patients, respectively; stage I=1, II=5, III=7 and IVa= 4; histology: adenocarcinoma 16, squamous cell 1; dysphagia at baseline 13/17 (76%). Median OS was 7.3 months (95% CI: 4.5-22.3) with 12 pts dead (of 5 patients currently alive, 3 are still on treatment). Fourteen patients came off study due to disease progression (n=6), toxicity (n=5), withdrew consent (n = 1), completed one year of treatment n = 1), death from unrelated cause (n=1). There were 2 mucosal complete responses and one residual carcinoma in situ, 3 partial endoscopic responses of the 9 pts who had post RT endoscopy. Estimated PFS was 5.3 months (95% CI: 2.4-11). Sites of progression - distant (n = )3, locoregional (n = 6), unknown (n = 5), and too early to determine (n = 3). Estimated one year survival was 26 %, 3 pts lived >12 months. Smoking status - current/past/never in 3, 12, and 2 patients, respectively. Treatment related toxicities (any grade, n ≥ 5) were rash (16), fatigue (16), diarrhea (11), lymphopenia (10), anorexia (7), and dehydration (6), Twenty-one 21 grade 3/4 toxicities occurred. IHC results - EGFR neg: 1/16; pos: 15/16 and pEGFR neg: 2/16; pos 14/16.

**Conclusions:** For elderly pts with localized EC and no chemotherapy options, erlotinib monotherapy with RT is a tolerable treatment option with modest activity. Further studies are needed to define the role of EGFR inhibition with RT in EC.