INTERIM SAFETY RESULTS FROM A RANDOMIZED TRIAL OF ADJUVANT CHEMOTHERAPY WITH LV5FU2 VS. FOLFOX FOR ESOPHAGEAL SQUAMOUS CELL CARCINOMA

Se Hoon Park1, Jeeyun Lee2, Yong Soo Choi2, Jae Zo2, Young Mok Shim2
1Department of Medicine, Sungkyunkwan University School of Medicine, Seoul, Korea, 2Samsung Medical Center, Seoul, Korea

Background: Although node-positive esophageal squamous cell carcinoma (SCC) is considered potentially resectable, recurrence is common and the role of adjuvant treatment is uncertain. The urgent need for new effective therapy with better safety profile for locally-advanced esophageal SCC patients strongly warranted the current randomized phase 2 trial.

Methods: Patients with completely-resected, node-positive esophageal SCC, an ECOG performance status <2 were randomized to receive either LV5FU2 (leucovorin 200 mg/m2 and 5-fluorouracil 400 mg/m2 intravenously on D1, followed by a 46-h protracted infusion of 5-fluorouracil 2,400 mg/m2) or FOLFOX (LV5FU2 plus oxaliplatin 85 mg/m2 on D1). Treatment started within 6 weeks after surgery and continued up to 8 cycles. Primary endpoint was DFS but only safety data were analyzed in this interim analysis. Quality-of-life (QOL) data (EORTC QLQ-C30) were collected at baseline, after 4 cycles and end of treatment.

Results: The trial was opened in Dec 2010. As of Jan 2013, data are complete for 34 patients (LV5FU2, n = 18; FOLFOX, n = 16) who received a total of 231 cycles (130 for LV5FU2; 101 for FOLFOX). All patients received 2- or 3-field lymph node dissection and the median number of resected nodes was 39 (range, 11 to 63). There was no relevance difference in the occurrence of overall toxicities between the two groups, with grade 1 or 2 anemia and anorexia being most common ones. No patient discontinued treatment because of toxicity. Dose reduction was required in three treatment cycles, and 7 patients had a delay of >one week at some time during treatment. QOL data showed no relevant differences between the two groups.

Conclusion: Both LV5FU2 and FOLFOX appear to be well tolerated as adjuvant treatment for curatively-resected, node-positive esophageal SCC. The trial continues to enroll to the target population of 80 patients.