

International Society of Gastrointestinal Oncology  
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ABSTRACTS

**Esophageal Cancer**

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**Neoadjuvant Paclitaxel Poliglumex (PPX), Cisplatin, and Radiation (RT) for Esophageal Cancer**

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**Background:** Paclitaxel poliglumex (PPX) is a drug conjugate that links paclitaxel to poly-L-glutamic acid thereby increasing its radiation enhancement factor to 4.0-8.0 compared to 1.5-2.0 for paclitaxel. In previous phase I studies, The Brown University Oncology Group evaluated PPX with concurrent radiation and PPX/cisplatin/RT. A phase II study was subsequently performed to evaluate the pathologic response rate of neoadjuvant PPX, cisplatin, and radiation for patients with esophageal cancer.

**Methods:** Eligible patients had pathologically confirmed adenocarcinoma or squamous cell carcinoma of the esophagus or GE junction with no evidence of distant metastasis. Patients received weekly PPX 50 mg/m<sup>2</sup> and cisplatin 25 mg/m<sup>2</sup> for 6 weeks with concurrent 50.4 Gy of radiation. Six to eight weeks after completion of chemoradiotherapy, patients underwent surgical resection.

**Results:** The study has completed accrual of 40 patients, 37 with adenocarcinoma and 3 with squamous cell cancer. The median age is 62 years. Toxicity data are available for the first 35 patients. Four of 35 patients experienced grade 4 non-hematologic toxicities, which included electrolyte abnormalities, glucose intolerance, hypersensitivity reaction, and thromboembolus. Eleven of 35 patients had grade 3 non-hematologic toxicities including electrolyte abnormalities (n=5), nausea (n=3), dysphagia (n=2), fatigue (n=2), glucose intolerance (n=2), and hypersensitivity reaction (n=1). Grade 3 anorexia was reported in only 1 patient who subsequently was given TPN. No patients required a feeding tube. There were no grade 4 hematologic toxicities; grade 3 hematologic toxicities included neutropenia (n=2) and anemia (n=1). Of the first 28 patients undergoing surgery, all with adenocarcinoma, 7 of 28 (25%) have had a pathologic complete response.

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**Conclusion:** PPX, cisplatin and concurrent radiation is a well tolerated, easily administered regimen for esophageal cancer with a very low incidence of significant esophagitis and a promising pathologic complete response rate consistent with the preclinical data of PPX and radiation.