

survival (OS) was 12.0 months (95% CI, 8.1–15.9 months). Among the variant alleles, patient with CYP2A6*4 had significantly inferior TTP than those without CYP2A6*4 (median TTP, 3.7 vs. 4.8 months; $P=0.04$) and tend to have inferior OS (median OS, 9.7 vs. 15.0 months; $P=0.09$). Univariate analyses for age, sex, ECOG performance status (PS), tumor histology, and number of metastatic organ sites showed that ECOG PS was significantly associated with TTP (median TTP, 5.3 [PS 0/1] vs. 2.4 months [PS 2/3]; $P<0.001$), as well as CYP2A6*4. In multivariate analysis, after adjusting for PS, the CYP2A6*4 allele remained a statistically significant predictor of TTP; patients with CYP2A6*4 showed a 3.63-fold (95% CI, 1.54–8.55; $P=0.003$) increased risk of progression compared to those without CYP2A6*4.

Conclusion: Our findings showed CYP2A6*4 allele correlated with decreased treatment efficacy of S-1 plus cisplatin in previously untreated MGC patients.

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POSTER

The role of PET-TC in predicting the pCR in locally-advanced esophageal cancer (LAEC) after a preoperative CT-RT treatment: data from B152 trial

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Background: the improvement of overall survival in pts with LAEC after a preoperative CRT treatment is correlated to the complete pathologic response (pCR). We aimed to examine the ability of PET-TC in predicting the complete pathologic response in LAEC pts enrolled in the B152 trial.

Methods: Eligibility criteria: resectable, locally advanced (uT3-T4 N0, any uT N1) squamous cell carcinoma (SCC) or adenocarcinoma (AC) of the esophagus; age 18–70y; PS<2; normal organ functions. All pts received induction treatment with 8 administration of Cetuximab (C) (400 mg/m² as starting dose followed by 250 mg/m²/weekly) and 4 cycles of FOLFOX-4 every two weeks. In case of response pts underwent daily RT (180cGy fractions to 5040 cGy) with concurrent weekly C. At the end of treatment, pts without PD had esophagectomy. PET-TC was performed before starting treatment (time 0), after chemotherapy (time 1) and after radiotherapy (time 2). The purpose was to evaluate if there was a correlation between the metabolic response recorded by PET-TC on time 2 and the histopathological response on the surgical specimen.

Results: Up to April 2009, 42 pts, 32 men and 10 women, were enrolled from 4 institutions; among these pts, 6 were not evaluable (5 are still on therapy and 1 refused surgery). Among 36 pts evaluable, 22 pts were considered positive for residual disease at PET-TC evaluation and pathologic examination, 2 pts presented a pRC although the PET-TC was positive, 5 pts resulted false negative (PET-TC negative but surgical specimen positive for disease), 7 pts were true negative (PET-TC negative with pRC obtained). Sensitivity to detect response was 81%, with a corresponding specificity of 77%. The positive and negative predictive values were 92% and 58%.

Conclusions: FDG-PET could be a valuable tool for the non invasive assessment of histopathologic tumor response after neoadjuvant radiotherapy and chemotherapy.

Total of pts 36 (100%)	Residual disease pts (%)	pRC pts (%)
PET positive	22 (61%)	2 (6%)
PET negative	5 (14%)	7 (19%)

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POSTER

A multicenter phase II study of induction CT with Folfex-4 and Cetuximab followed by RT and Cetuximab in locally advanced esophageal cancer (LAEC)

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Background: Preoperative CRT improves the survival of pts with EC when compared with surgery alone. Epidermal growth factor receptor (EGFR) is overexpressed in 30–90% of EC and is associated with poor prognosis, providing the rationale for using the anti-EGFR monoclonal antibody Cetuximab (C). The purpose of the study was to investigate the efficacy, toxicity and feasibility of C with FOLFOX-4 regimen as induction CT followed by C and RT in pts with LAEC in a multicenter setting.

Methods: Eligibility criteria: resectable, locally advanced (uT3 or uN1, T4 if deemed resectable) squamous cell carcinoma (SCC) or adenocarcinoma (AC) of the esophagus; staged by EUS, CT and PET scan; age 18–70y; PS<2; normal organ functions. All pts received induction treatment with C at a starting dose of 400 mg/m² and further weekly infusion at a maintenance dose of 250 mg/m² and 4 cycles of FOLFOX-4 every two weeks. Post-induction EUS and CT scans were performed, while a PET scan was repeated early before second cycle of CT: pts without PD were given daily RT (180cGy fractions to 5040cGy) with concurrent weekly C. Post RT, EUS plus biopsies, CT scan and PET were performed. At wk 18, pts without PD had esophagectomy. A Simons two stage design was used. Primary endpoint was histopathological response rate.

Results: Up to January 2009, 42 pts, 32 men, were enrolled from 4 institutions; median age 59y (35–70y); AC 12; SCC 30; stage II 15, stage III 27 pts. At this time 39/42 pts were evaluable. The most frequent grade 3/4 toxicity of chemoradiotherapy were skin (32%), neutropenia (29%) and esophagitis (9%); 10 pts had no resection (9 progressive disease, 1 patient's refusal). Of 23 operated pts, 18 pts (77%) had RO-resection, 5 pts had palliative surgery. 2 pts died due to complications after surgery (1 after >30 days). The pathological response rate was 68%, with a complete histopathological remission recorded in 7 pts (38%); 18 pts (42%) are still alive without residual or recurrent disease.

Conclusions: These results suggest the feasibility of incorporating Cetuximab into a preoperative regimen for LAEC pts and an encouraging antineoplastic activity with 68% histopathological responders.

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POSTER

Preoperative radiochemotherapy with cisplatin plus infusional high-dose 5-fluorouracil/leucovorin (LV5FU2) in locally-advanced esophageal carcinoma of UICC stages II and III – ongoing study

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Background: Esophageal squamous cell carcinoma is a highly aggressive malignancy with a poor prognosis. Surgical resection has been the standard treatment for this cancer. Radical resection is limited because of the advanced stage of the disease at the time of diagnosis. Neoadjuvant radiochemotherapy has been proposed in this study on the basis that local down staging could increase the resectability rate in locally advanced carcinoma of the esophagus. Long term survival may be possible if the carcinoma of the esophagus respond to radiochemotherapy (CRT) and radical surgery is performed.

Material and Methods: This study is a part of Ministry of Science project number 145059 started in december 2006. Since then, 46 patients have been enrolled in this study: 6 females (13.04%) and 40 males (86.96%). Mean age was 56y (range 37–74 y) According to UICC staging system 11 pts have been in clinical stage II (T3N0M0) and 35 pts in clinical stage III (T3N1M0, T4N0–1M0). Tumor location was as follows: cervical oesophagus 2 pts, upper third of thoracic oesophagus 21 pts, medium third 17 pts and lower third 6 pts. Preoperative radiotherapy with tumor dose of 45–50.4 Gy in 24–28 fractions have been applied with concomitant chemotherapy with Cisplatin plus infusion high/dose 5/fluorouracil/leucovorin (LV5FU2).