

days 1-5 repeated every 3 weeks for 3 cycles, unless progression, unacceptable toxicity, patient refusal or no change was noted after 2 cycles. Patients were then treated weekly with Carboplatin (AUC 1.5) and standard fractionated radiotherapy. Elective modified neck dissections were allowed in patients with N2 or greater disease after CRT.

Results

538 patients were randomized between May 1999 and December 2003; 501 were

evaluable. OS was based on a minimum 2 year follow up. Median follow-up was 41.9 months, 69% of patients were followed for 3 years. Baseline demographics were balanced between arms. OS significantly favored the TPF arm vs PF (HR=0.70, p=0.0058). The Kaplan-Meier estimates for OS at 3 years are 62.1% (95% CI.= 55.9-68.2) for TPF and 48.1% for PF (95% CI=41.7-54.5). 234 of 501 (46.7%) patients have died as of the December 05 cutoff (40.8% TPF and 52.8% PF). Patients lost to follow up and safety profiles were similar in both arms. No

unanticipated toxicities were noted due to Docetaxel.

Conclusions

TPF based sequential therapy is associated with a significant 30% risk reduction in mortality compared to PF (p<.006), thus demonstrating an OS advantage. Treatment was well tolerated with an acceptable toxicity profile. This data supports the use of sequential multi-modality therapy with TPF followed by CRT and surgery for the treatment of SCCHN. ★

FINAL RESULTS OF THE EORTC INTERGROUP RANDOMIZED PHASE III STUDY 40983 [EPOC] EVALUATING THE BENEFIT OF PERI-OPERATIVE FOLFOX4 CHEMOTHERAPY FOR PATIENTS WITH POTENTIALLY RESECTABLE COLORECTAL CANCER LIVER METASTASES

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Author(s): B. Nordlinger, H. Sorbye, L. Collette, B. Glimelius, G. J. Poston, P. M. Schlag, P. Rougier, W. Bechstein, E. Walpole, T. Gruenberger

Background

The 5-year survival after resection of colorectal cancer liver metastases is 30% but recurrence is common. This study evaluates the benefit of combining peri-operative chemotherapy and surgery for patients with initially resectable liver only metastases from colorectal cancer (LM).

(HR=0.71). Safety was a secondary endpoint (already reported at ASCO 2005). PFS results are reported at the 2-sided 0.0434 significance level (adjusting for one interim analysis).

based on pre-op imaging, but 31/182 pts (CT arm) and 30/182 pt (S arm) could not undergo resection. There were 2 (S arm) and 1 (CT arm) deaths after surgery. At a median follow-up of 3.9 years, 254 PFS events were reported (240 in eligible pts) and the results are as follows (see chart).

Methods

Between September 2000 and July 2004, 364 pts with up to 4 LM were randomized between peri-operative FOLFOX4 (oxaliplatin 85mg/m² and LV5FU2), 6 cycles before and 6 cycles after surgery, (CT), and surgery alone (S). The primary endpoint was progression free survival (PFS) with the goal to increase median PFS by 40%

Results

Baseline characteristics were similar in both arms. Eleven of 182 pts were ineligible in each arm, mostly for more advanced disease. In the CT arm, a median of 6 pre-op cycles were delivered and 151 patients were resected. 115 pts (63%) received post-op CT, with a median number of 6 cycles and a relative dose intensity of 79% to 86%. In the S arm, 152 pts were resected. Due to the nature of the trial, evaluation of resectability (relevant for eligibility) was

Conclusions

Peri-operative FOLFOX4 chemotherapy improved PFS over surgery alone in patients whose metastases were actually resected. The benefit was slightly diluted when also pts considered resectable on imaging but eventually not resected were taken into account. FOLFOX4 given peri-operatively is safe and does not prevent the pts from undergoing surgery. ★

	N pts CT	N pts Surgery	% Absolute Difference in 3-y PFS	HR (CI)	P-value
All patients	182	182	+7.2% (28.1% to 35.4%)	0.79 (0.62-1.02)	P=0.058
All eligible	171	171	+8.1% (28.1% to 36.2%)	0.77 (0.60-1.00)	P=0.041
All resected	151	152	+9.2% (33.2% to 42.4%)	0.73 (0.55-0.97)	P=0.025