(26%, median delay: 28 days), motivated by recent surgery in 26 cases (26%) and co-morbidities in 8 cases (8%). Median duration of BV treatment was 5.4 months. Treatment discontinuation was observed in 150 patients (40%): 106 (28%) had treatment-free interval, 44 (12%) had a maintenance therapy (16 with BV alone). Among those receiving irinotecan-based regimens, the incidence of any events (grade 3/4) was 48% (vs 85% in PCT; $p < 0.0001$): neutropenia (17 vs 37%; $p < 0.0001$) and diarrhea (11 vs 32%; $p < 0.0001$). In line with the known safety profile of BV (any grade), hypertension was observed in 21 vs 22% ($p = 0.58$), arterial/venous thrombosis (11 vs 19%; $p = 0.0009$), proteinuria (32 vs 27%; $p = 0.10$) and gastrointestinal perforation (0.3 vs 1.5%; $p = 0.097$).
ETNA is one of the first real-life, post-marketing cohort study conducted to compare results of real practice with those of the PCT. Primary data indicated that patients differed to those included in the PCT with regard to several aspects. Common BV-associated effects were similar to those observed in the PCT. The safety profile of FOLFIRI regimen seems more manageable than that of IFL regimen but the lower frequency of neutropenia and diarrhea could also be related to an under-reporting of these in real-life.

6071 POSTER

Radioembolization with 90Y-resin microspheres as a salvage treatment for refractory liver-dominant colorectal metastases: a matched-pair analysis

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Background: Despite advances in systemic chemotherapy and biological agents, liver metastases continue to present a life-limiting prognosis for colorectal cancer (CRC) patients. This prospective study assessed the safety and efficacy of radioembolization (RE) with ^{90}Y-resin microspheres as a salvage therapy in patients with progressive liver-dominant CRC metastases compared with matched historical controls who received best supportive care (BSC).
Materials and Methods: A matched-pair analysis for overall survival was conducted in patients who presented after multiple lines of systemic chemotherapy/biological agents with extensive (>20%) liver involvement and tumour progression as confirmed by imaging (CT/MRI), alkaline phosphatase (ALP), tumour markers (CEA) and/or clinical symptoms. Patients treated with RE were matched with historical controls by tumour load, synchronous/metachronous metastases, ALP and CEA >200 U/mL. Overall survival from the date of progression prior to salvage treatment was calculated using Kaplan-Meier analysis. The relationships between baseline covariates (including Karnofsky performance status, tumour load, number of lines chemotherapy) and overall survival were examined by multivariate Cox proportional hazard model (SAS, Carey, NC).
Results: 58 patients (29 RE; 29 BSC) were recruited with extensive liver tumour involvement: median (range) 30% (20−50%) and 25% (10−75%) respectively. Patients in both cohorts received a median of 3 (2−6) prior lines of chemotherapy. RE was a significant predictor of survival (Hazard Ratio = 4.8; 95%CI 2.4−9.5) and the only parameter found to be a significant contributor to the prognosis. Compared with BSC, patients receiving RE survived significantly longer (median: 8.3 vs. 3.5 months; $p < 0.001$). This benefit was clearly evident at 3 months (97% vs. 59% survival) and sustained through 12-months follow up (24% vs. 0% survival). Progression-free survival was 5.5 and 2.1 months with RE and BSC, respectively ($p < 0.001$). Adverse events following RE included thrombocytopenia and sepsis (3%), and abdominal pain (3%). Three possible cases of radiation-induced liver disease were medically managed and not considered life-threatening (median survival: 9.8 months; range: 9.0−16.6 months).
Conclusions: RE provides substantial clinical benefit as evidenced by significant increased liver disease stabilization and prolonged overall survival in patients for whom there are limited treatment options.

6072 POSTER

Bevacizumab related adverse events in patients affected by metastatic colorectal cancer: a meta-analysis

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Background: Bevacizumab, a recombinant humanized monoclonal antibody targeting the vascular endothelial growth factor, is widely used in patients with metastatic colorectal cancer. Bevacizumab suffers by several adverse events which may be different according to the diverse kind of treated tumours. We performed a systematic review and meta-analysis of published randomized clinical trials (RCTs) investigating bevacizumab in the treatment of patients affected by advanced colorectal cancer to better understand the overall risk of side effects.
Methods: PubMed, Medline, CancerLit, and Embase databases were searched for RCTs, comparing chemotherapy plus bevacizumab *versus* chemotherapy alone in metastatic colorectal cancer patients. Also abstracts presented at the main international meetings until April 2009 were analyzed. Odds ratios (ORs) and Number Needed to Harm (NNH) for main side effects were calculated with their 95% confidence intervals (CI) using fixed-effects model.
Results: Nine controlled trials encompassing 7,132 patients, were eligible for the present analysis. Patients receiving bevacizumab plus chemotherapy have a risk twice superior (OR 1.92 95% CI 1.51−2.44) of developing all-grade hypertension corresponding to a NNH 9 and seven times superior of developing grade 3−4 hypertension (OR 6.94 95% CI 5.07−9.52; NNH 11). Moreover, the risk of the other grade 3−4 toxicities were: bleedings (OR 1.83 95% CI 1.11−3.01 NNH 83), proteinuria (OR 4.20 95% CI 2.17−8.12 NNH 73), thromboembolic events (OR 1.19 95% CI 0.98−1.45 NNH 77), cardiac events (OR 1.72 95% CI 0.72−4.13 NNH 167), and oxaliplatin-related neuropathy events (OR 1.55 95% CI 1.29−1.87 NNH 17).
Conclusions: Patients affected by metastatic colorectal cancer and treated with chemotherapy plus bevacizumab have a significant increased risk of developing severe hypertension, proteinuria, and bleedings. Surprisingly, in our analysis, bevacizumab is not associated with higher onset of thromboembolism events, but it increases the oxaliplatin-related neurotoxicity.

6073 POSTER

Interim analysis of epidermal-growth factor receptor (EGFR) expression in a single-arm, phase II, first-line study (20060314) of panitumumab with FOLFIRI in the management of metastatic colorectal cancer (mCRC)

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Background: The fully human anti-EGFR monoclonal antibody panitumumab (Vectibix®) is an important monotherapy treatment option for chemotherapy-refractory patients (pts) with EGFR-expressing, *KRAS* wild-type mCRC. Preclinical data show sensitivity of EGFR inhibitors to be linked to EGFR expression as determined by immunohistochemistry (IHC). Thus, EGFR expression has historically been a defining criterion for treatment with an EGFR inhibitor. However, growing clinical evidence suggest that this marker correlates poorly with response, with objective responses observed in pts with no or all levels of EGFR expression.
Material and Methods: Pts with histologically confirmed mCRC receive panitumumab (6 mg/kg) and FOLFIRI every 2 weeks. This Amgen-sponsored study (20060314) is ongoing to evaluate the primary endpoint