Conclusions: Within the limits of the current results, the OXXEL regimen was equivalent to the OXAFAFU regimen in terms of efficacy. Comparative analysis of quality of life of pts in the two arms of treatment is ongoing.

3045 POSTER

Serious arterial thromboembolic events (sATE) in patients (pts) with metastatic colorectal cancer (mCRC) treated with bevacizumab (BV): results from the BRiTE registry

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Introduction: Bevacizumab (BV, Avastin®) prolongs overall survival (OS) and progression-free survival (PFS) when added to 1st-or 2nd-line chemotherapy (CT) in mCRC. Though serious toxicities specific to BV are uncommon, a retrospective pooled analysis of 5 randomized trials showed an association of arterial thromboembolic events (ATEs) with BV use (3.8% vs 1.7% with CT alone), with age ⩾65yr and prior history of ATE identified as associated risk factors (Skillings, JCO, 2005). The BRiTE mCRC registry evaluated BV-associated serious adverse events (SAEs), including ATEs presenting as SAEs (sATE), in a general practice setting.
Methods: Patients and methods have been described (Hedrick, ASCO, 2006;A3536). History of sATE, timing of prior sATE relative to starting BV, and use of anti-platelet (anti-plt) therapy were summarized. Definition of sATE included myocardial infarction (MI), cerebral vascular accident (CVA), transient ischemic attack (TIA), and peripheral arterial disease. Incidence rate of sATE was expressed as events per patient-year of follow-up. Fisher's exact test and multiple logistic regression were used to assess the univariate and multivariate associations.
Results: Median follow-up time was 19.6 months. Of 1953 evaluable patients, 45.9% (n = 896) were ⩾65yr, 18.0% (n = 352) had history of sATE, and 11.2% (n = 219) received anti-plt therapy. A total of 38 sATE [CVA (n = 14), MI (n = 11), sudden cardiac death (n = 1), TIA (n = 7), and other (n = 5)] were reported in 34 (1.7%) patients. Median time to sATE was 3.6 months. The calculated sATE rate was 2.2/100 patient-years overall and 4.7/100 patient-years in patients with prior sATE. Table 1 summarizes the results of univariate and multivariate analyses.
Conclusions: In this uncontrolled observational study of BV-treated mCRC patients, the incidence of sATEs associated with BV use was comparable to the rate of analogous events reported in previous controlled trials of BV in mCRC. In this multivariate analysis, a prior history of sATE and ECOG PS were found to be associated with an increased risk of developing an sATE while on BV therapy.

Table 1.

Characteristics	Univariate sATE frequency	Multivariate P value
ECOG PS		
0	7 (0.8%)	0.020
⩾1	23 (2.4%)	
ATE history		
Yes	13 (3.7%)	0.018
No	21 (1.3%)	
Hypertension history		
Yes	21 (2.5%)	NS
No	13 (1.2%)	
Age ⩾65yr		
Yes	20 (2.2%)	NS
No	14 (1.3%)	
Age ⩾65yr		
With ATE history	11 (4.3%)	NS
Without ATE history	9 (1.4%)	

NS = not significant.

3046 POSTER

A randomized, open-label phase II study evaluating the efficacy and safety of FOLFOX6 + Cetuximab versus FOLFIRI + Cetuximab as first-line therapy in patients with metastatic colorectal cancer

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Background: FOLFOX6 and FOLFIRI are standard regimens in first-line mCRC. The IgG1 monoclonal antibody cetuximab (Erbitux ®) has proven activity in combination with chemotherapy. This trial aimed to compare cetuximab plus FOLFOX6 (Arm A) with cetuximab plus FOLFIRI (Arm B) as first-line therapy in mCRC pts.
Material and Methods: Pts were randomized to receive either: FOLFOX6 (folinic acid [FA] 400 mg/m^2 administered with oxaliplatin 100 mg/m^2, followed by 5-FU 400 mg/m^2 bolus, then 5-FU 2400 mg/m^2 over 46 hours) or FOLFIRI (same 5-FU/FA with irinotecan 180 mg/m^2) every two weeks. Both arms received cetuximab, 400 mg/m^2 initial dose, then 250 mg/m^2 /week. The primary endpoint was the progression free survival (PFS) rate at 9 months, with secondary endpoints of 3-, 6-, 12-month PFS rates, objective response rate (RR), overall survival (OS) and toxicity.
Results: Between July 2005 and July 2006, 155 pts at 25 centers in 13 countries were randomly assigned to arm A (n = 77) or Arm B (n = 78). In total, 150 patients received study treatment (Arm A: n = 76, Arm B: n = 74).

Characteristics	Arm A (n = 76)	Arm B (n = 74)
Median age (years)	62	63
ECOG Performance Score		
0	46 (61%)	38 (51%)
1	30 (39%)	36 (49%)
Gender		
Female	34 (45%)	29 (39%)
Male	42 (55%)	45 (61%)
Prior therapy		
Neoadjuvant	4 (5%)	3 (4%)
Adjuvant	12 (16%)	9 (12%)
None	60 (79%)	62 (84%)
Metastases at initial diagnosis[a]	44 (59%)	46 (62%)
Number of involved organs		
1−2	58 (76%)	56 (76%)
>2	18 (24%)	18 (24%)

[a]Missing information in one patient of arm A.

Conclusions: No significant differences in pt characteristics occurred between the two treatment arms. Final data (PFS-rates, RR, OS, toxicity) will be presented within the meeting.