at initial diagnosis II/III/IV 21%/14%/64%; no. of metastatic sites 1/>1 46%/54%; most common metastatic site liver; prior adjuvant therapy 33% (Mayo 5-FU/LV). Pts received a median of 12 cycles (range 1–12) of capecitabine + irinotecan + bevacizumab; capecitabine + bevacizumab range: 0–26. All 28 pts are evaluable for safety and 26 for efficacy. The overall response rate is 69% (3 CR, 15 PR); 2 pts (8%) have stable disease and 6 have progressed. One pt has died. Median PFS and median OS have not yet been reached. The only grade 3 adverse events are diarrhoea (11%), hand–foot syndrome (7%), fatigue (4%), mucositis (4%), enteritis (4%) and ileus (4%); there is one report of grade 4 leukopenia. All other adverse events are mild-to-moderate.
Conclusions: The capecitabine + irinotecan + bevacizumab combination appears to be highly active and well tolerated as first-line treatment for MCRC, providing support for further evaluation of this combination.

3069 POSTER

Study of CPT-11, oxaliplatin, UFT triple therapy (SCOUT) in advanced colorectal cancer (ACRC): an effective and well-tolerated regimen

H.Y. Sheikh[1], J.W. Valle[2], K. Palmer[2], A. Sjursen[3], O. Craven[2], G. Wilson[2], R. Swindell[3], M.P. Saunders[1]. *[1]Christie Hospital, Clinical Oncology, Manchester, United Kingdom; [2]Christie Hospital, Medical Oncology, Manchester, United Kingdom; [3]Christie Hospital, Medical Statistics, Manchester, United Kingdom*

Background: Treatment-related toxicity and poor performance status can prevent patients from receiving second-line therapy after failure of first-line treatment. We investigated the feasibility of triple-drug therapy with irinotecan, oxaliplatin, and UFT with leucovorin (LV) in a phase I/II open-label dose-finding trial in patients with ACRC. Of particular interest was whether patients could benefit further from chemotherapy after disease progression.
Methods: Eligible patients aged ⩾18 y had histologically confirmed advanced, inoperable, measurable metastatic disease, no prior chemotherapy other than adjuvant 5-fluorouracil (5-FU) ⩾6 mo previously, and adequate bone marrow, liver, and kidney function. In phase I, patients received irinotecan 180 mg/m^2 on d1, oxaliplatin 85–100 mg/m^2 on d15, and UFT 200–300 mg/m^2/d with LV 90 mg/d on d1–21 of a 28-d cycle. The maximum tolerated dose (MTD) was established at irinotecan 180 mg/m^2, oxaliplatin 100 mg/m^2, UFT 250 mg/m^2/d, and LV 90 mg/d. Patients were treated at the MTD in the phase II study.
Results: Patients (median age 62 [range 24–79] y, ⩾3 marker lesions in 32 patients, disease confined to liver in 12 patients) were recruited, 25 in phase I and 20 added in phase II for a total of 29 at the MTD. Treatment was highly effective, with a response rate of 66% (95% CI 49–80%) in 38 evaluable patients and clinical benefit in 89% (95% CI 75–97%). At a median follow-up of 10.3 mo, median time to progression was 8.5 mo (95% CI −7.6 to 10.4 mo) in 40 evaluable patients; median overall survival (ITT population n = 45) was 16.8 mo (95% CI −11.3 to 28.3 mo). Two patients underwent resection of liver metastases (1 R0, 1 R1). Grade 3 adverse events at the MTD included: diarrhea (n = 3; 10%); neurotoxicity (n = 1; 3%); lethargy (n = 1; 3%). One patient had grade 4 cardiac toxicity. No hand–foot syndrome (HFS) was seen. In 30 patients with confirmed radiologic progression, 21 (70%) had second-line therapy (Table).

Second-line regimen	N
SCOUT retreatment[a]	8
Irinotecan/cetuximab	3
Mitomycin C/capecitabine	4
Oxaliplatin/5-FU	2
Capecitabine	1
Phase I studies	3

[a]Up to four 6-mo cycles.

Conclusions: In the first-line treatment of patients with ACRC, UFT plus LV with alternating irinotecan and oxaliplatin gives a high response rate, with minimal alopecia and neurotoxicity and no HFS, thus permitting administration of repeated treatment courses and resection in suitable patients. The SCOUT regimen is an effective and convenient treatment for patients with ACRC.

3070 POSTER

Bevacizumab in patients with previously treated metastatic colorectal cancer: preliminary results of a phase II study (bevacolor)

C. Borg[1], J.P. Delord[2], F. Husseini[3], V. Trillet Lenoir[4], R. Faroux[5], E. François[6], M. Ychou[7], L. Bergougnoux[8], J. Bennouna[9], J.Y. Douillard[9]. *[1]INSERM U 645 CHU Besançon, Oncologie, Besançon, France; [2]Institut Claudius Regaud, Oncologie, Toulouse, France; [3]Hôpital Pasteur, Oncologie, Colmar, France; [4]Centre Hospitalier Lyon-Sud, Oncologie Médicale, Lyon, France; [5]Centre Hospitalier Départemental, Service d'Hépatogastroentérologie, La Roche sur Yon, France; [6]Centre Antoine Lacassagne, Oncologie, Nice, France; [7]C.H.R.U., Oncologie, Montpellier, France; [8]Roche, Dépt. Statistiques, Neuilly sur Seine, France; [9]Centre René Gauducheau, Oncologie, Nantes, France*

Background: The activity of bevacizumab(Avastin®) as part of second-line therapies in metastatic colorectal cancer (mCRC) is currently under investigation. The aim of this study was to determine the safety and efficacy of adding bevacizumab (BV) to common chemotherapy regimens used in second-line therapy in mCRC.
Methods: A multicentre phase II study was conducted in fifty-three patients with mCRC progressing after first-line oxaliplatin or irinotecan-based chemotherapies. They received bevacizumab (BV) 2.5 mg/kg/week, until disease progression, on day 1 of a chemotherapy regimen chosen by the investigator.
Results: Overall, 35 men and 18 women, performance status 0 to 2, median age 62 (33−80) years, were treated. Ten patients (19%) had liver metastases and 39 patients (74%) had more than one metastatic site. The first-line treatment previously administered to patients was Folfox (53%), Folfiri (22%), Xelox (20%) and other chemotherapies (5%). Second line treatments included Folfiri (57%), Folfox (26%), Irinotecan (15%), Xeliri (2%). Patients received a median of 8 cycles (2−13) of chemotherapy and BV and 43 (81%) received BV at the dose of 5 mg/kg every 2 weeks.
After a follow up of 6 months, best response was assessed: one (2%) patient had a complete response (CR), 16 (30%) had partial response (PR), 29 (55%) had stable disease (SD) and 5 (9%) progressed. The rate of disease control defined as CR +PR +SD was 87% [95% CI, 78%-96%] and objective response rate (CR +PR) was 32% [95% CI, 19%-46%].
A total of 51 (96%) patients had adverse events and thirty-two (60%) had Grade 3/4 CTC AE toxicities including neutropenia in 11 (21%) patients, diarrhea in 7 (13%) and asthenia in 5 (9%). Grade 3/4 targeted toxicities (known to occur with BV) were reported in 6 (11%) patients, they included hypertension in 3 (6%) patients and thromboembolism in 3 (6%). Three deaths occurred mainly due to disease progression, no toxic death was observed.
Conclusions: The administration of BV, associated to chemotherapy is acceptable as 2nd line treatment in patients with mCRC, achieving an objective response rate of 32%. The toxicity profile of Bevacizumab in combination with standard chemotherapies in mCRC was acceptable. More details including progression free survival and overall survival will be given at the congress.

3071 POSTER

Impact of intensity modulated radiation therapy (IMRT) on bone marrow tolerance during combined treatment with chemotherapy for patients with anal canal cancer

T. Vuong[1], R. Ruo[2], J.P. Le Gruguel[3], S. Faria[1], S. Bucatel[1], S. Devic[2]. *[1]McGill University Health Centre, Radiation Oncology, Montreal, Canada; [2]Mcgill University Health Centre, Medical Physics, Montreal, Canada; [3]Boreal Primum, Statistics and Epidemiology, Montreal, Canada*

Background: IMRT has been introduced as a mean to improve sparing of normal structures during radiation therapy. Present study is reporting the experience of a single institution with the use of IMRT and conformal external beam radiation combined with chemotherapy for patients with anal canal carcinoma.
Materials and Methods: From 2004–2007, fifty patients with T2−4 squamous cell anal canal carcinoma were treated to doses of 54−59.8 Gy in 30−33 fractions without interruption and concurrently with 2 cycles of chemotherapy during weeks 1 and 6 of radiation using 5-Fluorouracil (5-Fu, 1000 mg/m^2/day, 96 hours continuous infusion) and Mitomycin C (MMC, 10 mg/m^2, bolus on day 1). Radiation was delivered with IMRT in 18 patients and 3D-conformal radiation therapy (3D-CRT) in 32 patients. Dose of 30 Gy in 15 fractions were prescribed to elective iliac and inguinal nodes and 54−59.6 Gy to the tumor bed and involved nodes. A two-phase CT-based planning is done for both techniques. Pelvic bone marrow was defined as the region extending from the iliac crests to the ischial tuberosities. Hematological toxicity was assessed by weekly blood counts