of a subgroup of colorectal cancer patients with liver metastases only, who were enrolled in the randomized CApecitabine, IRinotecan, Oxaliplatin (CAIRO) phase III study between January 2003 and December 2004.
Results: Ninety-nine patients were treated with IHP, and 111 patients were included in the control group. All patient characteristics were comparable except for age. Median follow up was 78.1 months for IHP versus 54.7 months in the control group. Median overall survival was 25.0 (95% CI 19.4−30.6) months for IHP and 21.7 (95% CI 19.6−23.8) months for systemic treatment (P = 0.29). Overall survival was not influenced by gender, age, LDH, location of primary tumor, timing of liver metastases and adjuvant treatment of the primary tumor and was only influenced by metastasectomy after study treatment (P < 0.001). However, the number of patients in whom metastasectomy was performed did not differ significantly between the two groups. Treatment-related mortality was 2% for the systemic treatment and 6% for IHP (P = 0.11).
Conclusion: Compared to a patient group with comparable characteristics treated with systemic chemotherapy, IHP does not provide a benefit in overall survival in patients with isolated non-resectable colorectal liver metastases. Currently the use of IHP cannot be advocated outside the scope of clinical study protocols.

6055 POSTER

A randomized phase II study of Xeloda with or without oxaliplatin as a first-line treatment in the elderly patients with metastatic colorectal cancer: Korean Cancer Study Group

Y.S. Hong[1], S.Y. Kim[1], K.H. Jung[1], J.L. Lee[2], Y.S. Park[3], J.B. Ahn[4], J.H. Kim[5], B.Y. Shim[6], D.Y. Zang[7], T.W. Kim[2]. *[1]National Cancer Center, Center for Colorectal Cancer, Goyang, South Korea; [2]Asan Medical Center, Medical Oncology, Seoul, South Korea; [3]Samsung Medical Center, Hematology and Medical Oncology, Seoul, South Korea; [4]Yonsei Cancer Center, Medical Oncology, Seoul, South Korea; [5]Seoul National University Bundang Hospital, Hematology and Medical Oncology, Seongnam, South Korea; [6]Saint Vincent's Hospital, Medical Oncology, Suwon, South Korea; [7]Hallym Sacred Heart Hospital, Medical Oncology, Seoul, South Korea*

Background: More than half of colorectal cancer (CRC) patients (pt) are >70 years old in the western countries and the incidence of CRC in this age group is also increasing. Optimal chemotherapy, however, are not well defined in elderly pts yet. We investigated Xeloda (X) alone and Xeloda plus oxaliplatin (XELOX) as a 1st-line treatment for elderly mCRC pts.
Methods: This is a randomized, open-label, multicenter phase II study. Pts with previously untreated mCRC were randomized stratifying by age, performance status and center; X group (X 2500 mg/m^2/d on D1−14 q 3 wks) and XELOX group (X 2000 mg/m^2/d on D1−14, O 100 mg/m^2/d in 1st cycle only and escalated to 130 mg/m^2/d on D1 in further cycles q 3 wks). Main eligibility criteria were histologically proven adenocarcinoma; measurable lesion; age ⩾70 (PS 0−2) or ⩾65 (PS 2) yr; no prior chemotherapy. Primary endpoint was to investigate response rate (RR) and secondary endpoints were to evaluate toxicity, progression-free survival (PFS), overall survival and quality of life (QoL). QoL was assessed by EORTC QLQ-C30 questionnaire.

	X	XELOX
Confirmed RR	22.5%	32.5%
PFS	5.6 mo	6.0 mo
Toxicity (grade ⩾2)		
Neutropenia	11%	45%
Thrombocytopenia	8%	48%
Diarrhea	5%	20%
Stomatitis	13%	10%
HFS	29%	23%
Sensory neuropathy	8%	3%

Results: Between May 2006 and Apr 2008, 80 pts (X: 40 vs XELOX: 40) were enrolled. Baseline characteristics were balanced between each arm; median age 71 (66−81) vs 72 yo (65−79); M/F 23/17 vs 22/18; PS 0/1/2 12/18/10 vs 9/19/12. The confirmed RR were 22.5% and 32.5% (HR 0.603 [0.22−1.63]) and PFS were 5.6 mo and 6.0 mo (HR 0.762 [0.46−1.26]) in X and XELOX group, respectively. Oxaliplatin dose was escalated to 130 mg/m^2 in 77.5% of pts (31/40) from their 2nd cycle in the XELOX arm. Higher incidences of hematologic toxicities were observed in XELOX group, but significant toxicities were not different except G2−3 diarrhea. Global health status, 5 functional and 4 symptom scales of QoL were deteriorated in XELOX arm.
Conclusions: Combination chemotherapy of reduced dose of XELOX could be a preferable option for elderly patients in terms of efficacy and tolerable toxicity profiles. However, further studies are needed to define optimal dosage and schedule to improve QoL of reduced dose of XELOX regimen in this population.

6056 POSTER

Changing monoclonal antibody keeping unaltered the chemotherapy regimen in metastatic colorectal cancer (mCRC) patients (pts): is efficacy mantained?

R. Grande[1], G. Cianci[1], G. Grassi[1], I. Sperduti[2], F. Narducci[1], A. Gelibter[3], C. Nuzzo[3], L. Mentuccia[1], M.A. Giampaolo[1], T. Gamucci[1]. *[1]ASL Frosinone, Medical Oncology Unit, Frosinone, Italy; [2]Regina Elena National Cancer Institute, Department of Bio-Statistics, Rome, Italy; [3]Regina Elena National Cancer Institute, Medical Oncology, Rome, Italy*

Background: Bevacizumab (B) and Cetuximab (C) both improve overall survival (OS), progression free survival (PFS) and overall response rate (ORR) when combined with irinotecan-containing regimens. The optimal sequence of these monoclonal antibodies in combination with chemotherapy (CT) is controversial. In this study we analysed the efficacy of C associated with irinotecan-based CT (FOLFIRI) after progression with the same regimen plus B in pts with mCRC.
Materials and Methods: Eligibility criteria: progression disease (PD) after chemotherapy with Folfiri-B (FB)->B; ECOG PS 0−1. Primary endpoints: ORR and disease control rate (DCR:ORR plus stable disease >6 months); secondary endpoints: PFS, duration of response, OS and toxicity. ORR and DCR were reported with their confidence interval at 95%, Kaplan-Meier method was used for PFS/OS evaluation.
Results: 41 pts were enrolled to receive Folfiri-C (FC)->C after progression to FB->B. Median age was 67 (44−80), M/F 25/16, ECOG PS 0/1 was 14/27, WT Kras 37 (90%). Median cycles of first line FB->B was 12 (range 4−16)/8 (range 1−23) and median cycles of second line FC->C was 7 (range 1−12)/6 (range 2−12). The ORR was 22% (CI 95% 9.3−34.6), DCR was 36.6% (CI 95% 21.-51.3); 43.8% of pts responders to FB->B obtained a new response to FC->C and 10% of non responders obtained a response. Median duration of response was 4 months (range 1−8) and clinical benefit 6 months (CI 95% 2−13). PFS and OS are shown in table.

Endpoints	6 months (%)	12 months (%)	24 months (%)	Median (CI 95%)
PFS	47.9	19.5	–	6 (3−9)
OS	91.4	54.1	21.2	13 (6−20)

Acne-like rash occurred in 68.3% of pts (34.1% grade⩾2). No grade 4 toxicity was observed.
Conclusions: Efficacy in response and survival is maintained in pts with mCRC treated with the same chemotherapy regimen changing monoclonal antibodies. Data collection is ongoing, and update results will be presented.

6057 POSTER

The final results; bevacizumab (BV) safety post marketing large cohort survey (PMS) in 2712 japanese colorectal cancer patients (PTS)

D. Toshihiko[1], K. Shirao[2], H. Uetake[3], K. Hatake[4]. *[1]National Cancer Center Hospital East, Internal Medicine GI Oncology Division, Kashiwa, Japan; [2]Oita University, Faculty of Medicine, Oita, Japan; [3]Tokyo Medical and Dental University, Translational Oncology, Tokyo, Japan; [4]The Cancer Institute Hospital of JFCR, Medical Oncology, Tokyo, Japan*

Background: BV was approved in Japan in Apr. 2007 with indication for advanced colorectal cancer (CRC). Due to rather limited clinical data on Japanese patients, the Japanese regulatory authorities required Chugai to design a company-initiated PMS on all pts treated with BV as a post-approval commitment in order to evaluate the incidence of adverse drug reactions (ADRs). This study represents a large-scale, well managed, first safety cohort data available in Asian markets as of today.
Objectives: To assess the use of BV in clinical practice and to evaluate ADR incidence in the post-marketing setting.
Material and Methods: All pts treated with BV were registered before initial administration since market launch of BV in Japan in June 2007. The follow-up period was 6 months.
Results: 2712 pts were registered from 574 institutions between Jun. and Nov. 2007. 2696 pts were eligible for analysis. Pts characteristics were colon/rectum/colon and rectum cancer: 1577/1105/14; M/F: 1632/1064; median age: 61 (15−86); ECOG P.S. 0/1/2/3: 2191/474/29/2; combination chemotherapy regimen with BV [FOLFOX/FOLFIRI/5-FU LV/Other (IFL etc.)]: 1711/779/142/64. Of 2696 pts, ADRs were reported in 1668 pts (61.9%) and serious ADRs in 412 pts (15.3%).