diarrhea (28.4% Arm A, 15.7% Arm B); acneiform rash was significantly more common in Arm A (8.0% vs 0.2%). Baseline HRQoL scores for social functioning, fatigue, dyspnea, and appetite loss, showed significant differences in favor of Arm A. Pts in Arm A had significantly improved Global Health Status ($p = 0.047$), and 10/15 HRQoL scales, including pain ($p = 0.006$), nausea/vomiting ($p < 0.001$), insomnia ($p < 0.001$), and physical ($p = 0.023$) and cognitive functioning ($p = 0.008$).
Conclusions: Cetuximab plus irinotecan in mCRC pts who failed on oxaliplatin resulted in a significantly longer PFS, higher RR and improved QoL than irinotecan alone. The observed safety profile was as anticipated. Overall survival was similar between the two arms but this may result from the substantial post-study use of cetuximab.

Efficacy results[a]

	Arm A (cetuximab + irinotecan) (N = 648)	Arm B (irinotecan alone) (N = 650)	p	HR	OR
OS, mo [95% CI]	10.7 [9.6, 11.3]	10.0 [9.1, 11.3]	0.712	0.975	
PFS, mo [95% CI]	4.0 [3.2, 4.1]	2.6 [2.1, 2.7]		0.692	
RR, % [95% CI]	16.4 [13.6, 19.4]	4.2 [2.8, 6.0]			4.460

[a]HR, hazard ratio; OR, odds ratio.

3004 ORAL

Cetuximab plus 5-FU/FA/oxaliplatin (FOLFOX-4) in the first-line treatment of metastastic colorectal cancer (mCRC): a large-scale phase II study, OPUS

C. Bokemeyer[1], E. Staroslawska[2], A. Makhson[3], I. Bondarenko[4], J.T. Hartmann[5], Y. Shelygin[6], O. Kolesnik[7], C. Volovat[8], A. Zubel[9], P. Koralewski[10]. *[1]University Hospital Hamburg-Eppendorf, Oncology Center, Hamburg, Germany; [2]Oddzial I Chemioterapii Onkologicznej, Oncology Center, Lublin, Poland; [3]Moscow City Oncology Hospital #62, Oncology, Moscow, Russian Federation; [4]City Clinical Hospital #4, Oncology, Dnepropetrovsk, Ukraine; [5]Universitaetsklinikum Tübingen, Oncology, Tübingen, Germany; [6]State Scientific Center of Colproproctology, Oncology, Moscow, Russian Federation; [7]Institute of Oncology AMS Ukraine, Department of Abdominal Oncology, Kiev, Ukraine; [8]Centrul de Oncologie Medicala, Oncology, Iasi, Romania; [9]Merck KGaA, Medical Sciences Oncology, Darmstadt, Germany; [10]Wojewodzki Szpital Specjalistyczny Oddziac, Oncology, Krakow, Poland*

Background: FOLFOX-4 is a standard first-line treatment for patients (pts) with mCRC. The IgG1 monoclonal antibody cetuximab (Erbitux®) has proven activity in combination with cytotoxic chemotherapy. Excellent response rates (RRs) have been reported with first-line cetuximab plus FOLFOX-4. This randomized, controlled study compared the RRs of FOLFOX-4 +/− cetuximab first-line in mCRC.
Methods: Pts with previously untreated, epidermal growth factor receptor (EGFR)-expressing mCRC, which was not resectable with curative intent, were eligible for entry in to the study. Randomization was 1:1; pts stratified by ECOG performance status (PS) (0−1 vs 2), to either Group A (cetuximab 400 mg/m^2 initial dose, then 250 mg/m^2/week plus FOLFOX-4 every 2 weeks [oxaliplatin 85 mg/m^2 day 1; FA 200 mg/m^2 day 1 and day 2; 5-FU 400 mg/m^2 bolus + 600 mg/m^2 infusion over 22 hours, day 1 and day 2]) or Group B (FOLFOX-4 only). The primary endpoint was best overall confirmed response as assessed by independent review. Secondary variables were progression-free survival time (PFS), overall survival time (OS), status of resection for subsequent metastatic surgery with curative intent, and safety.
Results: Between July 2005 and March 2006, 337 pts were randomized and treated in >70 centers in Europe. 181 (53.7%) pts were male; median age of all pts was 61.0 years [24–82]; 305 (90.5%) pts had an ECOG PS of 0 or 1 at the time of randomization, and 32 (9.5%) of 2. The best overall confirmed RR was 45.6% in Group A and 35.7% in Group B. The RR for pts with ECOG PS 0−1 was 49.0% in Group A and 36.8% in Group B (Odds Ratio 1.648, 95% CI [1.043−2.604]). OS data are not yet available. The most common reported grade 3/4 adverse event (AE) was neutropenia, experienced by 31.5% pts in Group B and 27.6% pts in Group A. The other most common grade 3/4 AEs were diarrhea (7.1% Group A, 6.0% Group B), leucopenia (7.1% Group A, 5.4% Group B) and rash (9.4%, Group A only).
Conclusions: RRs achieved with the addition of cetuximab to FOLFOX-4 in the first-line treatment of mCRC were higher than those achieved with FOLFOX-4 alone (45.6% in Group A vs 35.7% in Group B). For the ECOG 0−1 group, the RR was significantly higher in cetuximab arm. Of the grade 3/4 AEs reported, only skin rash was significantly more frequent in the cetuximab arm. PFS results will be available at the meeting.

3005 ORAL

Can we predict the nodal status in primary rectal cancer accurately with USPIO MRI?

G.L. Beets[1], M. Lahaye[2], S.M.E. Engelen[1], A.P. de Bruïne[3], M.F. von Meyenfeldt[1], J.M.A. van Engelshoven[2], C.J.H. van de Velde[4], R.G.H. Beets-Tan[2]. *[1]University Hospital Maastricht, Surgery, Maastricht, The Netherlands; [2]University Hospital Maastricht, Radiology, Maastricht, The Netherlands; [3]University Hospital Maastricht, Pathology, Maastricht, The Netherlands; [4]Leiden University Medical Center, Surgery, Leiden, The Netherlands*

Background: Rectal cancer is notorious for its local recurrence. An important risk factor is nodal disease. So far this cannot be accurately predicted with non-invasive imaging. The purpose of this prospective study was to determine the accuracy of Ultrasmall Superparamagnetic Iron Oxide (USPIO) MRI for predicting of the nodal status in rectal cancer patients.
Material and Methods: From February 2003 to July 2007 53 patients with primary rectal cancer underwent 1.5-T high-resolution MRI 24 hr. after administration of USPIO (Sinerem®) contrast agent. Sequences used were axial 2DT2WFSE, 3DT1WGRE & 3DT2*. All patients were treated with Total Mesorectal Excision (TME) surgery, after pre-operative radiotherapy (5×5 Gy). A MR radiologist recorded the amount, localization and signal-intensity of (extra)mesorectal lymph nodes, depicted by MR images. Lesion by lesion analysis was performed with histology as the reference standard.
Results: In 53 patients MR Imaging depicted 531 lymph nodes, which could be recovered in the TME-specimen. Thirty-three patients were predicted as node-positive due to the MRI results. After histopathologic evaluation 21 of these 33 patients were staged as node-positive. The patient-based sensitivity, specificity, PPV and NPV were 100%, 63%, 64% and 100%, respectively. The lesion by lesion analysis results in sensitivity, specificity, PPV and NPV were 97%, 94%, 66% and 99%, respectively.
Striking finding is the high NPV, suggesting that N0 patients can be identified accurately.
Conclusion: This prospective study suggests that USPIO-MRI is highly accurate in identifying N0 patients, stratifying rectal cancer into different risks, allowing individual tailored treatment according to risks.

3006 ORAL

Preoperative evaluation with virtual colonoscopy (VC) in colorectal cancer (CRC) patients candidates to laparoscopic colon resection (LCR)

A. Tamburini[1], S. Cappio[2], R. Nicoletti[2], S. Di Palo[1], M. Cellina[2], E. Orsenigo[1], A. Del Maschio[2], C. Staudacher[1]. *[1]University Vita-Salute San Raffaele, Gastrointestinal Surgery, Milan, Italy; [2]University Vita-Salute San Raffaele, Department of Radiology, Milan, Italy*

Background: Aim of our study was the preoperative evaluation with virtual colonoscopy in patients affected by colorectal cancer, candidates to laparoscopic colectomy.
Patients and Methods: We prospectively evaluated with virtula colonoscopy 55 patients affected by CRC, candidates to laparoscopic resection. We compared virtual colonoscopy data with surgical specimens and follow up data. 45 patients had a prior conventional colonoscopy diagnosis of colorectal cancer. 40 patients had incomplete colonoscopy caused by stenosing lesions. All studies were conducted with 16 slices MSCT after colonic cathartic cleansing and colonic gas distension. We evaluated the presence and site of the lesions, metastases, colon synchronous lesions and polyps.
Results: Virtual colonoscopy detected the presence and site of the lesions in all cases, with an accuracy of 100%; Colonoscopy, incorrectly diagnosed the neoplasm site in 8 patients (18%). In our study Virtual colonoscopy allowed complete evaluation of the colon in 87.2% (n = 48) of the patients with stenosing lesions, versus 15% of Colonoscopy. Synchronous polyps were detected in 13 of these patients (27%), and 1 patient had 3 synchronous lesions. All patients were initially scheduled for laparoscopic surgery. In 16 pts (29%) Virtual colonoscopy data caused changes in therapeutic approach that lead to a more extensive laparoscopic resection in 2 cases (4%), to laparotomic resection in 8 patients (14%), to neoadjuvant therapy in 6 patient (11%).
Conclusionis: Virtual colonoscopy contributes greatly to the treatment planning in patients with Colorectal cancer, especially in those with incomplete endoscopy. We think that Virtual colonoscopy should be the first choice diagnostic modality in the preoperative evaluation of patients affected by stenosing colorectal cancer.