patients (78%) responded. After propensity score matching, a total of 162 patients were involved in this study.
Results: Patients' gender, age, location of tumour, marital status, education, work and number of comorbidity were not significantly different between two treatments. In capecitabine (Xeloda®)-based treatment, Physical, Role, Emotional, Social, Global Health status, Future perspective Functioning, Fatigue, Diarrhea, Defecation problems and Weight loss Symptoms improved from Q0 to Q3 and Q0 to Q7. In 5-FU/LV-based treatment, Physical, Role, Global health status Functioning, Gastrointestinal tract and Weight loss Symptoms also improved. Total cost of capecitabine (Xeloda®)-based and 5-FU/LV-based treatment were € 690 (NT$27,706) and €1,512 (NT$60,691), respectively.
Conclusions: To the authors' knowledge, the current study is the first to examine trends over time regarding the effects of adjuvant treatment on HRQOL and direct cost of colorectal cancer patients. The results indicate that adjuvant chemotherapy for colorectal cancers has no negative impact on the HRQOL. Between the two adjuvant chemotherapies in the study, capecitabine (Xeloda®)-based treatment perform better in HRQOL improvement and has less direct cost.

6149 POSTER

Preliminary Results of a Phase 2−3 Clinical Study With the Immunomodulator MGN1703 in Patients With Advanced Colorectal Carcinoma (IMPACT Study)

M. Schmidt[1], H.J. Schmoll[2], F. Ghiringhelli[3], F. Mayer[4], H. Kröning[5], R. Ziebermayr[6], M. Schroff[1], E. Weith[1], M. Tschaika[1], B. Wittig[7]. *[1]MOLOGEN AG, Berlin, Germany; [2]Martin-Luther-University Halle-Wittenberg, University Clinic and Policlinic for Internal Medicine IV, Halle, Germany; [3]Centre Georges François Leclerc, Dijon, France; [4]University of Tuebingen, Medical Clinic, Tübingen, Germany; [5]Schwerpunktpraxis für Hämatologie und Onkologie Magdeburg, Magdeburg, Germany; [6]Elisabethinen Linz, 1. Interne Hämatologie mit Stammzeltransplantation und medizinischer Onkologie, Linz, Austria; [7]Freie Universität Berlin, Foundation Institute Molecular Biology and Bioinformatics, Berlin, Germany*

Background: MGN1703 is a synthetic DNA-based immunomodulator and acts as an agonist of toll-like receptor 9 (TLR9). Based on the promising data from currently finished phase 1 study in patients with metastatic solid tumours including those with CRC, a phase 2−3 study was initiated in patients with advanced CRC. The objective of the study is to assess safety and efficacy of the MGN1703 treatment in comparison to placebo.
Methods: This randomized double-blinded placebo-controlled phase 2−3 clinical study (IMPACT study; MGN1703-C02; EudraCT number: 2009–017432−40; Sponsor: Mologen AG) is conducted in patients with advanced CRC showing disease control after first-line therapy with standard chemotherapy regimen. The study is conducted in Germany, Austria, France, United Kingdom, Czech Republic and Russia, and 129 patients will be recruited into the study. The patients are subcutaneously treated twice a week either with 60 mg MGN1703 or with placebo (using ratio of 2:1). The efficacy and safety of the study treatment will be evaluated based on extensive immunological tests, radiological assessment, safety laboratory results and assessments of the quality of life. The study treatment will be continued until tumour progression, intolerable toxicity, exclusion criteria, withdrawal of consent or death.
Results: Thirty-two adverse events have currently been reported. Out of those, 26 (81.2%) were assessed as not drug-related by the investigator: The remaining were mild night sweat (not assessable), mild fever (at three occasions, possible related), mild injection site itching (probable related) and mild arthralgia (certain related) in one patient each. One not drug-related SAE − ileus − was reported. Only in single patients local reactions such as mild redness and swelling at injection site were reported. No laboratory or clinical signs of autoimmunity or dose-limiting toxicities were reported, so far.
Conclusions: The preliminary safety results of this ongoing clinical study in patients with advanced CRC show that treatment with MGN1703 at the dosage of 60 mg is well tolerated and safe. Reported adverse events were not accompanied by any signs of autoimmunity.

6150 POSTER

Survival Outcomes With Use of Bevacizumab Beyond Progression (BBP) in Metastatic Colorectal Cancer (MCRC) Patients (Pts)

T. Cartwright[1], E. Yu[2], Y. Yim[2], H. Hartnett[3], H. Chung[3], M. Halm[3], M. Forsyth[3]. *[1]Ocala Oncology, Ocala Oncology, Ocala, USA; [2]Genentech, Health Outcomes, South San Francisco, USA; [3]U.S. Oncology, Healthcare Informatics, Houston TX, USA*

Background: Bevacizumab (BV) prolongs overall survival (OS) when added to chemotherapy (CT) in 1st line (1L) and 2nd line (2L) treatment (Tx) of MCRC. Findings from the observational cohort studies BRiTE and ARIES suggest that continued use of BV beyond the first progression improves survival for MCRC patients. A retrospective analysis was conducted to evaluate the association between survival outcomes and the use of BBP in MCRC Pts treated in the community setting.
Methods: Data was derived from the US Oncology's iKnowMed electronic medical record system. MCRC Pts who received 2L Tx after receiving 1L CT with BV between 7/1/2006 and 6/30/2009 were identified. Date of progressive disease (PD) was defined as initiation of 2L Tx. Pts were followed until death or loss to follow up, whichever came first. Pts were divided into 2 cohorts: Pts who continued BV post-PD in 2L (BBP) and Pts who received post-PD treatment in 2L without BV (No BBP). Clinical outcomes were measured by OS, defined as time from initiation of 1L Tx to death and survival beyond progression (SBP), defined as time from initiation of 2L Tx to death. Baseline characteristics were compared between groups using chi-square analysis for categorical variables and t-tests for continuous variables. OS and SBP were estimated using Kaplan–Meier method. Cox proportional hazards model was used to assess effects of Pt and Tx characteristics on OS and SBP, adjusting for age at 2L start, time to 1st PD, use of anti-EGFR therapies post PD, gender, ECOG performance status at 2L start, time between end of 1L and start of 2L, exposure to three active CT agents (5-FU, oxaliplatin and irinotecan), and primary tumour site.
Results: 641 Pts met criteria for No BBP (n = 368) and BBP (n = 273). Pt and Tx characteristics between groups were similar except age at 2L start (median 62 yrs vs 60 yrs for No BBP vs. BBP), practice region, use of anti-EGFR therapies post PD, and 2L CT. Median OS and SBP were longer in the BBP cohort (OS 28.2 mo; SBP 15.4 mo) compared to the No BBP cohort (OS 21.0 mo; SBP 8.8 mo). BBP was associated with longer OS (HR = 0.64; 95% CI 0.50–0.81), and longer SBP HR = 0.59; 95% CI 0.46–0.75, after adjusting for covariates in the Cox model.
Conclusion: In MCRC patients treated in the community setting, the use of BBP appears to be significantly associated with prolonged OS and SBP. These results are consistent with previous results from large observational cohort studies.

6151 POSTER

Follow up After Hepatectomy for Colorectal Liver Metastases − a Systematic Review and Meta-analysis

R. Jones[1], D. Dunne[1], S. Fenwick[1], G. Poston[1], P. Malik[1], P. Ghaneh[1]. *[1]University Hospital Aintree NHS Foundation Trust, Department of Hepatobiliary Surgery, Liverpool, United Kingdom*

Background: Follow up of patients after liver resection offers two potential benefits; clinicians can assess the efficacy of treatment, and recurrent disease can be detected and treated. The majority of recurrence occurs within the first two years of resection, and many centres concentrate follow up in this period.
Objective: To review the evidence surrounding follow up after liver resection for metastatic colorectal disease and define an evidence base for intensive early follow up.
Methods: A systematic review using databases, trial registers and conference proceedings. We included any studies that described potentially curative primary resection of colorectal liver metastases that included a defined follow-up protocol between Jan 2003 − May 2010. Studies were divided into intensive early follow up and standard follow up based on pattern of review.
Results: 335 studies were identified, of which 35 met the inclusion criteria, involving 7330 patients. Intensive early follow up showed median survival of 39.8 months (95% CI 34.3–45.3), with 1-,3- and 5-year survival of 91.5% (95% CI 83.4–99.6), 57.6% (95% CI 50.7–64.5) and 41.9% (95% CI 34.4–49.4). Routine follow up showed median survival of 40.2 months (95% CI 33.4–47.0), with 1-, 3- and 5-year overall survival of 86.7% (95% CI 78.3–95.1), 52.8% (95% CI 46.9–58.7) and 38.4% (95% CI 32.56–44.3) respectively. Only 5 studies directly assessed the most appropriate method of follow-up after resection, and adopted a combination of radiological and haematological assessment. Most recurrence was detected within 3 years of resection. One study specifically assessing the impact of intensive (3-monthly) CT-based follow-up found it was associated with better overall survival than palliative treatment.
Conclusions: Evidence surrounding follow up after liver resection is poor. Meta-analysis failed to identify an advantage to intense early follow-up.

6152 POSTER

Trends in Survival and Chemotherapy (CTx) Usage in Elderly Patients With Metastatic Colorectal Cancer (mCRC)

V. Shankaran[1], S. Beck[2], D. Blough[3], L. Koepl[2], Y. Yim[4], E. Yu[4], S. Ramsey[2]. *[1]University of Washington, Medical Oncology, Seattle WA, USA; [2]Fred Hutchinson Cancer Research Center, Cancer Prevention, Seattle WA, USA; [3]University of Washington, School of Pharmacy, Seattle WA, USA; [4]Genentech, Health Outcomes, San Francisco CA, USA*

Background: Several drugs [including bevacizumab (Bv), oxaliplatin (Ox), and irinotecan (Iri)] have been approved since 2002 for the treatment of

mCRC. The goals of this study are to examine patterns of newer CTx use and survival trends in elderly mCRC patients (pts).
Methods: Pts ⩾ age 65 with mCRC diagnosis (Dx) between 2001 and 2005 were identified from SEER-Medicare, a database which links Medicare claims with a population-based cancer registry representing ~25% of the U.S. population (SEER). Pts were excluded for enrollment in Medicare HMO, lack of Medicare parts A and B, or prior cancer Dx. 1st line (1L) CTx was identified from claims within 3 mo of Dx. Pts were categorized by treatment (none, CTx, CTx + Bv) and Dx year (2001−3 vs. 2004−5). Factors associated with 1L Bv use were identified using logistic regression. A Cox model assessed the association of various factors [age, comorbidity, hepatic resection (rsxn), CTx] with survival.
Results: 5,725 pts (median age 77) met criteria. 2,647 (46%) received 1L CTx. In 2004−5, 32% and 12% of treated pts received Ox and Iri (vs.1% and 34% in 2001−3). Following its approval in 2004, 25% of treated pts received Bv. Factors associated with 1L Bv use include age <75 (OR 1.43, p = 0.02) and concurrent use of Ox (OR 10.11, p < 0.001) or Iri (OR 5.82, p < 0.001). In a Cox model, survival was greater in pts with lower comorbidity, age <75, hepatic rsxn, 1L CTx, and Dx in 2004−5. Pts Dx in 2004−5 who used Bv had the greatest survival compared with untreated pts Dx in 2001−3 (HR 0.46, p < 0.001, median OS 15 vs. 6 mo).
Conclusions: In an elderly mCRC cohort, nearly half of pts received 1L CTx, often with Iri, Ox, or Bv. Survival was greatest in pts who underwent hepatic rsxn and who were Dx in 2004−5 and received Bv. Future SEER-Medicare analyses may elucidate the relative benefit of other new agents in the elderly, a growing population worldwide that is under-represented in clinical trials.

Table: Multivariate Cox Proportional Hazards Model

Factor	Median OS, mo (vs reference)	HR (95% CI)	P
Age <75	12 vs. 6	0.71 (0.66–0.75)	<0.001
Comorbidity ⩽1	10 vs. 6	0.75 (0.70–0.80)	<0.001
Hepatic rsxn	14.5 vs. 8	0.68 (0.58–0.79)	<0.001
Dx 2001−3 + 1L CTx	10 vs 6	0.84 (0.78–0.91)	<0.001
Dx 2004−5 no 1L CTx	7 vs 6	0.88 (0.81–0.95)	0.002
Dx 2004−5 + 1L CTx	12 vs. 6	0.63 (0.57–0.69)	<0.001
Dx 2004−5 + 1L CTx and Bv	15 vs. 6	0.46 (0.39–0.55)	<0.001

Reference: Age ⩾75, Comorbidity >1, No hepatic rsxn, Dx 2001–2003 (no 1L CTx).

6153 POSTER

Association of Rs6983267 G > T Locus With the Risk of Colorectal Cancer − a Systematic Review and Meta-analysis

B.S. Haerian[1], M.S. Haerian[2], L. Baum[3]. [1]*University Malaya Medical Center, Pharmacology, Kuala Lumpur, Malaysia;* [2]*Shaheed Beheshti University, Research Center for Gastroenterology and Liver Disease, Tehran, Iran;* [3]*The Chinese University of Hong Kong, School of Pharmacy, Hong Kong, Hong Kong*

Objective: Recent genome-wide association studies of colorectal cancer (CRC) have identified a key variant in the 8q24 region to be associated with CRC. In the present study, we performed a meta-analysis to determine whether the rs6983267 G > T locus is associated with susceptibility to CRC.
Materials and Methods: We meta-analyzed the non-familial studies that evaluated the role of rs6983267 G > T polymorphism with susceptibility to CRC under alternative genetic models.
Results: Meta-analysis of 17 studies (71,445 subjects) from Asian, European, and American populations showed a significant association of rs6983267 alleles and genotypes with the susceptibility to CRC in the overall or in the Asians and Europeans.
Conclusion: Our data suggest that the rs6983267 G > T polymorphism was a risk factor for CRC in the Asians and European populations.

6154 POSTER

Accuracy of CT Colonography in Detection of Colorectal Polyps − Systematic Review and Meta Analysis

K. Siddique[1], S. Mirza[1], G. Harinath[1]. [1]*William Harvey Hospital, Lower GI, Canterbury Kent, United Kingdom*

Aims: To determine the methodologic quality of studies as well as accuracy of CT colonography in detection of colorectal polyps in symptomatic patients and screening population combined.
Methods: An extensive online English Medical Literature search was made on reports of diagnostic accuracy of CTC between 2000–2009. Quality of the studies was assessed using a tool called “quality assessment of diagnostic accuracy studies (QUADAS)”. (Fig. 1). Per patient sensitivity and specificity of CT colonography for polyps of different size was computed for each study and pooled sensitivity and specificity was also calculated. Forest plots and summary receiver operating characteristic curve (s ROC) was computed. Pooled sensitivity was measured for polyps of various sizes. Meta analysis was performed using Meta DiSc version 1.4.
Results: Out of a total of studies 11 met our inclusion criteria. Total patrients were 3688 out of which 62.5% were male, rest were female. The average age was 64 years (Age range 25−90). Patient demographics and eligibility criteria were clearly defined in 10 out of 11 studies. Six studies which used Conventional Colonoscopy (CC) as a reference standard have not described the procedure details on the technique. Index test (CTC) formed a part of the reference standard in five studies using ‘segmental unblinding of the colonoscopy’ as the reference standard. Information bias in interpreting CT colonography results was found in none of the studies. Per patient pooled sensitivity and specificity for polyp of any size with 95% CI was 69% (66−72%) and 75% (73−78%) respectively with area under curve 0.787 and standard error of 0.066. The Pooled sensitivity for all studies in the detection of colorectal polyps showed too heterogeneous results i.e., for polyp of size <5 mm, 6−9 mm and ⩾10 mm sensitivity was found to be 32% (30−34%), 65% (62−68%) and 74% (70−78%) respectively.
Conclusions: Per patient sensitivity for detecting polyp of any size is less as compared to its specificity and per polyp sensitivity increased with polyp size indicating that CT colonography may not detect smaller lesions accurately.

6155 POSTER

Panitumumab in Patients With Chemorefractory Wild-type KRas MCRC − Results of a Second Interim Analysis From a Community-based Non-interventional Cohort Study (VECTOR) in Germany

B. Scheuer[1], K. Kroening[2], C. Lerchenmueller[3], M. Stauch[4], E. Boecher[5], E. Hellebrand[6], A. Kuhn[6], M. Groschek[7]. [1]*Praxis fuer Haematologie und Internistische Onkologie, Pirmasens, Germany;* [2]*Schwerpunktpraxis fuer Haematologie und Onkologie, Magdeburg, Germany;* [3]*Praxis fuer Haematologie und Onkologie, Muenster, Germany;* [4]*Onkologische Schwerpunktpraxis, Kronach, Germany;* [5]*MVZ Kloster Paradiese, Soest, Germany;* [6]*AMGEN GmbH, Munich, Germany;* [7]*Haematologisch-Onkologische Praxis, Wuerselen, Germany*

Background: Panitumumab (pmab) monotherapy has been shown to significantly improve progression-free survival compared with best supportive care in patients (pts) with chemorefractory wild-type (wt) *KRAS* metastatic colorectal cancer (mCRC). This observational cohort study was initiated to evaluate the safety and efficacy of pmab in daily practice in Germany.
Material and Methods: To ensure a population representative of routine clinical practice, eligibility criteria were largely unrestricted. Patient needed to have histological confirmed *KRAS* wt mCRC, treatment for >4 weeks with pmab, failure of prior fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy (CTx) regimens, be >18 years old, adequately consented and undergoing appropriate contraception. Predefined endpoints were: tumour response rates (according to investigator‘s assessment) and overall skin toxicity assessed by the NCI Common Terminology Criteria for Adverse Events v3.0. For this second interim-analysis, 240 pts with completed treatment documentation of a total of 488 enrolled pts were analysed.
Results: A total of 221 pts were considered eligible for evaluation of efficacy. At start of treatment, pts had a median age of 70 years (range 22−88), 63% (n = 140) were male and 79% (n = 175) had an ECOG performance status 0−1. About 95% (n = 209) of pts underwent prior surgical intervention and 37% (n = 81) were pretreated with at least one cycle of adjuvant CTx. Pts received a median number of 3 prior CTx regimens (range: 1−12); mostly FOLFOX/FOLFIRI with or without antibody before pmab therapy was introduced. Approximately 88% of these regimens were given with palliative intent. The mean dosage by patient was 6 mg/kg (range 2.5−6.1) q2w for a median of 7 cycles, with 30% (n = 68) receiving more than 10 cycles. Overall response rate with pmab was 16% (n = 36; complete response: 1% [n = 3], partial response: 15% [n = 33]) and disease control (incl. stable disease) reached 57% (n = 125). Skin toxicities were reported in 153/240 pts (64%) with CTC grade 1: 12%; 2: 35%; 3: 14%; and unspecified: 3% mainly specified as acneiform rash. In 42/240 patients (18%) additional toxicities were reported including 11 cases of grade ⩾3 severity and only 2 pts with a grade 1 infusion reaction (<1%).
Conclusions: The therapeutic efficacy and safety profile of pmab monotherapy observed in this routine population of pts with wt *KRAS* mCRC was consistent with the data from the published randomised trials of pmab.