

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.

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POSTER

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

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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.

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POSTER

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

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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.

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POSTER

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

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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.

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POSTER

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

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