3603 POSTER

Management of unresectable metastatic colorectal cancer (MRCC) in the real world with successive regimens with targeted therapies (Bevacizumab and cetuximab): the experience of the OMIT Bretagne Pays de Loire

J.P. Metges<sup>1</sup>, E. Gamelin<sup>2</sup>, R. Faroux<sup>3</sup>, V. Klein<sup>4</sup>, G. Ganem<sup>5</sup>, J.Y. Douillard<sup>6</sup>, C. Stampfli<sup>7</sup>, S. Corbinais<sup>8</sup>, C. Riche<sup>9</sup>, F. Grude<sup>10</sup>. 

<sup>1</sup> Universitary Hospital MORVAN, Institut de Cancérologie et d'Hématologie and OMIT Bretagne Pays de Loire, Brest, France; <sup>2</sup> Centre Paul Papin, Oncology, Angers, France; <sup>3</sup> Centre Hospitalier Général, Hépatogastroentérologie, La Roche sur Yon, France; <sup>4</sup> clinique Océane, Oncologie, Vannes, France; <sup>5</sup> centre Jean Bernard, Oncologie, Le Mans, France; <sup>6</sup> Centre R Gauducheau, Oncologie, Nantes, France; <sup>7</sup> Centre Hospitalier Général, Hépatogastroenterologie, Laval, France; <sup>8</sup> Centre hospitalier, Hépatogastroenterologie, Saint Malo, France; <sup>9</sup> Universitary Hospital Brest, Pharmacology, Brest, France; <sup>10</sup> Centre Paul Papin, OMIT Bretagne Pays de Loire, Brest, France

The use of targeted therapies associated with conventional chemotherapy (Folfiri Bevacizumab and campto cetuximab) in MRCC as successive regimens is allowed in our practise until 2006 in Europe but little is known about the real benefit for the patients in "the real world". OMIT (Observatory of the Drugs and Therapeutic Innovations in Bretagne and Pays de la Loire) is a french network created since 2003 directed by Regional health agencies and a medical staff (oncologists-pharmacistspharmacologist) and representing 40 public and private cancer centers from West of France. This structure gathered prospectively data from all the 40 centers concerning targeted therapies and good clinical practice. The aim of this study is to analyze the impact of the use of two sequential regimens incorporating bevacizumab and cetuximab in the management of unresectable MRCC (FOLFIRI Bevacizumab as first line and cetuximabirinotecan as second line or more). Prospectively, each patient with these inclusion criteria are included in our database from each centers of the OMIT. This trial is still ongoing. In each case, age, sex, type of tumor, side effects, secondary resection (ie liver or lung metastasis), progression free survival, each line of treatment (type and dose), elderly patients subgroup results, overall survival and costs of each line are analyzed. Data from the 41 first consecutive patients with long follow up are presented.

Results: Median age 60.5 years (47–83) Males: 61%, colon 71%, rectum: 17%, colorectal jonction: 12%. Response rate (OR+SD) with Folfiri Bevacizumab: 53.6%. 22% of the patients underwent hepatic surgery with curative intent (all during Folfiri bevacizumab). Time to progression with Bevacizumab: 6 months. 56 percent of the patients are still alive with a median follow up of 24 months (4–35). Median overall survival was not reached. The 12 months and 24 months overall survival rates are respectively 78% and 68% (date of point: 01/01/2009). Actualisation of the data and specific analyzes concerning elderly patients will be provided during the meeting.

In conclusion, this study concerns unselectated patients from the real world (OMITdatabase) with unresectable MCRC treated with sequential regimen using targeted therapies and the strategy to use to obtain good clinical practice. It confirms the potential increase of overall survival and optimization of the management of this type of patients with the use of sequential regimen incorporating targeted therapies.

3604 POSTER

AVOID: antiemetics for chemotherapy induced nausea and vomiting (CINV): a retrospective descriptive study, describing the use of aprepitant in Belgium

S. Van Belle<sup>1</sup>, A. Awada<sup>2</sup>, M. Dicato<sup>3</sup>, N. Schrameijer<sup>4</sup>, M.P. Derde<sup>5</sup>, T. Wisniewski<sup>6</sup>, J. Vansteenkiste<sup>7</sup>. <sup>1</sup>University Hospital, Department of Medical Oncology, Ghent, Belgium; <sup>2</sup>Jules Bordet Institute, Medical Oncology Clinic, Brussels, Belgium; <sup>3</sup>Centre Hospitalier, Hematology-Oncology, Luxembourg, Luxembourg; <sup>4</sup>Merck Sharpe & Dohme, Clinical Research and Operations, Brussels, Belgium; <sup>5</sup>Veeda Clinical Research, Department of Biometrics, Brussels, Belgium; <sup>6</sup>Merck & Co. Inc., Global Outcomes Research, Whitehouse Station, USA; <sup>7</sup>Gasthuisberg University Hospital, Respiratory Oncology Unit (Pulmonology), Leuven, Belgium

**Background:** Reimbursement criteria for CINV in Belgium are aligned with international guidelines. Guidelines recommend aprepitant for highly emetogenic chemotherapy (HEC) or anthracycline-cyclophosphamide moderately emetogenic chemotherapy (AC MEC). They do not recommend use of 5HT3 antagonists (5HT3s) in the delayed phase (Days 2–6) of HEC or AC MEC, but allow for substitution in the delayed phase of non-AC MEC. Belgian health authorities required this study be performed to ensure

guideline consistent use of all antiemetic therapies during acute (Day 1) and delayed phases.

Materials: This was a retrospective study of cancer patients treated with aprepitant for CINV between 1 January – 1 December 2007 in 13 Belgian centers. Patients were included if they had malignant disease, received their first cycle of HEC or MEC in the study period, received combination antiemetic therapy including aprepitant in the study period, and received aprepitant according to label (125 mg Day 1, 80 mg Day 2/3). Data were assessed for 6 days following and up to 6 cycles of chemotherapy. Mean, median, standard deviation, and ranges were calculated for continuous variables; number and proportions for categorical variables.

Results: Among 261 patients, 68% were women (N = 178); mean age was 56 (std.11). The most common cancers were breast (48%), respiratory (18%) and digestive (12%). The most common chemotherapies were AC with fluorouracil (39%) and cisplatin based (32%). Across 6 cycles of chemotherapy, 41% of patients received aprepitant for 2 cycles, 31% for 3 cycles, 9% for 4 cycles, 3% for 5 cycles and 16% for 6 cycles. Nausea was experienced by 38% of patients; vomiting by 10%. Across all cycles, the majority of patients received 5HT3s, with most use observed on Day 1 only (64%-91%). 5HT3 use in the delayed phase decreased from 8% in cycle 1 to 0% in cycle 6. Corticosteroids were administered in the delayed phase to the majority of HEC (77%) and MEC (51%) patients in cycles 1 and 2 (77% and 51%), but use declined in subsequent cycles, with the minority of patients receiving corticosteroids for the delayed phase in MEC (13%-31%) and HEC (35%-42%).

Conclusions: Consistent with guidelines, aprepitant use coincided with use of SHT3s in the acute but not delayed phase. Use of corticosteroids was more consistent with guidelines for MEC than HEC. Future research should determine whether guideline appropriate prophylaxis is associated with better patient outcomes.

3605 POSTER

Large age and hospital dependent variation in administration of adjuvant chemotherapy for stage III colon cancer in the south of the Netherlands

<u>V.E. Lemmens</u><sup>1</sup>, L. van Steenbergen<sup>1</sup>, H.J.T. Rutten<sup>2</sup>, G.J. Creemers<sup>3</sup>, J.W.W. Coebergh<sup>1</sup>. <sup>1</sup>Comprehensive Cancer Centre South, Department of Research, Eindhoven, The Netherlands; <sup>2</sup>Catharina Hospital, Department of Surgery, Eindhoven, The Netherlands; <sup>3</sup>Catharina Hospital, Department of Internal Medicine, Eindhoven, The Netherlands

**Background:** Adjuvant chemotherapy significantly decreases mortality among patients with stage III colon cancer. The purpose of the present study was to assess factors associated with receipt of chemotherapy and their relation to survival at a population-based level.

**Materials and Methods:** All cases with primary colon cancer stage III, diagnosed between 2001 and 2007 in the area of the Eindhoven Cancer Registry were included (n = 1,637). We examined determinants of receipt of adjuvant chemotherapy and their relation to survival.

Results: The proportion of patients receiving adjuvant chemotherapy decreased with rising age from 85% in patients <65 yr to 68% in those aged 65−74 yr and 17% in patients aged ≥75 yr, with large inter-hospital variation. In a multivariable analysis, elderly patients (≥75 yr) (odds ratio (OR) 0.10 (95% confidence interval (CI) 0.07−0.13)), and those with comorbidity (OR 0.58 (95% CI 0.45−0.75)) received adjuvant chemotherapy less often. Patients with an intermediate (OR 1.41 (95% CI 1.05−1.89)) or high socio-economic status (OR 1.48 (95% CI 1.08−2.03)) or stage IIIC (any T, N2) (OR 1.49 (95% CI 1.12−1.99)) received more often adjuvant chemotherapy. Differences between hospitals remained significant after correction for patient and tumour characteristics. Adjuvant chemotherapy was the most important predictor for survival. In a multivariable analysis, older age was no longer a significant predictor for survival, in contrast with comorbidity, higher tumour stage, poor tumour grade, and female gender. Overall survival did improve significantly between 2001 and 2006.

**Conclusion:** Adherence to guidelines concerning adjuvant chemotherapy was still suboptimal in 2007, especially among elderly patients, and differs widely between hospitals.