according to body-surface area in two divided doses daily, after meals) was administered orally on days 1 to 28 of a 42-day cycle, which was repeated. The primary endpoint was progression-free survival (PFS). Secondary endpoints were time to treatment failure (TTF), response rate (RR), overall survival (OS), treatment completion status, and the incidence and severity of adverse events.
Results: From October 2007 through March 2010, a total of 56 patients were enrolled. Their median age was 75 years. The RR was 54% (95% confidence interval [CI], 40% to 67%), the median TTF was 7.6 months (95% CI, 6.1 to 9.1), and the median PRS was 9.4 months (95% CI, 7.6 to 11.0). The main Grade 3 or higher averse events were hypertension (18%), diarrhea (9%), and neutropenia (7%).
Conclusions: Our results suggest that combination therapy with S-1 and bevacizumab can be administered safely and continuously and is therapeutically effective in elderly patients with advanced or recurrent colorectal cancer.

6122 POSTER

Impact of Cetuximab-based Therapy and KRas Genotypes in Japanese Patients With Chemotherapy-refractory Metastatic Colorectal Cancer

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Background: Clinical trials have demonstrated that cetuximab improves the response rate and survival of patients with metastatic KRAS wild type colorectal cancer and this agent was approved in July 2008 in Japan. This retrospective study evaluated the treatment outcome and clinical relevance of KRAS mutational status in chemotherapy-refractory Japanese metastatic colorectal cancer patients treated with cetuximab-based therapy.
Materials and Methods: The study included 65 patients with metastatic colorectal cancer who received cetuximab-based therapy from August, 2008 to October, 2009 at the Department of Surgery and Science, Kyusyu University and related facilities. The tumours were retrospectively screened for KRAS mutations (codons 12 and 13) using direct sequencing and the association between KRAS mutations and the treatment outcome was also analyzed.
Results: Cetuximab was administered in 2nd line therapy to 4 (6.2%), in 3rd line therapy to 28 (43.1%), and in $\geqslant$ 4th line therapy to 33 patients (50.8%). Cetuximab monotherapy was administered to 11 patients (16.9%), combination therapy with CRT-11 for 39 (60.0%), and with FOLFIRI for 15 (23.1%). A partial response and stable disease was observed in 19 (29.2%) and 23 (35.4%) patients, respectively. There was no therapy-related death. Grade 3−4 neutropenia and anemia was observed in 21 (32.3%) and 9 (13.8%) patients, respectively. A skin rash was observed in 50 patients (76.9%), and among them, 3 patients (4.6%) experienced a Grade 3 of skin rash. The median progression-free survival was 3.5 months and the 6-month overall survival (OS) rate was 75.4%. An ongoing KRAS mutational analysis revealed that 23 wild type and 9 mutant tumours (codon 12 mutation: 8 cases and codon 13 mutation: 1 case) were included in the subjects. A KRAS mutation was associated with resistance to cetuximab-based treatment (0% vs. 47.8% of responders among 9 mutant and 23 wild type patients, respectively; $P < 0.05$) and a tendency to show a poorer survival (1-year OS rate: 0% vs. 60.3% in 9 mutant and 23 wild type patients, respectively; $P = 0.0764$).
Conclusions: Cetuximab-based therapy was therefore demonstrated to be effective for chemotherapy-refractory metastatic colorectal cancer patients. Appropriate management of the skin toxicity associated with cetuximab therapy is necessary to allow for both adequate drug administration and to improve the patients' quality of life. These results indicate the clinical relevance of KRAS mutations for predicting the efficacy of cetuximab-based therapy in Japanese metastatic colorectal patients.

6123 POSTER

Panitumumab in Patients With Metastatic Colorectal Cancer (mCRC) − Single Center Experience

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Background: Panitumumab (Pmab) has demonstrated to provide clinical benefits in randomized, controlled trials (RCTs) both in combination with chemotherapy (CT) or in monotherapy in patients (pts) with mCRC with wild-type (WT) KRAS. There are limited data of the efficacy and safety of pmab in clinical practice.
Material and Methods: We retrospectively analyzed all pts treated with pmab in our center from Jan07-Dec10. Demographic variables, clinical outcomes until Dec10, and adverse events were collected by reviewing pts files. Efficacy variables were analyzed only for KRAS WT pts. Overall survival (OS) was calculated from the initiation of first-line treatment for metastatic disease, and progression-free survival (PFS) from the initiation of pmab.
Results: From 2007 to 2010, 67 pts were treated with pmab: 48 pts (72%) were KRAS wild-type, 17 pts (25%) had unknown KRAS status, and 2 pts (3%) were KRAS mutant. The median age was 63 years (range 31−77); 33% women; 90% ECOG 0−1 and 10% ECOG 2. Pmab was administered as first-line treatment in 55% of cases (median 11 cycles), second-line in 34% (median 9 cycles) and third-line or later in 11% (median 3 cycles). The most common concomitant CT was FOLFOX/XELOX (64%), followed by irinotecan (27%), FOLFIRI/XELIRI (3%) and 5-fluorouracil/capecitabine (1.5%). Pmab monotherapy was used in 4.5% of the pts. Median follow-up time since pmab initiation was 10 months (m) (range 0.6−45). For pts with WT KRAS, median PFS (by Kaplan–Meier) was 12.0 m (95% confidence interval (CI) = 6.0, 18.0). In the subset of pts receiving pmab as first-line, median PFS was 15.5 m, compared to 8.5 m in pts undergoing second-line and 1.5 m in third-line or later. Overall response rate was 56.3% (27/48): Partial response 74, 56 and 0% in first, second and other lines respectively Median OS was 26.0 m (95% CI: 18.0, 34.0). 52.1% pts were alive at time of analysis. In the overall sample, grade 3/4 adverse event rates were similar to those reported in clinical trials: acne-like skin or ungueal toxicity, 11.5%; diarrhea, 11.7%; other, 21.3%. Pmab was suspended due to toxicity in 8 cases (12.3%) mostly due to toxicity associated with CT treatment.
Conclusions: Pmab showed similar efficacy results than RCTs in a non-selected cohort of WT KRAS mCRC pts. Pmab was well tolerated and observed toxicities did not exceed the rates reported in prior clinical trials.

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The Role of Bevacizumab (B) in the Maintenance Treatment After Chemotherapy (CT) for Metastatic Colorectal Cancer (mCRC) Patients (pts) − an Italian Multicenter Retrospective Analysis

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Background: Maintenance treatment with B is considered an option for mCRC pts in responding pts after a first line CT + B, but few data are available on its real benefit on progression-free survival (PFS).
Methods: Data were obtained by reviewing the clinical chart of pts treated in any single institution from 2005 to 2010. Two-hundred-twenty mCRC pts treated with first line CT + B achieving a response [partial (PR) or complete (CR)] or a stable disease (SD) were considered eligible. 118 pts had received B maintenance (BM) whereas 102 did not (noBM). The two groups were homogeneous for main characteristics. First-line therapy in the BM vs noBM group included FOLFIRI regimen (96 vs 73 pts), FOLFOX (18 vs 28 pts) and FUFA (4 vs 1 pts). The median age of pts was 62 ys (range 34−80) for BM and 65 ys (range 32−82) for noBM. K-ras status was analyzed in 115 pts with an higher percentage of wild-type (wt) in the BM group (65 vs 50 pts, $p = 0.04$). A CR or PR have been achieved in 56% of pts in the BM group and 49% of noBM group, while a SD was observed in 34% and 31% of pts respectively for the BM and noBM group. The median number of BM cycles administered was 7 (range 3−25). PFS analysis of was conducted on the entire population comparing BM and noBM and by response to prior CT+B (PR and CR versus SD).
Results: At a median follow-up of 18 months (1–109), the median PFS was 13 months (C.I.95%: 11−15) vs 8 months (C.I.95%: 7−10) $p < 0.0001$, and the 1-year PFS 53.% vs 28% for BM and noBM respectively. According to the response, pts with CR/PR had a mPFS of 15 months (CI 95% 12−19) vs 10 months (CI 95% 10−12) $p = 0.004$, and a 1-year PFS of 62.6% and 33.7% for the BM vs noBM group respectively. No difference in PFS was found in pts showing SD after first-line CT + B: the 1 year-PFS was 37.1% in the BM group and 37.3% in the noBM group, the mPFS was respectively 12 mo (CI 95% 10−13) and 8 mo (CI 95% 7−10) ($p = 0.11$). Furthermore, no difference was observed in PFS comparing, in the BM group alone, CR/PR vs SD nor when the k-ras status was considered.
Conclusion: In our retrospective analysis the maintenance strategy with B shows a longer PFS in pts responding to the first line chemotherapy + B whereas for pts who achieving an SD no difference was observed. Results from ongoing randomized phase III studies addressed to explore the issue of maintenance treatment are needed.