is the initial report of the impact of HTN development and treatment in a population-based observational study that had no prespecified patient characteristics for study participation. Thus, the findings are more reflective of the outcomes associated with general use of BV.
Methods: Population and methods have been described previously (Kozloff, ASCO 2006; A3537). Data on HTN requiring medication and specific classes of anti-HTN medications were collected at baseline and on a quarterly basis. Blood pressure readings were not collected. HTN was defined as requirement for anti-HTN medications. "Increased HTN" was defined as any anti-HTN medication dose increase or addition.
Results: Of 1953 evaluable patients, 827 (42.3%) patients had HTN at baseline; 155 (18.7%) patients developed increased HTN over the treatment course. Frequency of increased HTN was dependent on intensity of baseline anti-HTN; the rate was lowest in patients with ⩾3 anti-HTN classes of medications at baseline. A total of 1126 patients were without HTN at baseline; 207 (18.4%) developed HTN; 48.3% of these de novo HTN patients required modification of anti-HTN medications due to increased or uncontrolled HTN. Use of specific classes of anti-HTN medications was similar for patients with or without baseline HTN. The majority of patients had only 1 modification of anti-HTN medications over the treatment course regardless of the presence of baseline HTN. There have been only 8 patients with a BV-related HTN SAE.
Conclusions: In BRiTE, a large BV treatment registry, there was no difference in the percentage of patients requiring treatment of BV-associated HTN based on the presence of HTN at baseline. These findings suggest that HTN at baseline does not increase the risk of developing increased HTN associated with BV use. Furthermore, the rate of HTN observed in BRiTE is comparable to rates seen in controlled BV trials suggesting that use of BV in the general patient population continues to be well tolerated.

3050 POSTER

A prospective analysis of the incidence of local recurrence in relation to the macroscopic and microscopic distal bowel margin in patients with rectal cancer receiving preoperative radiotherapy

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Background: The primary end-point of our randomized trial was sphincter preservation. The secondary aim was to find out whether short distal bowel margin (⩽1 cm) is associated with a greater risk of local recurrence as compared to a longer margin.
Material and Methods: The study randomised 312 patients with cT3−4 resectable low-lying and mid rectal cancer to receive either preoperative irradiation (25 Gy in 5 fraction of 5 Gy) with total mesorectal excision (TME) within 7 days or chemoradiation (50.4 Gy in 28 fractions of 1.8 Gy, bolus 5-fluorouracil and leucovorin) and TME 4−6 weeks later. In patients after sphincter-preserving surgery pathologists prospectively measured macroscopic and microscopic distal bowel margins. Macroscopic margin was defined as the distance between distal edge of the macroscopic tumour or scar tissue (in case of clinical complete response) and resection bowel margin. Microscopic margin was defined as the distance between the most distally located cancer cells in a bowel wall or distal edge of the mucosal ulceration (in case of pathological complete response) and resection bowel margin.
Results: The sphincter preservation, macroscopic and microscopic distal bowel margin, local control, disease-free survival and overall survival did not differ in the both randomized groups. The pooled analysis of the both randomised groups showed that the cumulative incidence of local recurrence at 4 years (median follow-up) for patients with macroscopic margin ⩽1 cm (N = 42) and >1 cm (N = 121) was 11.3 and 15.8%, respectively, p = 0.48, hazard ratio (HR) 0.68, 95% confidence interval (CI) 0.23−2.01. The corresponding values for patients with microscopic margin ⩽1 cm (N = 44) and >1 cm (N = 96) were 11.1% and 18.6%, p = 0.28, HR 0.55, 95% CI 0.19−1.66.
Conclusions: For patients receiving preoperative radiotherapy the risk of local recurrence did not increase in those with macroscopic or microscopic bowel margin ⩽1 cm as compared to those with longer margin.

3051 POSTER

Phase II trial of sequential chemotherapy with capecitabine and irinotecan followed by capecitabine and oxaliplatin in elderly vulnerable patients (pts) with metastatic colorectal cancer (MCRC)

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Background: The overall survival of MCRC pts is correlated with the rate of pts who received all the 3 active cytotoxics (fluoropyrimidine, oxaliplatin and irinotecan) in the course of their disease. Elderly vulnerable pts are frequently excluded from clinical trials and are often treated suboptimally in the clinical practice. Clinical trials to validate in this setting the results obtained in the younger population are needed.
Patients and Methods: We enrolled in this phase II trial MCRC pts aged 75−85 years, or pts 70−75 years old but with ECOG PS 1 or 2, previously untreated with chemotherapy (CT) for advanced disease, with measurable and not resectable disease. To exclude frail pts, a comprehensive geriatric assessment (CGA) was performed baseline. Pts received irinotecan 180 mg/sqm day (d) 1 plus capecitabine 1500 mg/sqm/d d1−14 repeated every 3 weeks (ELD-XELIRI) up to 9 cycles. After progression or treatment interruption because of toxicity, pts received oxaliplatin 100 mg/sqm d1 plus capecitabine 1500 mg/sqm/d d1−14 repeated every 3 weeks (ELD-XELOX) up to 9 cycles. After a planned interim analysis, irinotecan dose was reduced to 150 mg/sqm because of an excessive incidence of diarrhea.
Results: Up today 30 pts have been enrolled and 24 pts (80%) have received both regimens. Baseline patients' characteristics are: median age 76 years (70−82), ECOG PS 1 83%, multiple sites of disease 53%, previous adjuvant CT 7%. A median of 9 cycles of first-line ELD-XELIRI per pts have been administered. Grade 3−4 observed toxicities were: diarrhea 37%, vomiting 3% and neutropenia 7%. Objective responses and stable disease were respectively 27% and 50% and median PFS was 7.3 months (mos). A median of 5 cycles of second-line ELD-XELOX per pts have been administered and the only grade 3−4 toxicity observed was diarrhea (8%). Objective responses and stable disease were respectively 10% and 52% and median PFS was 4.9 mos. After a median follow up of 31.0 mos the median time to second progression (primary objective) was 11.8 mos and the median survival was 19.3 mos.
Conclusions: These data indicate that the CGA is a useful instrument to evaluate elderly pts and to select them for treatment. The sequential treatment with ELD-XELIRI followed by ELD-XELOX is feasible in elderly vulnerable MCRC pts and it produces results comparable to those obtained in the younger population. (Partially supported by Fondazione ARCO)

3052 POSTER

Impact of diabetes mellitus on the development and outcomes of colorectal cancer

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Background: Diabetes mellitus (DM) is reported to be a risk factor for colorectal cancer (CRC), and to adversely influence the tumour specific outcomes. Previous studies however have had limited detail regarding CRC pathology and staging, and the potential impact of the frequently associated obesity.
Methods: Via the MMIM comprehensive CRC database, patients with CRC were identified and the impact of DM was examined.
Results: 1116 patients with CRC were identified, 327 (29%) of whom were diabetic. Diabetics patients were significantly older at diagnosis (median age 67 vs 70 years, p = 0.002), more likely to be male (61% vs 54%, p = 0.004) and more overweight than those without diabetes (median Body Mass Index 28 vs 26, p < 0.001). Analysis of pathology revealed more poorly differentiated tumours in the diabetic patients (34% vs 19%, p < 0.001), but no difference in frequency of mucinous tumours or lymphovascular invasion. The observed difference in tumour differentiation was independent of BMI.
There was no statistically significant difference in stage at presentation, or tumour location between the two groups. Examination of survival data revealed a significantly lower 5 year overall survival rate for diabetics. Stage specific survival for diabetics with stage I and III CRC was significantly lower than non-diabetics. This difference was not significant in stage II and IV disease.
Conclusion: Our data implies diabetes is a strong risk factor for the development of CRC, as the incidence of diabetes in our patient population would be expected to be less than 10%. We report the novel finding of significant differences in pathology between diabetic and non-diabetic patients.