4016 POSTER

Predicting the Risk of Cardiovascular Comorbidity in Cancer Survivors

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Background: Preventable conditions, such as heart disease and diabetes mellitus, represent a major threat to the life of many cancer survivors (CS). However, there are limited data on how to identify CS at the greatest risk who may benefit most from prevention. Our goals were to: 1) characterize the clinical factors associated with ischemic heart disease (IHD) and congestive heart failure (CHF) among CS; and 2) develop a stratification schema for predicting the risk of cardiovascular comorbidity in CS.
Methods: CS and non-cancer controls (NCC) were identified from the U.S. National Health and Nutrition Examination Survey. Multivariate logistic regression models were constructed to determine independent clinical factors associated with an increased relative risk (RR) for cardiovascular comorbid conditions. Based on a composite scoring system that assigned 1 point for each risk factor identified, a cardiovascular risk stratification schema was devised that correlated the risk score with the prevalence of cardiovascular comorbidity in CS.
Results: A total of 2,734 CS and 23,832 NCC were included: mean age was 45.0 years (SD 17.4), 48.1% were male, and 88.6% were White in the entire cohort. Baseline characteristics were similar between CS and NCC. When compared to NCC, CS were significantly more likely to report IHD (8.5 vs. 2.9%, $p < 0.01$), CHF (7.1 vs. 2.0%, $p < 0.01$), or both (3.2% vs. 0.67%, $p < 0.01$). Based on multivariate analyses, risk factors for cardiovascular problems included: age $\geqslant$ 60 (RR 6.4, 95% CI 5.3−7.7); male gender (RR 1.8, 95% CI 1.6−2.1); racial minorities (RR 1.7, 95% CI 1.4−2.1); those who were separated or widowed (RR 2.4, 95% CI 1.8−3.4); less than high school education (RR 1.5, 95% CI 1.3−1.8); and an annual income less than $20,000 USD (RR 1.9, 95% CI 1.6−2.3). A cardiovascular risk stratification schema for IHD and CHF in CS was developed (please see Table).
Conclusions: Independent risk factors for IHD and CHF in CS were identified. A risk stratification schema may be helpful in developing a risk-based approach to cardiovascular preventive strategies for CS.

Table: Prevalence of cardiovascular comorbidity (IHD, CHF, or both) based on risk score

Comorbidity	Score			
	$\leqslant$ 2	3	4	5+
IHD	0.8%	6.4%	13.6%	19.5%
CHF	0.4%	6.2%	10.6%	16.7%
IHD and CHF	0.2%	2.2%	3.2%	9.1%

4017 POSTER

Treatment of Elderly Patients With Oxaliplatin − Frequency and Severity of Adverse Drug Events and Quality of Life

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Background: Although colorectal cancer (CRC) occurs most frequently in patients >65 y, elderly patients are underrepresented in clinical trials. This lack of study data causes uncertainty about the optimal cancer treatment in this population.
Material and Methods: Data were collected in the outpatient ward for cytotoxic drug administration of a secondary care clinic between 11/2009 and 04/2011. CRC patients at the beginning of an oxaliplatin-based chemotherapy (CTx) were included. Patients >65 y underwent geriatric assessment (ADL, IADL, MMSE, TU&G, MNA) before the 1st and the 12th course. Blood count and serum creatinine were obtained for all patients before every course, as well as their retrospective perception of selected symptomatic adverse drug events (ADE: nausea, vomiting, diarrhea, mucositis, alopecia, fever, infection, allergic reaction, neurotoxicity). The data were classified according to the NCI CTCAEv3.0. Also, all patients answered the EORTC QLQ-C30 before the first and every third courses of CTx.
Results: 18 patients (12 male, 6 female) were included and followed for a total of 207 courses. Four patients were <65 y (median: 58.7, range 45.0- 64.3), 14 patients >65 y (median: 73.4, range 70.3–81.5). 15 patients were treated with FolFOx 4, 14 of which completed all 12 courses. One female patient (73.3 y) discontinued CTx after 6 courses due to intolerable adverse events. Of 3 patients receiving FuFOx, all discontinued after a time, for different reasons (82yo female patient: insult after a cumulative oxaliplatin dose of 75 mg/m^2; 75yo male: neurotoxicity, 820 mg/m^2; 78yo female: allergic reaction, 740 mg/m^2). Interestingly, dose density was higher in older patients: 86.5% of the scheduled dose, vs. 77.3% in patients <65 y. Although patients >65 y were more prone to leucopenia, fever and infections occurred in both groups to the same extent. Nephro- and neurotoxicity as well as nausea and vomiting were slightly more pronounced in patients <65 y, whereas diarrhea, alopecia and thrombopenia occurred to a greater extent in patients >65 y. Both groups showed the same extent of anemia, mucositis and allergic reactions.
Quality of life (QoL) did not change significantly in either group during CTx. By trend, patients >65 y had a higher QoL than patients <65 y.
Conclusions: Oxaliplatin-based CTx is reasonably tolerable in elderly patients and does not impair quality of life. The spectrum of ADE seems to be slightly different in younger vs. elderly patients.

4018 POSTER

Metastatic Renal Cell Cancer Treated With Sunitinib − Toxicity and Efficacy in the Elderly

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Background: Renal cancer accounts for 3% of adult malignancies with the highest rates observed in persons over 65 years-old. Metastatic renal cell cancer (mRCC) has a poor prognosis with 5-year survival rates <20%. Sunitinib is effective in the first-line treatment of mRCC. Our purpose was to assess the toxicity and efficacy of Sunitinib in elderly mRCC patients.
Material and Methods: Retrospective cohort study of sunitinib treated patients in a single Portuguese cancer center. Elderly patients were defined as those aged $\geqslant$ 65 years (group A). Efficacy and toxicity patterns of elderly patients were compared with those of younger patients (group B) treated in the same time period.
Results: Between 2007 and 2010, 71 patients were treated with Sunitinib, of which, 53 mRCC patients in first line setting for previous treatments. Median age was 66 years, with 29 patients (55%) aged $\geqslant$ 65. Groups A and B were comparable in terms of gender distribution, histology and proportion of prior nephrectomy. MSKCC risk scores was available in 37 patients (group A, n = 19). Patients distribution according to MSKCC risk scores was significantly different ($p = 0.015$). Group A tended to be more commonly in the intermediate risk group, and patients of group B tended to be more favorable or high risk patients. Median overall survival (OS) was 19 months (IC95% 15−23). Survival estimated stratified by MSKCC risk group was similar in both groups. OS according to MSKCC risk scores prognostic group for elderly patients were: favorable risk group OS 35 months; intermediate risk group OS 17 months; high risk group OS was 0.5 months. Number of treatments cycles were higher in younger patients (4 treatments vs. 8 treatments, $p = 0.008$). The toxicity profile was similar between groups (adverse events rate 89 vs 87%, $p = 0.585$), but elderly patients had a trend toward more treatment interruptions and delays.
Conclusions: Elderly patients with mRCC benefit from first line treatment with Sunitinib. However, they seem to be more prone to toxic events. This may be due to a higher prevalence of co-morbidities and impaired drug metabolism. Special attention is needed in patients at a high risk according to MSKCC prognostic score. A more tailored approach to the management of elderly mRCC patients is warranted.

4019 POSTER

Aromatase Inhibitors as Neoadjuvant Treatment in Elderly Patients (>70 Years) With Locally Advanced Breast Cancer: a Monoinstitutional Experience

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Background: There are scarce data on activity and tolerability of neoadjuvant treatment with aromatase inhibitors in elderly patients (pts) with locally advanced breast cancer (BC). In particular, data on surgery rate and correlation with Multidimensional Geriatric Assessment (MGA) are lacking.
Methods: Medical records of elderly ($\geqslant$70 years) pts with locally advanced BC (cT> = 2 and/or cN+) treated at our Institution in the years 2003–2010 were reviewed and data on age, stage, MGA classification, comorbidities, treatment, objective (clinical or radiological) response, adverse events, survival were collected. Statistical analysis was performed using Kaplan–Meier method and log-rank test.

Results: Sixty pts were eligible (median age 82 years, range 71−95); pts' characteristics are outlined in Table I. MGA was done in 42 pts. More than half pts were evaluated as frail. After 6 months of treatment, 53 pts (88.3%) had either clinical or radiological objective response. After a median treatment time of 16.2 months, surgery was performed in 5 pts; surgery was not done either because not proposed (31 pts), or refused (13 pts) or not indicated by surgeon (11 pts). Adverse events were reported in 36 pts: arthralgias (*43.3%*), gastrointestinal side effects (*11.7%*), hot flashes, memory disorders and headaches (*6.7%*). At median follow-up of 35.1 months, 48 pts (80%) are alive and 10 pts (16.7%) have relapsed. OS and PFS at 3 years were 80.7% and 89.8%, respectively, with median time to first progression of 5.9 years. No statistical difference was observed for PFS between fit and unfit pts and between pts with grade 3−4 comorbidity vs pts with none, whereas a trend towards worse PFS was observed for pts who had side effects vs those who had not. OS was worse for frail vs fit pts ($p = 0.07$), and was significantly worse for Her2-positive vs Her2-negative pts ($p = 0.05$); a trend for poorer survival was observed for pts with grade 3−4 comorbidity, whereas no difference was seen for pts who had side effects vs those who had not.

Conclusion: Most of the pts who were started on neoadjuvant endocrine treatment did not undergo further surgery. Local relapse was observed in about 10% of pts; worse PFS for pts who had side effects could be influenced by higher discontinuation rate. Median OS has not been reached, despite surgery was omitted in most of the pts. For frail pts, definitive endocrine treatment is an alternative option to surgery.

Table I: Pts' characteristics

		N (%)
Tumour size	cT2	24 *(40.0)*
	cT3	7 *(11.7)*
	cT4	29 *(48.3)*
Lymphnodes	Positive	23 *(38.3)*
	Negative	10 *(16.7)*
	Unknown	27 *(45.0)*
Hormone receptors	Positive	56 *(89.0)*
	Unknown	7 *(11.0)*
Ki67	<5%	8 *(13.3)*
	5−20%	28 *(46.7)*
	>20%	16 *(26.7)*
	Unknown	8 *(13.3)*
Her2 status	Positive	5 *(8.3)*
	Negative	35 *(58.3)*
	Unknown	20 *(33.4)*
Grade	G1−2	25 *(40.6)*
	G3	9 *(15.0)*
	Unknown	26 *(43.3)*
MGA	Fit	11*(18.3)*
	Vulnerable	15 *(25.0)*
	Frail	34 *(56.7)*
ADL	Independent	16 *(26.7)*
	Dependent	26 *(43.3)*
	Unknown	18 *(30.0)*
IADL	Independent	29 *(48.3)*
	Dependent	13 *(21.7)*
	Unknown	18 *(30.0)*
Comorbidity	G3-G4	26 *(43.3)*
	All grade	60 *(100)*
Treatment type	Exemestane	26 *(43.3)*
	Letrozole	26 *(43.3)*
	Anastrozole	8 *(13.4)*

*Activities of Daily Living; **Instrumental Activities of Daily Living.

4020 POSTER

Efficacy and Toxicity of Adjuvant FOLFOX Chemotherapy in Elderly Patients With Stage III Colon Cancer − Single Center Study

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Background: Elderly patients derive similar benefit from 5-FU based adjuvant chemotherapy in stage III colon cancer. However, conflicting data exist regarding additional benefit from Oxaliplatin, fluorouracil, and leucovorin (FOLFOX) chemotherapy in elderly patients and there are scarce data on the efficacy of adjuvant chemotherapy in elderly population in Asian countries.

Methods: Single center, retrospective analysis was performed to compare the safety and efficacy of adjuvant FOLFOX-4 chemotherapy, in elderly (⩾ 65 yrs) vs younger patients with stage III colon cancer after R0 surgical resection. Endpoints included grade 3, 4 toxicities, 3 year disease free survival rate and dose intensities.

Results: Using prospectively maintained cancer registry, 1221 patients were identified to have received surgery for colon cancer from May 2003 − March 2010 in Seoul National University Bundang Hospital (stage I: 213, stage II: 371, stage III: 391, stage IV: 246). Out of 391 patients with stage III colon cancer, more patients in the elderly group were treated with capecitabine (34.5% vs 7.7%) or received no adjuvant chemotherapy (14.7% vs 6.6%). Total of 229 patients received adjuvant FOLFOX chemotherapy and were included in the analysis; 87 (62%) ⩾ 65 yrs vs 142 (75%) <65 yrs. The median number of cycles of chemotherapy received was 11.0 (⩾ 65 yrs) vs 11.5 (<65 yrs, $P = 0.57$), and percentage of patients who received the planned 12 cycles were 81.6% (⩾ 65 yrs) vs 89.4% (<65 yrs). Elderly patients had similar clinical and pathologic characteristics as younger patients in terms of T and N stage, histologic types, MSI status, ECOG PS and BMI, but more patients had Charlson's co-morbidity score of >2 (41.4% vs 16.2%, $p < 0.05$) in the elderly. Estimated 3 yr DFS rate was 74.9% vs 74.8% ($p = 0.713$), and 3 yr OS rate was 93.7% vs 93.9% ($p = 0.868$) in the ⩾65 vs <65 years age group. There were no significant differences in the occurrence of grade 3−4 anemia, thrombocytopenia, nausea, vomiting, diarrhea and neuropathy. Grade 3−4 neutropenia was the only toxicity that showed higher frequency in the elderly (62.1% vs 46.5%, $p = 0.022$). Elderly patients received less relative dose intensity of oxaliplatin (0.757 vs 0.788) and 5-FU (0.746 vs 0.795).

Conclusions: Elderly patients showed similar efficacy without significant increase in toxicity from adjuvant FOLFOX chemotherapy in curatively resected stage III colon cancer in Korean patients.

	Elderly patients (N = 87)	Young patients (N = 142)	P-value
Neuropathy (>Gr2)	25 (28.7%)	28 (19.7%)	0.116
Neutropenia (Gr3−4)	54 (62.1%)	66 (46.5%)	0.022
Emesis (Gr3−4)	1 (1.1%)	0	0.163
Diarrhea (Gr3−4)	6 (6.9%)	6 (4.2%)	0.379
Infection	5 (5.7%)	4 (2.8%)	0.269
Hospitalization	1 (1.1%)	1 (0.7%)	0.729

4021 POSTER

Dacarbazine as First Line Treatment of Metastatic Melanoma in Elderly Patients

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Background: Incidence and mortality of melanoma is increasing worldwide. As population ages, more elderly patients are diagnosed with melanoma. Dacarbazine (DTIC) is used as 1st line agent with response rates of 10−20% and median overall survival of 6 months. Older patients are generally underrepresented in cancer clinical trials. Our purpose was to assess the comparative effectiveness of dacarbazine as 1st line treatment of metastatic melanoma in elderly versus younger pts.

Materials and Methods: Retrospective cohort study, in a Portuguese cancer centre, of metastatic melanoma patients treated with DTIC as 1st line systemic treatment. A cutoff of ⩾ 65 years was used to define elderly patients. Toxicity was evaluated using common terminology criteria for adverse events (CTCAE), version 3, and efficacy through Kaplan–Meier's method. Differences in demographics, baseline status, treatment delivery and toxicity between age groups were compared with parametric and non-parametric tests as appropriate. Log rank test was used to compare efficacy across groups.

Results: Between 2005 and 2009, 109 metastatic melanoma patients were treated with DTIC. Median age was 58 years (39% ⩾65; 18% ⩾70). Baseline characteristics of the two age groups were comparable in gender, ECOG status and pattern of metastases. DTIC median relative dose intensity was 99% and median number of DTIC cycles was 4, similar in both age groups. Toxicity profile of DTIC was similar between groups: global severe adverse event (SAE) rate was 19%; most common SAEs were myelosuppression (17%) and asthenia (2%). Two deaths occurred on treatment due to undetermined causes, both in patients <65 years. Main reason for treatment discontinuation was disease progression (68%).