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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 <i>(16.7)</i>
	Unknown	27 (45.0)
Hormone receptors	Positive	56 <i>(89.0)</i>
	Unknown	7 (11.0)
Ki67	<5%	8 (13.3)
	5-20%	28 (46.7)
	>20%	16 <i>(26.7)</i>
	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 <i>(25.0)</i>
	Frail	34 (56.7)
ADL	Independent	16 (26.7)
	Dependent	26 (43.3)
	Unknown	18 <i>(30.0)</i>
IADL	Independent	29 (48.3)
	Dependent	13 (21.7)
	Unknown	18 <i>(30.0)</i>
Comorbidity	G3-G4	26 (43.3)
	All grade	60 (100)
Treatment type	Exemestane	26 (43.3)
	Letrozole	26 (43.3)
	Anastrozole	8 (13.4)

<sup>\*</sup>Activities of Daily Living; \*\*Instrumental Activities of Daily Living.

4020 POSTER

Ffficacy and Toxicity of Adjuvant FOLEOV Chamatherapy in Eldarly

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%)  $\geqslant$  65 yrs vs 142 (75%) <65 yrs. The median number of cycles of chemotherapy received was 11.0 ( $\geqslant$  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 1<sup>st</sup> 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%).