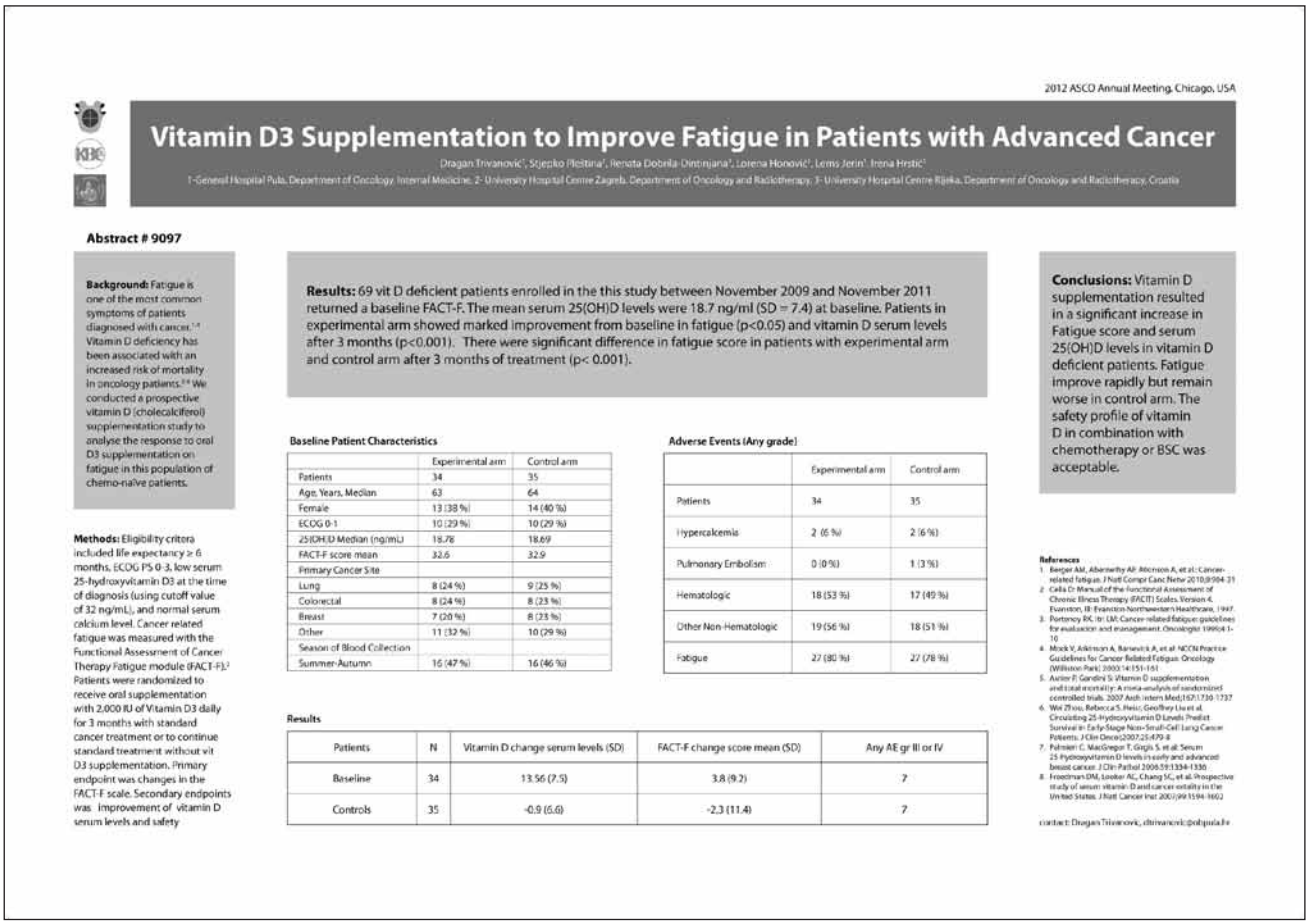

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Vitamin D3 Supplementation to Improve Fatigue in Patients with Advanced Cancer

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Abstract # 9097

Background: Fatigue is one of the most common symptoms of patients diagnosed with cancer.[1-4] Vitamin D deficiency has been associated with an increased risk of mortality in oncology patients.[5-6] We conducted a prospective vitamin D (cholecalciferol) supplementation study to analyse the response to oral D3 supplementation on fatigue in this population of chemo-naïve patients.

Methods: Eligibility critera included life expectancy > 6 months, ECOG PS 0-3, low serum 25-hydroxyvitamin D3 at the time of diagnosis (using cutoff value of 32 ng/mL), and normal serum calcium level. Cancer related fatigue was measured with the Functional Assessment of Cancer Therapy Fatigue module (FACT-F).[7] Patients were randomized to receive oral supplementation with 2,000 IU of Vitamin D3 daily for 3 months with standard cancer treatment or to continue standard treatment without vit D3 supplementation. Primary endpoint was changes in the FACT-F scale. Secondary endpoints was improvement of vitamin D serum levels and safety

Results: 69 vit D deficient patients enrolled in the this study between November 2009 and November 2011 returned a baseline FACT-F. The mean serum 25(OH)D levels were 18.7 ng/ml (SD = 7.4) at baseline. Patients in experimental arm showed marked improvement from baseline in fatigue ($p<0.05$) and vitamin D serum levels after 3 months ($p<0.001$). There were significant difference in fatigue score in patients with experimental arm and control arm after 3 months of treatment ($p< 0.001$).

Conclusions: Vitamin D supplementation resulted in a significant increase in Fatigue score and serum 25(OH)D levels in vitamin D deficient patients. Fatigue improve rapidly but remain worse in control arm. The safety profile of vitamin D in combination with chemotherapy or BSC was acceptable.

Baseline Patient Characteristics

	Experimental arm	Control arm
Patients	34	35
Age, Years, Median	63	64
Female	13 (38 %)	14 (40 %)
ECOG 0-1	10 (29 %)	10 (29 %)
25(OH)D Median (ng/mL)	18.78	18.69
FACT-F score mean	32.6	32.9
Primary Cancer Site		
Lung	8 (24 %)	9 (25 %)
Colorectal	8 (24 %)	8 (23 %)
Breast	7 (20 %)	8 (23 %)
Other	11 (32 %)	10 (29 %)
Season of Blood Collection		
Summer-Autumn	16 (47 %)	16 (46 %)

Adverse Events (Any grade)

	Experimental arm	Control arm
Patients	34	35
Hypercalcemia	2 (6 %)	2 (6 %)
Pulmonary Embolism	0 (0 %)	1 (3 %)
Hematologic	18 (53 %)	17 (49 %)
Other Non-Hematologic	19 (56 %)	18 (51 %)
Fatigue	27 (80 %)	27 (78 %)

Results

Patients	N	Vitamin D change serum levels (SD)	FACT-F change score mean (SD)	Any AE gr III or IV
Baseline	34	13.56 (7.5)	3.8 (9.2)	7
Controls	35	-0.9 (6.6)	-2.3 (11.4)	7

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