9145 POSTER

The Effect of an Oral Nutritional Supplement With Eicosapentaenoic Acid on Body Composition, Energy Intake, Quality of Life and Survival in Advanced Non-small Cell Lung Cancer

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Background: Patients with non-small cell lung cancer (NSCLC) often lose weight. Malnutrition is associated with increased morbidity and diminished in quality of life. Eicosapentaenoic acid (EPA) is of interest in cancer patients as it has potential to impact on the inflammatory response and reduce catabolism. The aim of this study was to evaluate the impact of EPA supplement on body composition, quality of life and survival in advanced NSCLC patients.
Methods: NSCLC Patients naïve to treatment were evaluated and randomly assigned to receive 2 cans of supplement (2g of EPA daily) or isocaloric diet during 2 patlin/taxane chemotherapy. Subjective global assessment (SGA), anthropometric parameters, dietary quantitative parameters, segmental bioelectrical impedance analysis (BIA), biochemical (albumin, hematologic count) and EORTC QLQ-C30 quality of life questionnaire were performed. Study was approved by clinical trials.
Results: Ninety two patients were included (46 EPA, 46 standard groups). No basal differences between groups were found at baseline. Experimental group present increased albumin levels, and inflammatory parameters significant reduced; increased in energy, protein, lipids and carbohydrate intake after chemotherapy; patients in experimental group presented minor prevalence of weight loss and increased 1.6 kg of lean body mass compared with controls. In quality of life, experimental group presented an improvement in global and physical scale ($p = 0.06$ both) less fatigue, anorexia and neuropathy. There was no significant difference in overall survival between groups.
Conclusion: Intention to treat group comparisons indicated that enrichment with EPA supplement provide a therapeutic advantage in improving appetite and body composition, increasing lean body mass; and showing quality of life benefits in NSCLC patients under chemotherapy treatment.

		Control	Experimental	p
Weight (kg)	T0	65.0±13.6	601±11.5	0.05
	T2	63.1±14.4 *	59.5±11.8	
BMI	T0	25.5±4.2	24.0±3.8	0.06
	T2	24.6±4.2 *	23.7±4.1	
% weight loss	T0	6.7±10	8.7±8.5	0.238
	T2	9.3±118 *	9.9±8.6	
% LBM	T0	65.1±10.6	60.2±12.6	0.04
	T2	64.8±8.2	61.8±10.8	
Albumin (mg/dl)	T0	3.4±0.51	3.2±0.51	0.06
	T2	3.3±061	3.8±0.47	
Kcal (g/day)	T0	1937.2±991.8	1552.6±640.2	<0.001
	T2	1533.6±640.9 *	2186.0±707.0 *	
Protein (g/day)	T0	68.3±33.2	57.9±25.3	<0.001
	T2	54.0±26.4 *	85.5±23.5*	
Lipids (g/day)	T0	63.4±33.7	56.7±30.8	0.002
	T2	48.9±23.8 *	72.2±32.2 *	
Carbohydrates (g/day)	T0	286.0±167.9	201.7±82.2	<0.001
	T2	226.1±101.6 *	301.6±120.7 *	
Fatigue	T0	34.4±19.3	42.7±25.0	0.037
	T2	31.5±17.3	34.2±24.8 *	
Anorexia	T0	31.9±31.0	41.5±34.1	0.05
	T2	29.0±27.9	34±40.1 *	
Neuropathy	T0	11.7±22.3	19.4±28.4	0.05
	T2	31.8±30.5 *	22.3±25.4	

T0 = basal; T2 = after second cycle of chemotherapy.
*$p \leqslant 0.05$ between T0 and T2.

9146 POSTER

Sarcomatoid Malignant Pleural Mesothelioma − a Series of 44 Cases Treated at a Single Oncological Department

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Background: Sarcomatoid malignant pleural mesotheliomas (SMPM), accounting for roughly 10% of pleural malignant mesotheliomas, have a poor prognosis and are particularly resistant to conventional chemotherapy with median survival in the range of 6 months. Here we report on clinical outcome of a series of SMPM patients treated at a single Oncological Department.
Patients and Methods: We selected 44 SMPM patients (11 females, 33 males) in our MesoDB including 569 cases diagnosed between 1993 and December 2010 at Alessandria and Casale Monferrato Hospitals. Diagnosis was always confirmed by the same expert pathologist. We reviewed the clinical records focusing on treatments, response to chemotherapy (CT) and outcomes.
Results: Median age at diagnosis was 67 years, range (44−77). Forty-two patients received a first line CT and regimens adopted were as follows: platinum derivatives and pemetrexed in 26, pemetrexed in 6, platinum derivatives and raltitrexed in 3, others regimens (platinum and gemcitabine, anthracycline-based and ifosfamide-based) in 9 cases. Only 1 patient, having received platinum and gemcitabine, had a partial response, 10 patients had stable disease, 26 patients had progressive disease and 7 patients were not evaluable for response. Thirty-three patients received only one CT line, 9 patients 2 CT lines and 2 patients 3 CT lines. Six patients underwent palliative pleurectomy and 6 palliative radiotherapy. Median PFS was 7.5 months (IQR 3.9−8.8) and median overall survival 8.5 months (IQR 5–13.6).
Conclusions: SMPM accounts for 8% of patients in our series, in line with the literature. With the clear limitation of the small number, intriguingly 25% occurred in women: this proportion is higher than that previously reported and an effort to retrieve more detailed information on asbestos exposure is currently ongoing. To our knowledge this is the largest series of SMPM analyzed for treatments outcome. The results confirms that standard CT has a negligible impact on the prognosis. SMPM patients should be ideally treated within phase I-II studies with investigational agents. There is an highly unmet clinical need in this setting and new drugs with novel mode of action are eagerly awaited.

9147 POSTER

Treatment and Clinical Outcomes of Young Patients ($\leqslant$40 Years) With Advanced Non-small Cell Lung (NSCLC) − Data From a Retrospective Multicentric Database

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Background: NSCLC diagnosed in young patients (pts) is usually considered as a disease with a better prognosis compared to NSCLC in older pts. In the last decade, the introduction of both third generation chemotherapeutic agents and targeted therapies in the treatment of IIIB/IV stage NSCLC led to a clinical outcomes improvement, with a median survival (MS) of 12−14 months. Some studies have reported small series of young pts with NSCLC but the age cut-offs varied among studies and most of them did not specifically address the clinical outcomes of the IIIB/IV stage pts. The present report specifically addresses the treatment and the clinical outcomes of pts $\leqslant$ 40 years with IIIB/IV stage NSCLC treated after 2000 in our institutions.
Materials and Methods: We reviewed all pts referred for NSCLC from 2000 to 2010 to our Institutions and have selected a consecutive series of 100 pts $\leqslant$ 40 years older. Eleven pts with early stages were excluded and 89 with IIIB/IV NSCLC entered this study. Pts characteristics: male/female 55%/45%; median age 36 years (range 21−40); stage IIIB/IV 8%/92%; histological type: adenocarcinoma 71%, squamous 9%, other 20%. Metastatic sites of these pts were lung in 52%, liver in 15%, lymph

nodes in 43%, brain in 25%, bone in 28%, pleural in 21%, and adrenal in 8%.
Results: All but 4 pts received systemic treatment for their IIIB/IV disease. Seventy-one pts received as first-line a platinum-based doublet (among them 46 were treated with cisplatin + gemcitabine and 5 received bevacizumab too), 6 a platinum-based triplet, 8 a single-agent therapy. In evaluable patients we observed 3 complete responses and 21 partial responses. Forty eight pts received a second-line treatment (consisting of non cross resistant chemotherapy in 31 pts and of TKIs in 17), 27 a third-line (16 chemotherapy, 11 TKi) and 11 a fourth-line treatment (2 received chemotherapy, 9 TKi). The MS is 19 mos with a 62.5% 1-y OS.
Conclusions: Our experience confirmed that $\leqslant$ 40 years IIIB/IV NSCLC pts presented survival outcomes better than expected in the overall population.

9148 POSTER

Incidence of Bone Metastases and Skeletal-related Events in Patients With Advanced Lung Cancer − Results of a Multicenter, Prospective, Cohort Study (CSP-HOR13)

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Background: The incidence of bone metastases (BM) in patients with advanced lung cancer based on prospective study is not known so far despite the frequent complication. BM can be associated with skeletal-related events (SREs), which include pathologic fracture, need for surgery or radiation to bone, spinal cord compression, and hypercalcemia of malignancy. The aim of our study is to investigate prospectively the incidence of BM, the incidence and types of SREs, time interval between BM and SREs, influence of SREs on QOL, and predictive factors for SREs.
Materials and Methods: Eligibility criteria included newly diagnosed patients with stage IIIB or IV lung cancer, age over 20 years old, and written informed consent. Staging of lung cancer was evaluated with chest and abdominal CT, brain CT or MRI, and bone scintigraphy or PET/CT. Patients were closely followed up every 4 weeks to see if they developed SREs. During the follow-up, radiological examinations were performed every 4 weeks for the chest and abdomen, and every 6 months for the brain and bone. Treatment for lung cancer and use of zoledronate were at the discretion of the investigator. QOL questionnaire was carried out at enrollment, 3 months, and 12 months. Serum concentrations of Alb, Ca, PTHrP, bone-specific alkaline phosphatase (BALP), and type I collagen cross-linked N-telopeptides (NTx) were measured at enrollment.
Results: Two hundred and seventy four patients were enrolled into the study between Apr. 2007 and Dec. 2009 from 12 institutions. Median age was 68 years, small cell/non-small cell=77/197, IIIB/IV=73/124, M/F=193/81, PS 0/1/2/3−4=76/171/23/4. Median follow-up period was 10.3 months (0–27.2 months). Seventy eight patients (28% of all and 62% of stage IV) had BM already at enrollment. Among them, 24 had SREs concomitantly and additional 11 developed SREs during the follow-up. Among 196 patients without initial BM, 31 developed BM, and 14 of these 31 patients developed SREs during the follow-up. Eventually, 49 (18%) of all 274 patients developed 64 SREs, consisting of pathologic fracture in 13 (5%) cases, radiation to bone in 42 (15%) cases, spinal cord compression in 3 (1%) cases, and hypercalcemia in 6 (2%) cases. One-year incidence rate of SREs from the diagnosis of BM was 50%.
Conclusions: In 274 patients with advanced lung cancer, the incidence of BM and SREs was 28% and 9% at initial diagnosis, respectively, whereas BM and SREs eventually developed in 40% and 18% during the follow-up, respectively. Furthermore, details of predictive factors for SREs and influence of SREs on QOL will be provided.

9149 POSTER

Diagnosis of Bone Metastasis in Patients With Lung Cancer Using Urinary and Serum Collagen Type I Telopeptide (NTx)

H. Daga[1], M. Tamiya[2], S. Tokunaga[1], H. Okada[1], M. Kobayashi[2], N. Okamoto[2], S. Sasada[2], H. Suzuki[2], T. Hirashima[2], K. Takeda[1]. *[1]Osaka City General Hospital, Clinical Oncology, Osaka, [2]Osaka Prefectual Medical Center for Respiratory and Allergic Diseases, Respiratory Medicine, Osaka, Japan*

Background: Many cancers metastasize to bone. Bone metastasis may cause an increase in bone resorption due to direct effects of the tumour itself or osteoclastic activation. This study evaluates the bone resorption biomarkers urinary NTx (uNTx) and serum NTx (sNTx) for the diagnosis of bone metastasis in patients with lung cancer.
Methods: uNTx and sNTx were measured in 100 patients with lung cancer and 50 control patients with benign respiratory diseases using the uNTx:OSTEOMARK™ and sNTx:OSTEOMARK™ serum NTx assays (Inverness Medical Japan). Bone metastasis was characterized by scintigraphy. The extent of disease (EOD) was determined by the number of sites of bone metastasis. Area under the curve (AUC) for receiver operating characteristic (ROC) analysis was used to evaluate the detection of bone metastasis. Sensitivity and specificity of uNTx and sNTx to detect bone metastasis were calculated using cutpoints of 64 nM BCE/mM Cr for uNTx and 22 nM BCE/mM Cr for sNTx. All patients were required to provide written informed consent.
Results: Patients with bone metastasis had significantly higher levels of both uNTx and sNTx (uNTx; 93.2$\pm$105.1 nM BCE/mM Cr., sNTx; 24.0$\pm$14.6 nM BCE/L) vs. lung cancers without bone metastasis (uNTx; 51.6$\pm$26.8 nM BCE/mM Cr., sNTx;17.2$\pm$4.1 nM BCE/L), or benign respiratory diseases (uNTx; 42.8$\pm$21.8 nM BCE/mM Cr., sNTx; 16.8$\pm$7.9 nM BCE/mM Cr.). There was good correlation between uNTx and sNTx (R = 0.807). ROC AUC for the detection of bone metastasis was 0.743 for uNTx and 0.712 for sNTx. The sensitivity and specificity for the diagnosis of bone metastasis using uNTx was 48.0% and 86.0%, and using sNTx was 40.0% and 87.0%, respectively. Levels of uNTx and sNTx were increased in patients classified as EOD grade I compared to controls and in patients classified as EOD grade II or greater, compared to patients classified as EOD grade I.
Conclusions: Both biomarkers may have value as an aid in the diagnosis of bone metastasis in patients with lung cancer.

9150 POSTER

Testing Practices for EGFR and KRAS in Advanced Non-small Cell Lung Cancer in a Comprehensive Cancer Care Setting in Korea

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Background: Guidelines for management of non-small cell lung cancer (NSCLC) patients strongly recommend testing for EGFR. These recommendations are particularly relevant in Asian countries that have a higher prevalence of EGFR mutation positive patients, but also in Western countries despite the lower mutation prevalence. The objective of this study was to explore current testing practice of EGFR and KRAS mutation in advanced NSCLC patients in a large comprehensive cancer center in Korea.
Material and Methods: Retrospective cohort study of stage IIIb/IV NSCLC patients 18 years of age or older who attended Samsung Medical Center in Seoul, Korea, from January 2007 through July 2010. Trained oncology nurses reviewed electronic medical records for clinical and pathology data. Mutation status was assayed using bidirectional direct sequencing.
Results: The study included 1,527 patients with a median age of 60.5 years (interquartile range 52.4 to 68.0), 37.3% were female and 52.7% never smokers. The most common histology was adenocarcinoma (70.3%), followed by squamous cell carcinoma (18.1%). The proportions of patients tested for EGFR and KRAS mutations were 38.0% and 25.0% respectively; 364 (23.8%) study participants were tested for both markers. For EGFR testing, the proportion of patients tested in 2007, 2008, 2009, and 2010 were 5.2%, 17.6%, 37.1%, 40.0% respectively. The median time elapsed between confirmed diagnosis of cancer and receiving EGFR testing results was 21 days. EGFR testing was most frequently ordered by oncologists (57.7%) and pulmonologists (31.9%), followed by thoracic surgeons (6.6%).