

status. Little is known about the actual approach in clinical practice in Italy. Therefore the aim of the present work is to describe first line pharmacological treatment (PT) choices in Italian routine clinical practice from the SUN (Survey on the Lung Cancer Management) study.

**Materials and Methods:** SUN is a 12-month longitudinal observational study aimed at enrolling patients aged  $\geq 18$  years and newly diagnosed stage IIIB-IV NSCLC in 74 oncology/pneumological centers throughout Italy. Target therapy and chemotherapy (CT) were considered as possible PT choices. Survival was calculated from the baseline to death or censoring by means of Kaplan-Meier method application.

**Results:** A cohort of 1003 stage IIIB-IV NSCLC Italian patients was enrolled from January 2007 to January 2008 and followed-up for one year. Preliminary analyses show 6% of patients did not receive any pharmacological treatment at baseline, 12% started PT in clinical trial, 82% patients started 1<sup>st</sup> line PT according to routine clinical practice. Baseline features of patients starting 1<sup>st</sup> line PT according to routine clinical practice were: 37% aged  $\geq 70$  yrs, 76% males, 82% current or previous smokers, 77% with PS. The median overall survival of patients starting 1<sup>st</sup> line PT according to routine clinical practice was 8.7 (95% CI 8.0–9.6) months. Median time to progression was 4.9 months (IQR: 3.0–7.6).

**Conclusions:** SUN preliminary results report almost all patients undergoing cancer treatment: combination CT represents the main therapeutic approach. Further analyses are ongoing as regards second and third line PT.

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POSTER

#### Positive urine cytology in patients with lung cancer without obvious urine tract metastases

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**Purpose:** The presence of positive urine cytology in patients with lung cancer without obvious urine tract metastases is unexpected. Following our recent publication regarding the presence of the phenomenon in a small group of our patients, we decided to study our findings in a larger group of patients with early and metastatic lung cancer as well as 3 control groups. We also conducted an experimental study of the phenomenon.

**Patients and Methods:** Urine cytology of 150 patients with early and advanced/metastatic lung cancer were studied: 122 patients with non small cell lung cancer (stages I–III: 42 and stage IV: 80) and 28 with small cell lung cancer (extensive: 18 and limited: 12). The urine cytology of 15 patients with metastatic colorectal cancer, 15 with metastatic breast cancer and 15 with non Hodgkin's Lymphoma were used as control group. The experimental study of the phenomenon was conducted in BALB/C mice with the injection of 4T1 (breast) cancer cells and LLC (Lewis Lung Carcinoma) cells using a standardized protocol for the detection of cancer cells in urine as well as for the detection of renal and adrenal metastases.

**Results:** Among the 80 patients with metastatic NSCLC and the 16 with extensive SCLC, positive urine cytology was detected in 15% of them (12 with the former and 2 with later). None of these patients had radiological verification of metastasis to urinary tract. The morphological appearance of the cells coming from the biopsy and the urine cytology were identical. Urine cytology of the patients with non metastatic lung cancer as well as of those in the control group were negative. The experimental study revealed the presence of positive urine cytology in mice injected with LLC cells and negative for those injected with 4T1. No renal or adrenal metastases were found in mice.

**Conclusions:** The presence of positive urine cytology in patients with lung cancer without obvious urine tract metastases is a phenomenon first described by our study. Our study is ongoing in order to elucidate the possible mechanisms underlying this phenomenon and to collate these results with clinicopathologic tumor characteristics as well as their -if one-predictive and prognostic significance.

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POSTER

#### The correlation of serial pro-gastrin-releasing peptide and neuron specific enolase with radiological response and overall survival of patients with small-cell lung cancer

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**Background:** Pro-gastrin-releasing peptide (ProGRP: P) and Neuron specific enolase (NSE: N) are specific serological markers in patients (pts) with small-cell lung cancer (SCLC). The aim of this study was to investigate whether decreasing rate (DR) of these tumor markers correlate with radiological response and prognosis in pts with SCLC.

**Material and Methods:** Out of 194 newly diagnosed SCLC pts from September 2002–April 2008 at our institution, we retrospectively reviewed consecutive 118 pts who had measurable lesions and elevated baseline levels of P and N before initial therapy (IT) including chemotherapy or chemoradiotherapy, and survived more than one month. P and N were measured on the first day of the every treatment course and after the final course of IT. Computed tomography (CT) was documented on baseline and every 2 courses of IT, and radiographic response was assessed by the New Response Evaluation Criteria in Solid Tumors (RECIST 1.1).

**Results:** 46 (38.9%) pts had limited stage disease (LD) and 72 (61.0%) pts had extensive stage disease (ED). Patients with partial or complete response (n=89) had a better overall survival than those of stable or progressive disease (n=23, Median survival time [MST]: 21 vs. 14.6 months, respectively; p=0.04). Median DR of P and N after 2 courses were 87.1%, 77.8%, respectively at partial response group (n=88). Both P and N levels at baseline were correlated with the sum of diameters (SOD) in baseline CT; Spearman's  $\rho$  was 0.42 (p<0.001) and 0.48 (p<0.0001), respectively. DR of P clearly correlated with DR of SOD after 2 courses, p=0.50 (p<0.0001) and after 4 courses, p=0.42 (p<0.0001). DR of N weakly correlated with DR of SOD after 4 courses, p=0.27 (p=0.005), but not after 2 courses, p=0.22 (p=0.27). In univariate analysis, 80% decrease of P after 2 courses was the strongest prognostic factor (MST: 27.1 [DR $\geq$ 80%] vs. 15.5 months [DR<80%], p<0.0001), but not in N (MST: 20.8 [DR $\geq$ 80%] vs. 20.7 months [DR<80%], p=0.92). In Cox's multivariate analysis, 80% decrease of P after 2 courses of the IT was significantly associated with prolonged survival, when adjusted by sex, age, PS, and disease extent (LD or ED), and radiographic response (p=0.0018, hazard ratio: 0.11, 95% CI 0.028–0.43).

**Conclusions:** DR of P correlated with radiographic response stronger than DR of N, and 80% decrease of P after 2 courses of IT might be useful predictor for favorable prognosis of SCLC pts.

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POSTER

#### Vaccination with autologous dendritic cells pulsed with allogeneic tumour lysate in patients with advanced or metastatic non-small cell lung cancer (NSCLC)

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**Background:** Metastatic non small cell lung cancer (NSCLC) has a poor prognosis and the effect of chemotherapy is limited. Therefore there is a need for new treatment options for this disease. Immunotherapy may represent one such option. Dendritic cell (DC) vaccination is a relatively nontoxic treatment which has been used in several solid tumors. In this study we examined the clinical and immunological response to intradermal administration DCs.

**Materials and Methods:** Monocyte derived autologous DC's were pulsed with allogeneic tumor lysate rich in cancer/testis antigens (MelCancerVac®). From February 2007, 22 patients received a total of 190 vaccines. Inclusion was closed in December 2008. The vaccine was combined with the administration of IL-2, imiquimod and celecoxib in order to facilitate response. The patients received 6 vaccines in 3 months followed by an evaluation CT scan. If there were no progression, booster vaccines were given on a monthly basis, until progression. Several factors such as clinical findings, CT, DTH, ELISpot and quality of life were evaluated in this single arm phase II trial. Here the clinical data is presented.

**Results:** The intention to treat population was 28 patients. All were previously treated with at least one line of chemotherapy. Six patients did not receive the first vaccine and 7 were excluded prior to the first evaluation scan (3 months). Out of 15 evaluable patients 8 was excluded due to progressive disease and 7 had stable disease according to RECIST criteria after 6 vaccines (3 months). Of these, 3 remained stable after 10 vaccines (6 months) and two of them are still stable after 32 and 18 vaccines (26 and

14 months). One patient awaits the evaluation scan after 10 vaccines. No objective responses were achieved. One patient with progressive disease at inclusion obtained stable disease during the vaccination course after 6 and 10 vaccines. Preliminary immunological results suggest a correlation between the patients with stable disease and immunological response. At this time 13 of the 22 treated patients are still alive and 3 are still receiving monthly DC vaccines.

**Conclusion:** The production of individual vaccines is feasible and the administrations of the adjuvants are manageable. This treatment with tumor lysate pulsed DC's may have a stabilizing effect on patients with NSCLC and could form a basis for future research.

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POSTER

#### Indication of surgery for patients with clinical M1 lung cancer

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**Background:** Usually, surgery is not indicated to treat the primary focus in patients with clinical M1 lung cancer. Some M1 patients achieve prolonged survival, although this is rare. This study was conducted to examine the indication of surgery.

**Material and Methods:** Of 1,334 patients who underwent total resection of the primary pulmonary focus in our hospital between October 1986 and July 2007, we retrospectively investigated information on treatment for M1 lung cancer, relapse, and prognosis in 11 (0.8%) clinical M1 patients except pulmonary metastasis.

**Results:** Of the 11 patients, brain metastasis was detected in 6, adrenal gland metastasis in 3, and bone metastasis in 2. Concerning the clinicopathological background of 11 patients, they consisted of 7 males and 4 females, and 8, 1, 1, and 1 patients had adenocarcinoma, squamous cell carcinoma, large cell carcinoma, and atypical carcinoid, respectively. We reviewed the prognosis in the 11 patients. The 5-year survival rate was 34%, and the median survival time (MST) was 21 months. In 10 of the 11 patients, relapse was detected. The 5-year relapse-free survival rate was 18%, and the MST was 8 months. In 2 patient with adrenal gland metastasis, radiotherapy was performed. In 1 with adrenal gland metastasis and 2 with bone metastasis, surgery was conducted. However, these patients died of relapse. In 6 with brain metastasis, surgery or radiotherapy (with a g-knife) was performed. Of these, recurrent brain metastasis was detected in 4, and liver metastasis in 1. In the former, additional surgery or radiotherapy was selected. A complete response (CR) was achieved in 3 patients, and there has been no relapse. The 5-year and 10-year survival rate in the 6 patients with brain metastasis were equally 63%.

**Conclusions:** Therapies other than surgery may be appropriate when selecting a treatment for the primary pulmonary focus in clinical M1 cancer patients. However, in patients with brain metastasis alone, a favorable prognosis may be achieved by performing pulmonary surgery and treatment for brain metastasis. The results also suggest that, when a recurrent brain tumor is detected in clinical M1 brain metastasis patients, the positive treatment of recurrent brain metastasis prolongs survival.

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POSTER

#### Lung cancer screening with low dose spiral CT and autofluorescence bronchoscopy in high risk group

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**Background:** The best prognosis for lung cancer can be expected by diagnosis at an early stage of the disease. low dose spiral CT scanning is a good tool in detecting small pulmonary nodules, but not central airway lesions. Autofluorescence bronchoscopy can localize pre-malignant and early stage malignant lesions in the large central airways, but not lung parenchyme. We investigated the effectiveness of early detection of lung cancer with low dose spiral CT and autofluorescence bronchoscopy both in high risk group.

**Methods:** in this study, 136 participants (adult > 50 years old who had smoked at least 30 pack-years or lung cancer family history) underwent prevalence screening with LDCT and autofluorescence bronchoscopy from October 2006 through september 2008.

**Results:** The mean age of the patients was 61.74±7.5 years. smoking history were current smoke 100, ex-smoker 32, non-smoker 32, non-smoker 4, lung cancer family history 16. During the baseline screening stage 1a BAC 1, noncalcified SPNs 20, 2GO lesions were detected by LDCT screening, 6squamous metaplasia case, 1 hyperplasia case, 1 stage 0 lung cancer case, 1 carcinoma in situ case were detected by autofluorescence bronchoscopy.

**Conclusion:** screening with LDCT and autofluorescence bronchoscopy seems to be a promising method for screening early lung cancer in high risk group.

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POSTER

#### Short term (2-month) survival prognostication in newly-diagnosed patients with Non-Small Cell Lung Cancer

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**Purpose:** Accurate short-term prognosis is important in guiding therapeutic decisions but so far has been studied mainly in patients with end-stage disease. The aim of this study was to evaluate which baseline characteristics can accurately predict short-term (2-month) survival, in newly-diagnosed patients with metastatic Non Small Cell Lung Cancer (NSCLC) intended to receive first-line therapy.

**Patients and Methods:** One hundred one patients were studied on admission for the initiation of first-line chemotherapy. Patients' baseline demographic characteristics are depicted in the following table:

	N	%
	101	100
Males	90	89.1
Age [median (±SD)]	68 (±11.2)	
Current Smokers	78	77.2
Adenocarcinoma	58	57.4

The following clinical and laboratory parameters were recorded: sex, age, body mass index (BMI), performance status (PS), % weight loss, Mini Nutritional Assessment (MNA), smoking history, cardiovascular disease history, histologic subtype, number of metastatic sites, hemoglobin, white blood cell count, lymphocytes, platelets, albumin, calcium (levels corrected for albumin), LDH and C-reactive protein (CRP), interleukin 6 (IL-6) and interleukin 8 (IL-8) levels. A statistical analysis was then performed for the identification of the prognostic value of the aforementioned parameters.

**Results:** 15 patients (14.8%) died within 2 months after diagnosis. Of the studied parameters, PS, MNA, albumin, CRP, IL-6 and IL-8 were highly significant ( $p < 0.01$ ), while hemoglobin and lymphocytes were significant ( $p < 0.05$ ) predictors of 2-month survival.

**Conclusion:** Baseline characteristics could be used to predict short-term survival in newly diagnosed patients with NSCLC. This prediction may facilitate treatment decisions.

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POSTER

#### Gene expression profiles according to smoking status in early non-small cell lung cancer (NSCLC)

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**Background:** Approximately 10–15% of lung cancers occur in patients (pts) who never smoked. Characterization of NSCLC in non-smokers may allow better understanding of this entity and provide clues to new therapeutic targets.

**Methods:** Snap-frozen tumor samples from 48 NSCLC pts (42 women and 6 men; 27 non-smoking and 19 matched smoking pts) with corresponding normal lung tissue (NLT) samples from 15 and 10 pts, respectively were analyzed. Expression of 21 genes (including genes associated with smoking, kinases, growth factor receptors, transcription factors, genes indirectly involved in HPV infection pathways and others) was assessed by qRT-PCR. Reactions were carried out in microfluidic cards (TLDA) in HT7900 cyclers (Applied Biosystems). Gene expression was obtained by 2<sup>-ΔΔC<sub>T</sub></sup> method with the raw expression data normalized against the expression of 18S, POLR2A and ESD. Statistical analysis used parametric test with Bonferroni correction for multiple comparisons.

**Results:** Five genes were significantly overexpressed in tumors from non-smokers vs. from smokers: aryl hydrocarbon receptor (AHR;  $p = 0.001$ ), Ras-related associated with diabetes (RRAD;  $p = 5 \times 10^{-3}$ ), colony stimulating factor for macrophages receptor (CSF1R;  $p = 0.01$ ), receptor 2