

of the time to symptom progression (TSP), time to deterioration (TTD) in trial outcome index (TOI), and time to deterioration (TTD) in QoL. An exploratory analysis based on the time to analgesia and appearance of key symptoms (pain, cough, and dyspnea) was also performed. **RESULTS:** FACT-L completion rates were above 90% at almost all study visits. At baseline, QoL measures were similar between the two treatment groups. Maintenance therapy with erlotinib did not negatively impact on QoL, compared with placebo, as illustrated by comparable TSP (HR = 0.91 [0.74–1.12], n = 785), TTD in TOI (HR = 1.06 [0.87–1.31], n = 781), or TTD in QoL (HR = 0.96 [0.79–1.16], n = 776). Exploratory analysis of NSCLC-related symptomatology showed that time to pain and time to analgesic use were significantly delayed in patients receiving erlotinib compared with placebo (HR = 0.61 [0.42–0.88];  $P = 0.0080$  and HR = 0.66 [0.46–0.94];  $P = 0.0199$ , respectively). There was also a nonsignificant trend toward delayed time to cough and time to dyspnea (HR = 0.77 [0.49–1.21] and HR = 0.75 [0.48–1.17], respectively). **CONCLUSIONS:** Erlotinib maintenance therapy significantly extends progression-free survival, without compromising patient QoL and with some improvement in symptoms.

## PCNI33

#### EPICLIN-LUNG STUDY: NON-SMALL-CELL LUNG CANCER (NSCLC) PATIENT QUALITY OF LIFE AND HEALTH-STATE ASSESSMENT

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**OBJECTIVES:** The aim of the EPICLIN-Lung study is to provide information on the impact and overall resource burden of the diverse strategies used across Europe for the management of NSCLC. Quality of life (QoL) and health state (HS) were determined by patient-reported outcome (PRO) questionnaires. **METHODS:** The EPICLIN-Lung study (NCT00831909) is a noninterventional prospective cohort study conducted in Belgium, France, Germany, Greece, Italy, Portugal, Spain, and Turkey. Patients with confirmed NSCLC attending a participating clinical department for the first time between January and March 2009 were included. QoL and HS were assessed at baseline (Visit 1) by the responses to the PRO questionnaires FACT-L (Functional Assessment of Cancer Therapy-Lung) and EQ5D (EuroQoL-5D), respectively. **RESULTS:** Patients (N = 1500) received the questionnaires at Visit 1. QoL data were available for 1500 patients and overall FACT-L mean score ( $\pm$ SD) was 93.4 (21.3). HS data were available for a total of 1402 patients, overall EQ5D mean score ( $\pm$ SD) was 63.3 (19.9). Mean scores ( $\pm$ SD) split by disease stage IIIb (FACT-L, n = 276; EQ5D, n = 258) and IV (FACT-L, n = 694; EQ5D, n = 653) were 93.5 (20.1) and 91.3 (21.6) for FACT-L, respectively, and 64.2 (18.7) and 61.0 (20.5) for EQ5D, respectively. Mean scores ( $\pm$ SD) split by age <80 (FACT-L, n = 1,428; EQ5D, n = 1,348) and age  $\geq$ 80 (FACT-L, n = 61; EQ5D, n = 54) were 93.5 (21.4) and 92.9 (18.7) for FACT-L, respectively, and 63.5 (19.9) and 60.4 (19.9) for EQ5D, respectively. Mean scores ( $\pm$ SD) for patients with performance status 0, 1, 2, 3, and 4 were 100.9 (18.7), 94.3 (21.3), 84.9 (20.9), 84.4 (21.0), and 85.0 (20.4), respectively, for FACT-L and 71.6 (17.6), 63.4 (19.3), 57.3 (17.9), 54.5 (21.3), and 55.0 (15.3), respectively, for EQ5D. **CONCLUSIONS:** This study provides a robust utility that could be used in the final analysis to assess the QoL and HS of NSCLC patients across Europe. More mature results and analysis will be provided at the meeting.

## PCNI34

#### DEALING WITH CULTURALLY SENSITIVE QUESTIONS IN THE COURSE OF TRANSLATING EORTC QUALITY-OF-LIFE GROUP QUESTIONNAIRES

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**OBJECTIVES:** The Translation Unit of the EORTC is responsible for coordinating new translations of HRQOL tools. According to the Translation Procedure described in the Translation Manual, one step is pilot-testing, involving 10 to 15 patients who comment on the new translation. This abstract's aim is to review the difficulties in translating sensitive issues (body image, death, etc.). **METHODS:** During the pilot testing, patients are interviewed about the translation, filling in answer sheets, a report with their comments is reviewed by the Translation Unit. All questions with comments from at least two patients must be analyzed. The three possible reactions are to accept new translations suggested by the patients, to reword the English item, and provide a new translation or to provide no change (e.g., because the only solution would be to delete the item). Fifteen reports of QLQ-MY20 translations were analyzed. **RESULTS:** In the most recent 15 translations of QLQ-MY20, pilot-tested on 85 patients in 16 countries, there were five language versions that caused no problem and 10 that received comments about offensiveness or disturbing nature of questions about body image and future perspectives (especially in countries such as China, Hong Kong, Thailand, Lebanon, where body image and death are taboos). All together, there were 82 comments about four items (giving 20 translated questions causing difficulties) which required thorough analysis and discussion. Results of the analysis included changing six translations (rewording, accepting patients' suggestions), refusing five suggestions (they deviated from the source too much) and leaving nine translations without changes (since there were no suggestions and rewording was impossible). **CONCLUSIONS:** Scales concerning sexual functions, body image, and future perspectives tend to raise concerns, especially in Asian and Arabic countries. However, such

issues are resolved in the pilot-testing stage of the Translation Procedure through discussions, and linguistic and medical analyses of both source and target items.

## PCNI35

#### IMPROVEMENT IN QUALITY OF LIFE OUTCOMES IN INTERFERON-ALPHA TREATED PATIENTS COMPARED TO SUNITINIB IN ADVANCE OR METASTATIC RENAL CELL CARCINOMA

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**OBJECTIVES:** The objective was to assess the improvement in quality-of-life outcomes with interferon-alpha compared to sunitinib in treatment-naïve advanced/metastatic renal cell carcinoma in patients. **METHODS:** Studies were retrieved from Embase, Pubmed, Cochrane, and DARE databases using relevant search strategies. Randomized controlled trials which compared IFN with sunitinib were included according to prespecified inclusion/exclusion criteria. The quality-of-life (QoL) data presented in the studies was independently extracted by two reviewers and differences were reconciled by a third reviewer. All studies were critically appraised and data was analyzed using STATA version 9.2. **RESULTS:** Of the 463 studies identified, three studies met the inclusion criteria. FKSI-DRS index was reported in one study with baseline and endpoint values as 29.55 and 27.4 with IFN- $\alpha$  and 29.74 and 29.4 with sunitinib ( $P < 0.0001$ ). FKSI-15 index was reported in two studies with mean baseline and endpoint values as 46.1 and 42.1 with IFN- $\alpha$  and 46.45 and 45.3 with sunitinib ( $P < 0.0001$ ). FACT-G score was reported in one study. The baseline FACT-G score was 81.25 with IFN- $\alpha$  and 82.3 with sunitinib. The endpoint FACT-G score was 76.8 with IFN- $\alpha$  and 82.3 with sunitinib ( $P < 0.0001$ ). EQ-5D score was reported in two of the included studies and was reported to be 0.76 and 0.73 as mean baseline and endpoint score for IFN- $\alpha$  group and 0.76 and 0.76 for sunitinib group. EQ-VAS score was reported in one study and was 71.43 and 68.7 as baseline and end point for IFN- $\alpha$  group and 73.8 and 73.4 for sunitinib group. The overall survival rate and response rate was better with sunitinib as compared to IFN- $\alpha$ . **CONCLUSIONS:** Improvement in quality-of-life outcomes was better in patients treated with IFN- $\alpha$  as compared to sunitinib at the end point. IFN- $\alpha$  continues to remain a treatment of choice despite of limited efficacy and tolerability.

## PCNI36

#### QUALITY OF LIFE AFTER CHEMOTHERAPY IN BREAST CANCER: A STUDY IN SOUTH OF IRAN

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**OBJECTIVES:** The aim of this study was to compare the impact of two common treatment of breast cancer on quality of life in women with early stage of breast cancer. **METHODS:** A double-blind cohort study was done in 100 breast cancer patients with node positive that used 5-fluorouracil, doxorubicin, cyclophosphamide (FAC) or docetaxel, doxorubicin, and cyclophosphamide (TAC) regimen as adjuvant therapies. Patients were followed for 4 months since end of chemotherapy. Health-related quality of life was assessed using questionnaire from European organization for research and treatment of cancer (EORTC) QLQ-C30. Independent *t*-test analysis was used at the significant level of 0.05 for analyzing the results. **RESULTS:** The mean of age was 49.2911.59 and 46.718.23 years old in TAC and FAC groups, respectively. In the end of chemotherapy, QoL score were 64 and 68 in TAC and FAC groups, respectively ( $P < 0.005$ ). After 4 months, patients in TAC and FAC groups experienced 11.45 and 7.14 units improvement in QoL scores, respectively ( $P = 0.02$ ). **CONCLUSIONS:** Although, TAC had a more negative impact on QoL during chemotherapy, it created a higher improvement than FAC during 4 months since end of treatment. These effects on quality of life should be considered in making decision for providing and financing cancer treatments in Iran.

## PCNI37

#### EMPLOYMENT STATUS AND WORK-RELATED DIFFICULTIES IN LUNG CANCER SURVIVORS COMPARED WITH GENERAL POPULATION

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**OBJECTIVES:** Although improved lung cancer survival is likely to result in increased lung cancer survivors, little was known about work situation among lung cancer survivors. The purpose of this study was to investigate employment status and work-related difficulties of lung cancer survivors compared with the general population. **METHODS:** We enrolled 917 lung cancer survivors from two hospitals 12 months after lung cancer surgery and 1000 volunteers from the general population. Multivariate logistic regression was used to identify the factors associated with work situation. **RESULTS:** Employment decreased from 69.6% to 38.7% after cancer treatment. The proportion of lung cancer survivors who remained working was significantly smaller relative to that of the general population (63.5%) (adjusted odds ratio [aOR] = 2.59; 95% confidence interval [CI]: 1.91 to 3.51). In subgroup analyses, female survivors over 65 years had unemployed after treatment (aOR = 89.24; 95%CI = 10.52 to 756.91) than at the diagnosis of cancer. Among cancer survivor who remained employed after treatment (n = 284), 71.8% found no meaning of working and 15% experienced decrease wages. **CONCLUSIONS:** This is the first study with the largest number of patients investigating employment situation among lung cancer survivors reported poorer employment status than the general population. Among cancer sur-