(Stage IIIb); 61.15±20.33 (Stage IV). An adjusted analyses was performed on the EQ-5D scores with imputation of missing data at V2 as '0' for pts who had died and '70' for pts who had progressed. This was to account for potential bias as more favourable outcomes may have been more likely to complete the QoL self-assessment form at 2nd study visit, compared with those with poorer outcomes, and those who had died. In the analysis, variables associated with increased risk of worsening QoL (V1-V2) were Stage at diagnosis IIb ($p = 0.045$), IIIa ($p = 0.010$), IIIb ($p = 0.022$), and IV ($p = 0.010$); performance status (PS) 3 or 4 ($p = 0.049$); and presence of CTCAE>2 ($p = 0.006$). Variables associated with a lower risk of worsening QoL were CTCAE⩽2 ($p = 0.001$); being treated in Greece ($p = 0.027$), France ($p = 0.002$), Spain ($p \leqslant 0.0001$), Italy ($p \leqslant 0.0001$); or being treated in a university hospital ($p = 0.006$).

Conclusions: QoL is an important multi-component clinical outcome in NSCLC. The EPICLIN-Lung study represents a large database on QoL outcomes in pts with NSCLC in Europe. Disease stage at diagnosis, PS, presence of AEs, hospital setting and country affect risk of worsening QoL. These data demonstrate the marked burden of NSCLC on pts, and highlight the need for new strategies to improve QoL outcomes. An understanding of how to better assess QoL may help drive improvements in QoL.

3030 POSTER

Preliminary Characterization of Visual Events Reported by Patients (Pts) Receiving Crizotinib for the Treatment of Advanced ALK-Positive Non-Small Cell Lung Cancer (NSCLC)

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Background: Crizotinib is a potent, selective, ATP-competitive, small molecule ALK inhibitor demonstrating clinical activity and high response rate (61%) in advanced *ALK*-positive NSCLC. Two initial studies reported predominantly Grade 1 visual events (including image carryover, flashing/trailing lights/floaters and/or blurry vision; often during light adaptation) in 40−45% of pts. A pt questionnaire (Visual Symptom Assessment Questionnaire [VSAQ]) was developed to further characterise symptoms and their effect on activities of daily living (ADLs).

Materials and Methods: The VSAQ 7-item questionnaire was developed with physicians and nurses treating pts experiencing visual disturbances, and with translation experts. Pts completed the VSAQ at day 1 of each cycle (C; 21 days) and at end of treatment in the PROFILE studies. We present preliminary data from 57 pts completing baseline and ⩾1 post-baseline assessment from the ongoing Phase 2 study of 250 mg BID crizotinib in *ALK*-positive NSCLC (PROFILE1005, NCT00932451; Pfizer). Impact on ADLs was scored on a scale of 0 (no effect) to 10 (completely prevented).

Results: As of 1 Feb 2011, 56% (31/55) of pts at C2 and 50% at C3 (16/32) and C4 (8/16) reported visual disturbance, which did not necessitate dose alteration. In most patients, each event lasted ⩽1 minute (71% C2; 67% C3; 75% C4), and ⩽30 seconds in 48−53% of pts (C2−4). Frequency of visual disturbance varied in C2 (19% ⩽1 day/wk; 23% 2−3 days/wk; 25% 4−6 days/wk; and 32% reporting 7 days/wk), however in C3 and C4 most pts reported experiencing ⩽1 day/wk (47% and 50%, respectively). Symptoms usually occurred in the morning and/or evening but rarely in the afternoon (6−7% of pts). Visual disturbances were not bothersome (23% C2; 19% C3; 50% C4) or only a little bothersome (52% C2; 50% C3; 25% C4) to most as assessed on a 6-point Likert scale ("did not experience," "not at all" to "extremely"). Most pts did not report difficulty seeing at night or adjusting to light (bright or dim) on the same scale. Most pts indicated no effect on ADLs (score 0: 61% C2; 50% C3; 63% C4) or minimal impact (score 1−3: 25% C2; 31% C3; 38% C4). Updated data will be presented.

Conclusions: Preliminary analysis of the VSAQ found visual disturbances to be short in duration and have no or minimal impact on pt ADLs in the ongoing PROFILE1005 study.

3031 POSTER

Sexual Problems in Patients With Head and Neck Cancer

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Background: Studies show that the incidence of sexual dysfunction ranges between 40% and 100% in patients where the tumour and treatment have a direct impact on sexuality. Head and neck cancer is a physically and emotionally devastating disease. Unlike other forms of cancer the disease and side-effects of treatment cannot be hidden as tumours of the head and neck affect the most visible area of the body. Treatment include surgery, radiotherapy and chemotherapy often in combination leading to severe side-effects such as facial disfigurement, pain in the mouth and throat, thick and ropy saliva and taste changes leading to malnutrition and loss of energy and strength. In addition, fatigue, social isolation and low self esteem − factors that are known to influence sexuality − are common and apparently, patients with head and neck cancer are at high risk to develop sexual problems. However, little is known regarding sexual problems and sexual adjustments among this group of patients under treatment as well as during the rehabilitation period. Therefore this study was conducted with the objective to examine occurrence of sexual problems during and after the medical treatment.

Materials and Method: In this descriptive study 40 consecutive patients treated with surgery and radiotherapy for head and neck cancer participated. Data were collected each week during radiotherapy and six and twelve months after completed radiotherapy using EORTC QLQ-30 and EORTC H&N35, for health-related quality of life. The questionnaires include specific questions regarding sexual functioning and sexual desire. Descriptive and non-parametric statistics were used.

Results: Sexual problems were common and were reported to occur quite a lot or a lot by 60% after completed radiotherapy, 30% after six months, and by 32% after one year. Data analysis is ongoing and further results will be presented at the conference.

Conclusions: Sexual problems are common in patients with head and neck cancer and this issue needs to be further studied.

3032 POSTER

Health-related Quality of Life in Patients With HER2-positive Advanced Gastric or Gastroesophageal Junction Cancer With High HER2 Expression Levels − Exploratory Analysis of the Phase III ToGA Study

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Background: A pre-planned exploratory analysis of the Phase III ToGA (Trastuzumab for GAstric Cancer) study showed that adding trastuzumab (H) to capecitabine or 5-fluorouracil and cisplatin (XP/FP) prolonged median overall survival (OS; 16.0 mo) vs XP/FP alone (11.8 mo) in patients with high HER2 expressing advanced gastric or gastroesophageal junction tumours (IHC 2+/FISH-positive or IHC 3+, Bang and Van Cutsem *et al*. *Lancet* 2010; 376: 687–697). We report an exploratory health-related quality of life (HRQoL) analysis from this patient subgroup. The ToGA study is registered with ClinicalTrials.gov, number NCT01041404 (CenterWatch study number 147440). It was sponsored by F Hoffmann-La Roche.

Materials and Methods: Patients completed EORTC HRQoL questionnaires, QLQ-C30 V3.0 (general HRQoL) and QLQ-STO22 (gastric cancer), prior to dosing and every 3 weeks from Day 1 until disease progression (scoring range: 0–100). Summaries and descriptive statistics for both treatment arms were analyzed, along with changes from baseline (Week 0) to Week 64.

Results: Of the ITT population ($N = 584$), 446 patients had high HER2 expressing tumours: 218 in the XP/FP arm and 228 in the H+XP/FP arm. Questionnaire compliance was high (91–100%) but decreased over time due to withdrawals, mostly because of disease progression.

QLQ-C30: Global Health Status improved from baseline at Week 4 onwards in both arms. There was an additional improvement in the score by the end of chemotherapy (CT, Week 19), which improved further by an average of 15 points from baseline at Week 31, sustained to Week 61 in the H+XP/FP

arm. The XP/FP arm showed a 5-point average improvement from baseline between Weeks 22−34.
Role functioning and fatigue scores were similar in both arms until Weeks 34 and 28, respectively, after which H+XP/FP showed sustained improvement over XP/FP.
QLQ-STO22: HRQoL improved over time in both arms. Slight improvements from baseline in the dysphagia score were seen, notably after Week 19 until Weeks 31 (XP/FP) and 61 (H+XP/FP).
Conclusions: In ToGA, adding H to XP/FP improved OS without compromising HRQoL; this effect was greater in patients with high HER2 expressing tumours in the H+XP/FP arm, where the time to deterioration in QoL was significantly longer. Consistent with these results, improved HRQoL was observed over time in this patient subgroup, with a sustained effect beyond CT administration when adding H to XP/FP.

3033 POSTER

Living Through Pelvic Radiotherapy − Responses of Maintaining Self

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Background: Before introducing interventions against distressful symptoms, it is important to describe patients' experiences and the self-care activities that are initiated by patients living through cancer treatment. This study was designed to explore the impact on life living through pelvic radiotherapy with focus on experienced symptoms and self-care activities.
Materials and Methods: Twenty-nine women undergoing pelvic radiotherapy were prospectively followed were baseline, 3 weeks and 5 weeks of treatment served as time points for data collection. Data were collected within a mixed method design including structured and semi-structured interviews which reflected impact on daily life, symptom experience and self-care activities. Grounded Theory formed data collection and analysis of the semi-structured interviews. Experienced symptoms and aspects of health related quality of life was assessed by EORTC-QLQC30 and MFI-20.
Results: To be able to maintain oneself was concluded as being central living through pelvic radiotherapy. Being highly distressed by gastrointestinal symptoms respondents set out to do what it takes to survive, to keep the body intact and to be seen and treated as always by others. Diarrhea increased significantly ($p < 0.001$) during treatment as did fatigue ($p < 0.001$). Impact on physical, social and role functions was evident in both the questionnaires and in the semi-structured interviews. Self-care activities in relation to diarrhea and fatigue are described.
Conclusion: The result of this study shows that undergoing pelvic radiotherapy has a major impact on the individual with physical, social and role concerns. The gastrointestinal symptoms cased highest distress. Interventions aimed at alleviating distressful symptoms should be complemented with a care based on patients' own experiences and strategies for alleviating symptoms. The caregiver should be supportive in confirming the patients' experiences in the process of maintaining self.

3034 POSTER

Health-Related Quality of Life in Small-Cell Lung Cancer: a Systematic Review on Methodological Issues in Randomized Controlled Trials

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Background: Lung cancer is a common cancer site and randomized clinical trials (RCTs) often assess lung cancer patients' Health-Related Quality of Life (HRQOL). This study examines the HRQOL methodology reporting in small-cell lung cancer (SCLC) RCTs. The objective was to evaluate the adequacy of HRQOL methodology reporting since 1990 and its benefits for clinical decision making.
Methods: A Medline systematic literature review was performed in randomized clinical trials. Eligible RCTs implemented patient-reported HRQOL assessments and oncology treatments (e.g. chemotherapy, radiotherapy, surgery) for adult SCLC patients. Included studies were published over the last two decades, between April 1991 and February 2011. Only studies with sample size $\geqslant$100 and patient age $\geqslant$18 were included. Two independent reviewers evaluated all selected RCTs.
Results: Twenty-nine RCTs out of seventy-one studies were classified as eligible for inclusion in our review. HRQOL was the primary endpoint in five RCTs and a secondary endpoint in 24 RCTs. Of the 29 RCTs, 62% reported that there was no significant difference in overall survival (OS). 50% of the RCTs that did not find any OS differences did find significant differences in HRQOL scores. Tests of statistical significance were applied in 97% of the RCTs and a HRQOL difference between treatment arms was found in 62% of the RTCs. 32% of the RCTs showed clinically significant differences and reported clinical conclusions. The EORTC QLQ-C30 tool was used in 48% of the RCTs.
Conclusions: HRQOL assessment in SCLC RCTs provides an added value in the studies where no OS difference is found. However, while the reporting of HRQOL was overall of acceptable standards, improvement in reporting RCT is to be encouraged.

3035 POSTER

Effect of Completion-time Windows in the Analysis of Health-Related Quality of Life (HRQOL) Outcomes

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Aims: Our aims were to assess if HRQOL scores of the EORTC QLQ-C30 are affected by the specific time point, before or during treatment, at which the questionnaire is completed and whether this could unduly bias the treatment comparisons.
Patients and Methods: We analyzed data from one closed EORTC 2-arm RCT of 430 advanced colorectal cancer patients who were treated with CPT-11 in combination with weekly 24-hour infusion 5-FU plus folinic acid versus weekly 24-hour infusion of 5-FU plus folinic acid alone. HRQOL was measured as a secondary endpoint at baseline and over the 9-scheduled chemotherapy cycles using the EORTC QLQ-30 questionnaire. To investigate the effect of questionnaire completion before and during treatment, a 'completion-time window' variable was created to indicate when the EORTC- QLQ-30 was completed relative to cycle dates, defined as 'before' (up to 10 days before the cycle date), 'on' (on cycle date), and 'after' (up to 10 days after the cycle date). Additional sensitivity analysis was performed using extended completion-time windows of 30 to 40 days. HRQOL mean scores were calculated using a linear mixed model including treatment, cycle number, treatment-by-cycle interaction, and the completion-time window variable.
Results: The analysis was limited to 6 cycles with the number of patients who completed the EORTC QLQ-C30 ranging from 31–329 over the 6 cycles, yielding a total of 782 completed questionnaires. There were no statistically significant differences in scores in the "before" to "on" comparisons; however statistically significant differences ($p < 0.05$) were observed on 5 subscales for "on" to "after" comparisons. We then formed two groups of patients in which questionnaires were completed "before" or "on", compared to "after". The following statistically significant differences were found in the estimated HRQOL mean values between "before-or-on" compared to "after" completions: decreased social functioning (-5.8) and global health status/QoL (-5.5), and increased nausea/vomiting (4.8), appetite loss (7) and fatigue (7.5). Similar results were observed during the sensitivity analysis. Although all of these differences were in the same direction (i.e., worse mean scores in the after treatment completions), these differences were below the 10 points accepted as clinically meaningful. Treatment effect comparisons between arms were not significantly altered by the inclusion of the completion-time window variable in this trial.
Conclusion: Our findings suggest that scores after treatment may be affected by the treatment and thus, the effect of completion-time windows should be tested during the analysis of HRQOL scores. Accounting for this information did not alter the decision regarding treatment comparisons in this case, but might possibly vary in other situations. We recommend, therefore, that outcome bias due to the possible effects of the timing of completion- time windows should be examined in future clinical trials.