metastatic disease (1.36 [1.27–1.46]), and survived <1 year but longer than 2 months post-diagnosis. The propensity for continued chemotherapy in patients' last month was significantly increased by being cared for by a medical oncologist (3.49 [3.04–3.99]) or in a teaching hospital (1.39 [1.11–1.74]) and with the highest intensity of total inpatient hospital beds (1.63 [0.99–2.68]) but was not influenced by regional healthcare resources (total hospital and hospice beds).

Conclusion: The propensity to continue chemotherapy in the last month of life was determined by patient demographics and disease characteristics, physician specialty, and healthcare resources at the primary hospital level. Maintaining a delicate balance between deciding to continue chemotherapy and starting palliative care remains a challenge. However, appropriate discussion of transition from curative to palliative care may minimize the over-estimated effectiveness of chemotherapy to achieve end-of-life care that best meets cancer patients' needs and preferences.

3026 POSTER

Pain and Insomnia in Institutionalized Cancer Patients: a Prospective Analysis

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Background: Pain and insomnia are among the most prevalent symptons experienced by cancer patients. Although previous research has demonstrated that sleep disturbances are correlated with chronic pain little is known about the occurrence and severity of insomnia and pain between patients with cancer diagnoses. The aim of this study is to evaluate the relationship between pain and sleep disorders in this population.

Material and Methods: In this prospective observational study 142 cancer patients were interviewed by a single investigator. We surveyed the subjects' demographic and tumour-related characteristics. Sleep quality was assessed by a seven item questionnaire that investigated onset sleep problems, the presence of nighttime awakenings, restorative sleep and daytime sleepiness. Pain was assessed using the numerical verbal scale and participants were divided into 3 groups depending on self-reported pain: without pain, mild or moderate-severe pain.

Results: 66% of patients (n = 89) presented pain with a median score of 3 (range 0−7) and 51.7% of them required opioide analgesics. Pain intensity and sleep quality weren't related with patient's demographic or clinical data. Median duration of nocturnal sleep was 6.74 hours (range: 3−10 hours) with a median of 1.72 waking by night (range: 0−10 aroused). All patients had at least one of the explored sleep alterations. Pain severity was found to be related with shorter sleeping time ($p = 0.05$) and an increased number of night awakenings ($p = 0.01$). Results showed higher pain levels predicted increased frequency in intiating sleeping problems ($p = 0.0001$), frecuency of non-restorative sleep reports ($p = 0.0001$) and daytime sleepiness ($p = 0.0001$).

Conclusions: Pain is related with worse sleep quality in different aspects: greater onset problems, more daytime sleepiness and more non-restorative sleep. Therefore, pain plays a major role in sleep disturbance among cancer patients. They are necessary new explorations to obtain more conclusive results, as well as studies including behavioral or pharmacological interventions.

3027 POSTER

Emotions, Picture and Radiotherapy

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Background: Drawing is one of the most important psychological projective tests. It deeply investigates human personality, gathering its essential aspects. Pictures are the reflection of the internal affective world (Winnicott, 1971) and they express feelings and conflicts (Quaglia, 2007) without inhibitions.

Material and Methods: In our Hospital, 50 patients in radiotherapy treatments were asked to undergo a specific psychological interview, to the Mini-Mac scale (Watson, 1994) and to illustrate their experience of radiotherapy. 90% of them completed test and interview, but only 60% of patients decided to make the picture.

Results: The refusal could express difficulties in facing the assignment, that could force patients to cope with inner emotions.

Patients could simpler contain feelings during the tests.

Results showed a decline of negative emotions such as fear and worry (2%).

The qualitative psychological analysis of the pictures revealed the prevalence of the following subjects: room of the radiotherapy (47%), rays of the machine (19.4%), streets (10.4%), clouds (7%) and a prevalence of the symbol of a circle (58.6%).

The sphere is the unconscious and universal symbol of unity and perfection, it is an archetype that represents psyche. A circle is often present in the pictures and in the dreams of a person who perceives a danger in his existence and fears for his integrity (Jung, 1964).

This evidence is linked to the emotional difficulties that patients should face during radiotherapy treatments, but they do not express in the interview.

Prevalent coping styles of the patients that decided to paint were: reactivity (44.8%) and fatalism (41.3%). Coping styles of the other patients are distributed in a more homogeneous way: fatalism (37.5%), reactivity (31%), deny (25%) and anxiety (6.25%).

Conclusions: It is our aim to proceed in order to evaluate if the decision to omit the picture could be linked to a fear of facing inner emotions or to a characteristic personality.

3028 POSTER

A Qualitative Study of Survivorship Issues in the Families of Patients With Cancer

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Background: A cancer diagnosis has psychosocial impacts on the affected family, some experiencing increased distress. As cancer incidence and survival rates rise, the number of people living with cancer will increase significantly, but there is little studied of the impact on the family of one of their members surviving cancer.

Methods: 23 families (as defined by them) of cancer survivors (12 more than 3-years post-diagnosis) were recruited through Australian media and participated in a family interview covering long-term outcomes. Interviews were recorded, transcribed verbatim, and then thematically-analysed.

Results: Participants discussed various long-term sequelae within their families. Many reported challenges in managing changes in their working life and their geographical location. Some noted that the physical effects of cancer and treatment of the family member had changed what they could do as a family. For some, relationships with external family members were problematic due to disagreements regarding familial choices. Families spoke of difficulties in managing their own or others' emotions, or in adjusting to changes of personality or priorities exhibited by the cancer patient. Finally, several families raised management of cancer risk factors as problematic: views about the importance and consequences of behavioural change to manage risk varied, and could cause on-going tension.

Conclusions: These (relatively high-functioning) families faced ongoing psycho-social challenges long after diagnosis. Cancer changed the present circumstances and the future possibilities resulting in changed behaviour, and related to issues around identity. This required, adjustments within and without the family, which did not always occur. Some families may benefit by psycho-therapeutic family-centred interventions to address these issues.

3029 POSTER

Quality of Life (QoL) in Patients Receiving Treatment for Non-small Cell Lung Cancer (NSCLC) Across Europe: EPICLIN-Lung Study

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Background: Data collected from the EPICLIN-Lung study (NCT00831909) reflects outcomes approach and QoL assessment in a large scale European NSCLC population.

Materials and Methods: Patients (pts) with confirmed NSCLC attending the relevant hospital for the first time between 1 January and 31 March, 2009 were enrolled, and followed for a minimum of 12 months or until death. Only pts not participating in clinical trials were asked to participate in this QoL sub-study within the EPICLIN-Lung study. A sample of pts were asked to complete self-assessment questionnaires (FACT-L, EQ-5D) at baseline; subsequent QoL assessments were not mandatory.

Results: 3508 pts were enrolled in the EPICLIN-Lung study. Baseline (visit 1; V1) QoL data were available for 1626 pts; of these, 734 provided QoL data at visit 2 (V2). At V1, mean EQ-5D scores were 63.97 ± 20.02 for pts <70 years old and 62.42 ± 19.03 for pts $\geqslant$70 years old; $p = 0.179$. Mean EQ-5D scores by disease stage at V1 were: 64.51 ± 20.51 (Stage I); 68.24 ± 18.72 (Stage II); 67.06 ± 18.49 (Stage IIIa); 64.21 ± 18.82

(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$\leqslant$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 $\geqslant$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 $\leqslant$1 minute (71% C2; 67% C3; 75% C4), and $\leqslant$30 seconds in 48−53% of pts (C2−4). Frequency of visual disturbance varied in C2 (19% $\leqslant$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 $\leqslant$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