Conclusions: Most patients, especially younger females, maintain good QL following potentially curative treatment for NSCLC, although for a third of all patients changes in perceived health do not recover after treatment. Baseline QL is a guide to later QL whereas treatment regimen appeared to have no long-term impact.

1117 POSTER

Scalp cooling in cancer patients receiving chemotherapy in the Netherlands

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Background: Scalp cooling is worthwhile supportive care. It can be applied in all patients with chemotherapy schedules that cause (severe) hair loss. In 2004, only 4 hospitals in the Netherlands offered scalp cooling to cancer patients. Reasons for this low level of application were time pressure on nursing activities, medical reluctance due to fear of scalp skin metastasis and unfamiliarity with scalp cooling and the positive results among patients, nurses and oncologists. In 2005 a PhD-project was started, comprising several topics related to scalp cooling. Renewed attention for scalp cooling stimulated curiosity of medical doctors (MD) and nurses in the introduction of a new service and enlarged opportunities for funding of scalp cooling machines. In 2007 scalp cooling is practised in 34 (1 out of 3) hospitals in the Netherlands.
Methods: Research comprehends the optimisation of scalp cooling methods. The impact of post-infusion cooling times on the preservation of hair is determined in the 3-weekly docetaxel regimen. In the first phase of the study the post-infusion cooling time was 90 minutes. In the second phase patients are randomised between post-infusion cooling times of 45 and 90 minutes. Scalp cooling is offered to patients with a variety of chemotherapy schedules. Methods and results of scalp cooling are recorded in all scalp cooled patients in the Netherlands. Research also focuses on assessment of Quality of Life (QOL) in relation to the degree of hair loss in breast cancer patients. QOL-questionnaires (among others EORTC QLQ-C30 and -BR23) were completed before starting chemotherapy, 3 weeks and 6 months after the last chemotherapy session.
Results: The number of eligible patients who are offered scalp cooling and seize the opportunity to preserve their hair during chemotherapy varies between 70% and 90%. Severe side effects are never reported in literature or by Dutch health care professionals who offer scalp cooling for many years. Ninety six patients with 3-weekly docetaxel chemotherapy are included in the study. In the fist phase 90 minutes post-infusion cooling time resulted in 82% of patients (n = 34) not requiring a wig. Results of scalp cooling in randomised patients are not known yet, data will be presented at ECCO conference. Recording of results shows preservation of hair in 54% of patients (n = 160) with FEC-high dose (epirubicine 90 mg/m^2 or more) chemotherapy.
QOL is better in successfully scalp cooled patients (n = 30) than in patients not receiving cooling (n = 142).
Conclusion: Introduction of scalp cooling in the Netherlands has received a great impulse. More than half of the patients do not require a wig during chemotherapy schedules that normally induce severe hair loss. The ongoing clinical investigations will lead to further improvement of methods of cooling and will contribute to more general use of scalp cooling.

1118 POSTER

Return to paid and unpaid activities after radiotherapy for early stage breast cancer

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Purpose: To look at the effect of radiotherapy (RT) treatment on paid and unpaid activities in patients with early breast cancer randomised into the phase III START trials.
Methods: As part of the START Trials, a subgroup of women were recruited to a quality of life (QL) and Health Economics (HE) study and asked to complete questionnaires at specific time points from baseline to 5 years. HE data have been analysed at 1 year following randomisation, including return to paid or unpaid work, type of work, time taken to return, numbers of hours worked and ability to perform tasks compared with prior to their diagnosis. Age and education levels, physical and emotional functioning scales and the financial scale of the EORTC QLQ-C30 questionnaire were compared between women who did and did not return to work. Reasons why women had not returned to work were analysed.
Results: Of the 2028 women in the HE study (mean age 56.5 yrs range 27−86), 53% were in paid employment prior to their diagnosis and 85% of those continued to work throughout treatment or had returned by 1 year. At 1 year, a third worked fewer hours and 56% were less able to perform at work. Lost hours were mainly covered by existing employees (54%). Physical, emotional functioning and financial problems were more prevalent in those that had not returned to work with 55% giving a reason; the majority took voluntary retirement (38%) or were forced to give up due to ill health or redundancy (37%). There was no difference in age or education level between women returning or not returning to work. Over 90% had returned to shopping, housework and looking after children by 3 months. Return to voluntary work or education took longer, with over 70% returning within a year.
Conclusions: These results are encouraging as RT does not seem to affect the ability of women to return to normal activities within a year of treatment, although for some this resulted in reduced working hours and performing the task less well. Patients' return to both paid and unpaid work may serve as a measure of recovery from their illness.
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1119 POSTER

Safety concerns of polyurethane catheters connected to totally implantable venous access devices

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Background: Manufacturers of totally implantable venous access devices with silicone catheters provide warranty on the quality of the self-sealing silicone membranes closing their ports: 2,000 punctures with Huber-tip needles are allowed, without risk for leakage. However, when polyurethane catheters became available for access ports, there was no mention of their potential changes with time nor on their risks for the patients.
Materials and Methods: A series of 47 venous access devices of the same brand, with polyurethane catheters, were removed at the end of the therapy or for complications. Ports and catheters were examined for eventual damage and photographs taken; catheter indwelling time, accessed vein, patients condition, list of injected drugs and device lot number were recorded.
Results: The devices belonged to 32 different lots; 33 were inserted in the cephalic vein and 7 in the external jugular vein; subclavian and arm veins were used once each. Typical longitudinal cracks were noticed on 20 catheters, at the place they were distended over the port outlet (2 of these showed leakage of chemotherapy or contrast dye), 2 presented a horizontal tear distal of the outlet and 25 were unremarkable beside some rough external surface. The incidence of catheter damage was only correlated with the duration of the device in situ: median indwelling time for damaged catheters was 716 days (range 130–1721) and 497 days (range 214–1015) for undamaged items (unpaired t-test).
Conclusion: Since there is a definite and increasing risk of "fatigue" for polyurethane catheters after more than 2 years of indwelling time, manufacturers should notify this potential hazard and adapt the polyurethane in order to resist for a longer time.

1120 POSTER

Evaluation of the association between hemoglobin (Hb) events and safety outcomes in cancer patients (pts) with chemotherapy-induced anemia (CIA): an integrated analysis of patient-level data from 6 randomized, placebo-controlled trials (RCTs) of darbepoetin alfa (DA)

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Background: Erythropoiesis-stimulating agents (ESAs) increase thromboembolic events (TE) risk in the CIA population. Some studies targeting higher Hb have been associated with increased risk of death and

progression and so we examined the relationship of achieved Hb and outcome.
Materials and Methods: We performed a combined analysis of pt-level data from 6 Amgen-sponsored RCTs of DA to treat CIA in pts with screening Hb⩽11g/dL, nonmyeloid malignancies, ⩾1 prior chemotherapy (CTX) cycle, and additional planned CTX cycles. Adverse events (AEs) were mapped to a common reporting dictionary (MedDRA v.9) to consistently define TE. Deaths or DP were identified based on reasons given for drug or study discontinuation and either a reported fatal AE (death) or end-of-study disease status (DP). An exploratory analysis examined if a Hb event (Hb > 12 or 13 g/dL, or Hb increase >1 g/dL in a 14-day window during study, excluding Hb within 28 days after a transfusion) is associated with an increased risk of death, DP, and TEs. Each Hb event was assessed individually as a time-dependent covariate (based on time to first occurrence) in a Cox proportional hazards model.
Results: The analysis included 901 DA pts who received ⩾1 DA dose (mean[SD] age, 62.3[12.3] yrs; 54.6% women; 48.3% ⩾65 yrs old; 81.9% with stage III or higher/extensive disease). The risk of on-study death was lower if a Hb event occurred, reported as HR (95% CI): 0.41 (0.20−0.83) for Hb > 12 g/dL, 0.60 (0.25−1.45) for Hb > 13 g/dL, and 0.48 (0.26−0.89) for a >1-g/dL increase in 14 days. A similar pattern was seen when deaths were identified during a study's follow-up period. Risks of DP and progression-free survival (PFS; time until death or PD, whichever earlier) were lower when Hb > 12 g/dL (HR: 0.45 to 0.67), Hb > 13 g/dL (HR: 0.63 to 0.84), or a >1-g/dL increase in 14 days (HR: 0.55 to 0.64). Achieving a Hb event was associated with an increase risk of TEs, though CIs include 1: 1.66 (0.90−3.04) for Hb > 12 g/dL, 1.82 (0.86−3.83) for Hb > 13g/dL, and 1.67 (0.96−2.88) for having >1 g/dL increase in Hb in 14 days.
Conclusions: In these DA studies in CIA pts, having Hb >12 or 13 g/dL or a >1 g/dL increase in Hb in 14 days was associated with a decreased risk of death or DP, and an expected increased risk of TEs. Therefore, in these pts, the primary health risk associated with Hb > 12 g/dL (above the current recommended treatment target in the US) or >1 g/dL increase in Hb in 14 days appears to be increased risk of TEs.

1121 POSTER

The effect of methylnaltrexone on global clinical impression of change (GCIC) in the bowel status of cancer patients with opioid-induced constipation

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Cancer patients frequently use opioids and suffer from opioid-induced constipation (OIC) that is refractory to laxative therapy. Previously reported study results demonstrated that methylnaltrexone, a selective peripheral mu-opioid receptor antagonist rapidly induces laxation without affecting analgesia.
The current analysis examines effect of methylnaltrexone on patient and clinician reported Global Clinical Impression of Change (GCIC) in bowel status in a sub-group of cancer patients.
In this randomized, double-blind placebo-controlled trial, advanced illness patients with OIC were treated with placebo or methylnaltrexone (0.15 mg/kg SC QOD dosing) for 2 weeks with the option to double the dose on Day 9 if there had been <3 rescue-free laxations in the first week. Baseline laxatives were continued during the study with rescue laxatives not permitted for 4 hrs before and after each dose. Patients and clinicians reported their assessment of change in bowel status on Day 7 and Day 14 using a 7-point Likert GCIC scale (1 = Much worse, 7 = Much better). Patients assessed constipation distress using a 5-point Likert scale (1 = None, 5 = Very much) at baseline, Day 7 and Day 14. A sub-group of cancer patients (N = 64) was selected and proportion of patients showing improved status (GCIC score >4) as indicated by patient and clinician GCIC scores were compared between methylnaltrexone and placebo using chi-square test. Correlation coefficients were estimated between patient and clinician reported GCIC and change in constipation distress scores.
Significantly higher percentages of methylnaltrexone-treated cancer patients and their clinicians rated patient's bowel status as improved compared to the placebo group on Day 7 (patient: 75% vs 37.5%: $p < 0.05$; clinician: 65.6% vs 37.5%: $p < 0.05$) and Day 14 (patient:75% vs 37.9%: $p < 0.05$; clinician: 68.8% vs 46.7%: $p < 0.05$). A significant positive correlation was found between patient and clinician reported GCIC scores across both groups on day 7 ($r = 0.86$; $p < 0.001$) and day 14 ($r = 0.84$; $p < 0.001$). A significant inverse correlation ($p < 0.001$) was found between the change in constipation distress and GCIC scores in the methylnaltrexone group on Day 7 (patient: $r = -0.79$; clinician: $r = -0.84$) and Day 14 (patient: $r = -0.55$; clinician: $r = -0.49$).
Methylnaltrexone showed a significant positive impact on bowel status in this study of cancer patients with opioid induced constipation as reflected by the patient and clinician reported GCIC scores.

1122 POSTER

Prevention of anemia by early intervention with once weekly epoetin alfa during chemotherapy

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Background: There is good evidence that epoetin alfa (Eprex®, EPO) is effective in treating moderate to severe anemia during cytotoxic cancer treatment. Further research is required to clarify its role in the treatment of mild anemia and the prevention of anemia in this setting.
Materials and Methods: In a randomised, multicentre trial the effects of EPO on hemoglobin (Hb) levels and the need for bloodtransfusions (BT) were assessed in cancer patients (pts) started on chemotherapy (CT). Pts with Hb < 12.1 g/dl and likely to receive CT for at least 12 weeks, were randomised (1:1) to EPO (40.000 U QW) to be started with CT simultaneously (early EPO) or when Hb dropped below 10.1 g/dl (standard EPO).
Results: A final analysis was performed after enrolling 110 pts (55 early EPO versus 55 standard EPO) as planned. Treatment groups were comparable for gender, age, performance score and tumor type. Mean Hb at baseline was 11.2 and 11.3 g/dl, respectively, and EPO was started at an average Hb value of 11.2 and 10.0 g/dl. Hb values in the two treatment groups diverted significantly after week 6, 8/9, 10, 12 and 15/16 ($p < 0.05$, Wilcoxon two sample test). No significant difference was observed in the percentage of pts receiving BT's after early versus standard EPO (27.8% of patients transfused in both groups). The amount of blood transfused, however, was almost twice as high in the standard EPO group versus the early EPO group. EPO treatment was well tolerated in both groups. Adverse events (AE's) were as expected in a population of cancer pts treated with CT. Slightly more thrombovascular events (TVE's) were observed in the early EPO group. There was no significant difference in overall survival between both groups.
Conclusions: EPO treatment for mild CT-induced anemia (Hb < 12.1 g/dl), increases Hb values and results in significantly higher Hb values as compared to EPO therapy initiated when Hb drops below 10.1 g/dl. Percentage of pts receiving BT's after early versus standard EPO was similar, however, the amount of blood transfused was almost twice as high in the standard EPO group. Maintaining Hb values around 12.1 g/dl may have a positive impact on quality of life according to several literature reports on this topic.

1123 POSTER

Neoplastic pulmonary lymphangitis: clinical aspects, symptomatic treatment and quality of life in a prospective palliative care series

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Background: Neoplastic pulmonary lymphangitis (NPL), or lymphangitis carcinomatosa, has a poor prognosis and is a distressing form of lung metastasis. Since measuring quality of life is an important step toward improving management in cancer patients, and breathlessness in pulmonary lymphangitis is a complex syndrome in end-of-life care, we evaluated a cohort of those individuals.
Methods: 52 consecutive patients with NPL were prospectively followed in 3 services, with clinical data gathering, and quality of life (QoL) evaluation also, using Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) and Saint George's Respiratory Questionnaire (SGRQ).
Results: Sixty-five percent of patients were female; age ranged from 37 to 84 years (median: 60.5). Primary tumor sites were: 28 lung (54%),