

each class (class 1: 100%; class 2: 100%; class 3: 100%; class 4: 100%; class 5: 88%).

**Conclusion:** Understanding and identifying different types of information preference groups that exist, may help physicians to tailor information to CP and/or refer them to other health professionals in oncology who are responsible for social questions and/or health promotion. As a result, physicians may enhance CPs' psychosocial health outcomes.

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POSTER

#### **Determinants and patient-reported long-term outcomes of physician empathy in oncology: A structural equation modelling approach**

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**Background:** Physician empathy (PE) is assumed to improve desirable outcomes e.g. compliance, reduction of distress and enablement. As there is currently limited empirical evidence about PE in cancer care, its effectiveness for cancer patients (CP) as well as determinants of PE, the purpose of this cross-sectional study was to explore the influence of PE on long-term outcomes in German CP and to analyze CP- and physician-specific determinants of PE.

**Methods:** A postal survey was administered to 710 CP, who had been inpatients at the University Hospital Cologne (response rate 49.5%). PE was measured with the German translation of the Consultation and Relational Empathy (CARE) measure, and patient-reported long-term outcomes were assessed using the STATE-Scale of the State-Trait-Anxiety-Inventory, the Major Depression Inventory (MDI) as well as the EORTC-Quality of Life (QoL) Questionnaire-QLQ-C30. Hypotheses were tested by structural equation modeling with "AMOS 4.0" software to analyze the relationships between variables.

**Results:** PE (a) had a moderate indirect effect on "depression" and a smaller indirect effect on "socio-emotional-cognitive QoL" by affecting "information from physician: findings and treatment options" and (b) had via "information about health promotion" a moderate indirect effect on "socio-emotional-cognitive QoL" and a smaller effect on "depression". The determinant with the greatest importance was "general busy-ness in hospital staff": it had a strong negative influence on PE, indirectly influencing "information from physician: findings and treatment options" and also patients' "depression".

**Conclusion:** PE seems to be an important pre-requisite for information giving by physicians and through this pathway having a preventive effect on depression and improving QoL. Conversely, physicians' stress negatively influences these relationships.

The research findings suggest that reducing physicians' stress at the organizational and individual may be required to enhance patient-physician communication and patient-reported outcomes. Therefore, future research should prospectively investigate physicians' working conditions from the perspective of CP and physicians to analyze the influence of physicians' working conditions on the patient-physician relationship (e.g. PE, information) as well as on patient-reported and physician-reported outcomes (e.g. stress, burn-out, job dissatisfaction) in an integrated and evidence-based study approach.

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POSTER

#### **Epidermal Ggrowth Factor Receptor Inhibitor (EGFRI)-associated rash: a suggested novel management paradigm. A consensus position from the EGFRI Dermatologic Toxicity Forum**

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**Background:** Epidermal Growth Factor Receptor Inhibitors (EGFRIs) are associated with unique, class-specific skin, hair and nail reactions that have

potential to disrupt optimal dosing. These are often best addressed by symptomatic treatment, but there is limited controlled, clinical evidence on which to base such treatments. In October 2006, at a US-based EGFRI dermatologic toxicity forum, therapeutic interventions were evaluated and a consensus treatment algorithm was developed. We present this approach within the context of the EU.

**Method:** 13 experts (oncologists, oncology nurses, pharmacists, dermatologists) attended the forum; all had extensive experience in the management of EGFRI-associated cutaneous toxicities.

**Results:** Moisturizing dry areas twice a day with thick alcohol-free emollient and limiting exposure to sunlight will likely decrease incidence of dermatologic toxicities. A physical sunscreen (zinc oxide or titanium dioxide) with an SPF  $\geq 15$  should be applied 1–2 hours prior to sun-exposure. Should dermatologic toxicity occur, an EGFRI-specific three-tiered grading system and step-wise treatment algorithm is proposed.

Mild toxicity—generally localized rash that is minimally symptomatic, with no sign of superinfection, and no impact on daily activities, may not require any form of intervention, but alternatively may be treated with low dose corticosteroid cream or antimicrobial gel/cream.

Moderate toxicity—generalized rash, accompanied by mild pruritus or tenderness, with minimal impact upon daily activities, and no signs of superinfection, should be treated with doxycycline or minocycline (100 mg PO BID) plus low dose corticosteroid cream, antimicrobial gel/cream, or a topical calcineurin inhibitor.

Severe toxicity—generalized rash, accompanied by severe pruritus or tenderness, that has significant impact upon daily activity, and has potential for superinfection should be treated as for moderate toxicity, plus a short term course of oral corticosteroid. EGFRI dose-reduction is also recommended for severe symptoms, in accordance with the product information. If dermatologic symptoms do not abate, despite treatment, then EGFRI interruption is recommended, but should be restarted once the cutaneous reactions have sufficiently diminished in severity.

**Conclusions:** EGFRI-associated dermatologic reactions are generally manageable, without dose reduction or interruption of EGFRI therapy. The practical application of this strategy is discussed.

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POSTER

#### **Impact of pre-operative chemotherapy on the Quality of Life of patients with resectable non-small cell lung cancer using data from the MRC LU22/NVALT 2/EORTC 08012 multicentre randomised clinical trial**

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**Background:** There is a paucity of data relating to the longer-term Quality of Life (QL) of patients undergoing potentially curative treatment for non-small cell lung cancer (NSCLC). QL evaluation was therefore integrated into the LU22 trial to assess and compare the QL of patients receiving either surgery alone (S) or 3 cycles of platinum-based chemotherapy (CT-S) followed by surgery.

**Methods:** All patients were asked to complete SF-36 QL questionnaires prior to randomisation, at 6 and 12 months then annually to 5 years. SF-36 scores were combined into 8 domains and also summarised as a Physical Component Summary (PCS) and Mental Component Summary (MCS). Multivariable regression was used to identify baseline prognostic factors for the 6, 12 and 24 month PCS and MCS scores.

**Results:** There was no evidence of a survival difference between the 2 treatment groups (519 patients, 244 deaths, median S: 54 months, CT-S 49 months, HR 1.02, 95% CI 0.80, 1.31). Compliance in completion of the SF36 was 82% at baseline, 59%, 60% and 67% at 6, 12 and 24 months respectively. At 6 months, the S and CTS groups reported comparable functioning in 7 domains, but there was a significant difference in role physical in favour of the S group. No differences were observed between the treatment arms for any of the domains at 12 or 24 months. Regression analyses indicated that better physical health outcomes (PCS) were predicted at all follow-up points by baseline PCS and MCS (all  $p < 0.05$ ), whereas longer time since surgery predicted better PCS at 6 months ( $p < 0.05$ ), and younger age predicted better PCS at 24 months ( $p = 0.07$ ). Better MCS was predicted at all time points by baseline MCS ( $p < 0.05$ ). In addition, female gender and baseline PCS were predictors at 6 months ( $p = 0.07$  and  $p < 0.05$  respectively) whilst younger age predicted better MCS at 24 months ( $p < 0.01$ ). 39% patients rated their health as excellent or very good at baseline, which reduced to 26% at 6 months, no further changes occurred at 1 or 2 years. More than 50% patients considered their health comparable to others, and over 45% were generally optimistic about their future health at 1 and 2 years.

**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.

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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 first 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 (epirubicin 90 mg/m<sup>2</sup> 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.

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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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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.

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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