AV, of whom 22/69 pts (32%) receiving ApAR had no DV while 20/136 pts (15%) receiving SAR had no DV. Although pts with no AV were more likely to have no DV, 204/838 pts (24%) with no AV still had DV. However, the similar magnitude of improvement in the prevention of DV with ApAR in pts with AV (17%) and with no AV (16%) showed that the effect of Ap on DV is a pharmacologic effect rather than simply a "carryover" effect of prevention of AV.

946 POSTER

#### Compulsory constipation? - an evaluation of the prevalence and management of constipation in palliative care

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Background: Constipation is a side effect of many drugs commonly used in palliative care. About 50% of patients admitted to British hospices cite constipation as a major concern. There has been little evaluation of the effectiveness of constipation management or assessment of the effect of constipation on the quality of life of patients with palliative care needs. A multi-centre study was conducted to evaluate; 1) how effectively constipation is managed in different palliative care settings; and 2) any differences in perceptions of the effect constipation has on quality of life between patients and their carers.

**Methods:** Patients (in-patient and day therapy) were recruited from the Marie Curie Cancer Care specialist palliative care services across the UK. Self administered questionnaires incorporating the Patient Assessment of Constipation Symptoms, the Palliative Care Outcome Scale and study-specific questions were completed by patients, their named nurse and where possible their main family carer. Informed consent was obtained. Questionnaires were completed on day 1 and 7 - 10 days later.

**Results:** 413 patients completed both questionnaires (207 in-patients and 206 day patients).

Conclusions: Results from the questionnaire data will be discussed. Differences in the management of constipation across the care settings will be highlighted together with variations in patients perception of constipation and actual constipation symptoms. Laxative efficacy varied between individuals supporting the notion that laxative type and dose should be titrated to patient response. Variations in perception of the impact of constipation on quality of life between patients and their carers will be discussed.

947 POSTER

# Chemotherapy-associated anemia in breast cancer patients: Prevalence and incidence from the European Cancer Anemia Survey (ECAS)

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New treatment (tx) regimens and chemotherapy (CT) agents have increased chances for survival for breast cancer (BC) patients (pts). Anemia remains a significant adverse effect of BC and its tx, and is reported in substantial numbers of pts treated with conventional and new agents (Groopman 1999). The large, prospective, multinational ECAS followed pts for up to 6 months to evaluate prevalence and incidence of anemia (hemoglobin [Hb]/=12 ydL, respectively. Only 26% of BC pts who had anemia during ECAS received anemia tx. Mean Hb level was 9.0 g/dL for first transfusion and 10.4 g/dL for first administration of epoetin. These results show that the prevalence and incidence of anemia in pts with BC is high regardless of CT regimen. Anemia is a serious consequence of tx with newer agents and regimens, as well as standard, non-platinum regimens. Despite the significant negative impact of anemia on PS, most anemic BC pts did not receive anemia tx.

948 POSTER

# The "comprehensive geriatric assessment" evaluation: a selection of informative questionnaires for essential parameters. Preliminary experience by a single institution

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Comprehensive geriatric assessment (CGA) is a structured approach aiming at measuring the most important parameters to identify needs and

to plan care in elderly patients. They may be identified as: functional, cognitive, presence of comorbidity and nutritional. The selected instruments were: the activity of daily living (ADL) and the instrumental activities of daily living (IADL) scales in addition to PS for function, the Mini-Mental Status Examination and the Beck's Depression Inventory (cognitive); the Charlson's scale (comorbidity) and the Mininutritional Assessment (MNA) for nutrition. The aim of our study was to develop a best-practice model both exhaustive and feasible for geriatric assessment of elderly cancer patients (i.e. aged 65 years or older). 58 elderly patients (M/F: 31/27, mean age 72 years, range 65-86) with cancer at different sites were assessed. 10% of patients had stage II, 22% stage III and 68% stage IV disease. 13.8% of patients had PS 0, 62% PS 1, 13.8% PS 2, 5.2% PS 3 and 5.2% PS 4. Overall, 46.6% of patients had no limitations for ADL, 6.8% were completely dependent. Approximately 30% of patients had no limitations for IADL, 53.4% showed symptoms of depression (15.4% of them had an heavy depression). 39.7% of patients showed a mild to serious cognitive defects: no correlation was observed with increasing age and education. 43.1% of patients showed comorbidities and 17.3% were malnourished. Patients showed an optimal compliance for the instruments used. The study is ongoing to assess the prognostic role of CGA on the disease outcome.

949 POSTER

#### Fecal human DNA as a marker of intestinal toxicity in patients undergoing abdominal radiotherapy

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Background: Radiotherapy can damage intestinal tissues and impair gut function. Specifically, radiation impairs crypt cell proliferation and induces epithelial denudation and atrophy. Acute toxicity is manifested by symptoms of diarrhea, proctitis and colitis. There is no reliable biological marker to evidence and quantify intestinal toxicity. The aim of the study was to evaluate the relations between acute intestinal toxicity and epithelial exfoliation in patients submitted to therapeutic pelvic radiation.

Material and methods: Twenty-four patients ongoing radiotherapy for various turnour sources were studied: 54% rectum, 25% endometrium, 13% cervix uteri and 8% prostate. Four stool samples were collected on each patient (before starting the treatment, between the second and third week of radiotherapy, at the end of treatment and two weeks later). Exfoliation of the epithelium was determined in these samples by quantitative PCR amplification of a fragment of the human beta globine gene from purified DNA. This gene is not encountered in bacteria present in the gut, and therefore specific for host DNA. Results were expressed as copies of DNA per milligram dry weight of stool. In parallel, severity of diarrhea associated with radiotherapy was scored according to the CTC (Common Toxicity Criteria) into four levels: degrees 0 to 3 of diarrhea.

**Results:** Fecal DNA levels expressed as median (range) in the four groups classified according to severity of diarrhea were: Degree-0: 1.8x10³ (7.0x10¹ 4.6x10⁴); Degree-1: 4.2x10³ (3.9x10² 1.1x10⁴); Degree-2: 2.2x10⁴ (1.2x10³ 3.4x10⁶); Degree-3, 1.1x10⁴ (8.0x10² 6.2x10⁶). Analysis of variance (Kruskal-Wallis) showed statistical differences among groups (p=0.006). Spearman's rank correlation between fecal DNA and severity of diarrhea was significant (r=0.33, p=0.002).

**Conclusions:** Fecal DNA may be a good quantitative marker of intestinal radiotoxicity.

950 POSTER

Darbepoetin alfa significantly improved fatigue in patients with lymphoproliferative malignancies undergoing chemotherapy: results of a phase 3 multicenter, randomized, double-blind, placebo-controlled study

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Background: Anaemia-related fatigue is associated with reduced quality of life in patients undergoing cancer chemotherapy. Elevation of haemoglobin by treatment with erythropoletic agents, darbepoetin alfa and recombinant human erythropoietin, has been shown to reduce fatigue and improve other patient-reported outcomes in patients with solid tumors (Kallich et al, 2002; Berndt et al, 2002). This phase 3 study in patients with lymphoproliferative

malignancies was designed to evaluate the effects of darbepoetin alfa on haemoglobin and transfusion endpoints, as well as on health-related quality of life (HRQOL).

**Methods:** A multicenter, randomized, double-blind, placebo-controlled study of 12-week treatment with darbepoetin alfa (2.25 mcg/kg once weekly) was conducted in anaemic (haemoglobin < 11.0 g/dL) cancer patients with lymphoproliferative malignancies receiving multicycle chemotherapy. Patients completed the 13-item FACT-Fatigue subscale score at baseline and after 4, 8, and 12 weeks.

**Results:** 349 patients were randomized to the study (176 darbepoetin alfa; 173 placebo). Mean change (SE) in haemoglobin for patients completing 12 weeks of treatment was significantly greater for the darbepoetin alfa group vs the placebo group (2.66 [0.20] g/dL versus 0.69 [0.14] g/dL, p < 0.001). Patients treated with darbepoetin alfa showed a greater improvement in their FACT-Fatigue subscale score compared with placebo, regardless of their level of fatigue at baseline. However, baseline FACT-Fatigue score had a significant (p < 0.001) effect on the change in FACT-Fatigue score such that patients with lower baseline scores had greater improvements than patients with higher baseline scores. After adjusting for baseline score, increases in FACT-Fatigue subscale scores with darbepoetin alfa treatment were significantly greater than those observed with placebo (difference of 2.28 points [95% CI, 0.19, 4.37], p = 0.032. In addition, there was a statistically significant (p < 0.001) relationship between change in haemoglobin and change in FACT-Fatigue over the treatment period.

**Conclusion:** The results of this phase 3 study confirm that darbepoetin alfa is effective in significantly improving both haemoglobin concentrations and fatigue relative to placebo in patients with lymphoproliferative malignancies receiving concurrent chemotherapy.

951 POSTER

### Quality of life in breast cancer patients eighteen months after diagnosis

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A longitudinal study was conducted to measure quality of life in breast cancer patients. Quality of life was assessed at three points in time: baseline, 3 months after diagnosis and completion of the initial treatment and after 18 months post diagnosis. The EORTC QLQ-C30 and its breast cancer questionnaire (QLQ-BR23) were used to measure quality of life. In all, 167 breast cancer patients were interviewed. Of these, for 99 patients both baseline and follow-up data were available. Thus, paired test analysis was performed to compare baseline data with that of 18 months follow-up assessment. The results showed that there was reduction in patients' physical, role, social emotional and cognitive functioning. The change in global quality of life was significant (mean score 59.2 vs. 31.9, P<0.0001). In addition body image, and sexual activity as measured by the QLQ-BR23 showed a significant worsening (all P<0.0001). Also patients reported a higher degree of symptoms at follow-up. Of these pain, fatigue and breast symptoms were significant (all P<0.0001). In general the findings indicate that breast cancer patients even after 18 months post diagnosis suffer from a poor quality of life. This suggests that the continuity of care for breast cancer patients is needed to ensure patients' health status. Since most reduction was observed in patients' global quality of life, indeed this is a good indicator to ascertain clinical achievements in management of breast cancer patients.

952 POSTER

### Treatment of radiation - induced lung damages after breast conserving therapy

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**Background:** Studying the improvement opportunity and the response of treatment on acute and late symptomatic radiation pulmonary damages by applying the Indomethacin<sup>®</sup> and moderate dose of Dexamethason<sup>®</sup> after breast-conserving therapy.

Material and method: Between 1992 and 1997 yrs., 122 early breast cancer patients were treated with postoperative radiotherapy after preserving surgery by "negative" margin (BCT). For all patients CT treatment planning was made for precise outlining of the CTV and the organs of risk. The target volume was irradiated with two tangential fields (<sup>60</sup>1⇒) without boost for the tumor bed to the prescribed total dose of 50Gy in 25 fr. for

5 wks. The adjuvant system treatment includes VI courses chemotherapy type sandwich of application and Tam in patients, with SR+.

Results: 8 year local control in 95, 1% of patients were accomplished, as in 1, 6% acute radiation pulmonitis (RP) and 1, 6% pulmofibrosis (PF) were diagnosticised. Symptoms of RP 6-9 mnths after completion of therapy and 4-6 yrs in patients with PF become evident. The cardinal symptoms in all patients were dyspnea and nonproductive cough. All patients with PF did not present previous history of RP. CT scans of the chest and 99<sup>m</sup>Tc MIBI imagine were more sensitive than chest radiography in the detection of radiation damages. The patients are between 61-70 years old as with 50% of them diabetes mellitus type II is present. With 75% of the patients with lung damages low graded oedema of the arm is found. The irradiation of the homolateral IMN with wide field leads to frequent lung toxicity (p=0,006). The treatment schemes included 14 days cycle of administration of Indomethacin<sup>®</sup> (3X25mg daily) and Dexamethason<sup>®</sup> 3 times weekly x 4mg and than with Vitamin E and A. Complete resolution of signs and symptoms were observed 1 month after RP and 3-6 months after PF.

Conclusions: The treatment of post-radiation pulmonary complications with Indomethacin® and moderate doses of Dexamethason® leads to complete response in all patients after BCT.

953 POSTER

## The health related quality of life and preference of breast conservation for breast cancer patients in north Taiwan.

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**Introduction:** To evaluate the quality of life and preference of breast conservation of breast cancer patients after radical treatment.

Material and Method: There were 220 breast cancer patients received questionnaire to report their health related quality of life (QoL) and preference of treatment choice in two different hospitals in northern Taiwan, one in metropolitan and other in suburb area. The median age was 49 (32-69). The median year after radiotherapy was 5 year (ranging from 1 to 12 years) Functional Assessment of Cancer Therapy Breast (FACT-B) questionnaire was used to assess QoL. The preference of treatment and need of breast reconstruction was also evaluated. Sixty three (28.6%) patients received breast conservation treatment and 157 (71.3%) patient received modified radical mastectomy. One hundred and seventy eight (80.9%) patients received chemotherapy as adjuvant chemotherapy, 82 patients received adjuvant radiotherapy, 119 patients received hormone therapy.

Result: There is no significant difference in QoL including in different subscales between breast conservation patients or mastectomy patients. Education level, income, martial status, living alone or not and adjuvant therapy did not affect the QoL in different subscale. However, there are 2 (3.2%) patients received breast reconstruction or wearing artificial breast in breast conservation group and 78 (49.7%) patients received breast reconstruction or wearing artificial breast in mastectomy group (p=0.00). If choosing again for the treatment, 12 (19.0%) patients will change to mastectomy in breast conservation group and 76(48.4%) patients will change to breast conservation treatment in mastectomy group (p=0.00).

Conclusion: Mastectomy or not had no impact to quality of life of breast cancer patients in northern Taiwan. However, about half mastectomy patients will want to receive breast reconstruction treatment and will change to breast conservation treatment if they had second chance.

954 POSTER

#### Role of palliative radiotherapy in pediatric solid tumours.

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Background: Palliative radiotherapy is given with the intent of relieving symptoms in advanced tumors. Although pediatric malignancies are exquisitely sensitive to chemotherapy, in certain circumstances radiotherapy has a role in symptomatic management of advanced tumors. The common indication for palliative radiotherapy are pain relief from bone metastasis and nerve compression, control of bleeding, ulceration and fungation, impending air way obstruction, SVCO, spinal cord compression, impending and or pathological fracture, brain metastasis etc. As in developing country its still common to see the childhood patients presenting with advanced cancers, palliative radiotherapy has been offered to most of them for symptomatic treatment. We did a retrospective study to define the role of palliative radiotherapy in pediatric solid tumors.