in these 37 patients. The majority of lesions were melanoma (59%); 41% were other tumour types (carcinoma, adenocarcinoma and sarcoma).

Two drugs were used, bleomycin (BLM) and cisplatin (CDDP). BLM was delivered intratumourally or intravenously, while CDDP was administered only intratumourally. ECT was performed under general or local anaesthesia. Electric pulses were delivered by CLINIPORATOR™. EP occurred following the delivery of 8 high voltage pulses (1kV/cm), 100 μs long. Three different types of electrodes (plate, linear needle and hexagonal needle) were available for treatment. Evaluation of anti-tumour efficacy was based on WHO criteria: Complete Response (CR), Partial Response (PR), No Change (NC) and Progressive Disease (PD).

Results: Among the 37 patients, the average age was 63. The average size of tumour nodules before treatment was 1.82 cm<sup>3</sup> (SD 7.86 cm<sup>3</sup>). The Objective Response (OR) rate (CR+PR) was 78.5% with a 63.2% CR rate. Non-melanoma nodules had a significantly higher OR rate (83.5%) than melanomas (75%), p = 0.009.

There was no significant difference between drug delivery modes: OR rate was 75.3% for the intratumour versus 82.9% for the intravenous route. Intratumour CDDP was found to be slightly more efficient (OR 82.5%) than intravenous CDDP (69.2%), N.S.

When the current levels delivered were considered, the best results were observed when at least 1.5 amps and 2 amps were delivered via needle electrodes and plate electrodes respectively.

Conclusion: ECT is a safe and effective treatment capable of controlling tumour growth locally. Negative side effects were rare and were tractable. This multicentre study allowed us to develop Standard Operating Procedures to be used as guidelines in daily clinical practice.

# 1306 PUBLICATION Amenorrhea in younger women treated with neoadjuvant/adjuvant chemotherapy for early breast cancer

C. Zamagni, A. Bernardi, F. Massari, M. Rosati, S. Quercia, N. Cacciari, A. Martoni. S. Orsola-Malpighi Hospital, Medical Oncology Unit, Bologna, Italy

Chemotherapy (CT)-related amenorrhea can influence heavily the quality of life of younger women with early breast cancer (menopausal symptoms, loss of fertility, long-term side-effects). On the other hand the suppression ovarian function has a major therapeutic role in hormonal receptors positive patients (pts). The risk of amenorrhea is related to the type and doses of CT and to patient age (less than 20% in pts younger than 35 years treated with standard-dose CT). We analyzed 45 consecutive pts aged  $\leqslant$  39 years with early or locally advanced breast cancer (Stage I to IIIc) treated with primary and/or adjuvant CT: 21 and 24 pts were aged  $\leqslant$  35 and 35–39 years, respectively.

Characteristics of the pts: Stage I: 8 (18%); Stage II a-b: 18 (40%); Stage III a-b-c: 19 (42%); hormonal receptors (ER and PgR) were both positive (>10% by IHC) in 17 pts (38%), both negative in 14 pts (31%), ER+/PgR-in 10 pts (22%) and ER-/PgR+ in 4 pts (9%); 67% of the pts treated with adjuvant CT were node positive and the median number of axillary lymphnodes involved was 4 (range 1–16).

CT regimens (all doses are in mg/m²): CMF d1-8 for 6 courses: 8 pts (18%); epirubicin 120 for 3-4 courses followed by CMF d1-8 for 3-4 courses:12 (27%); epirubicin 90 or doxorubicin 60 plus paclitaxel 175-200 for 4-6 courses: 9 pts (20%); FEC 75-100 for 6 courses: 6 pts (13%); high-dose sequential CT with peripheral haematopoietic stem cells support (cyclophosphamide 7000; methotrexate 8000; thiotepa 600 or mitozantrone 60 followed by melphalan): 10 pts (22%); three pts were treated with primary CT with anthracyclines/paclitaxel before surgery and high-dose adjuvant CT. CT was followed by hormonal therapy if ER and/or PgR were positive.

Results: after a median follow up of 46 mo.s (range 2–90) 7 patients relapsed (16%) and 3 died for metastatic breast cancer (7%). Forty pts are evaluable for amenhorrea (5 pts are still on treatment). Permanent amenorrhea was observed in 14 pts: 4 /17 (24%) in the group aged under 35 and 10/23 (43%) in the group aged over 35 yrs. These patients had received high-dose CT (4/4 in the former group and 6/10 in the latter), anthracyclines and paclitaxel (n = 3) or FEC (n = 1).

**Conclusions:** in this group of younger patients (aged  $\leqslant$ 39 years) amenhorrea was universal after high-dose sequential CT and rare (13%) in pts treated with standard dose CT (anthra.  $\pm$  paclitaxel containing regimens). No permanent amenorrhea was observed in 20 pts treated with i.v. CMF or with epirubicin 120 mg/m² followed by CMF.

307 PUBLICATION

Zoledronic acid provides early reduction in the occurrence of skeletal complications in patients with bone metastases from a broad range of solid tumors

L. Rosen<sup>1</sup>, F. Saad<sup>2</sup>, Y. Hei<sup>3</sup>. <sup>1</sup>Premiere Oncology, Director, Developmental Therapeutics, Santa Monica, USA; <sup>2</sup>Hôpital Notre-Dame, Montreal, Quebec, Canada; <sup>3</sup>Novartis Oncology, East Hanover, USA

Background: Bone metastases are associated with significant skeletal morbidity in patients with advanced cancer. Patients with skeletal metastases are at risk for developing painful skeletal-related events (SREs), including pathologic fractures, spinal cord compression, and radiation or surgery to bone. Zoledronic acid is the only bisphosphonate that has demonstrated efficacy in preventing SREs in patients with bone metastases from any solid tumor.

**Material and methods:** In this retrospective analysis, the occurrence of SREs was evaluated at 1, 2, and 3 months after treatment initiation (zoledronic acid 4 mg or placebo every 3 or 4 weeks) in patients with bone metastases from prostate cancer (n = 422) or lung cancer and other solid tumors (n = 507).

Results: The numbers of SREs experienced at months 1, 2, and 3 are shown in the table below. Compared with placebo, zoledronic acid 4 mg substantially reduced the total number of SREs within the first 3 months of treatment in patients with prostate cancer or lung cancer and other solid tumors. While the number of patients was similar between the zoledronic acid and placebo groups, the total number of SREs was higher in the placebo group and the effect was observed as early as the first month of treatment.

Total Number of Skeletal-Related Events in the First 3 Months of Treatment.

|       | Number of events (number of patients at risk) |           |                     |           |
|-------|---|-----------|---------------------|-----------|
|       | Prostate cancer                               |           | Lung cancer and OST |           |
| Month | Zoledronic acid                               | Placebo   | Zoledronic acid     | Placebo   |
| 1     | 12 (214)                                      | 21 (208)  | 43 (257)            | 64 (250)  |
| 2     | 27 (203)                                      | 50 (199)  | 75 (229)            | 120 (215) |
| (186) | 88 (190)                                      | 133 (185) | 179 (174)           |           |

OST = Other solid tumors

**Conclusions:** Zoledronic acid has a fast onset of action in the prevention of SREs in patients with bone metastases from any solid tumor with the effect observed within the first 3 months of treatment.

# 1308 PUBLICATION Care during the last 3 days of life of patients in hospital

L. Veerbeek<sup>1</sup>, L. Van Zuylen<sup>2</sup>, M. Folsche<sup>2</sup>, G. Jongeneel<sup>2</sup>, E. Reyerink<sup>3</sup>, J. van den Berg<sup>4</sup>, J. Rehorst<sup>4</sup>, S. Swart<sup>5</sup>, E. van den Aardweg<sup>6</sup>, A. van der Heide<sup>1</sup>. <sup>1</sup>Erasmus MC, University Medical Center Rotterdam, Public Health, Rotterdam, The Netherlands; <sup>2</sup>Erasmus MC-Daniel den Hoed Cancer Center, Medical Oncology, Rotterdam, The Netherlands; <sup>3</sup>Medical Center Rijnmond Zuid, Medical Oncology, Rotterdam, The Netherlands; <sup>4</sup>Erasmus MC-Daniel den Hoed Cancer Center, Radiotherapy, Rotterdam, The Netherlands; <sup>5</sup>Nursing Home Antonius IJsselmonde, Rotterdam, The Netherlands; <sup>6</sup>Comprehensive Cancer Center Rotterdam, Rotterdam, The Netherlands

Background: of all deaths in the Netherlands, about 40% occurs in the hospital. Whereas patients are usually admitted to a hospital to temporarily receive intensive treatment, care in the hospital may not be tailored to dying patients. Therefore it is worthwhile to investigate the characteristics of terminal care in the hospital.

Patients and methods: Between December 2003 and February 2005 data were collected concerning patients who died at the department of medical oncology of a general hospital and at the departments of medical oncology, radiotherapy, pulmonary diseases and gynaecological diseases of a university hospital in the Netherlands. Nurses who had been closely involved with the care for these patients were asked to fill in a written questionnaire on the care that was provided during the last 3 days of life. Medical information was gathered from the medical record.

Results: Hundred thirteen deceased patients were included in the study. For 99% of them the nurses filled in a questionnaire. The median age of the deceased patients was 66 years (range 19-90) and 50% of the patients were male. The cause of death was a malignancy in 89% of all patients. The median number of symptoms during the last 3 days of life was 15 (range 0-24). The most troublesome symptoms were fatigue, lack of appetite, shortness of breath and pain. Patients received a median of 2 medical interventions during the last 3 days of life, such as the set

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up of a syringe driver (58%), vena punctures (46%), or antibiotics (26%). Patients had undergone a median of 3 nursing types of care during the last 3 days of life, such as daily washing or showering (76%), measurements of body temperature (63%) and blood pressure (61%), and a routine turning procedure to prevent bedsores (25%). **Discussion:** Most patients dying in hospital receive medical and nursing

**Discussion:** Most patients dying in hospital receive medical and nursing types of treatment that may have decreased their comfort during the dying process. Caregivers in the hospital may not in all cases have been aware that patients were dying and that care had to be refocused. Currently, it is studied whether the Dutch version of the *Liverpool Care Pathway for the Dying Patient* can be helpful in these situations.

#### 1309 PUBLICATION

### Procalcitonin in cancer patients with febrile neutropenia

A. Uys<sup>1</sup>, B.L. Rapoport<sup>1</sup>, H. Fickl<sup>2</sup>, P.W.A. Meyer<sup>2</sup>, R. Anderson<sup>2</sup>. <sup>1</sup>The Medical Oncology Centre of Rosebank, Research, Johannesburg, South Africa; <sup>2</sup>University of Pretoria and Tshwane Academic Division of the National Health Labo, Immunology, Pretoria, South Africa

Background: This study was undertaken to determine the value of procalcitonin (PCT), measured in cancer patients on presentation with chemotherapy-induced febrile neutropenia (FN), as a predictive marker to distinguish patients with serious infection from those with less serious infection and non-infective causes of pyrexia, as well as relationships between PCT and the Multinational Association of Supportive Care in Cancer (MASCC) score, as well as the leucocyte, monocyte and neutrophil counts.

Patients and methods: Baseline and serial PCT levels were determined in 78 febrile neutropenic episodes. Patients were classified into groups with normal (<0.5 ng/mL) or elevated (>0.5 ng/mL) initial circulating PCT values. Results: of 57 patients (73%), mostly with fever of unknown origin (FUO), who had low PCT values at baseline, 56 survived. The remaining 21 patients (27%), 11 (57.1%) of whom had microbiologically proven infections, presented with elevated PCT values, and 7 (31.8%) of these died (p < 0.0001). With respect to relationships with clinical and haematological criteria, PCT was found to correlate significantly and negatively with the MASCC score, as well as with the leucocyte, monocyte and neutrophil counts.

**Conclusion:** If used as an adjunct to conventional scoring systems, PCT measured on resentation with FN is a potentially useful strategy to distinguish between patients who are at high risk of life-threatening infection and those with either less severe infection or non-infective causes of pyrexia.

1310 PUBLICATION

Speed of response to epoetin beta in patients with solid tumours undergoing chemotherapy: results of a meta-analysis

M. Nowrousian<sup>1</sup>, C. Oberhoff<sup>2</sup>, J. Morère<sup>3</sup>, S. Monfardini<sup>4</sup>, C. Hayward<sup>5</sup>, H. Burger<sup>5</sup>. <sup>1</sup>West Germany Cancer Centre, Department of Internal Medicine (Cancer Research), Essen, Germany; <sup>2</sup>Centre for Gynaecology and Obstetrics, University Hospital, Essen, Germany; <sup>3</sup>University Paris XIII, Paris, France; <sup>4</sup>Division of Medical Oncology, Azienda Ospedale Università, Padova, Italy; <sup>5</sup>F. Hoffmann-La Roche, Basel, Switzerland

Background: Anaemia is common in patients with solid tumours undergoing myelosuppressive chemotherapy. Recombinant human erythropoietins (epoetins) have been available for the treatment of anaemia for many years and have a proven efficacy across a range of malignancy types. Patients generally undergo around six cycles of chemotherapy (18–24 weeks), and so it is important for patients to obtain a rapid haemoglobin (Hb) rise when receiving epoetin therapy to maximise quality of life and minimise the need for transfusion. A meta-analysis was performed to investigate the speed of response to epoetin beta (NeoRecormon®) in patients with solid tumours undergoing chemotherapy.

**Methods:** Data were pooled from three randomised, controlled clinical trials of epoetin beta in anaemic patients with solid tumours undergoing chemotherapy (ten Bokkel Huinink et al 1998; Oberhoff et al 1998; Boogaerts et al 2003). Patients were divided into those receiving epoetin beta (~30 000-60 000 IU per week) or standard care (control). Changes in Hb level from study records over a treatment period of 16 weeks were collected and analysed.

Results: A total of 454 patients were included in this analysis (epoetin beta, n = 255; control, n = 199); the most common tumour types were ovarian (39%) and breast cancer (11%). Treatment groups were well balanced with regard to demographic characteristics. Hb levels increased rapidly, with a mean Hb increase from baseline of 1.0 g/dl seen after 4 weeks of treatment with epoetin beta. In contrast, a mean Hb increase from baseline of 0.1 g/dl was seen in the control group. A sub-analysis of change in

Hb level based on the type of chemotherapy received (platinum versus non-platinum) was also conducted. In patients receiving platinum-based chemotherapy, a mean increase of 1.0 g/dl was seen after 4 weeks in the epoetin beta group compared with no change from baseline in the control group. In those receiving non-platinum-based chemotherapy, mean Hb increases of 1.0 g/dl and 0.4 g/dl were seen after 4 weeks in the epoetin beta and control groups, respectively.

Conclusions: Epoetin beta rapidly increases Hb levels in anaemic patients with solid tumours undergoing myelosuppressive chemotherapy. Moreover, this rapid increase is seen regardless of the type of chemotherapy used.

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## 1311 PUBLICATION

The prevalence of concern about weight loss and decline in food intake in people with advanced cancer

J.B. Hopkinson, D.N.M. Wright, J.W. McDonald, J.L. Corner. *University of Southampton, Macmillan Research Unit, Southampton, United Kingdom* 

Aim: This paper reports findings of a survey of the prevalence of concern about weight loss and decline in food intake in patients with advanced cancer. It was part of a larger study with the purpose of exploring the potential for helping patients and their families live with the symptoms.

Background: Weight loss and anorexia are commonly reported symptoms in people with advanced cancer. Little is known about patient experience of the symptoms, in particular whether they find them of concern. If patients are troubled by the symptoms, mitigating this distress may be important in enabling them to die at home.

**Methods:** The research was a case study design. The cases were two community palliative home care teams serving a population of over 1 million people in the South of England in 2003. Multiple methods of data collection included a questionnaire survey and semi-structured conversational style interviews with a purposive sample of patients (n = 30), carers (n = 23) and nurse specialists (n = 14). The survey was of 233 patients with advanced cancer (response rate 85%). These people represented 67% of the total caseload across the two study sites over a two week period.

Analyses of the survey data were conducted using SPSS (Statistical Package for Social Scientists version 12.0). Interview data were analysed thematically.

**Results:** More than three-quarters of the 199 patients who returned questionnaires reported weight loss (78.8%) and/or to be eating less (75.9%). More than one third of the people reporting weight loss (35%) and nearly half (45%) of people who reported eating less considered the changes of concern.

Patients who were within 6 months of death were found most likely to report concern about either weight loss and/or eating less. The interview data provide insights into the reasons why the symptoms can be experienced as distressing.

Conclusion: Weight loss and eating related distress are commonly experienced and previously unresearched problems in people with advanced cancer. Further work is needed to establish if concerns are amenable to interventions that translate into meaningful outcomes for patients and their families.

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1312 PUBLICATION

A prospective survey of the management of cancer patients undergoing invasive procedures: evolution during the last five years

M. Di Palma<sup>1</sup>, I. Krakowski<sup>2</sup>, B. George<sup>3</sup>, D. Serin<sup>4</sup>, D. Feminier<sup>5</sup>, P. Dielenseger<sup>1</sup>, N. Vuillemin<sup>6</sup>. <sup>1</sup>Institut Gustave Roussy, Ambulatory Dept, Villejuif, France; <sup>2</sup>Centre Alexis Vautrin, Supportive Care, Nancy, France; <sup>3</sup>Hopital Saint-Louis, Pain Clinic, Paris, France; <sup>4</sup>Clinique Ste Catherine, Oncology, Avignon, France; <sup>5</sup>Institut Ste Catherine, Oncology, Avignon, France; <sup>6</sup>Centre Hospitalier, Pain Clinic, Mulhouse, France

All along the course of their disease cancer patients are submitted to a lot of repeated invasive procedures. Little is known about the distress and pain induced by these procedures.