programs for both the patients and their family members should be employed.

Table 1

	PFr	RPr	BPr	GHr	VTr	SFr	REr	MHr	PCSr	MCSr
PF	**	**	**	NS	**	**	NS	**	NS	*
RP	NS	NS	NS	NS	*	**	NS	*	NS	**
BP	**	*	**	*	NS	*	NS	*	NS	NS
GH	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
DVT	**	NS	NS	NS	NS	NS	NS	NS	NS	NS
SF	NS	NS	NS	NS	**	**	NS	*	NS	*
RE	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
MH	NS	NS	NS	NS	NS	*	NS	NS	NS	NS
PCS	**	**	**	*	**	**	NS	**	*	*
MCS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

r = relatives, * = 0.05, ** = 0.01. NS = Not Significant.

3052 POSTER

Biosimilar filgrastim is an effective primary prophylactic therapy for neutropenia in patients (pts) receiving doxorubicin and docetaxel (AT) for breast cancer (BC)

C.F. Waller[1], V.F. Semiglazov[2], S. Chan[3], R. Challand[4]. *[1]Freiburg University Medical Center, Department of Haematology/Oncology, Freiburg, Germany; [2]N.N. Petrov Research Institute of Oncology, Breast Tumor Department, Saint Petersburg, Russian Federation; [3]Nottingham University Hospital NHS Trust, Oncology Department, Nottingham, United Kingdom; [4]Hospira, Oncology, Leamington Spa, United Kingdom*

Background: Recombinant granulocyte colony-stimulating factor (filgrastim; Neupogen®, Amgen) is integral to supportive care for pts receiving myelosuppressive chemotherapy. Hospira has developed a biosimilar filgrastim, Hospira filgrastim, which has been evaluated in preclinical and clinical studies. Here we report the results of a phase III, randomised, double-blind, therapeutic equivalence study to evaluate the efficacy, safety and tolerability of Hospira filgrastim versus Neupogen in pts receiving AT for BC (GCF071).
Materials and Methods: Female pts with BC suitable for (neo)adjuvant or first-line treatment with AT were randomised (2:1) to receive a subcutaneous injection of 5 μg/kg Hospira filgrastim or 5 μg/kg Neupogen once daily until the documented absolute neutrophil count (ANC) nadir had passed and ANC was $>3\times10^9$/L or for a maximum of 14 days. Up to 6 cycles of Hospira filgrastim or Neupogen were given at 3-weekly intervals.
Results: 279 pts from 37 centres in 10 countries were randomised: 184 to receive Hospira filgrastim and 95 to receive Neupogen. One pt from the Hospira filgrastim group withdrew consent and did not receive study medication. The mean number of injections in cycles 1–6 was similar in the two groups: 42.0 for Hospira filgrastim and 41.9 for Neupogen. The confidence interval for the difference in duration of severe neutropenia (DSN) in cycle 1 between Hospira filgrastim and Neupogen (primary endpoint) was within the predefined range and demonstrated equivalence of the two agents (DSN = 1.85 days and 1.47 days for each drug respectively). Incidence of severe neutropenia in cycle 1 was similar for Hospira filgrastim (77.6%) and Neupogen (68.2%). In cycle 1, mean time to ANC recovery was 7.8 days for both groups. Incidence of febrile neutropenia (FN) over cycles 1–3 was 2.4% for both treatments, and incidence of hospitalisation due to FN was similarly low at 2.1% in each group. Incidence of treatment-related adverse events (TRAEs) was similar (24.6% for Hospira filgrastim, 23.2% for Neupogen). Consistent with previous studies of filgrastim, the most common TRAE was bone pain.
Conclusions: Hospira filgrastim was equivalent to Neupogen for all parameters tested. These included short DSN and low rates of FN in pts receiving cytotoxic chemotherapy. Hospira filgrastim may provide an effective alternative to Neupogen for the primary prophylaxis of neutropenia.

3053 POSTER

Management of anaemia in oncology: use and efficacy of Darbepoetin alfa in CIA patients

B. Levache[1], B. Sousselier[1], L. Cany[1], C. Maguire[2], F. Saillour-Glenisson[3], F. Fagnani[4]. *[1]Polyclinique Francheville, Oncology Unit, Perigueux, France; [2]Polyclinique Francheville, Clinical Research Unit, Perigueux, France; [3]CHU Bordeaux, Evaluation Qlinique et Qualité, Perigueux, France; [4]CEMKA-EVAL, Pharmaco-Economics Department, Paris, France*

Objectives: To assess the management of chemotherapy-induced anaemia with ESAs, and to evaluate the place of RBC transfusions.
Methodology: A retrospective observational study was conducted in a single center (Francheville Polyclinic, Périgueux), with a register of 1153 cancer patients treated with chemotherapy from July 2006 to March 2008. This period coincided with implementation of a protocol for treating anaemia in the unit. RBC transfusions and the use of Darbepoetin alfa (DA, Aranesp®) were recorded as well as associated haemoglobin (Hb) levels. The choice of DA was justified by the Q3W schedule (once every 3 weeks) which enabled synchronisation with chemotherapy protocols. The efficacy of treatment was defined according to increase in Hb levels after 3 successive injections.
Results: Of the total group of 1153 patients, 325 (28.1%) were treated for anaemia with DA (72% received 500 μg Q3W). 90.1% of patients presented solid tumours (breast, lung and colorectal representing 40% of the total). The cumulative number of delivered chemotherapy cycles was 392.
127 of 325 patients (39.1%) had at least one transfusion during the study (cumulative number: 352 transfusions), 76.7% of evaluable patients (N = 214) responded to treatment after 3 or even 2 consecutive DA injections. The improvements in Hb levels over successive DA injections were greater in the patients with initially low Hb levels. After DA treatment, 80% of patients presented an Hb level between 10−12 g/dL, according with the new EMEA recommendations. In 27.3% of cases, patients had previously received RBC transfusion before receiving DA. Use of DA as anaemia treatment in this unit showed a progressive reduction of the transfusion number.
Conclusion: clinical practice in this centre seems to be consistent with recommendations from health authorities concerning the management of chemotherapy-induced anaemia and the efficacy results for darbepoetin alfa are similar to those provided in clinical studies. It has been suggested that darbepoetin alfa could act as an optional treatment, and it would be interesting to consider it in medical-economic studies. The great complexity of descriptive analyses of oncology and anaemia practices, taking into account the multiplicity of clinical situations, follow-up durations and disease managements, must be highlighted; therefore a prospective study has been implemented in this unit to fill out this analysis.

3054 POSTER

An analytical web portal for estimation of survival in cancer patients receiving standard antineoplastic treatments

N. Knud Mejer[1], G. Torben Gøth[2], N. Dorte Nielsen[1], D. Gedske Daugaard[2]. *[1]Herlev University Hospital, Clinical Research Unit, Herlev, Denmark; [2]Rigshospitalet University Hospital of Copenhagen, Clinical Research Unit, Copenhagen, Denmark*

Background: Documentation of standard treatment quality is important in order to perform a proper in-formation of the patient and to compare own data with the best international standard. When part of a clinical trial is introduced as a new standard treatment in daily clinic, the in- and ex-clusion criteria often change and the patient group is no longer a well defined population with respect to inclusion criteria. This may change survival data as compared to the survival in the clinical study. Therefore, survival on all standard treatments should be followed as part of a department's quality control.
We have created "The Analytic Web Portal (AWP)", a web application intended to provide an integrated environment for data analysis and visualization. The system offers two statistical procedures: survival time analysis and response rates to cancer treatments.
Materials and Methods: The system consists of two parts: A data integration part and a data analysis part. The data integration part deals with data collection, filtering treatment data based on a specified format, and saved in a data storage. This is done by the use of data ware-house technology. Patient treatment data are extracted from a hospital application and merged with death data from a centralized governmental data registry. The analytical part deals with statistical calculations and presentation of results.
All the statistical processing in AWP was derived from SPSS algorithms and cross checks were made to confirm the validity of the generated results from AWP.

Results: AWP provides a graphical user interface for the selection of analysis type and parame-ters, for performing the analysis and for displaying the results in text and in graphs. It also allows the user to save a statistical report in Microsoft Word and PDF format.
At present, a functional Web portal has been established at one department.
Conclusion: The Analytic Web Portal helps physicians and decision makers to assess the efficacy of standard cancer treatments.
Data on the quality of standard treatment can be generated whenever needed. It facilitates a possibility to change standard treatment if data shows inferior survival compared to what would be expected. Survival data between different institutions can be compared due to the well defined interface of AWP to other databases.

3055 POSTER

Does self regulation and autonomic regulation have an influence on survival in breast and colon carcinoma patients? – results of a prospective study

M. Kröz[1], H.B. von Laue[2], A. Bockelbrink[3], M. Reif[4], D. Brauer[1], R. Zerm[1], F. Schad[1], G. Feder[5], S.N. Willich[3], M. Girke[1].
[1]Gemeinschaftskrankenhaus Havelhöhe, Forschungsinstitut Havelhöhe, Berlin, Germany; [2]Schwerpunktpraxis Öschelbronn, Onkologische Praxis, Öschelbronn, Germany; [3]Charité, Institut für Sozialmedizin und Epidemiologie, Berlin, Germany; [4]Institut für klinische Forschung, Statistik und Methodologie, Berlin, Germany; [5]University of Bristol, Academic Unit of Primary Care, Bristol, United Kingdom

Background: Cancer Related Fatigue (CRF) and circadian rhythm both have a substantial impact on the quality of life (HRQL) of patients with breast (BC) and colorectal cancer (CRC) patients. In these patients, new measures of adaptability and resilience, such as sense of coherence or self regulation, could be more sensitive prognostic tools than classical HRQL measures. The aim of this study was to assess the influence of autonomic regulation (aR) and self regulation (SR) on survival. For this, we tested a) a scale to measure autonomic regulation (aR) and its subscale for rest-activity rhythm (RA.aR); and b) a psychosomatic self-regulation scale.
Material and Methods: 146 cancer patients and 120 healthy controls (C) took part in an initial evaluation in 2000/2001. On average 6 years later, 62 of 95 BC, 17 of 51 CRC patients, and 87 of 120 healthy controls completed the follow-up questionnaire. 41 of 266 participants (14 BC, 25 CRC, 2 C) had died. For the follow-up evaluation, participants were requested to complete the aR and SR questionnaires as well as a self-evaluation of the Karnofsky index (KPI).
Results: On average, cancer patients had survived for 10 years with the disease, at an actual KPI: 93%. Survival was analyzed using Cox proportional hazard regression including age, gender, diagnosis group, with aR and SR as independent parameters. Of the latter two, aR did not influence survival (odds ratio (OR) = 1.043, n.s.), whereas SR showed a positive and independent effect, with an OR of 0.502 (95%-CI: 0.307 – 0.819; p = 0.006). This positive effect was corroborated by the analysis of subscales for **Achieve satisfaction/well-being** (OR = 0.918; 95%-CI: 0.867 – 0.972) and **Change behaviour to reach goal** (OR = 0.936; 95%-CI: 0.942 – 0.987), and also reproducible when diagnoses were replaced by their respective tumour stages in the analysis for a finer resolution of the cancer diseases.
Conclusions: Self regulation might be an independent prognostic factor for the survival of breast and colon carcinoma patients. Further prospective studies are required to elucidate the prognostic relevance and utility of self regulation.

3056 POSTER

Risk factors for severe anaemia: a prospective, multicentric, observational survey of 645 patients treated with first-line chemotherapy (INDEX study)

C. Linassier[7], C. Hennequin[1], F. Goldwasser[2], N. Casadeval[3], B. Asselain[4], J.E. Kurtz[5], V. Leblond[6]. *[1]Hôpital Saint louis, Oncology Unit, Paris, France; [2]Hôpital Cochin, Service Medecine Interne, Paris, France; [3]Hôtel Dieu, Hematology Unit, Paris, France; [4]Institut Curie, Biostatistics, Paris, France; [5]Hôpital Hautepierre, Hematology-oncology, Strasbourg, France; [6]La pitié Salpétrière, Hematology, Paris, France; [7]Hopital Bretonneau, Tours, France*

Aim of the study: To describe clinical, therapeutical and biological factors associated to the occurrence of chemotherapy-induced anaemia (haemoglobin (Hb) level <10 g/dl).
Methods: A French prospective, multicentric, observational survey was conducted between November 2007 and March 2008, in cancer patients treated by first line chemotherapy (CT). All pts were followed during 24 weeks or until prescription of erythropoietin-stimulating agents (ESA). Risk factors for anaemia were studied by multivariate logistic regression.
Results: A total of 645 patients (pts) were evaluable, including lung (n = 299), breast (n = 114), ovarian cancer (n = 68) and lymphomas (n = 164). In the whole population, 151 pts (23.4%) developed anaemia during the survey (Hb level <10 g/dl); ESA prescription or blood transfusion were performed in 340 pts (52.7%) and 73 pts (11.3%) respectively. Regarding the factors associated to the occurrence of chemotherapy-induced anaemia in this population the results were: age >62 years, Hb level at baseline and CT including cisplatin.
Concerning the use of ESA in this population, associated factors were age $\geqslant$62 yrs, CT including anthracyclines, initial Hb level <12 g/dl, performance status (PS) at baseline, PNN and Lymphocytes levels.
Conclusion: In routine oncology practice, ESA is prescribed in more than 50% of the patients in first line CT for a metastatic cancer. Risk factors for CT-induced anaemia and ESA prescription for each type of tumours will be presented during the meeting.

3057 POSTER

KalinoxTM: an effective and well-tolerated method for pain management during invasive procedures in oncology – results of a randomized study

I. Krakowski[1], D. Baylot[2], E. Collin[3], G. Chvetzoff[4], R. Coulouma[5], F. Dixmerias[6], L. Feuvret[7], C.h. Freyssinet-Durand[8], E. Lauwers-Allot[9]. *[1]Centre Alexis Vautrin, Oncology, Vandoeuvre les Nancy, France; [2]Clinique Mutualiste, Pain, Saint Etienne, France; [3]Hôpital de la Pitié Salpétrière, Pain, Paris, France; [4]Centre Léon Bérard, Oncology, Lyon, France; [5]Centre Val d'Aurelle P. Lamarque, Oncology, Montpellier, France; [6]Institut Bergonie, Oncology, Bordeaux, France; [7]Hôpital de la Pitié Salpétrière, Radiotherapy, Paris, France; [8]Clinique Mutualiste, Pain, Saint Etienne, France; [9]Centre René Huguenin, Pain, Saint Cloud, France*

Background and Aims: In oncology, general pain management is essential to ensure to the patient (pt) a good quality of life. Painful procedures are recognized as a real problem, specialy for long term chronic pts. The aim of this clinical study was to evaluate the effectiveness and the safety of Kalinox^{TM} (premix 50% N_2O/50% O_2) inhalation method during invasive procedures for cancer pts.
Methods: Pts, older than 18 years, scheduled for different types of exploratory acts or therapeutic cares, were randomized in this double-blind study between Kalinox^{TM} or placebo (PCB: 50% nitrogen/50% oxygen) in complement of usual preventive medication. Pts, were stratified into 2 arms: pts with or without previous permanent pain (ppp). Kalinox^{TM} efficacy was evaluated by patient's self-assessment using Visual Analogic Scale (VAS); safety by recording adverse events. Patient's behaviour and satisfaction and medical staff's satisfaction were assessed.
Results: 204 pts were included: 199 were analysed as Intended To Treat. Demographic data were: 147 women and 50 men, 58 with and 139 without permanent pain, mean age: 59.5$\pm$13.9 years, mean gas inhalation 11.5$\pm$10.1 minutes, mean gas flow rate 9.3$\pm$1.4 L/min.
A significant difference (p = 0.006) of 10 points was observed between Kalinox^{TM} (n = 98) and placebo (n = 101) ITT randomized groups with a mean of 24 ($IC_{95\%}$: 19.1−29.0) and 35.2 ($IC_{95\%}$: 29.5−40.9) respectively. No serious adverse event was reported. 10.2% of patients under Kalinox^{TM} had an adverse event. Patient's and medical staff acceptability was higher than 89%. Patient's behaviour was good to excellent in 92.31% of cases.
Conclusions: Kalinox^{TM} administration during invasive procedures in oncology is an efficient and safe complementary method for patient's pain management that is well accepted by both patients and nurses and practitioners.

3058 POSTER

Opinion on different types of palliative care in Georgia

T. Rukhadze[1], T. Alibegashvili[2], M. Turkadze[2], T. Aladashvili[2], P. Dzotsenidze[3], D. Kordzaia[2]. *[1]National Cancer Centre, Palliative Care Service, Tbilisi, Georgia; [2]Palliative Care Association "Humanists' Union", Home Based Palliative Care Service, Tbilisi, Georgia; [3]Palliative Care Association "Humanists' Union", Pain Policy, Tbilisi, Georgia*

Purpose: The opinions of cancer-patients and their family members different types of palliative care (Hospice or Home-based Care) were studied.
Method: Using the subjective 5-grade-questionnaires the following points have been studied:
1. The quality of ***Pain Management*** and **Symptom Control** in terminally-ill cancer patients at hospice and at home;
2. Where do the cancer-patients and their family members prefer to receive palliative care – at hospice or at home?