3048 POSTER

The clinical implication of oral mucositis in solid tumor patients receiving conventional chemotherapy: as a bio-indicator for suffering adverse events and poor quality of life

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Background: Oral mucositis (OM) caused by chemotherapy can also be a troublesome and debilitating adverse effect in solid tumor patients. In addition, OM can be associated with the complicated aspects such as the poor oral intake and malnutrition in addition to the oral symptoms. Therefore we prospectively evaluated the OM and its clinical significance in solid tumor patients.
Material and Methods: From October 2007 to September 2008, we enrolled 344 consecutive patients with solid tumor who initiated a new chemotherapy cycle at Seoul National University Hospital. Each patient was prospectively evaluated for two cycles. The data were collected from interviews by a physician directly. Patients kept a diary on OM-related symptoms as patient-reported measurement. The visual analog scale (VAS) was used to quantify the degree of symptom (0 point = no symptoms, 4 point = the worst symptom).
Results: Finally, 322 patients were analyzed. The incidence of OM was 28% per each cycle and 45% per patient during the two cycles. OM occurred in 8.82±5.97 days and recovered in 15.83±5.90 days after chemotherapy. Oral dryness was the most prevalent symptom of the OM-related symptoms such as oral pain, poor oral intake, dysphagia, oral bleeding, scalloping of the tongue, and ulceration (VAS score more than 1: 47%, 27%, 39%, 15%, 7%, 14%, and 13%, respectively). In quality of life (QOL) by FACT-G, the physical and the emotional well-being were significantly lower in patients with OM compared with those without OM (19.09±6.48 vs. 22.47±5.95, $p < 0.001$; 16.74±4.10 vs. 17.97±3.38, $P < 0.001$, respectively). In addition, a higher VAS score for the other adverse effects was found in patients with OM compared with those without OM (activity, nausea, vomiting, fever, myalgia, and sensory neuropathy; $p = 0.0038$, $p < 0.0001$, $p = 0.0007$, $p = 0.0062$, $p < 0.0001$, $p < 0.0001$, respectively).
Conclusions: Forty five percent of patients with solid tumors experienced OM during two cycles of chemotherapy. In patients with OM, the QOL was worse and the other adverse effects were more prevalent. Therefore, OM could be a bio-indicator of QOL and other adverse effects during chemotherapy.

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Antitumoral therapy within 30 days from death: clinical and prognostics evaluations in very advanced cancer patients died in palliative care unit (PCU)

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Background: Advance in medicine have greatly improbe possibilities to treat seriously ill patients and to prolong the life. Howewer, other goals have to guide medical decision-making in palliative medicine, such as improvement of quality of life and relief of suffering, without cures not proportioned.
Methods: We have analyzed **244** patients who were died in our Palliative Care Unit during three years 2006, 2007, 2008. We researched the clinical relevant data, the causes for death in terminal and non-terminal patients and particularly the percentage of antitumoral therapy administration within 30 days from death.
Results: The median age of the patient was 69 yrs (range 25−98 yrs). The prevalent sites of tumour were: lung 24%, breast 14%, colon-rectum 9%, pancreas 6%, stomach 6%, bladder 4%, prostate 4%; prevalent metastatic sites – except lymphonodes – were: liver 25%, lung 17%, bone 14%, brain 7%, peritoneum 5%, pleura 4%. The median duration of hospitalization was **10 days** (range 1−61 days). We have documented: leucocitosis 55.% of cases, anaemia (Hb < 10 gr/dl) 34%, hypoalbuminemia 61%, hyperazotemia 43% hypercreatininemia 32%, increase of bilirubine 39%, increase of AST 47%, increase of ALT 40%, increase of LDH 59%. Of the died patients, 209 (**85%**) were recognized as terminal patients at the moment of admission in Palliative Care Unit; in 35 pts occur unexpected death: 12 pts of pulmonary embolism (34%), 5 pts of ictus cerebri (14%) 2 pts of IMA (6%) and 2 patients of arhythmia (6%); only 3 pt died for septic shock in neutropenia chemotherapy-correlated. About terminal patients the predominant causes of death were: respiratory insufficiency 28%, liver failure 26%, cardio-circulatory collapse 24%, endocranic hypertension 5%, kidney failure 3% heart failure 3%; 40 pts (**16%**) died within 30 days of the last antitumoral therapy: **19**% of patients in 2006, **17**% in 2007, **14%** in 2008; 65 pts (**27%**) died without ever having receveid chemotherapy.
Conclusions: The survey cover only patients who died in PCU but, altough the reduction is not statistically significant, the trend is comforting: these patients were the most severely symptomatic; a careful evaluation and recording of clinical data seems to result in itself reduction of cures not proportioned and detrimental of quality of life.

3050 POSTER

Three -day course of granulocyte colony-stimulating factor in patients on chemotherapy for cancer is a safe and cost-effective schedule to maintain dose-intensity: a study from India

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Background: To analyze the safety, tolerability and efficacy of a short course of granulocyte colony-stimulating factor (G-CSF) to maintain dose-intensity of subsequent cycles of chemotherapy and in a cost effective means which is feasible in resource constraint countries.
Material and Methods: One hundred patients undergoing adjuvant and neo-adjuvant chemotherapy were analyzed between January 2008 and December 2008.Aim to avoid having chemotherapy delays due to neutropenia (absolute neutrophil count [ANC] $<1.5 \times 10^9$/L) on day 22, the impact of neutropenic events [defined as either hospital admission due to febrile neutropenia (FN), dose delay $\geqslant$7 days due to neutropenia or dose reduction of $\geqslant$15% due to neutropenia] on dose intensity (DI) in 350 cycles of chemotherapy. G-CSF filgrastim (5 microg/kg/day subcutaneously) was administered on 3 days subsequently after each chemotherapy cycle.
Results: Neutropenic events occurred in a 35% proportion of cycles and in a 15% of patients. However, the severity of myelotoxicity was lessened with the addition of G-CSF therapy. Myelotoxic deaths were 4. Overall, dose delay occurring in 3% of patients. Dose reduction due to neutropenia was the most common neutropenic event, was noted in 20% of patients. Hospitalizations due to Febrile Neutropenia affected 8% of patients. Patients who received concomitant G-CSF and radiotherapy achieved a similar dose-intensity as patients who did not undergo radiotherapy. No patients discontinued G-CSF treatment due to musculoskeletal pain.
Conclusion: A 3-day course of G-CSF in patients on chemotherapy avoided delays due to prolonged neutropenia seems to be a safe and cost-effective schedule in developing countries to maintain dose-intensity in the adjuvant and neo-adjuvant treatment of cancer. The addition of short course of G-CSF to the regimen decreases the frequency of hospitalization for febrile neutropenia.

3051 POSTER

Health-related quality of life (HRQL) correlation between family members and cancer patients undergoing chemotherapy

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Background: It is widely experienced that health-related quality of life (HRQL) is greatly influenced in the family members of cancer patients. The aim of this study was to find the correlation of the HRQL parameters in cancer patients with the main mental component parameters of patients' relatives.
Materials and Methods: 212 cancer patients undergoing chemotherapy in our department (93 men and 119 women) of mean age 57.4±14.6 and their 212 relatives that accompanied them (79 men and 133 women) of mean age 48.9±14.3 completed the validated SF-36 health survey by personal interview. The SF-36 health survey summarizes the functional health status and general health into eight scales with higher scores (0–100 range) reflecting better-perceived health. In this study, physical functioning (PF), role physical (RP), bodily pain (BP), general health perception (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH), physical Component Summary (PCS) and Mental Component Summary (MCS) of the patients were correlated with the HRQL parameters of their family members using the Spearman's test. Data analysis was performed with SPSS version 13.0 and correlations were considered statistically significant when $p < 0.05$
Results: Table 1 summarizes the results of our study. Social Functioning and Mental Health of family members are highly correlated with the HRQL parameters of cancer patients. The rest parameters are correlated to a lesser extent. Patients' PF, BP and PCS were highly correlated with their relatives' parameters.
Conclusions: There is high correlation of HRQL parameter between cancer patients undergoing chemotherapy and their relatives. The identification of these inter-relationships should be registered before supportive

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.

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

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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

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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

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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.