Symptom Science 151

panel comprising of the European Association of Palliative Care (EAPC), European Oncology Nursing Society (EONS), the Lance Armstrong Foundation (LAF) and OPENMinds (OM).

Results: Completion of the full pan-European data set is expected in June 2007. In the UK pilot study, 400 patients were screened and 50 in-depth questionnaires completed. Results revealed:

- · Pain has a major impact on quality of life.
- The burden of pain is not appreciated by HCPs.
- Pain is not adequately controlled.
- Improved communication is urgently needed between patients and their HCPs

Conclusions: The pilot study revealed that action is needed to improve communication between HCPs and cancer patients about issues surrounding the disease. As a result, the Cancer Tales workbook has been produced. It uses themes from the play Cancer Tales, which was developed from a collection of cancer patients' personal stories, to highlight key areas for improvement in communication about cancer, and provides guidance and practical exercises. The workbook was reviewed by a European editorial board of palliative care, pain management, oncology, nursing and communications specialists.

The EPIC survey and Cancer Tales workbook are sponsored by Mundipharma International Limited, Cambridge, UK, under the auspices of the EONS and the EAPC.

1130 POSTER

Association of borna disease virus infection with depression in cancer patients

C. Jehn¹, L. Bode², S. Pfeiffer³, H. Ludwig². ¹Charite Berlin Mitte, Oncology, Berlin, Germany; ²Robert-Koch-Institute, Virology, Berlin, Germany; ³Charite Berlin Mitte, Immunology, Berlin, Germany

Background: Borna disease virus (BDV) is a RNA virus which can persistently infect neurons of the limbic system. Several seroepidemiologic data suggest an association of BDV with neuropsychiatric disorders, however inconsistent detectability has weakened a possible linkage. The objective of this cross-sectional study was to investigate, if an association exists between BDV infection and Major Depression (MD) in patients with advanced cancer receiving chemotherapy.

Methods: 55 inpatients (Pts) with metastatic cancer (Stage IV) were assessed by the Hospital Anxiety and Depression Scale (HADS) for depressive symptoms and diagnoses of major depression (MD) was established according to the DSM-IV criteria. IL-6, BDV-specific circulating immune complexes (CIC), antibodies and plasma antigens were determined by enzyme immunoassays (EIAs). In the statistical analysis the Mann-Whitney test and Spearman-Rho correlations were applied.

Results: 55 pts (age: 59.9 years; SD 10.2) had a mean Karnofsky index (KI) of 66.5% (SD 12.1). 26 pts had MD. Pts with MD showed a significant increase in BDV-specific antigens (p=0.050) and antibodies (p=0.045) and IL-6 (p<0.001), compared to patients without MD. CIC were not increased in MD (p=0.53). Depressive symptoms were more closely correlated with level of BDV antibodies (r=-0.296; p=0.028) and IL-6 (r=5.6; p<0.001) than symptoms of anxiety. Symptoms of anxiety showed a significant correlation to increased age(r=-0.28; p=0.042), whereas depressive symptoms correlated more closely with a decreased KI (r=-0.35; p=0.011). No correlations were found for level of symptoms vs. BDV-antigen or CIC.

Conclusions: In pts with metastatic cancer, MD is associated with increased levels of BDV-specific antigen and antibody. Symptoms of depression and anxiety are only correlated with increased levels BDV-antibody. Symptoms of anxiety seem to be related to age, whereas symptoms of depression are related to decreased KI.

1131 POSTER

Osteonecrosis of the jaw (ONJ) in patients treated with Bisphosphonates (BP): the experience of the "Rete Oncologica di Piemonte e Valle D'Aosta" (North-Western Italy)

 V. Fusco¹, M. Aglietta², M. Donadio³, A. Berruti⁴, A. Baraldi⁵, C. Ortega²,
A. Vandone³, C. Galassi⁶, O. Bertetto³. ¹Ospedale Santi Antonio e Biagio, SC Oncologia, Alessandria, Italy; ²IRCC, SC Oncologia, Candiolo, Italy; ³COES, SC Oncologia, Torino, Italy; ⁴ASO S.Luigi, SC Oncologia, Orbassano, Italy; ⁵Ospedale Santi Antonio e Biagio, SC Ematologia, Alessandria, Italy; ⁶CPO, Epidemiologia, Torino, Italy

Background: BP are very useful drugs for treatment of myeloma, metastatic bone cancers, osteoporosis, Paget's bone disease. Reports of cases of ONJ in patients (pts) treated with BPs, mainly with Pamidronate (P) and Zoledronic Acid (Z), are increasing since 2003.

Materials and Methods: Our regional ONJ Study Group (including oncologists, haematologists, maxillofacial surgeons, odontostomatologists)

diffused information and guidelines for diagnosis and prevention of ONJ, even by meetings and newsletters. A case data collection form was mailed to regional specialist care centers.

Results: we identified (on March 2007) 142 cases of ONJ, after cross-checking reports from centres of maxillofacial surgery / ORL odontostomatology (17), medical oncology (25) and haematology/internal medicine (14). Pts were affected by breast cancer (60), myeloma (45), prostatic cancer (19), other types of cancer (13), osteoporosis or Paget's disease (5). Pts characteristics: Sex: 53/89 M/F; median age 71 yrs (range 44-84). BP treatment (among 103 cases, with available data): Z in72, P in27 (19 "switched" to Z), alendronate/risedronate in 4. Clinical findings (exposed bone or infections, pain, mobile teeth, soft-tissue swelling, nonhealing fistulas) and dental comorbidities or precipitating events (as teeth extraction, periodontal surgery, dental implants, or traumatic use of dentures) were those described in recent ONJ literature. Conclusions: Our 142 cases, observed in a population of 4.3 million, are more than expected on the basis of some published estimations of incidence, for example those based on data concerning Australia (158 cases in a population of 20.3 million: 114 cancer pts, 44 with osteoporosis/Paget's disease) or even only South Australia (25 cases, out of 1.5 million) (Mavrokokki T et al, J.Oral Maxillofac. Surg. 2007). Our oncology network recommended screening of all pts under treatment with BPs, with panoramic X-rays and referral centre visit (w/o CT or MR scan in selected cases) and careful evaluation of pts candidate to be treated with BPs, with pretherapy dental care if necessary. A case-control study has been planned to search possible risk factors of ONJ (treatment- and clinical history-related). Prospective evaluation of incidence in future, after pretherapy dental care policy and avoiding (as possible) surgical dental procedures during BP treatment, is warranted. Trials about timing, duration, schedules of BP treatment are needed. The goal is optimize cost-effectiveness of BPs, preventing and minimizing a possible debilitating long-term side effect of a class of drugs otherwise very useful for cancer patients.

1132 POSTER

A large multicenter prospective randomised trial on the treatment of death rattle in terminal care

H. Wildiers¹, C. D'haenekint², P. Clement³, M. Desmet⁴, P. Demeulenaere⁵, R. Van Nuffelen³, E. Van Droogenbroeck⁶, F. Geurs⁷, J.P. Lobelle³, J. Menten³. ¹U.Z. Gasthuisberg, Department of Medical Oncology, Leuven, Belgium; ²A.Z. Sint-Elisabeth, Palliative Care Unit, Turnhout, Belgium; ³U.Z. Gasthuisberg, Palliative Care Unit, Leuven, Belgium; ⁴A.Z. Virga Jesse, Palliative Care Unit, Hasselt, Belgium; ⁵University of Antwerp, Palliative Care Unit, Antwerp, Belgium; ⁶Stedelijk Ziekenhuis Aalst, Palliative Care Unit, Halle, Belgium; ⁸St. Maria Hospital Halle, Palliative Care Unit, Halle, Belgium

Introduction: death rattle is a frequent symptom (25–50%) in the terminal stage of life, but there is neither standardized treatment nor prospective investigation performed on the efficacy of anticholinergic drugs.

Methods: We designed a large multicenter prospective randomised trial in 6 Flemish Palliative Care Units. Informed consent was required from the patient or the legal trustee. At the occurrence of death rattle, patients were randomized between one of three frequently used anticholinergic drugs: (1) atropine 0.5 mg bolus s.c., followed by 3 mg/24 h. (2) Butylhyoscine bromide 20 mg bolus s.c., followed by 60 mg/24 h. (3) Scopolamine 0.25 mg bolus s.c., followed by 1.5 mg/24h. The intensity of death rattle, and side effects, were scored at 30 min, 1 h (primary endpoint), 4 h, 12 h, 24 h and further q24h. The rattle intensity score was: 0 = not audible; 1 = only audible near the patient; 2 = clearly audible at the end of the patients bed in a quiet room; 3 = clearly audible at a distance of 7 meters in a quiet room.

Intensity difference in rattle 1 h after start of therapy

Difference ^a	Number of patients			
	Atropine	Butylhyoscine bromide	Scopolamine	Total
-3	3	1	1	5
-2	13	9	7	29
-1	27	25	30	82
0.58	60	62	180	
1.6	8	5	19	
Total	107	103	105	315

 $^{^{\}rm a}$ -3 indicates change from rattle grade 3 to grade 0, -2 from grade 3 to 1 or from grade 2 tot 0, etc.

Results: 315 patients recruited between 11–2001 and 11–2006 were eligible for analysis. The table contains the effectiveness data 1 hour after the start of the anticholinergic treatment and shows no statistical difference

Proffered Papers

between the three groups (p = 0.78). Also at further time points there is no significant difference between the 3 drugs, but an increasing percentage of patients had a decreased death rattle intensity. Also side effects (confusion, consciousness, bladder retention, ileus, heart failure, fever) and survival after start of therapy (mean 39.2, median 23.9 hours) did not differ between the treatment groups.

Conclusion: For the treatment of death rattle, there is no difference in effectiveness, side effects or survival between atropine, butylhyoscinebro-mide, and scopolamine. Overall, rattle improves in 37%, is stable in 57%, and is progressive in 6% after 1 hour of treatment, and improves further with time. Survival is short after diagnosis of death rattle. This study proves that large multicenter prospective randomised trials with informed consent are feasible in terminal care patients.

1133 POSTER

Residual damage to the small intestine induced by chemotherapy can be detected and monitored using the non-invasive ¹³C Sucrose Breath Test (SBT)

T.J. Price¹, L. Morelli², G.S. Howarth², J. Webster³, B. Zacharakis³, C. Brooker², D. Keefe⁴, P. Bardy¹, G.P. Davidson³, R.N. Butler³. ¹The Queen Elizabeth Hospital, Haematology/Oncology, Adelaide, Australia; ²Children Youth and Women's Health Service & Nidor Pty Ltd, Centre for Paediatric and Adolescent Gastroenterology, Adelaide, Australia; ³Children Youth and Women's Health Service, Centre for Paediatric and Adolescent Gastroenterology, Adelaide, Australia; ⁴Royal Adelaide Hospital, Medical Oncology, Adelaide, Australia

Background: Previous studies in our laboratory in paediatric oncology patients have suggested that intestinal damage becomes progressively worse with multiple chemotherapy regimens. We have extended these studies to adult cancer patients to further assess the likelihood of damage to the small intestine in a subsequent cycle. The response of the small intestine to cancer chemotherapy was monitored using the non-invasive ¹³C sucrose breath test (SBT).

Methods: The SBT was carried out on all patients (n = 34) according to the manufacturer's instructions (GaspackTM, Nidor Pty Ltd, Adelaide, Australia) as described previously [1]. Breath samples were collected over 90 mins a baseline (prior to chemotherapy) and at selected intervals after treatment (1, 3–5, 7–10 and 12–15 days). A baseline SBT measurement was carried out again at the beginning of the next chemotherapy regimen. The SBT activity level is determined as the % cumulative expired $^{13}\text{CO}_2$ @ 90 min (%CD90). The SBT level at which damage to the small intestine is likely is <4 4%

Results: Patients with colorectal cancer (n = 28), breast cancer (n = 2) and lymphoma (n = 4) were recruited. The SBT (mean \pm SEM) decreased from the baseline of one cycle to the baseline of the next (%CD90: 7.2 \pm 1.1 vs 4.7 \pm 0.65; p <0.02) and this continued to decrease in three patients who carried out a third cycle (%CD90: 3.5 \pm 1.1). The pattern of damage and repair within a cycle was consistent with a decrease on day 1 followed by recovery on day 3–5, then decreasing again with time thereafter until day 12–15 at which time there was a significant decrease compared with day 0 levels for that cycle (p <0.05).

Conclusion: The SBT indicated a significant decline in small intestinal integrity from one cycle to the next. It is likely that differing chemotherapeutic regimens, cycle number and disease state would contribute to the range of SBT results obtained at each data collection point throughout any given cycle. However, the residual damage of increasing severity supports the usefulness of a low baseline SBT as a potential predictor of susceptibility for mucositis occurring in subsequent cycles of chemotherapy. The degree of decline in SBT may also guide prediction of mucositis during treatment and interventions where available.

References

[1] Tooley KL, Saxon BR, Webster J, Zacharakis B, McNeil Y, Davidson GP, Butler RN. Cancer Biol Ther 2006;5(10):1275–81.

1134 POSTER

Survival prediction of terminally ill cancer patients by clinical and laboratory parameters: usefullness role of simple prognostic indicators

G. Vasini¹, G.P. Bacchini¹, V. Franciosi¹, C. Ghidini¹, A. Musolino¹, R. Camisa¹, T. Meschi², L. Borghi², A. Ardizzoni¹. ¹Parma University Hospital, Medical Oncology Unit, Parma, Italy; ²Parma University Hospital, Department of Clinical Sciences, Parma, Italy

Background: Although accurate prediction of survival is essential for palliative care, no clinical tools have been established. Aim of this

retrospective study was to assess clinical and laboratory factors predictive of survival in a population of patients with terminal cancer.

Patients and Methods: The study cohort comprised 98 advanced cancer patients, no longer suitable for anticancer therapy, transferred between January 2004 and December 2006 from the Medical Oncology Unit to the Palliative Care Unit of Parma University Hospital. The analysis was performed for 23 clinical and laboratory parameters evaluated on admission to palliative care ward, including tests for hepatic, renal and hematological functions, presence of symptoms such as dispnoea, anorexia, diarrhea, pain, fever, intestinal occlusion, arithmia, depression, hemorrhage, presence of therapies such as oppioids, oxigen-therapy, insuline administration, parentheral nutrition.

Results: Median age was 69 years (range 34–93). Tumor sites were: breast (22%); gastrointestinal (21%); lung (20%); head and neck (16%); others (21%). All the patients had previously been treated with more than 1 line of chemotherapy for metastatic disease. Overall median survival (MS) was 45 days. Seven factors were found to be indicators of a worse survival by univariate analysis: anorexia (P = 0.004); fever (P = 0.002); Braden Score (BS) for decubitus risk (<17 vs \geq 17) (P <0.001), pseudocholinesterase (pCHE) (\leq 4.300 U/l vs normal, P <0.001); white blood count (\geq 10,000 vs normal, P <0.001); LDH (>500 U/l vs normal, P <0.007); INR (>1.14 vs normal, P <0.002). Cox regression analysis revealed that only BS (<17 vs \geq 17: HR = 2.47, 95% Cl: 1.53–3.99, MS: 30 vs 87 days), p-CHE (altered vs normal: HR = 1.83, 95% Cl: 2.01–5.35, MS: 24 vs 103 days) and LDH (altered vs normal: HR = 1.83, 95% Cl: 1.14–2.97, MS: 25 vs 61 days) were independent predictors of survival.

Conclusions: a cluster of simply assessable clinical and laboratory parameters may be used to accurately predict survival in terminal cancer patients. These prognostic indicators may be useful in the day-by-day therapeutic decision-making process of palliative care and medical oncology specialists.

1135 POSTER

Anaemia management with epoetin alfa in real-life, daily oncology practice in the Netherlands – interim analysis results from an observational study

J. van den Bosch¹, L.G.M. Kerkhofs², J.J. Braun³, D.F.S. Kehrer⁴, R.G.P.M. Brok⁵. ¹Albert Schweitzer Ziekenhuis, internal medicine, Dordrecht, The Netherlands; ²Ziekenhuis Walcheren, internal medicine, Vlissingen, The Netherlands; ³Vlietland Ziekenhuis, internal medicine, Schiedam, The Netherlands; ⁴IJsselland Ziekenhuis, internal medicine, Capelle aan den IJssel, The Netherlands; ⁵Ortho Biotech a division of Janssen-Cilag B.V., Medical Affairs, Tilburg, The Netherlands

Background: In cancer patients (pts) who undergo chemotherapy (CT), anaemia is a serious issue for quality of life. ASCO/ASH and EORTC have published guidelines on the use of epoetins in cancer pts. This study is addressing the real-life situation of epoetin alfa (Eprex[®]) treatment (ET) in anaemic cancer pts receiving CT.

Material and Methods: Pts were eligible if they were 18 years or older, received CT or where about to receive CT within a week as a treatment for a solid turnour, Multiple Myeloma, Hodgkin's Disease or non-Hodgkin disease and received ET. Data on haemoglobin level (Hb), blood transfusions (BTx), CT and ET were collected. Data were analyzed for the first 200 pts enrolled. Averages are presented as value ± standard deviation.

Results: Gender distribution is 50% male and 50% female. Average age is 63.6 ± 11.0 years. Tumour types are divers with 44% lung cancer pts. Majority of pts had metastases (63%) and the majority received platinumbased CT (64.5%). All pts started with 40.000 IU ET once-weekly. During ET, dose was adjusted for 21 pts. ET lasted on average 12.6±7.5 weeks and was started at an average Hb of 10.5±1.1 g/dl which resulted in an average Hb-rise of $0.4\pm1.7 \,\text{g/dl}$ after 28 days (28–35 days) (p = 0.0032) and 1.3 ± 2.3 g/dl after 56 days (56-63 days) (p < 0.001), respectively. A Hb rise of 1 g/dl during ET occurred in 138 pts (75%). Response defined as either a $\geqslant 1\,\text{g/dl}$ Hb rise during the first 4 weeks of ET or a $\geqslant 2\,\text{g/dl}$ Hb rise from baseline or a maintenance of Hb within range 11-13 g/dl from 4 weeks ET onwards until end of study, resulted in 70% responders. BTx were received by 64 pts (35%) and 52 pts (28%) received BTx after ET start. Transferrin saturation (TS) could be assessed in 58 pts of whom 30 were iron deficient (TS < 20%). During ET 155 pts reported onset of 429 adverse events (AE) of whom 59 pts reported a serious AE. For 11 AE (2.6%) a relation to ET was assumed by investigators. Thrombotic events (embolisms and thromboses) were reported for 12 pts (6%), but only for 2 pts a relation with ET was assumed by investigators.

Conclusion: In real-life, daily oncology practice in the Netherlands, ET on average is started at Hb levels indicated in published guidelines, corrects CT-related anaemia and is safe. Iron storage parameters are not often assessed with about half of the iron deficient pts receiving iron suppletion. More patient data are needed to gain more insight and to be able to perform some tumour-specific analyses.